

The Report of the Independent Review of Children's Cardiac Services in Bristol

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Professor Sir Ian Kennedy
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The Bristol Review is an independent review of the safety and quality of children's cardiac services in Bristol from March 2010 to the date of the Review. It was established in June 2014 by the NHS Medical Director, Professor Sir Bruce Keogh, and chaired by Eleanor Grey QC. The Review's work is governed by its Terms of Reference. It has examined the children's cardiac services provided by the University Hospitals Bristol NHS Foundation Trust in Bristol and at outreach clinics in the South West, as well as in liaison with healthcare services in Wales.

Eleanor Grey QC

Professor Sir Ian Kennedy

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EXECUTIVE SUMMARY

Introduction

- 1.1 This Review is concerned with the care of children born with congenital heart disease. It was commissioned in June 2014 by NHS England's Medical Director after hearing the concerns expressed by a number of families regarding the care and treatment of their children while patients in Bristol Royal Children's Hospital. The Review concentrates on these concerns. It investigated a wide range of specific issues brought to it by parents and families. The Review's Terms of Reference also required it to carry out a wider examination of the paediatric cardiac service at the University Hospitals Bristol NHS Foundation Trust. This report presents an overview of the service from 2010 – 2014, informed by the results of the investigation it carried out. It follows the pathway of care, from initial diagnosis onwards. It examines the evidence of parents and members of staff.
- 1.2 The Review records its thanks to all those who took part. It pays particular tribute to parents whose persistence led to the involvement of the Care Quality Commission (CQC) in 2012.
- 1.3 The Review was advised by a Panel of Experts. At the request of the Review, the Experts also carried out a more detailed examination in response to specific concerns and questions raised by a number of individual families. The results of these Case Reviews have been reported back to these families. They are not published in this Report, given the need to respect patients' confidences.
- 1.4 Alongside of our work but in a separate and independent process, the CQC carried out a review of selected clinical case notes. We have been able to study its findings, prior to finalising this report.
- 1.5 After weighing all that it saw and heard, the Review sets out its conclusions and a number of recommendations.
- 1.6 The Review reached the firm conclusion that there was no evidence to suggest that there were failures in care and treatment of the nature that were identified in the Bristol Public Inquiry of 1998-2001. The outcomes of care at the Children's Hospital were broadly comparable with those of other centres caring for children with congenital heart disease. There was evidence that children and families were well-looked after and were satisfied with the care their children received. There was, however, also evidence that, on a number of occasions, the care was less good and that parents were let down. The principal focus of the Review was on Ward 32 where children were cared for. It was clear that, particularly prior to the CQC's inspection in 2012, the nursing staff were regularly under pressure, both in terms of the numbers available and the range of skills needed. This led on occasions to less than good care for children and poor communication with parents and families.

- 1.7 The Review also reached the conclusion that, on occasions, the senior managers of the Hospital, failed adequately to understand and respond effectively to the concerns of parents and adopted an unnecessarily defensive position in the face of the CQC's observations. This led to a deeply regrettable breakdown in communication which culminated in the commissioning of this Review.

The National Picture

- 1.8 The national picture regarding Congenital Heart Disease (CHD) is one in which more children have been receiving treatments which are increasingly successful and where more are reaching adulthood.
- 1.9 This improvement in results has been achieved despite the absence, at least until April 2016, of a mandatory set of standards on quality relating to CHD services in England and Wales. The period of time examined by the Review is one in which surgical units were aware that a future process of commissioning would prescribe such standards and were seeking to enable CHD services to meet them at some uncertain point in the future.
- 1.10 This uncertainty has been reduced by the adoption of the New Congenital Heart Disease Review's (NCHDR) standards, from April 2016. There remain a significant number of standards which must be met within the next few years rather than immediately. The point has not yet been reached where standards could be said to be met in a uniform fashion by all hospitals offering treatment for congenital heart disease.
- 1.11 At present, work on a 'quality dashboard' continues, seeking to ensure that an extended range of key information on quality and performance is made available to commissioners on a monthly basis. The measures are still under development. The commitment given by the NCHDR that the quality dashboard will become publicly available in due course was welcomed by this Review, as potentially such information could significantly add to understanding and accountability to the public.

The University Hospitals Bristol NHS Foundation Trust

- 1.12 Much has changed since the Public Inquiry into paediatric cardiac surgery at the Bristol Royal Infirmary, not least as regards the dedicated paediatric environment in which children with congenital heart defects are cared for. The CHD service at Bristol has developed from one in which two surgeons were employed and the number of open-heart congenital paediatric procedures was in the region of 130 – 140 procedures per annum, to a situation in which three surgeons were employed and, in 2014, the Children's Cardiac Service undertook 326 paediatric surgical operations.
- 1.13 The ability of commissioners and regulators to monitor the performance of hospital services, including cardiac services, has developed significantly.

Data on Mortality and Morbidity

- 1.14 There is a fundamental difference between the circumstances revealed by the Bristol Public Inquiry (where systemic weaknesses in the management of AVSD and switch operations by the two surgeons then employed at the Hospital were revealed by the Inquiry), and the situation now. The National Congenital Heart Disease Audit (NCHDA), which is managed by the National Institute for Cardiovascular Outcomes Research (NICOR), publishes information on activity and outcomes across surgical centres, and raises ‘alerts’ about potential outliers. This should ensure that such a situation would now not go undetected.
- 1.15 The value of the NCHDA, as a single trusted source of information upon activity and outcomes, is considerable. Those who manage it are aware that improvements are needed to the accessibility and ease of understanding of the information on NCHDA’s website, to assist patients and families.
- 1.16 The data available from the NCHDA shows that the outcomes of surgery and other interventional procedures at BRHC were comparable with those in other centres within the UK, from April 2010 – March 2015.
- 1.17 The Children’s Cardiac Centre did trigger ‘alert’ notifications from NICOR regarding the arterial shunt procedure, on the basis of data relating to 2009 – 2012 and 2010 – 2013. The BRHC paediatric cardiac services responded appropriately to these warnings, setting out its explanation for the outcomes and the actions taken. The results for the period 2012 – 2015 showed that Bristol was no longer triggering the alert.
- 1.18 Because information upon the responses made to these alerts was not easy to locate, we **recommend:**

<p>(1) That any review of the Department of Health’s Outlier policy (the policy followed by the NCHDA when its audits trigger alerts or alarms) should give specific attention to the need for publication of the responses to outlier alerts, and of any actions taken as a result.</p>
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- 1.19 Concerns were raised by parents that the data submitted by Bristol to the audit was inaccurate or incomplete were understandable, and they have led directly to changes and improvements in the national audit. But we have set out why, ultimately, those concerns about poor submission of data were not justified.
- 1.20 Any gaps in the data were not the result of incomplete or inaccurate information returns from Bristol, but were caused either by how the NCHDA checked those returns using information from the Office of National Statistics; or from the scope of the audit which did not, until recently, include the results of diagnostic catheterisation.

1.21 There are concerns that the Trust staff involved in this data collection remain over-stretched, and, given the importance of the integrity of the data returned, this requires attention.

1.22 In the light of the above, we **recommend:**

(2) That the Trust should review the adequacy of staffing to support NCHDA's audit and collection of data.

1.23 It is not possible at present to make robust comparisons of rates of morbidity between centres. A major research project on this topic is in hand which, together with data collected by the NCHDA, should secure improvements in the information available over the next few years.

1.24 It is important not to view statistical information in isolation and all sources of information should be examined when looking at a unit's performance. The statistical information summarised above is not a reason to dismiss the concerns of those parents whose unhappiness triggered the work of the Review.

1.25 In particular, the fact that statistics on mortality may not suggest cause for concern does not mean that there could not have been failings, or the need for improved practice, in individual cases or areas of practice. Such information cannot be seen in isolation. Furthermore, the death or suffering of any child is a tragedy, and any failings, if they occurred, would be profoundly distressing regardless of whether any failings were 'one-offs' or repeated. We set out to explore the concerns about the cases drawn to our attention with these perspectives in mind.

Networks, Diagnosis and Outpatient Care

1.26 In December 2010, the Safe and Sustainable Review's Independent Expert Panel had concluded that arrangements across the network were based on strong individual relationships rather than documented protocols. The Review noted limited change to that position in the course of the Review, the development of a protocol between clinicians in Bristol and Wales on the management of patent ductus arteriosus being an exception to this picture. But it felt such limited development was not surprising, given how the Safe and Sustainable process came to a halt. The Review noted the recent appointment of a Network Manager by the UHB, and the plans for future development as a result.

1.27 There were challenges in ensuring consistent information was given to families, particularly when care was shared or passed between referring clinicians outside of the Bristol service, and those based at the UHB. The difficulties in managing communication and expectations in the treatment of patent ductus arteriosus, between Wales and Bristol, was one example of those challenges.

- 1.28 The matters most frequently raised by families concerned recurring problems with the robustness of systems for booking outpatient appointments, for re-scheduling missed or cancelled appointments and for following up those who did not attend. There were also concerns about the capacity of the service, given the demand for outpatient clinics, and the need to systematise the procedures in the outpatient clinic, such as observations of patients, review of observations by medical staff, and procedures for taking more urgent action in the face of abnormal observations.
- 1.29 The causes of these difficulties appear to have been many and varied.
- 1.30 Appointments systems are frequently the source of patient frustration and complaint. It is difficult to eliminate occasional error or instances of poor communication. There is evidence that, as might be expected, problems in the management of outpatient appointments were not limited to the paediatric cardiac department, but were a Trust-wide issue. Without suggesting that the situation described was an acceptable one, the Review's Expert Panel felt that the challenges in the management of paediatric cardiac outpatient appointments were likely to be similar to those faced not only more generally in the UHB, but in many hospitals across the country. Moreover, the Review considered that there had been a 'step change' in the response to these issues from early 2013 onwards, when it appeared that more vigorous action had been initiated. That said, some clinicians still expressed concern that the outpatient service was still under pressure, the cardiologists were stretched and further support was required. There was also a need to review the facilities and resources for outpatients.
- 1.31 Cardiac children are a vulnerable group. Their condition can change and deteriorate quickly, with potentially life-threatening consequences. This highlighted both the general need for stringent adherence to the times planned for appointments and the importance of dealing properly with question of those children 'lost to follow-up'. It felt that this was an issue of real importance throughout the course of a child's life, and not only at the stage of transition to adult services.
- 1.32 The standards developed by the NCHD Review should enable the development of an effective network, with consistent standards to be met by all centres within the network, including in the planned deployment of professional expertise (e.g., the appointment of 'paediatricians with an interest') at local hospitals. Without underestimating the challenges that will be faced in meeting those standards, their development nevertheless represents an important step towards achieving equitable access to services.
- 1.33 The process of commissioning in Wales was outside the NCHD Review. This Review felt that there was an urgent need for the effective implementation of standards designed to ensure consistency of services for patients/families across the network, including in fetal medicine, maternity and neonatal services both within Wales and between Wales and Bristol.

- 1.34 The Review noted the commitment given by the Welsh Health Specialised Services Committee (WHSSC) to working with the NHS England Congenital Heart Disease Review Team, the new Congenital Heart Network and providers to ensure the coordination of plans to improve services. It endorsed the importance of ensuring the consistent provision of services, to a uniform standard, across both England and Wales.
- 1.35 In the light of the above, we make the following **recommendations**, addressed respectively to those named:

(3) That the Trust should review the information given to families at the point of diagnosis of CHD (whether antenatal or post-natal), to ensure that it covers not only diagnosis but also the proposed pathway of care. Attention should be paid to the means by which such information is conveyed, and the use of internet and electronic resources to supplement leaflets and letters.

(4) That the Commissioners and providers of fetal cardiology services in Wales should review the availability of support for women, including for any transition to Bristol or other specialist tertiary centres. For example, women whose fetus is diagnosed with a cardiac anomaly and are delivering their baby in Wales should be offered the opportunity, and be supported to visit the centre in Bristol, if there is an expectation that their baby will be transferred to Bristol at some point following the birth.

(5) The South West and Wales Network should regard it as a priority in its development to achieve better co-ordination between the paediatric cardiology service in Wales and the paediatric cardiac services in Bristol.

(6) There should be explicit recognition at a national level that children are 'lost to follow up' at points in time other than transition and transfer to other centres, which are the points explicitly reflected in the NCHD's current standard. The standard should be broadened by NHS England, to recognise the matters of safeguarding which can arise for vulnerable children.

(7) The paediatric cardiac service in Bristol should carry out periodic audit of follow-up care to ensure that the care is in line with the intended treatment plan, including with regards to the timing of follow-up appointments.

(8) The Trust should monitor the experience of children and families to ensure that improvements in the organisation of outpatient clinics have been effective.

(9) In the light of concerns about the continuing pressure on cardiologists and the facilities and resources available, the Children's Hospital should benchmark itself against comparable centres and make the necessary changes which such an exercise demonstrates as being necessary.

(10) NHS England should gather and/or publish, to the extent possible, the data necessary to assess the implementation of the NCHD standard, that tertiary centres should employ one consultant cardiologist per half million people served, working flexibly across the Network.

Admissions to Hospital

1.36 During the period of the Review, the ability of clinicians at Bristol and Cardiff to co-operative effectively in planning operations and interventions at the Children's Hospital was constrained by the difficulties in securing the consistent involvement of Cardiff clinicians in Bristol Joint Cardiac Conference (JCCs), in person or remotely. The difficulties were a product both of the limits upon the ability of Cardiff clinicians to attend meetings in Bristol, and of the limited technology available to them to share images and other clinical resources.

1.37 We recommended in the previous Chapter that achieving better co-ordination between the paediatric cardiology service in Wales and the paediatric cardiac services in Bristol should be recognised as a priority in the development of the Bristol network.

1.38 In the light of the above, we further **recommend:**

(11) That the paediatric cardiac service benchmarks its current arrangements against other comparable centres, to ensure that its ability, as a tertiary 'Level 1' centre under the NCHD Standards, to communicate with a 'Level 2' centre, are adequate and sufficiently resourced. Benchmarking would require a study both of the technical resources underpinning good communication, and the physical capacity of clinicians to attend planning meetings such as the JCC.

1.39 We heard a range of concerns expressed by some families regarding the process of obtaining consent to their child's treatment. These included concerns about the completeness of information provided and the manner in which it was conveyed and the support provided to parents during the process. We also heard of concerns about knowledge of the identity of the clinician who performed the procedure. There was, at times, a lack of transparency about who would be performing an operation. We noted that guidance on information to families about the identity of clinicians involved in procedures or treatment lacks clarity and consistency.

1.40 We note that improvements have been made to the arrangements for obtaining consent for surgical procedures from 2015 onwards, to provide additional support and information to families.

1.41 We **endorse**, the recommendation from the CQC's clinical case note review of the need to review the 'Recording [of] the percentage risk of mortality or other major complications discussed with parents or carers on consent forms.'

1.42 The Review considered that most if not all families would now readily be able to record discussions with clinicians by using their mobile phones. In the light of this we **recommend:**

(12) That clinicians encourage an open and transparent dialogue with patients and families upon the option of recording conversations when a diagnosis, course of treatment, or prognosis is being discussed.

1.43 We also make the following further **recommendations:**

(13) That the Trust reviews its Consent Policy and the training of staff, to ensure that any questions regarding the capacity of parents or carers to give consent to treatment on behalf of their children are identified and appropriate advice sought.

(14) That the Trust reviews its Consent Policy to take account of recent developments in the law in this area, emphasising the rights of patients to be treated as partners by clinicians, and to be properly informed about material risks.

(15) That a national protocol be agreed explaining the role of individuals and teams in paediatric cardiac surgery and cardiac catheterisations. Such a protocol should be shared at an early stage of the pathway of care, to ensure that all families are clear about how teams work and the involvement, under supervision of junior members of staff.

(16) As an interim measure pending any national guidance, that the paediatric cardiac service in the Trust reviews its practice to ensure that there is consistency of approach in the information provided to parents about the involvement of other operators or team members.

(17) That the Trust carry out a review or audit of (i) its policy concerning obtaining consent to anaesthesia, and its implementation; and (ii) the implementation of the changes to its processes and procedures relating to consent.

Surgery and Theatres

1.44 A number of parents were concerned that their children had not received proper care; at times this included concerns or questions about the management of operations or procedures in the operating theatre or catheter laboratory.

1.45 Reviews of individual cases which were carried out by this Review did not point to flaws in the management of cases or failures in the technical ability of the teams involved. We have borne in mind throughout the Review the cases before us in which children, tragically, died. They include children who did not recover after surgery or other interventions, or whose operations were unsuccessful. In other parts of this report, we have set out occasions when aspects of their care either fell short or could have been improved. But we have concluded that there is no evidence to suggest that

these cases point to specific or systemic failures in the conduct of individuals carrying out procedures, whether in the operating theatre or the catheter laboratory.

- 1.46 The CQC's clinical case note review noted that: 'The case reviewers were not critical of the standard of surgery in any individual case.'
- 1.47 During the period of this Review, there were serious pressures on the capacity of the cardiac surgical service, caused both by the limited operating slots available and the finite number of beds available in PICU. As a consequence, heavy strains were placed upon parents and children by the resulting cancellations of operations. There were times of particular pressure, e.g. in late September 2013 or during the winter of 2014/15. At times surgeons considered not taking referrals but did not do so because of similar pressures in other centres.
- 1.48 There is very limited evidence that cancellations affected outcomes, as opposed to inflicting serious stresses on the parents and children affected. The review or 'juggling' of waiting lists that took place was aimed at ensuring that children were operated upon at an appropriate time, and clinicians were plainly keenly aware of the need to achieve this.
- 1.49 Steps were taken both to increase the number of operating sessions over time and to improve the management of the surgical list in 2013. The recent appointment of the cardiac pathway co-ordinator should also assist.
- 1.50 Cancellations cannot be avoided, despite these increases in capacity. Rates of cancellation are now monitored through the transition dashboard. Data which would allow comparison with other sites is not yet publicly available.
- 1.51 In the light of the above we **recommend**:

(18) That steps be taken by the Trust to review the adequacy of the procedures for assessing risk in in relation to reviewing cancellations and the timing of re-scheduled procedures within paediatric cardiac services.

The Paediatric Intensive Care Unit

- 1.52 Viewed overall, there was a good standard of care provided in PICU throughout the period of our Terms of Reference. This was achieved despite significant pressure on beds. High rates of occupancy, however, were a reason why planned operations could not always proceed.
- 1.53 The PICU has effectively managed staffing constraints. In common with many other PICUs across the country, staffing has been consistently below recommended levels.
- 1.54 PICU's staff were active leaders in the reporting and investigation of clinical incidents.

- 1.55 During the period prior to the creation of dedicated High Dependency facilities, the multi-disciplinary procedure for agreeing discharges from PICU to Ward 32, though apparently formalised, was more often ad hoc and informal. It would have benefitted from the explicit identification and documentation of the nursing needs of infants and children, when transferred to the ward.
- 1.56 Clinicians were frustrated at the absence of dedicated beds for cardiac patients in PICU. They felt that they would be able to provide a higher quality service, with fewer cancellations, if such beds were available, and also that PICU's staff could further specialise in the needs of children with CHD.
- 1.57 On the other hand, it is apparent that designating certain beds for particular categories of children could reduce the ability of a PICU to admit children who needed critical care. Changing practice against this background is a complex challenge, with changes to one part of a system (e.g. by the creation of a HDU) affecting others, both inside and outside a of hospital with a PICU serving a wide area and a broad range of patients.
- 1.58 We were conscious of the heavy strains created by the limitations on the capacity of the Bristol PICU, during the period of this Review, and consider that this is likely to be a national issue that requires proper attention.
- 1.59 In the light of the above, we **recommend:**

(19) That NHS England should commission a review of Paediatric Intensive Care Services across England. We were conscious of the heavy strains placed on families by the limitations on the capacity of the Bristol PICU, during the period of this Review, and consider that this is likely to be a national issue that requires proper attention.

End of Life Care, Bereavement and Psychological Support

- 1.60 There were weaknesses in the provision made by the Trust for end-of-life care and bereavement support, particularly in the early part of the period covered by this Review. More recently, services had been strengthened and there were examples of excellent practice.
- 1.61 The need for psychological support for patients and families is a crucial part of the service that should be provided. Although there has also been some improvement in the provision of psychological support for patients and families, it remains under-resourced and is not able to meet the needs of all those who could benefit from it.
- 1.62 In the light of the above, we **recommend:**

(20) That the Trust should set out a timetable for the establishment of appropriate services for end-of-life care and bereavement support.

(21) Commissioners should give priority to the need to provide adequate funds for the provision of a comprehensive service of psychological support.

Ward 32 – the Cardiac Ward

- 1.63 One reason why the Review was set up was the expression of concerns by a number of parents that the numbers of nurses on Ward 32, and their skills, were not adequate to provide proper nursing care to the children on the ward. Some of these parents had been instrumental in triggering an inspection of the ward by the Care Quality Commission (CQC) in September 2012. We examined information about nursing care before that date.
- 1.64 The number and needs of children on ward called for a high level of nursing care. There is evidence to suggest that Ward 32 was potentially the ward with the highest level of acuity (level of acuteness of a patient's condition), compared with others in the Children's Hospital. The Trust's own data collection shows that there were a significant number of children who required augmented levels of nursing care on Ward 32 during the period of the Review, and prior to changes made in the organisation of ward care following the CQC inspection in September 2012.
- 1.65 There was confusion surrounding the term 'high dependency' or 'high dependency care' during this period. It could be used widely, including to describe children who were not critically ill but needed considerable input from staff. At times, staff use of the term probably reflected that confusion. We accept that because of this, it is likely that, on occasion, the term was used to describe the care on Ward 32, as some parents reported to us.
- 1.66 The demand for nursing care on Ward 32 was further increased by the fact that a large percentage of its patients were babies or very young children with cardiac problems, who needed high levels of attention, and the fact that there were a large number of small rooms or cubicles on the ward. Nurses and medical staff also had to respond to the needs of the 'ward attenders' (children who attended the ward for a day, or less, for short reviews), and 'non-cardiac' patients whose needs were, therefore, more diverse and less familiar.
- 1.67 Overall, there was evidence that suggested that Ward 32 was under heavier pressure than other wards, because of the circumstances of its patients.
- 1.68 At the time, there was a heavy reliance on professional judgment and discretion in order to assess the numbers of nurses and level of nursing needed, on a daily basis. We do not doubt the sincerity and good faith of all those staff made those judgments. But we do consider that they needed better tools to be developed, to support them to make them.
- 1.69 In recent years, much work has been done on ensuring safer nursing levels. Validated tools for measuring patient's acuity have been developed, with a tool for paediatric

patients soon to be available. Trusts are now also required to put information in the public domain about staffing levels in each hospital ward.

- 1.70 We **endorse** the importance of this work. We emphasise the importance of the early use of, in particular, a nationally recognised paediatric staffing tool for acutely ill children. When available, this should be utilised, together with the professional judgement of senior nurses responsible for the care of the patient, to review the basis of the current nursing establishment on the cardiac ward.

Managing Levels of Staffing

- 1.71 The most appropriate sources of guidance or recommendations on levels of nursing staff were the 2003 RCN's guidance and the 2010 PICS' standards. As regard the nursing establishment, in the light of the numbers of patients, their ages, their need for specialist care and the increasing acuity of patients, the Review felt that the nursing numbers would have fallen below the recommended levels on a reasonably frequent basis, and that there was a clear risk of harm as a result. Further, heavy reliance on Bank and agency nurses to maintain staffing levels is not consistent with providing an appropriate quality of care.
- 1.72 The picture of a ward under pressure was consistent with the picture formed from the Expert Case Reviews. It was apparent that staff worked hard to ensure that the children received proper attention, so that (for example) hourly observations were generally carried out. There was concern, however, that they lacked the 'time and space' to reflect on trends in the clinical status of the children they were caring for, as illustrated by the concerns expressed, in spring 2012, about the extent of the nursing staff members' ability to identify children whose condition was deteriorating.
- 1.73 In both late 2010 and early 2012, there were attempts to secure funding for dedicated high dependency beds in the BRHC. It was recognised that improvements were desirable. In February 2012, there was formal recognition of the risk 'of a reduction in the quality of care for patients in children's hospital when the number of children with higher dependency needs exceeds the level planned and staffed for.' But the Review asked whether sufficient attention had been paid not only to the desirability of improvement, but to the adequacy and safety of the existing model of care before any changes to it could be introduced, prior to the CQC's inspection in September 2012.
- 1.74 By late 2011, there was information available in the form of a draft risk assessment for Ward 32. This, together with details of incidents relating to 'low' or unsafe staffing on the ward, the expressions of concern voiced by members of the Cardiac Clinical Governance Committee, and by a consultant paediatric cardiologist in September 2011, suggested there was a need for careful review of the existing care.
- 1.75 By April and May 2012, a number of incidents had prompted further consideration, both of the staff's ability to recognise children whose condition was deteriorating and

of the adequacy of levels of nursing staff. Steps to increase these levels were outlined in an email from the Matron in mid-April 2012.

- 1.76 These proposed changes seemed to us reasonable, particularly when linked to further improvements which followed shortly. The Review noted, however, that the intention was to audit these changes. This does not appear to have occurred. The Review considered that this should have taken place at the time, as planned. In its absence, there was a dearth of information about exactly when the changes described took effect, and their efficacy. Against that background, the CQC found that there was non-compliance with, in particular, its staffing standards, when it inspected the ward in early September 2012.
- 1.77 More complex was the issue of whether the proposed steps to strengthen staffing could or should have been taken more quickly. We felt that, rather than focussing on early 2012, our primary concern remained the failure to carry out a proper risk assessment in late 2011. It was at this point that an effective evaluation of the risks on Ward 32 could, and we felt should, have been carried out.

Governance and Leadership

- 1.78 When the CQC raised concerns about the quality of care on Ward 32 in September 2012, this came as a surprise to the senior leadership of the Trust. Overall, review of the information that was reported upwards does not suggest that reports or warnings were ignored by the Trust Executive. Rather, in our opinion, the key information that was suggestive of a need to review existing risks remained at the level of the Women's and Children's Division.
- 1.79 The fact that the existence of concerns about the staffing of Ward 32 were not referred to the Board until after the CQC's visit demonstrates clearly that they were not taken sufficiently seriously by the relevant managers.
- 1.80 These events indicated a need to review the mechanisms for risk management within the Trust. But the Review noted evidence of, first, greater focus upon the study of 'low-risk' incidents since 2012, and, in addition, reviews examining patient safety and risk management that took place within the BRHC, in 2013 and 2014. It appeared that action had been taken to review the mechanisms by which matters to do with the safety of patients were addressed throughout the BRHC hospital.
- 1.81 However, the review of risk management in 2014 recorded that work remained to be completed to develop staff's understanding of the nature of patient safety incidents and how such incidents should be graded.

1.82 In the light of the above, we **recommend:**

(22) That the Trust review the implementation of the recommendation of the Kennedy Report that a member of the Trust's Executive, sitting on the Board, has responsibility to ensure that the interests of children are preserved and protected, and should routinely report on this matter to the Board.

(23) That the BRHC confirm, by audit or other suitable means of review, that effective action has been taken to ensure that staff possess a shared understanding of the nature of patient safety incidents and how they should be ranked.

The CQC's Involvement

1.83 There was effective co-ordination between commissioners, regulators and the Trust in the wake of the CQC's inspection with a view to sharing information and agreeing on the actions needed. Decisions were taken on funding for additional beds for high dependency care and there was effective monitoring of the Trust's action plan to effect widespread changes, as discussed further in the following chapter. The Risk Summit as a mechanism worked effectively to bring key individuals together.

1.84 The exception to this picture of communication and inclusion were the families who had first gone to the CQC. They were left largely outside this process and were not satisfied that proper action was being taken.

1.85 In relation to communication between families and the Trust, the Trust failed to continue attempts to involve one family in the actions recommended as a result of an RCA and to share information about continuing investigations. More generally, we perceived a sharp contrast between the early acknowledgement of either failings or areas for improvement in CDRs or RCAs shared with families, and the Trust's subsequent defence of the model of care in Ward 32 prior to September 2012, after the CQC had found that the Trust had not complied with its standards.

1.86 While there were some meetings with families held by the CQC and representatives of NHS Bristol, the SHA and the NHS's Commissioning Board and, in due course, NHS England, during the course of late 2012 and 2013 families were not only preparing for their children's inquests, but seeking support or help from a very wide range of bodies in the NHS and other organisations to answer further questions which they had. Their experience was of a lack of progress or action.

1.87 The Review concluded that organisations within the NHS, and more particularly NHS England, failed to engage consistently with families throughout 2013, and to develop and deliver a strategy for reporting on what had been done to investigate or to address concerns. This played a part in creating the situation which eventually led to the commissioning of this Review.

1.88 In the light of the above, we **recommend**:

(24) That urgent attention be given to developing more effective mechanisms for maintaining dialogue in the future in situations such as these, at the level of both the provider and commissioning organisations.

Trust Action Following the CQC Inspection

1.89 We accept that significant changes were made in the provision of care on Ward 32 and in cardiac services more generally, in the wake of the CQC's inspection of September 2012. They went substantially beyond the establishment of dedicated cardiac high dependency beds in Ward 32. They included improvements in areas such as procedures for triggering action in response to the clinical warning scores of children, listening to parents and families, improving nursing skills, and improving team-working and communication. We have set out the main areas where there was change and development.

1.90 In the Review's judgment, there had been substantial learning, within cardiac services, from the criticisms which had been voiced and from the findings of the Trust's own reviews and investigations.

The Commissioning of High Dependency Care at Bristol Children's Hospital

1.91 The Review was not able to access the entire archive on specialised commissioning from NHS England. This has limited the Review's ability to compile a comprehensive record of the discussions and actions regarding specialised commissioning involvement. We repeat a point which we fear is made all too often: that reorganisations will lead to a significant loss of 'organisational memory' unless comprehensive steps are taken to retain and organise archives.

1.92 In the light of the above, we **recommend**:

(25) That when structural changes are made, adequate resources are devoted to organising and archiving records in a way that will enable them to be retrieved and studied at a later date.

1.93 From the perspective of commissioners (both within the PCTs and the Specialised Commissioning Group), there were widespread gaps in the provision of high dependency care in the South West region from 2010 – 2012. Steps were taken to identify those gaps, through a Review of High Dependency Care in the South West which reported in July 2011. In the case of the BRHC, the Review did not lead to seeking explicit assurances that the gaps had been identified and risks were being properly managed. We took the view that, having been notified about non-compliance with the South West's standards on HD care, commissioners should have been clear about the need for all hospital Trusts in that situation to show that they had effective plans to manage the consequent risk.

- 1.94 The Review did lead to a more thorough consideration of the proposal for a medical HDU which was put forward by the Trust in early 2012. Although that bid was not immediately agreed, it was not wholly dismissed and further work on the proposal continued.
- 1.95 The manner in which the bid was presented by the Trust was consistent with its internal assessment of the risk, which we have discussed above. Consistently with this, commissioners perceived the issue as being more about children were being cared for in the wrong place, on PICU, rather than that children were at risk. Whilst we have examined information that would have supported a different judgement, viewed overall, we accept that until autumn 2012, there was an absence of information to indicate to commissioners a pressing need to prioritise the development of HD facilities at the Bristol Children's Hospital. In particular, and in relation to paediatric cardiac services specifically, the serious incidents that were reported, NICOR's data on outcomes and the manner in which the Trust itself presented its own bids for funding, did not suggest that immediate intervention was needed.
- 1.96 Neither an unsatisfactory debate over who was responsible for funding HD care, nor uncertainties caused by the reorganisation of the NHS taking place at the time, were reasons why no funding was agreed before commissioners had to respond urgently to the results of the CQC's inspection of September 2012. It would also be wrong to criticise (or second-guess with the benefit of hindsight) the judgments on the priorities for funding that were made by those who assessed the bids for funding of HD care made prior to the CQC's inspection.

Investigating the Concerns of Families

- 1.97 We examined difficult and complex situations, perhaps unrepresentative of the general range of complaints seen by the Trust. We saw examples of good handling of complaints and at least one case where good support was offered to a family to explore their questions.
- 1.98 But in the difficult and complex situations which lay at the heart of the Review, investigations and handling of complaints had not succeeded in resolving concerns. At times, the approach taken had, on the contrary, deepened suspicions and rifts.
- 1.99. In the light of the above, we **recommend:**

(26) That the Trust should explore urgently the development of an integrated process for the management of complaints and all related investigations following either a death of a child or a serious incident, taking account of the work of the NHS England's Medical Directorate on this matter. Clear guidance should be given to patients or parents about the function and purpose of each element of an investigation, how they may contribute if they so choose, and how their contributions will be reflected in reports. Such guidance should also draw attention to any sources of support which they may draw upon.

(27) That the design of the processes we refer to should take account also of the need for guidance and training for clinical staff as regards liaising with families and enabling effective dialogue.

(28) That guidance be drawn up which identifies when, and if so, how, an 'independent element' can be introduced into the handling of those complaints or investigations which require it.

(29) That as part of the process of exploring the options for more effective handling of complaints, including the introduction of an independent element, serious consideration be given to offering as early as possible, alternative forms of dispute resolution, such as medical mediation.

(30) That the Trust should review its procedures to ensure that patients or families are offered not only information about any changes in practice introduced as a result of a complaint or incident involving them or their families and seek feedback on its effectiveness, but also the opportunity to be involved in designing those changes and overseeing their implementation.

(31) That the Trust should review the history of recent events and the contents of this report, with a view to acknowledging publically the role which parents have played in bringing about significant changes in practice and in improving the provision of care.

1.100 In our 'concluding remarks' we have made a final **recommendation**:

(32) That the Trust redesignate its activities regarding the safety of patients so as to replace the notion of "patient safety" with the reference to the safety of patients, thereby placing patients at the centre of its concern for safe care.

1.101 We express the hope any response to this Report will strengthen not only paediatric cardiac services, but the partnership between families and staff which is the basis of delivering safe and effective care of a high quality.

1.102 We repeat our thanks to all those who took part and have contributed to it.

CHAPTER ONE: INTRODUCTION AND METHODOLOGY

Background to the Review

1 The Genesis of the Review

- 1.1 The genesis of this independent review lay in a meeting held in February 2014, between Sir Bruce Keogh, NHS England's Medical Director, and a number of concerned families. The core membership of this group consisted of families whose children had died following cardiac surgery or other related procedures at the University Hospitals Bristol NHS Foundation Trust in recent years. Another parent expressed concerns about suspected brain damage suffered by her child. Sir Bruce listened to the concerns of these families about the care and treatment that their children had received, as part of the Bristol Royal Hospital for Children's paediatric cardiac services, and agreed that an independent review of the service should be commissioned.
- 1.2 As the former Chair of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary (BRI) and former Counsel to that Inquiry, Sir Ian Kennedy and Ms Eleanor Grey were subsequently asked to hold two meetings with the families in question, seeking to explore their wishes and potential terms of reference. Sir Bruce's concern that any review should be 'parent-led' meant that, at an early stage, we explored whether one of the families concerned in these initial discussions might be represented on the Review's panel. However, none felt able to be involved in such a capacity. The Review has, nonetheless, sought to keep both the information gathered from all parents or families in contact with it, and all concerns raised by them, at the heart of its inquiries.
- 1.3 Maintaining independence and impartiality, coupled with the limitations of a small team, meant that we were perhaps more distant from them than some families would have wished. Equally we are aware that the perspective of NHS staff regarding our relationship with families may have been rather different.
- 1.4 The Terms of Reference of the Review were finalised by NHS England, as the Review's commissioners, in June 2014. The Review has sought to do two things: to investigate the issues brought to it by parents and families, and to carry out a wider examination of the paediatric cardiac service and its ability to meet any standards set for the service. Both streams of work are reflected in this Report.
- 1.5 Delivering both aspects of this investigation has presented challenges. It has required detailed analysis of the care of individual children, whilst at the same time taking an overview of the service as a whole. We are acutely aware that our work took longer than we, the families and the NHS organisations and staff involved would have liked.
- 1.6 It is equally important to record just how very difficult this process has been for all concerned. Families had to recount deeply painful events and the emotional toll was

evident. Staff from both the Trust and commissioning bodies also expressed distress about the impact on parents, when their concerns about the care of their children had not been relieved by the hospital's investigations.

- 1.7 We are also very aware to the impact on staff and the intensity of the scrutiny they have been under. A large number of staff were clearly overwhelmed during their discussions with us. One member of staff working on the cardiac ward talked of the stress of working in what he felt to be the 'most scrutinised ward in the UK.'

2 Further concurrent investigations

- 2.1 One reason for the scrutiny that the ward has been exposed to was the fact that the Review was not the only body examining paediatric cardiac surgery and the staff involved. A number of inquests had been held into individual deaths. In addition, our work ran alongside both the Care Quality Commission's Clinical Case Note Review described below and an investigation by the Parliamentary and Health Service Ombudsman (the PHSO) into the complaints made following the deaths of two children, that were also part of our work. We tried to co-ordinate our investigation with that of the PHSO as much as possible, but found there were limits to the sharing of information because of the statutory framework which regulates the work of the PHSO.
- 2.2 At the time of finalising this report, the outcome of the PHSO's investigations was not available to the Review. We acknowledge the possibility that, at times, we may have reached differing conclusions on similar issues. If so, this will be because we have worked independently, dealing with complex issues, both of us with the benefit of expert advice but from different individuals, and using evidence that will overlap but not be identical.
- 2.3 At the time when we were established, the Chief Inspector of Hospitals of the Care Quality Commission (CQC) was also asked by the Medical Director of NHS England to undertake a clinical case note review, to consider the cases of a number of the children who have received care from the service. The purpose of the review was to determine whether there was evidence of any systematic problems with pre-operative, operative and post-operative care in the service as currently provided. The children's cases selected for analysis did not, we understand, duplicate those reviewed by us in the course of our work.
- 2.4 We were kept informed by the CQC about its work, which proceeded alongside ours but independently of it. In order to ensure that the Review could take account of the emerging findings from CQC's work an oral briefing on those findings was given by the CQC's Professor Edward Baker to the Review, in March 2016 and the CQC shared a copy of its draft report with us. At the time of concluding our Report, the CQC was expecting to publish its report and findings on its website in June.

- 2.5 The findings of the CQC’s reviewers supplement the work of this Review and the expert case reviews which we undertook. We have referred to CQC’s findings in the course of this Report. They did not suggest the need for further investigation on the part of the Review.

3 Establishing the Review

- 3.1 The terms of reference are set out in Appendix 1. They required a review of the service at Bristol between March 2010 (when the Safe and Sustainable Review published the standards against which it would assess centres offering paediatric cardiac services) and the establishment of the Review. We therefore concentrated on the period from March 2010 – July 2014, albeit that this Report seeks to take account of and comment on more recent developments, when possible and appropriate.

- 3.2 We acknowledge that contrary to the wishes of some families concerned, a public inquiry was not commissioned. That would have been a matter for the Secretary of State for Health under the Inquiries Act 2005, not NHS England. Our Review did not have statutory powers. We did not set out to hold public hearings, whether with families, staff or other interested parties. Instead, the approach which we set out in our published Terms of Engagement was based on the analysis of documents and confidential discussions with individuals, in the hope and expectation that this might encourage a more candid discussion of any matters faced by the paediatric cardiac service. It seemed to us that this approach was also consistent with the fact that we discussed, on many occasions, patient-confidential information relating to the care of individual children. Whilst aware of the debates surrounding the merits of such an approach, as opposed to public hearings, it seemed to us that this approach was consistent with our status as a Review, and that any other approach would have been very difficult to manage (at least without the legal structure and further resources accompanying a public inquiry).

- 3.3 We acknowledge that there were also families who would have liked us to investigate experiences prior to 2010, or who told us of events in other parts of the Children’s Hospital. But, we were obliged to stay our terms of reference, thereby limiting the matters that we could examine.

4 Selection and appointment of the Expert Panel

- 4.1 An early priority was to select and appoint an independent Panel of expert advisors. It was essential that the Review benefited from the expert advice of clinicians with up-to-date operational and clinical knowledge and experience from across the spectrum of clinical disciplines involved in the care of children with congenital heart conditions.

- 4.2 The Review sought to identify experienced clinicians from other children’s cardiac centres across England and Scotland who could provide expert advice. This was not straightforward, as care of such children is a small discipline involving a fairly modest number of clinicians. It was difficult both for staff to be released, and to ensure that Panel members had no recent close associations with the service or clinicians in

Bristol, in order to ensure confidence in the independence of the Review. Securing the Panel members took longer than anticipated, partly for these reasons. The first meeting of the Panel took place in February 2015.

4.3 The following experts was appointed:

- Mr Asif Hasan, Consultant Congenital Cardiac Surgeon Freeman Hospital, Newcastle upon Tyne Hospitals NHS Foundation Trust
- Dr Frances Bu'lock, Consultant Paediatric Cardiologist, East Midlands Congenital Heart Centre, University Hospitals of Leicester NHS Trust
- Dr Janet Burns, Consultant Paediatric Cardiologist, formerly at Royal Hospital for Sick Children in Edinburgh, now retired
- Ms Pauline Whitmore, Clinical Operational Manager Critical Care and Cardiorespiratory Division Great Ormond Street Hospital
- Ms Elizabeth Leonard, Lead Educator for Critical Care and Cardiorespiratory, Great Ormond Street Hospital
- Dr Ian James, Consultant Anaesthetist, Great Ormond Street Hospital
- Professor Ian Murdoch, Professor of Paediatric Intensive Care, Guys and St Thomas's NHS Foundation Trust
- Dr Tina Biss, Consultant Haematologist, the Newcastle upon Tyne Hospitals NHS Foundation Trust
- Dr Gill Lawrence, formerly Director of the West Midlands Public Health Observatory and Director of the West Midlands Cancer Intelligence Unit, now retired

4.4 As the Review progressed, we identified that the Review would benefit from further expert advisors, namely:

- Sir Andrew Cash, Chief Executive, Sheffield Teaching Hospitals NHS Foundation Trust
- Ms Mandie Sunderland, Chief Nurse, Nottingham University Hospitals NHS Trust.

Methodology and analysis of evidence

5 Communication with the families of children receiving treatment

- 5.1 Having been established to listen to families, the Review was concerned to ensure that all those with experience of the paediatric cardiac service at the Children's Hospital should have an opportunity to contact us. Important though they were, the families who attended the initial meeting with Sir Bruce could not be the only families who might wish to contribute to the Review. While dependent on families contacting us if they wished to assist the Review, we tried to make it easy of them to contact us by holding a press launch, setting up a website with contact details, and sending out a letter to families with the assistance of the University Hospitals Bristol NHS Foundation Trust (UHB).

- 5.2 We were told that in excess of 8000 children received treatment from the Children's Cardiac Service over the period covered by the Review's terms of reference - March 2010 to July 2014. This included patients seen by the consultant cardiologists in the peripheral out-patient clinics. In July 2014 a letter was sent to all the parents and carers of these children by UHB, on behalf of the Review. The letter was sent by the Trust rather than by the Review as the Trust could not release the contact details of patients and parents. Families were invited to respond directly to the Review.
- 5.3 The Review received responses from 237 families. With the benefit of further discussions with those families (sometimes by telephone, sometimes after meetings held either with staff of the Review or the Chair), we set down in statements or recorded interviews, both their experiences and, at times, the questions which they wanted to see explored. The information received in this way included 33 formal statements from families the Review team met, and interview records from meetings between 20 families and the Chair of the Review.
- 5.4 The Review team also wrote in July 2015 to families who had made contact to ask them if their children would like to provide information about their experiences to the Review. An event was held on the 15th August 2015 with a small group of children and young people.
- 5.5 All of the information received from families was analysed to identify the issues which were raised, to explore whether there were any common themes and to see whether there were any trends in the time of when their experiences occurred. In addition to review by the Chair, all the statements or accounts were checked by a nursing expert and a cardiologist, both to identify themes and issues and to see if further expert input was needed. We have outlined the work of the Expert Case Reviews in section 7 below, as this was how we explored the most complex issues and sought to meet the expectation that we would investigate families' concerns.
- 5.6 Overall, the accounts, feedback and observations received from families who responded to our appeal for information formed a core part of the material analysed by the Review, and explored by its experts. It guided our exploration of many, if not all of the issues which are set out in this Report.
- 5.7 That said, information received in this way cannot necessarily be regarded as 'representative' of all families' experience and for this reason we have not attempted to evaluate the information in a quantitative fashion. Furthermore, the experiences set out were very individual and personal ones; they represented the perspectives of those who spoke to us. Some of the parents who contacted us explained that though they had some negative experiences during the care of their child, they had not previously felt able to bring them to the attention of the Trust or to complain. One family commented that they did not write to complain as 'they felt they should just be grateful that their child had got better'. So we were conscious that, on occasions, we were hearing

concerns that the Trust would sometimes not have had an opportunity to explore at the time.

- 5.8 It was rare for the Review to receive wholly negative comments. A very substantial number of those who contacted us reported good experiences of the service. Many spoke very highly of the care received and the dedication and professionalism of those who provided it. Some of those who praised the service in this way raised minor concerns or queries; others had none at all.
- 5.9 Generally, parents appeared very willing to praise staff for good care and to acknowledge the things that had been done well, even when they also had concerns.
- 5.10 Where there were negative experiences, there were recurring themes, sometimes supported by the clinical records, or by investigations carried out by the Trust.
- 5.11 These themes related to issues at various stages along the pathway of care for children with cardiac conditions. For many families, the pathway starts with ante-natal diagnosis and concludes with transition to adult services. Tragically, in some cases the journey is to palliative care, end-of-life care, and bereavement support. In order to reflect the experience of families, we have covered, as far as possible, the various matters as they arise along the pathway of care reflecting, as we do so, the comments of parents, carers and families. The exploration of that pathway forms the main part of this Report.
- 5.12 One concern repeatedly raised by those families who had had poor experiences of the care at Bristol was that the Review's attempt to hear from all families, including those who had had positive experiences, would mean that we would attach less weight to their negative experiences. They felt strongly that any number of positive accounts could not 'outweigh' the importance of failings, if they occurred. The Review's response has been to acknowledge that there is a range of views held by those with experience of the service. We have looked at all the evidence available to us to assess the care given in those cases where parents have asked us to consider their experiences and those of their children. We have, in turn, drawn on that evidence together with all that we heard or read to see whether those experiences pointed to failings, or lessons that could be learned to benefit all children who receive care in Bristol in the future; or to examples of good practice or care.

6 Information from the Trust

- 6.1 In response to the experiences we heard from families, we asked the Trust to provide a wide range of documents and information to enable us to gain insight into the service and its management. Further details are set out in Appendix 2. In total approximately 6,000 documents were received and analysed.

- 6.2 We also asked the Trust to make a series of presentations to us to gain insight into how the service and the Trust operated. Presentations were given on the following topics:
- ensuring quality and safety through processes and structures of clinical governance
 - managing capacity and demand
 - the Safe and Sustainable Review and meeting the standards for children's cardiac services
 - the Trust's approach to engaging and listening to patients and parents
 - support for and engagement with staff
 - implementation of the recommendations of the Bristol Public Inquiry.
- 6.3 Based on our analysis of all the documentary information and what we heard from families, we identified those staff whom we wanted to meet to discuss matters in detail. More generally, we asked the Trust to encourage staff to contact us; a few did so quite independently of any subsequent invitation from the Review.
- 6.4 Overall we held 50 meetings with staff from the Trust. The Chair was generally assisted by members of the Expert Panel in conducting these discussions. There were meetings with all the consultant medical staff in the children's cardiac service, those holding a relevant role in clinical management or general management, with senior executives of the Trust and nursing staff from PICU and Ward 32. Meetings with nursing staff, although not senior nursing leaders, were generally conducted as group interviews: we heard from staff on Ward 32, in PICU and the Cardiac Nurse Specialists in this fashion.
- 6.5 Some further evidence was taken through written statements, rather than meetings or by telephone conference. In some instances, written submissions were provided following interviews. We were able to interview face to face virtually all of those whom we invited to attend. No-one refused co-operation. In a few cases we could not contact individuals who had changed jobs and locations. Given the small number concerned and the availability of alternative sources of evidence in each case, we are confident that these exceptions made no material difference to the Review's findings.

7 The Expert Case Review

- 7.1 It was apparent from the outset that the concerns of some families who had been instrumental in triggering the Review would need detailed consideration with the help of the Expert Panel. But in addition, a cardiologist and nurse member of the Expert Panel reviewed all the statements or records of meetings with all of the families. They identified those cases where they felt that, in order to understand the issues raised by families, the clinical records relating to a child should be examined, or their care should be discussed with the Trust. Overall, some thirty cases were identified for further review.
- 7.2 These particular families were contacted to seek their consent for the Review to have access to the medical records of their children. Twenty-six families gave consent for the Review to obtain the medical records and for the Review to discuss the care of their

child with the Trust. Two families gave consent for the Review to examine the records of their children, but were not happy for the Review to discuss the care of their children with the Trust. Two families did not respond to the Review's request and had no further involvement in the Review.

- 7.3 For one child, the Trust was not able to locate the clinical records in question and a full report was not, therefore possible. In the other cases, which included eleven child deaths, each of the Review's experts considered the child's medical records, together with any supplementary material that might be relevant to issues raised by the family, to the extent that they fell within our Terms of Reference. Sometimes the further material consisted essentially of the family's account and questions. Sometimes it was more extensive, for example because root cause analyses or child death reviews had been carried out, or because a complaint had been made. In each case, the experts considered the care received as a whole as well as seeking to answer any questions raised.
- 7.4 The results of their work, together with such input in response to matter raised by the Review's Chair following her reading of the documentation, have been offered to the families concerned, as a report or letter. Families have also been offered the chance to meet members of the Expert Panel, to discuss the written documents. We have not published these reports or letters, as they contain private, patient-confidential information.

8 Information about outcomes: mortality and morbidity

- 8.1 Some of the questions raised by families were questions about the outcomes of surgery or other procedures carried out by the BRHC's paediatric cardiac services, and how they compared to the outcomes in other centres across the country. We looked at how we could investigate these issues.
- 8.2 In the United Kingdom, the chief source of information about outcomes takes the form of mortality rates following paediatric cardiac surgery or other interventions. It is derived from the National Congenital Heart Disease Audit. This is one of seven national audits managed by the National Institute for Cardiovascular Outcomes Research (NICOR). We contacted NICOR regarding questions relating to the reporting of mortality rates that were raised with us by families. We were greatly assisted both by the provision of documents and by a meeting held with key contributors to NICOR's work.
- 8.3 We understand that a number of families would also have wished the Review to examine the incidence of morbidity after paediatric cardiac surgery or other interventions at the Children's Hospital, with a view to comparing the results at the BRHC with other centres in the UK. By 'morbidity' we mean post-operative complications. Such complications include problems with the brain or nervous system, unplanned re-operations or difficulties with feeding.

8.4 We thought long and hard about whether, or how, we could study the incidence of such complications. But after investigating the information currently available, we decided that it would not be possible to do so in an acceptably rigorous way. This is because of the limits of the information that is currently available. We reached our decision after hearing about the substantial research programme which is currently taking place in five centres in the UK, including the Children's Hospital. Details of this are set out at Chapter Four. As this work progresses and matures, it should enable information to be gathered, to guide both parents and clinicians. Until that point, we did not feel that it would be possible to study (for example) the possible incidence of brain damage after cardiac operations at the BRHC or to compare it with results from other centres, in a way that would be robust or fair.

9 Other interested contributors

9.1 In addition to hearing from families who had direct experience of the children's cardiac service, the Review also received information from members of the public who had concerns about how the Trust had responded to a number of matters relating to its governance.

9.2 We also contacted key organisations or individuals who might have an interest in the Review's work. We received documentary evidence from NHS England, Bristol NHS Clinical Commissioning Group, CQC, Monitor, NICOR, Bristol City Council's Health Wellbeing and Adult Social Care Scrutiny Commission and the West of England Child Death Overview Panel. We were also significantly assisted by the Welsh Health Specialised Services Committee and by clinicians from the Paediatric Cardiac Unit at the Cardiff and Vale University Health Board, who not only contributed documents but held meetings with the Chair and Review's staff. We met with staff from a number of these organisations, including staff from former commissioning organisations and from NHS England South.

9.3 We encountered difficulties in accessing information in relation to former NHS bodies. In particular, the archive for the former South West Specialised Commissioning Group (SWSCG) was unavailable to NHS England. The Review received the full support of NHS England staff and they made significant efforts to trace documents. However, the documentary evidence was incomplete for the period 2009 to April 2013. For example, minutes from all committees associated with the South West Specialised Commissioning Group were not available for the entire time period.

10 Conclusion

10.1 We have presented the information gained from these investigations in two forms: first, in this Report, which gives an overview of our investigation as a whole, and, second, in the individual case reviews which have been sent directly to families.

CHAPTER TWO: CONTEXT – THE NATIONAL PICTURE

1. The National Context: Congenital Heart Disease

- 1.1 Congenital heart disease (CHD) refers to defects in a child's heart that develop in the womb and are present at birth. CHD is a life-long condition that can be life threatening.
- 1.2 The incidence of CHD in the UK is 8–9 per 1000 live-born infants annually, around 6000 babies per year. It is therefore a relatively common childhood disorder affecting a significant number of children and their families. CHD is a spectrum of cardiovascular malformations, in which the more serious and complex abnormalities are a significant cause of childhood mortality, morbidity and disability.
- 1.3 In England, over 5,800 patients of all ages undergo surgical or transcatheter procedures as treatment for paediatric and congenital cardiac disease each year. A high proportion of these are infants under a year old.
- 1.4 Overall survival is over 98%, with most of the deaths attributable to surgical procedures at younger ages. Around one-third of deaths occur before 14 years of age, with 21% of deaths from CHD occurring in the first year of life.¹
- 1.5 The need to treat adults with congenital heart disease is increasing as more children with CHD receive successful treatment and reach adulthood. As a result of the success of paediatric cardiology and cardiac surgery over the last four decades, it is thought that more adults with congenital heart disease will require medical care than children.²
- 1.6 Outcomes in paediatric cardiac surgery and interventional catheter procedures are monitored and published by the National Congenital Heart Disease Audit, a database which provides a means of comparing the outcomes of surgical treatments and interventional catheterisations in all the centres in the United Kingdom. See further Chapter Four.
- 1.7 Generally, outcomes after cardiac surgery have been improving steadily. Deaths within 30 days of children's cardiac surgery have almost halved in England over the past decade. The annual number of surgical procedures rose between 2000 and 2009 from 2283 to 3939, while the 30-day death rate fell consistently from 4.3% to 2.6% of cases. This compares favourably with similar data collected internationally. This improvement has been achieved notwithstanding an increase in the number and complexity of cases.

¹ See <http://bmb.oxfordjournals.org/content/111/1/5.long>

² Children and young people: Statistics 2013 (2013) Townsend N, Bhatnagar P, Wickramasinghe K, Williams J, Vujcich D, Rayner M, British Heart Foundation: London

1.8 CHD services are specialised services provided from specialist hospitals serving a large geographic area. Children in South-West England and South Wales receive services from the children's cardiac service at BRHC. More information about the service at BRHC is set out in Chapter 3.

2. Commissioning and Regulation

2.1 The commissioning of specialised services such as paediatric cardiac services was, until April 2013, the responsibility of local Primary Care Trusts (PCTs). They discharged this responsibility by forming Specialised Commissioning Groups with neighbouring PCTs. In April 2013, PCTs were abolished and responsibility for the commissioning of specialised services passed to NHS England. The commissioning arrangements are dealt with in more detail in Chapter 15.

2.2 At a national level, the BRI Public Inquiry led directly to the creation of the Healthcare Commission, the regulator of the hospital sector of the NHS until its abolition and replacement by the Care Quality Commission (CQC) in April 2009. During the period of the Review, the CQC was the regulator of the quality of care provided by hospitals. It developed a set of standards which healthcare providers were required to meet, and had powers of inspection and enforcement.

2.3 The role of the CQC in events in the BRHC in 2012, in particular, is dealt with in Chapter Thirteen. It subsequently carried out a full inspection of the Hospital Trust in autumn 2014, reporting in December 2014. The response to that inspection, and changes made, are summarised in Chapter Fourteen.

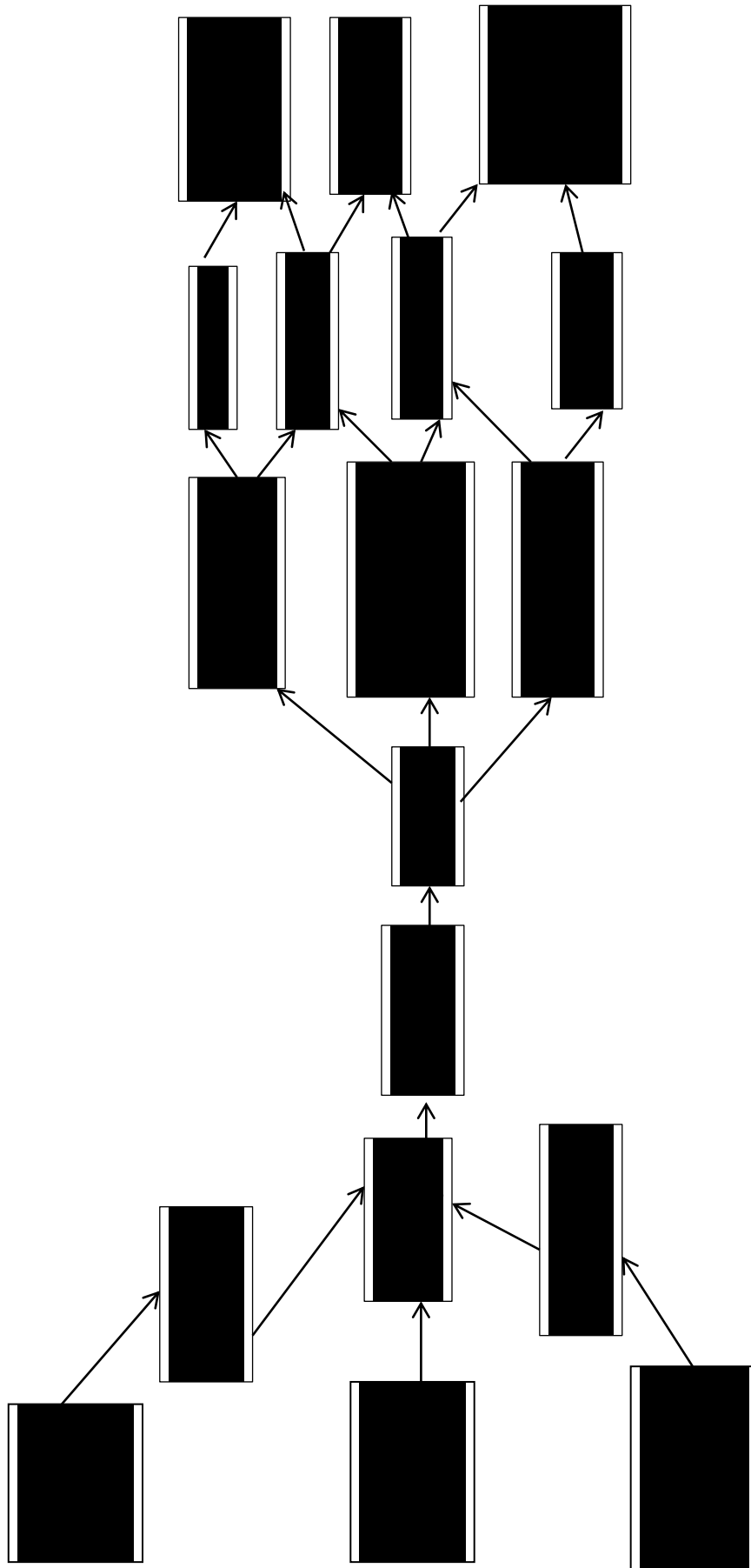
3. The Pathway of Care

3.1 The pathway followed by children with congenital heart disease may be summarised as follows (see flowchart overleaf).³

3.2 We have sought to follow that pathway in this Report.

³ Taken from the Safe and Sustainable Standards, March 2010.

3.1 The Congenital Heart Disease Pathway
The diagram below indicates the usual process a child's care will follow, from diagnosis, through to treatment and then to ongoing care.



4. The Safe & Sustainable Review

- 4.1 The attempt to set standards for the provision of care for children with congenital heart disease has a history stretching back to the Public Inquiry which examined the surgical care of children with congenital heart conditions at the Bristol Royal Infirmary from 1984 – 1995. The report of the Public Inquiry was published in 2001.
- 4.2 The Public Inquiry recommended that standards relating to quality with particular reference to children’s congenital cardiac surgery be developed, and that medical and nursing expertise for children needing heart surgery should be concentrated in a smaller number of specialist units.
- 4.3 The issues, however, remained unresolved when in May 2008, the National Specialised Commissioning Team was asked to undertake a review. The ‘Safe and Sustainable’ team was established to manage the review process on behalf of the ten Specialised Commissioning Groups (SCG) and their local Primary Care Trusts (PCTs) who were the ultimate commissioners of services. The Primary Care Trusts delegated their responsibilities regarding consultation and decision-making to a joint committee of PCTs, the JCPCT. The JCPCT was established in June 2010.
- 4.4 Draft standards on quality, against which surgical centres would be assessed, were published by the Safe and Sustainable team in September 2009. A revised version was published in March 2010. A process of self-assessment by surgical centres of their ability to meet the standards began in April 2010. The Bristol Royal Hospital for Children actively engaged in this process.
- 4.5 Between May and June 2010, an expert panel, chaired by Professor Sir Ian Kennedy, visited each surgical centre to meet staff and families and to assess each centre’s ability to comply with the standards.
- 4.6 The expert panel was not asked to analyse data on outcomes nor did the Joint Committee of PCTs, taking the advice of the professional bodies that the national caseload is too small to be able meaningfully to compare institutions. A report on an analysis of available data on outcomes was made to the JCPCT only in exceptional cases, for example in the case of the suspension of the children’s cardiac surgical service at the Oxford Radcliffe Hospitals NHS Trust in 2010.
- 4.7 The ‘Report of the Independent Expert Panel’ was completed in December 2010 and their assessments were submitted to the JCPCT. Subsequently, the JCPCT carried out a scoring exercise. The service at Bristol Royal Hospital for Children was ranked as sixth out of the eleven centres assessed.
- 4.8 A four-month public consultation on options for change began in March 2011. The proposals advocated concentrating surgical expertise on fewer sites by reducing the number of surgical centres from eleven to either six or seven. Bristol was included in all of the options consulted upon.

- 4.9 The JCPCT held its decision-making meeting on 4 July 2012 and agreed that seven managed clinical networks should be established across England, serving Wales as well. One recommendation was that the Bristol Royal Hospital for Children should lead a children's congenital cardiac network in the South West, working closely with the University Hospital of Wales in Cardiff.
- 4.10 Challenges were made to the decision of the JCPCT. The Secretary of State for Health asked the Independent Reconfiguration Panel to conduct a review in August 2012. On the 12th June 2013 the Secretary of State for Health decided that the work of the Safe and Sustainable review should be suspended, following publication of the report by the Independent Reconfiguration Panel.

5. The New Congenital Heart Disease Review

- 5.1 At the request of the Secretary of State, NHS England then began a fresh review of services for congenital heart disease in June 2013. The New Congenital Heart Disease Review (NCHDR) examined services for both children and adults with CHD.
- 5.2 The aims of the new review were to:
- secure the best outcomes for all patients, not merely the lowest mortality but reduced disability and an improved opportunity for survivors to lead better lives;
 - tackle variations so that services across the country consistently meet demanding standards of performance and are able to offer resilient 24/7 care; and
 - improve patient experience including how information is provided to patients and their families, and consideration of access and support for families when they have to be away from home.
- 5.3 We started our Review as this work gathered pace. A consultation on draft standards and specifications began in September 2014. The Board of NHS England approved the standards and specifications in July 2015 for implementation from April 2016. The Board set out an intention to take its commissioning decisions in the best interests of patients, taking into account and balancing all the main factors, including: affordability, impact on other services, access, patient choice, and not treating the standards as though they existed in isolation.
- 5.4 The standards are based on having three levels of services for CHD for children and adults, working as part of networks. These are:
- Specialist Children's Surgical Centres and Specialist ACHD (Adult) Surgical Centres (level 1);
 - Specialist Children's Cardiology and Specialist ACHD Centres (level 2); and
 - Local Children's Cardiology Centres and Local ACHD Centres (level 3).
- 5.5 The standards set out the detailed requirements for each level of the service and the way in which they need to work together as a network. They also set out the date by which it is expected the standards will be met. Some have to be met immediately and others have time periods ranging from 6 months to 5 years for implementation.

- 5.6 Units face challenges in identifying the resources to achieve improvements and developments.
- 5.7 The service at Bristol, in common with other centres offering paediatric cardiac services, completed an assessment of its ability to meet the standards, both immediately and in the future. At the time of writing NHS England had completed its evaluation of these assessments, and a report was due to be discussed by its Specialised Services Commissioning Committee (SSCC), a sub-committee of the NHS England Board.
- 5.8 The SSCC had already indicated that the status quo could not continue and that NHS England needed to ensure that patients wherever they lived in the country had access to safe, stable, high quality services. They recognised that achieving this within the current arrangement of services would be problematic.
- 5.9 No decisions about the future of services in England generally or specifically in Bristol were expected until after further discussions by SSCC at its meeting at the end of June 2016.

6. The Quality Dashboard

- 6.1 If centres providing CHD services and care are to be commissioned to meet defined standards, information about performance against those standards requires to be readily available. We discuss the information on outcomes available from the National Congenital Heart Disease Audit in Chapter Four. The Review was pleased to hear of work to develop a ‘quality dashboard’ which will provide an extended range of key information to commissioners on a monthly basis to monitor quality and performance. The measures are still under development, and validation of data and concerns over comparability will need to be addressed.
- 6.2 A commitment that the quality dashboard will become publicly available in due course was given in the report on the NCHDR’s Review. This is welcomed by our Review. We felt that, potentially, it could significantly add to public understanding and scrutiny of issues such as waiting lists and cancellations.

7. The Place of Standards in this Review

- 7.1 Our Terms of Reference ask the Review to ‘describe both achievements and any shortfalls by reference to published standards and any other relevant recommendations for change or improvement’. These published standards included the standards published by the Safe and Sustainable Review, in March 2010. However, as we have set out, neither the Safe and Sustainable standards nor the designation of specialist centres recommended by that Review were ever implemented. The Safe and Sustainable standards were to be met on designation – either immediately (mandatory

standards) or within a further period of time.⁴ For us, this meant that any assessment of ‘compliance’ with these standards during the period of our Review would be misleading. Rather, we were examining a period when units were aware of the aims of a future process of commissioning and were seeking to enable the service to meet them at an uncertain point in the future.

7.2 This uncertainty has been reduced by the adoption of the New Congenital Heart Disease Review’s (NCHDR) standards, from April 2016. That said, there remain a significant number of standards which must be met within the next few years, rather than immediately. We have not yet reached the point where standards where a complete range of standards could be said to be met in a uniform fashion by all hospitals offering treatment for congenital heart disease.

7.3 Against this background, we have had regard to the Safe and Sustainable standards in our work, together with other relevant, published standards such as those relating to nurse staffing levels.

8. Standards regarding the number of procedures

8.1 There has been a history of concerns relating the numbers of surgical procedures carried out by centres. The Bristol Royal Infirmary Inquiry recommended that, in any unit providing open-heart surgery on very young children, there should be two surgeons trained in paediatric surgery who must each undertake between 40 and 50 open-heart operations a year. This recommendation was the subject of further consideration in the Safe and Sustainable Review and subsequently in the New Congenital Heart Disease Review (NCHDR).

8.2 The NCHDR standards require that ‘Congenital cardiac surgeons must work in teams of at least four surgeons, each of whom must be the primary operator in a minimum of 125 congenital heart operations per year (in adults and/or paediatrics), averaged over a three-year period.’⁵ The timescale for the implementation of these standards is that, from April 2016 there should be ‘Teams of at least three (surgeons) immediate, teams of at least four within 5 years. 125 operations: immediate’. The current position in the BRHC is that a team of three surgeons is in place, but further development will be needed to meet the standards due to take effect within 5 years’ time.

9. Standards Regarding Levels of Staffing

9.1 The relationship between the Safe and Sustainable Review and the evaluation of staffing levels on the cardiac ward in the Children’s Hospital became of direct relevance in 2012, when the CQC inspected the ward and found a failure to meet a number of its standards. The most useful summary of the Safe and Sustainable Review’s work was provided by its Programme Director to the Risk Summit held to discuss care in the ward in December 2012, when it was stated:

⁴ For example, for ‘amber’ standards: ‘Following designation, robust plans/intentions must be in place to achieve all outstanding mandatory standards within a timescale agreed with NHS commissioners’.

⁵ Standard B10L1.

‘Whereas the Safe and Sustainable quality standards require each unit to be co-located with a level 3/4 paediatric intensive care unit, they do not require designated units to have a paediatric HDU. The standards state that HDUs, where there exist, ‘will be staffed in accordance with national standards’.⁶ The Kennedy panel had access to detailed information on staffing levels including paediatric cardiac nursing and paediatric intensive care nursing and it is likely that the panel’s discussions on the day of the visit to the Trust would have included arrangements for the discharge of children from critical care.

The Trust is the only paediatric congenital cardiac surgical unit that does not have a paediatric HDU but it should be understood that the Kennedy panel was not asked to critique the Trust’s model of not having a paediatric HDU as this was not a requirement of the standards. Neither was the panel asked to investigate individual cases of children discharged to Ward 32 from paediatric critical care.

The information supplied by the Trust in 2010 for the purpose of assessment makes clear that the Trust does not have a paediatric HDU but explained alternative arrangements:

‘The Paediatric High Dependency Outreach Team was established in September 2004 to support high dependency activity in the hospital. The team introduced the validated Paediatric Early Warning Assessment tool that helps to identify children on the wards whose condition is deteriorating and alerts nursing and medical staff. The team provide a 24-hour service supported by [consultant staff]’.

The information supplied by the Trust also made reference to development plans:

‘Above 400 procedures the cardiology ward would be re-located to Ward 31 ... a cardiac HDU would be developed on the cardiology ward to free up PICU capacity ... Ward 32 (to be 31) would need to attract and recruit additional qualified nursing staff for the extra beds and the HDU ... the introduction of 4 cardiac HDU beds would reduce dependency on PICU.’

Overall, the Kennedy panel assessed the Trust positively in regard to current and future compliance with the standards relating to staffing and critical care. The infrastructure for paediatric critical care was described as ‘strong’ and ‘compliant with the standards’. The panel did not record any concerns about staffing on Ward 32 or in the paediatric intensive care unit, either currently or in the future with increased patient numbers. The panel did not express any concerns about plans to develop a paediatric HDU service in the indicated timescales.’

⁶ The reference was to the Paediatric Intensive Care Society Standards for the Care of Critically Ill Children (2010) and the Royal College of Nursing Health Care Standards in Caring for Neonates, Children and Young People (2010)

10. Conclusions

- 10.1 The national picture regarding Congenital Heart Disease (CHD) is one in which more children have been receiving treatments which are successful and reaching adulthood.

- 10.2 This improvement in results has been achieved despite the absence, at least until April 2016, of a mandatory set of standards on quality relating to CHD services in England and Wales. The period of time examined by the Review is one in which units were aware that a future process of commissioning would prescribe such standards and were seeking to enable CHD services to meet them at some uncertain point in the future. This uncertainty has been reduced by the adoption of the New Congenital Heart Disease Review's (NCHDR) standards, from April 2016. There remain a significant number of standards which must be met within the next few years rather than immediately. We have not yet reached the point where standards could be said to be met in a uniform fashion by all hospitals offering treatment for congenital heart disease.

- 10.3 At present, work on a 'quality dashboard' continues, seeking to ensure that an extended range of key information on quality and performance is made available to commissioners on a monthly basis. The measures are still under development, and validation of data and questions of comparability remain to be addressed. The commitment given by the NCHDR that the quality dashboard will become publicly available in due course was welcomed by this Review, as potentially such information could significantly add to understanding and accountability to the public.

CHAPTER THREE: THE UNIVERSITY HOSPITALS BRISTOL NHS FOUNDATION TRUST

1 University Hospitals Bristol NHS Foundation Trust

- 1.1 University Hospitals Bristol NHS Foundation Trust (UHB) is one of the country's largest NHS acute trusts and a major centre of teaching and research for the South West of England. It has an annual income of over half a billion pounds. As a specialist teaching trust, it works in partnership with the University of Bristol, the University of the West of England and several other higher education institutions to provide medical, nursing, midwifery and allied health professional education at pre and post-graduate levels. We were told that the Trust's mission is to 'improve the health of the people it serves by delivering exceptional care, teaching and research every day.'
- 1.2 The Trust comprises eight hospitals in the heart of Bristol and employs around 8,000 staff who provide a wide range of routine and emergency services to the local population of central and south Bristol, as well as providing more specialist services such as children's cardiac and cancer, across the South West and into South Wales and beyond. Its main services are concentrated on one site in the centre of the city. This one site contains seven hospitals: the Bristol Royal Infirmary (BRI), Bristol Royal Hospital for Children (BRHC), Bristol Heart Institute, Bristol Oncology and Haematology Centre, St Michael's Hospital, Bristol Eye Hospital and The University of Bristol Dental Hospital.
- 1.3 The scale of the services provided is apparent from the fact that, during 2014/15, the Trust provided treatment and care to around 75,000 inpatients, 60,000 day cases and saw 120,000 patients in its emergency departments. It also saw approximately 610,000 patients as outpatients.
- 1.4 At a seminar with the Trust held in July 2015 we were told that UHB performs in line with or above national norms in a number of surveys of patients, including the Friends and Family Test, National Patient Surveys and the National Paediatric Survey 2014.
- 1.5 The Trust took active steps to review and strengthen its governance, on a frequent basis. Trust-wide reviews of systems of governance that we saw included:
- a Review on Patient Safety and Risk Management in 2011 by Derek Hathaway;
 - a Review of internal organisational arrangements focused on Divisional structures, senior leadership roles and relationships between Divisional and Executive levels and decision-making at Trust Management Executive Level initiated in December 2012 and undertaken by Irene Inskip;
 - the BRHC Patient Safety Culture Review 2013;
 - the BRHC Review of Risk Management System June 2014 by Ann Utley;
 - a Trust-wide Well-Led Governance Review June 2015 undertaken by Deloitte by reference to Monitor's Well-led framework.

- 1.6 Also important during the period of our terms of reference were a review of the nursing establishment in the whole Trust, carried out in 2011 by Ms Margaret Conroy, and a further review of nursing in the Children's Hospital carried out by Ms Carol Williams in the second half of 2012.

2 The Bristol Royal Hospital for Children

- 2.1 BRHC is part of the Trust and is the designated Major Trauma Centre for children in the South West region. Over 2,000 staff from a wide range of professional disciplines work in the Children's Hospital, providing general and specialist care to children and their families, both local and from the region.
- 2.2 The Children Hospital was opened in 2001 and was the first purpose-built children's hospital in the South West. In 2007, a further ward was opened to accommodate children's services from Southmead. Since May 2014, all specialist paediatric services in Bristol have been provided by the Children's Hospital following the move of paediatric burns, neurosurgery, plastics, and spinal surgery from Frenchay Hospital.
- 2.3 BRHC has on-site access to foetal and maternal medicine and neonatal intensive care provided by St Michaels Hospital, alongside access to the adult congenital heart service located in the adjacent Bristol Heart Institute. Adjacent services facilitate the transition of babies, children and young adults into age-appropriate care.
- 2.4 BRHC has a total of 140 inpatient beds, 15 of which are currently designated for high dependency patients. In addition, there are 18 day-case beds and a paediatric intensive care unit (PICU) with 17 cubicles. At St Michaels Hospital there is a neonatal intensive care unit (NICU) with a further 31 cots.
- 2.5 Children's surgical and interventional procedures are carried out in the eight dedicated paediatric theatres and hybrid catheter laboratory. During 2014/15, BRHC provided treatment and care to 14,000 inpatients, 4,500 day-cases and 35,000 patients who attended its emergency department; it also saw approximately 59,000 children and young people in outpatient services.
- 2.6 In December 2014, the Care Quality Commission undertook a Trust-wide inspection and assessed the Children and Young Persons Services as 'Good' across all domains and rated the service 'Outstanding' for Clinical Effectiveness.

3 The Children's Cardiac Service

- 3.1 The BRHC is the central hospital for the South West and South Wales Congenital Heart Network. It provides a specialist congenital cardiology and cardiac surgical service for patients in the South West of England as well as a cardiac surgical service to South Wales.
- 3.2 We were told that the paediatric cardiac service in Bristol is active in research; clinicians undertake a range of research projects in order to enhance understanding of

congenital heart disease and to improve care and treatment of children born with the condition now and in the future. We heard from a number of staff about the value of the research undertaken by staff across all disciplines involved in paediatric cardiac services. We noted the active participation of clinical leaders in professional societies such as the Paediatric Intensive Care Society, in research groupings, and in the National Congenital Heart Disease Audit. In 2010, the Expert Panel's assessment for the Safe and Sustainable Review accepted that the Trust had demonstrated a strong track record for research and good links with local universities.

- 3.3 In 2014/15, the Children's Cardiac Service admitted 957 patients for paediatric cardiac surgery and cardiology, undertook 326 paediatric surgical operations and 204 paediatric interventional catheter procedures. It also saw approximately 3,000 patients as outpatients in Bristol and over 1,500 in district general hospital clinics across the Network.
- 3.4 The paediatric cardiac surgical team at the Children's Hospital consisted of three consultant surgeons over the period of the Review. The Review was provided with data on cardiac surgical procedures. The 3 full time paediatric cardiac surgeons undertook between 350 and 325 cardiac surgical procedures per year over the period 2010-2014.
- 3.5 The Trust participated in the Safe and Sustainable Review, which recommended Bristol Royal Hospital for Children lead a children's congenital cardiac network in the South West, working closely with the University Hospital of Wales in Cardiff.
- 3.6 We noted that a Paediatric Cardiac Programme Board was established in March 2011 following the announcement that Bristol was shortlisted for designation under the Safe and Sustainable Review. Its terms of reference were specifically to address the preparatory work required to meet the mandatory standards. It was chaired by Dr James Fraser, Lead Doctor of Cardiac Services, and established a series of working groups each addressing key areas of the standards. It continued its work until mid-2012. During the period 2010/11 to 2011/12, investments were made in the service in Bristol to support compliance with a number of the Safe and Sustainable standards. Investments were made in cardiac nurse specialists, physiologists, sonographers, theatre capacity, and a research nurse.
- 3.7 As regards high dependency care for children, the Trust's self-declaration to the Safe and Sustainable process noted plans for a cardiac high dependency unit in the event of its being designated. The proposal was part of plans for development which, it was assumed, would have taken place should the catchment area for the Bristol Centre have been extended by virtue of the closing of other Centres.
- 3.8 As noted in Chapter Two, after the Safe and Sustainable Review, new national standards for the care and treatment of children with CHD were published by NHS England in July 2015. The Review was told that the South West and South Wales

Networks are working to ensure services meet the standards within the required timescales.

4 Changing Landscapes at the Children’s Hospital

- 4.1 One of the tasks we were asked to consider in this Review was the implementation of the recommendations from the Bristol Public Inquiry. Given the link with that earlier work, it is important to recognise the differences between the cardiac surgical services under investigation in relation to the years between 1984 and 1995, and the paediatric cardiac service which we saw, in the years from 2010 onwards.
- 4.2 During the period considered by the Public Inquiry, services were split between those provided at the Bristol Royal Infirmary (where for example open heart surgery was undertaken) and those provided from the Bristol Royal Hospital for Sick Children (where the cardiologists, for example were based). This ‘split site’ was one of the causes of the failings then observed. But in 1995, the service moved into the Children’s Hospital, with a dedicated Paediatric Intensive Care Unit (PICU) to support the care provided. The requirement for the co-location of supporting services set out in the 2010 Safe and Sustainable Standards, was one that the BRHC was well able to meet.
- 4.3 The change to a dedicated environment for children meant that some of the Public Inquiry’s recommendations, such as the need for care by nurses with specialised children’s qualifications, could much more readily be met. Work proceeded on others. We heard that the process of implementing the recommendations from the Public Inquiry was considered to have come to a natural end when the overseeing stakeholders’ committee, which included parents, decided to disband itself in early 2003 when ‘The Group feels assured that the Trust has done everything within its power and resources to address the recommendations from the Kennedy Report.’⁷ It presented a report which included an appendix documenting the current position in relation to implementation of the 105 recommendations from the Inquiry which fell within the remit of the Trust. The Group presented this report to the Secretary of State for Health.
- 4.4 We noted further that the service at Bristol had developed from one in which two surgeons were employed and the number of open-heart congenital paediatric procedures was in the region of 130 – 140 procedures per annum⁸, to a situation in which, in 2014, the Children’s Cardiac Service undertook 326 paediatric surgical operations.
- 4.5 When the Public Inquiry published its statistical work into the outcomes of surgical treatment at the hospital, the work was ground-breaking and the findings of major

⁷ Paragraph 5.3, ‘Report of the Work of the UBHT Paediatric Cardiac Surgery Inquiry Stakeholder Group’ (January 2003).

⁸ Report of the Bristol Royal Infirmary Public Inquiry (2001), Chapter 9, page 114 paragraph 5.

- concern. They revealed, in particular, failings in the results of two surgical procedures conducted at Bristol.
- 4.6 It is important to recognise that over the period of this Review, outcomes at Bristol have been within the expected range, when compared with those at other surgical centres in the country. It is important not to view this information in isolation and all sources of information should be examined when looking at a unit's performance. But the statistical data available does not support the suggestion that during this period there were higher mortality rates in Bristol or systemic flaws of such a nature or magnitude as to lead to higher death rates. More information, including about the continued need for further information about morbidity rates (i.e., adverse events or complications short of death), is set out in Chapter Four.
- 4.7 When the Public Inquiry reported, systems of oversight and scrutiny within the NHS were far less well developed than they are now. Within hospitals, systems of clinical governance were in their infancy. Since then, they have become more firmly rooted. For example, the machinery for the reporting of clinical incidents and for the analysis of serious incidents by root cause analysis (RCA) has developed, linked to the creation of the National Patient Safety Agency⁹ in 2001. Throughout the period of the Review, there was a requirement for the Trust to report serious untoward incidents to the local lead commissioner, the Bristol Primary Care Trust and latterly the Bristol NHS Clinical Commissioning Group. The commissioners would receive details of the incident, RCA report and action plan and close the incident when it was satisfied that the action plan had been implemented and lessons learned. We saw that this requirement was honoured, during the period of our Review.
- 4.8 In the 1980s and 1990s, concerns about the standards of safety and quality could only be expressed to the commissioners of the services, or perhaps to the professional regulators of healthcare professionals. We have already noted the establishment of the Care Quality Commission and its responsibilities for the quality of hospital services. In the summer of 2012, it was to the Care Quality Commission that two families turned. It responded by carrying an inspection of Ward 32 and the PICU, and by issuing a warning notice upon the failure of Ward 32 to meet its standards. This triggered action by the hospital and also by commissioners, who agreed to fund dedicated high dependency care.
- 4.9 Developments such as those we have noted above mean that the mechanisms for study of the adequacy of the service, and its outcomes, have become much more robust than was the case in the 1980s and 1990s.

⁹ The key functions of the NPSA were transferred to the NHS Commissioning Board Special Health Authority in June 2012.

5 Conclusion

- 5.1 Much has changed since the Public Inquiry into paediatric cardiac surgery at the Bristol Royal Infirmary, not least as regards the dedicated paediatric environment in which children with congenital heart defects are cared for. The CHD service at Bristol has developed from one in which two surgeons were employed and the number of open-heart congenital paediatric procedures was in the region of 130 – 140 procedures per annum¹⁰, to a situation in which three surgeons were employed and, in 2014, the Children’s Cardiac Service undertook 326 paediatric surgical operations.
- 5.2 The ability of commissioners and regulators to monitor the performance of hospital services, including cardiac services, has developed significantly.
- 5.3 In revisiting the contents and recommendations of the Public Inquiry, therefore, we were very aware of the passage of time, and the extent of progress and change since those recommendations were written.
- 5.4 To note this altered landscape, and these sources of assurance, is not to dismiss the concerns of those parents whose unhappiness triggered the work of the Review.
- 5.5 In particular, the fact that statistics on mortality may not suggest cause for concern does not mean that there could not have been failings, or the need for improved practice, in individual cases or areas of practice. The suffering or death of any child is a tragedy, and any failings, if they occurred, would be profoundly distressing regardless of whether any failings were ‘one-offs’ or repeated. We set out to explore the concerns about the cases drawn to our attention with these perspectives in mind.

¹⁰ Report of the Bristol Royal Infirmary Public Inquiry (2001), Chapter 9, page 114 paragraph 5.

CHAPTER FOUR: DATA ON MORTALITY AND MORBIDITY

1 Background

- 1.1 The Review heard that some families had concerns about the reliability of the published information about rates of mortality for the children's cardiac service in Bristol. They also wished to know who was responsible for gathering this data, how it was checked and what systems were in place to react and investigate, if a unit had poorer outcomes than might be expected.
- 1.2 We set out in what follows an account of the main resource for information available to clinicians, patients and parents, before addressing these issues in more detail.

2 The National Congenital Heart Disease Audit

- 2.1 In 1999, the Central Cardiac Audit Database (CCAD) was established by the British Cardiac Society, the Society of Cardiothoracic Surgeons of Great Britain and Ireland and the British Paediatric Cardiac Association. The Report on the Bristol Public Inquiry in 2001 was the trigger for developing this resource further, into a national system to enable outcomes of treatment for children with congenital heart disease to be reported.¹¹
- 2.2 Every year since 2000, all UK specialist centres have contributed procedure-related data to the Central Cardiac Audit Database, now known as the National Congenital Heart Disease Audit (NCHDA). This is one of the seven national audits managed by the National Institute for Cardiovascular Outcomes Research (NICOR), at University College London. Clinical leadership for the audit is still provided by representatives of the British Congenital Cardiac Association and the Society for Cardiothoracic Surgery in Great Britain and Ireland.
- 2.3 The Audit is commissioned by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit and Patient Outcomes Programme, on behalf of NHS England.
- 2.4 NCHDA is the main source of information for clinicians and families about surgery and interventional cardiology and outcomes at each centre for children's cardiac services. Information about the outcomes for individual types of procedure performed have been published online since 2007. The information is broken down to show the numbers of procedures, and their outcomes, at each centre.
- 2.5 At present, the NCHDA reports information about 72 surgical and transcatheter cardiovascular interventions undertaken to treat congenital heart disease at any age. It shows whether or not patients have died within 30 days of these interventions. That is, it only reports on the outcome or 'survival' at 30 days after the intervention. Data

¹¹ <http://bmb.oxfordjournals.org/content/111/1/5.long>.

used in the audit is provided by each of the NHS Trusts providing these services, validated by NICOR in the manner described below.

- 2.6 Discussion about outcomes has often been in the context of questions about surgical skills, or whether surgical operations had been properly performed. Yet, discussing outcomes in the context of the work of surgeons alone is highly artificial. The Public Inquiry recognised, and the Expert Panel agreed, that the work of the Children's Hospital, like any other unit performing paediatric cardiac surgery, was the product of a team effort. The outcome for any one patient and procedure depends on: factors specific to the patient, correctness of cardiology diagnosis, timeliness of referral and performance of the procedure, adequacy of the procedure performed, anaesthetic skill, perfusion and other support, intensive care, postoperative cardiology and surgical input, as well as the effects of chance. It is because of the consensus on this point that NICOR's database does not publish the outcomes of surgery and other interventional procedures by reference to individual clinicians, but by reference to the work of the unit as a whole.

3 **Analyses of Mortality**

- 3.1 Mortality following cardiac surgery or interventional cardiology is reported on the NCHDA web portal in two forms: 'table counts' and 'funnel plots'. Table counts are based on annual data and funnel plots are based on data aggregated over three years. So data for a single year will be published and updated every year for a three-year period. For example, a procedure undertaken in January 2012 will be part of the 2009/12, 2010/13 and 2011/14 analysis.
- 3.2 Until 2014, funnels and table counts were updated at different times. The tables used to change throughout the reporting cycle due to daily upgrades to the data from the cardiac centres. This was intended to provide the most up-to-date information about outcomes, rather than waiting for the year-end analysis. The funnel analysis was produced on an annual basis after the data had been validated by NICOR at each cardiac centre. NICOR recognised that this difference was a potential source of confusion. It changed its procedure from 2014 so that table counts and funnel plots were published simultaneously. This was in response to enquiries from some parents whose children had been treated in Bristol.
- 3.3 Until 2013, the NCHDA published the results directly into the portal in the form of tables and funnel plots for centre-level activity and specific procedures. The NCHDA started to produce a supplementary aggregate report in 2014 (report on 2010-13 information), when it first published 30-day centre level risk-adjusted aggregate data following paediatric surgery. This followed the release of model software in April 2013 to all UK centres, enabling clinicians to monitor their own programme-level outcomes.¹²

¹² <http://heart.bmj.com/content/early/2013/04/04/heartjnl-2013-303671.full>. The software was the PRAiS or Partial Risk Adjustment in Surgery software.

4 Alerts and Alarms

- 4.1 The NCHDA issues warnings in the event that data on 30-day mortality at any of the paediatric cardiac centres participating in the Audit demonstrate results which are statistically outside those which might be predicted.
- 4.2 For its analyses of specific procedures, the audit uses two control limits: an alert limit (98%) and an alarm limit (99.5%), following the Department of Health's Guidance on detecting outliers. If a unit is above both limits, then their performance is not statistically different from the national average.¹³
- 4.3 If a unit breaches either of these limits, the NCHDA follows the Department of Health's Outlier Policy. If a unit's outcomes for a particular procedure are statistically poorer than expected, this will be reported to the NCHDA Audit Steering Group.
- 4.4 If it is a notification of an alert, NICOR contacts the relevant hospitals and the relevant professional societies. Hospitals are required to summarise information about the case, local clinical practice and, if relevant, lessons learned. Responses are reviewed by members of the NCHDA Steering Committee and the President/President-Elect of British Congenital Cardiac Association and the Society for Cardiothoracic Surgery in Great Britain and Ireland. We were told that the responses from the hospitals and the Professional Societies will be published on NICOR's website.
- 4.5 If the notification is an 'alarm', NICOR also inform the Medical Director of the Trust, the Presidents of the British Congenital Cardiac Association and the Society for Cardiothoracic Surgery in Great Britain and Ireland. The expectation is that the centre concerned will also inform the Care Quality Commission. There are then established procedures followed by these organisations to investigate the situation, whether by correspondence, teleconferences or visits. Peer reviews may also be commissioned.
- 4.6 The Review heard from the team at NHS England responsible for the commissioning of congenital heart disease services that discussions are currently underway with the Department of Health relating to revisions to the Outlier Policy. The aim is to ensure a clear mechanism for ensuring that information is also provided to commissioners (via the Accountable Commissioner for the Congenital Heart Service Clinical Reference

¹³ For centre level Surgical Procedures: 30 day risk adjusted survival rates (Paediatric cases only), the audit uses a specifically designed and validated software programme to report 'risk-adjusted' whole centre outcomes, known as Partial Risk Adjustment in Surgery (PRAiS). PRAiS estimates the risk of death within 30 days of a primary surgical procedure in a paediatric patient, based on the specific procedure, age, weight and the patient's recorded diagnoses and comorbidities. With respect to the PRAiS mediated analysis, these limits are known as Prediction Limits as they are driven by the risk model and a set of statistical assumptions, as opposed to observed raw data, and are therefore centred on the risk adjusted predicted outcome. For the PRAiS mediated aggregate analysis a different set of control limits is used following department of health guidelines: control limits set at 97.5% (2 s.d.) and 99.9% (3 s.d.). As there are only 14 centres in the paediatric analysis this means that there is a 25.5% risk of at least one centre being beyond the 97.5% limit and a 1.35% chance of being beyond the 99.9% limit by random chance (i.e. a false outlier). If a unit is within the predicted range, then their performance is not statistically different from the national average.

Group) and the HQIP Contract Manager regarding any notifications. This should ensure comprehensive reporting of any outliers.

5 Notifications relating to Bristol Children's Cardiac Service

- 5.1 A number of the Centres have breached the statistical control limits over the years for specific procedures. The 2009-2012 procedure-specific analysis (made available to the hospital in March 2013 and published on the NICOR portal in May 2013) identified that Bristol had a higher than expected 30-day mortality for the arterial shunt procedure. It triggered the lower 'alert' level (rather than the higher 99.95% limit) and a letter noting this was duly sent by NICOR to the Trust's clinicians. The letter noted that the numbers of procedures were very small, and there was a 10% chance that the alert was triggered purely by chance.
- 5.2 In response, clinicians at the Trust submitted a detailed report to NICOR. There was further follow-up by NICOR in early 2014, when at NHS England's request, NICOR reported back to NHS England on the information held on this topic, as part of the analysis noted at paragraphs 6.1 and 6.2 below.
- 5.3 The 2010-2013 procedure-specific analysis, produced in April 2014 using risk-adjusted mortality data for the first time, again identified that Bristol Children's Hospital had a higher than expected 30-day mortality for the arterial shunt procedure. In line with NICOR policy, the Trust was again contacted and asked to produce a response. A further report dated 29th May 2014 was submitted to NICOR.¹⁴
- 5.4 The responses in 2013 and 2014 made similar points. The Children's Cardiac Service explained that it had undertaken¹⁵ a detailed audit of all cases of arterial shunts undertaken in Bristol between 1st June 2008 and 31st March 2012. It had conferred with two other centres to compare surgical and ITU practice as well as reviewing the coding of data and introducing a statistical monitoring process called cumulative sum control chart (CUSUM) data analysis to provide much faster alerts of any deviation from the expected statistical distribution of outcomes than could be achieved from NCHD's audit data.
- 5.5 The Trust noted further that the service was operating on higher risk patients than it had in the past. Clinicians also identified the fact that a significant proportion of babies who died did well during their stay in hospital but deteriorated at home. In response, a new home-monitoring programme had been introduced. It also explained that the number of arterial shunts is small and that small variations in results for one year can affect the statistics over a number of years when overall totals are low. The survival rates for this procedure for 2012-13 and 2013-14 identified improving outcomes at the Bristol Children's Hospital.

¹⁴

[https://nicor4.nicor.org.uk/CHD/an_paeds.nsf/9791867eff401e0d8025716f004bb8f2/5983f27e0b3ff3b080257d5d005cecc4a/\\$FILE/Bristol%20response%20to%20report.pdf](https://nicor4.nicor.org.uk/CHD/an_paeds.nsf/9791867eff401e0d8025716f004bb8f2/5983f27e0b3ff3b080257d5d005cecc4a/$FILE/Bristol%20response%20to%20report.pdf)

¹⁵ Retrospective audit, done between September 2012 – March 2013; reported 26.06.13.

- 5.6 The Trust's response was reviewed by NICOR's Steering Committee.¹⁶ It was noted to be a comprehensive response but more detail was felt to be needed on what actions had been taken locally; the Committee agreed to develop guidance for centres on how to respond to notification of potential outlier status. No further actions were recommended.
- 5.7 This is the only occasion on which the Children's Cardiac Centre at Bristol Children's Hospital has triggered a warning notification from NICOR. We noted that the results of the arterial shunt now available from the NCHDA for 2012 – 2015 showed that Bristol was no longer triggering an alert.¹⁷
- 5.8 Although the May 2014 response from Bristol is available from the NICOR website, information about alerts and the responses to them from the organisations or professionals concerned was not easy to locate. See our **recommendations**, below.

6 Reports on 30 Day Mortality

- 6.1 In response to a request from Sir Bruce Keogh, NICOR prepared analyses in January and February 2014 examining the overall data on 30-day mortality for BRHC for the years 2009-2012 and 2010-2013.
- 6.2 The conclusion of these analyses was that there was no evidence that the Children's Cardiac Service at Bristol Children's Hospital had any excess 30-day mortality overall after paediatric surgery in the three year periods 2009-12 and 2010-13.
- 6.3 The Review examined the reports on 30-day mortality produced by NICOR, to date. These showed that overall there was, and is, no evidence that Bristol Children's Hospital had any excess 30-day mortality after paediatric surgery or other interventions in the 3-year periods 2010-2013¹⁸, 2011-2014¹⁹ and 2012-2015.²⁰
- 6.4 That said, the Review bore in mind that the fact that, even if statistical analyses comparing a series of cases with those performed at other units suggested that 30-day survival was on a par with other units, it did not mean that failings in care could not have occurred in individual cases, or that there was not room for further improvement. In all its discussions with parents and staff, in the Expert Case Reviews and in its reviews of documentation, the Review was very conscious of this point.

¹⁶ Minutes of the NICOR Congenital Steering Committee, 10 June 2014.

¹⁷ https://nicor4.nicor.org.uk/CHD/an_paeds.nsf/0/0DE381B5C24B284980257F8E0050B1BF?OpenDocument?Benchmark

¹⁸ Report published September 2014.

¹⁹ Report published June 2015.

²⁰ Report published April 2016.

7 Delays in Recording Deaths in Hospital: Inquests and Death Certificates

- 7.1 The Review heard from some families that they had concerns about the accuracy of the information reported by the Trust to NICOR and whether, as a result, an inaccurate picture of the outcomes and safety of the service had been presented or published.
- 7.2 The basis of these concerns appeared to lie either in the procedures which NICOR adopted to make sure its information was accurate, or in the nature of the information that is collected and published.
- 7.3 The first concern related to why the death of one child, in early spring 2012, was not reported in NICOR's data, including its 2009-2012 funnel plot analysis of the 30-day outcomes for this procedure updated in spring 2013. The parents had seen the information, and pointed out that the operation appeared to have been listed, but not the death that had followed it.
- 7.4 As a result of these concerns and at the request of the Regional Director for NHS England in early 2014, NICOR and the Trust investigated what had happened.
- 7.5 In March 2014, NICOR reported back to NHS England that the Trust did, in fact, correctly enter the patient's death into NICOR's dataset on the 16th of May 2012. However up to November 2013, NICOR's policy for the audit was to include a death in its analysis only when official notification of the death had been received from the Office of National Statistics (ONS), the national dataset for data on mortality. NICOR noted that if the Coroner is involved and an inquest is required, ONS only records a date of death once the inquest has come to a conclusion and a death certificate has been issued by the Coroner. This process can take several months or more. In the case in question, waiting for the results of an inquest had resulted in a 20-month delay in ONS recording the death. This in turn explained why this particular patient's death was not reported in NICOR's statistics for 2009-2012. The death would have been subsequently recorded in NICOR's dataset following ONS notification to NICOR, but NICOR recognised that the time taken as a result of reliance on ONS was inappropriately long.
- 7.6 In a further example brought to the Review's attention by parents, there was a 22-month delay in reporting a death by ONS, for the same reason: the need to await the conclusion of an inquest. The death of this child was not included in the published information until September 2014, despite the death also occurring in spring 2012. It was included in the funnel chart analysis for the first time in the 2010-2013 data.
- 7.7 It is important to note that, in both of these cases, the Trust had reported the child's death correctly to NICOR, at the appropriate time. The problem arose not because of incorrect recording or submission of data on the part of the Trust, but because of the policy of waiting for confirmation of death from the ONS.

- 7.8 In order to check that the ‘updated’ or complete information did not affect or invalidate the analysis of mortality for 2009-2012, NICOR carried out further checks. In November 2013, NICOR requested that all congenital heart centres check their data on mortality retrospectively against that provided by ONS in order to ensure consistency. NICOR then updated its analysis. The updated analysis now included one additional death within 30 days from the Bristol Children’s Hospital (i.e., one of the children discussed above, who had died within that period and whose death had now been confirmed). Nevertheless, the updated analysis showed that mortality for paediatric cardiac surgery at Bristol Children’s Hospital was still not statistically different from those at the other UK centres for 2009-2012. Furthermore, the amended results for the specific procedure in question did not suggest that Bristol was a potential ‘outlier’, with regard to that procedure.
- 7.9 As a result of these investigations, NICOR changed its policy. From November 2013, deaths submitted by the hospitals have been included in the analysis of mortality, even before notification of the death by ONS. NICOR’s visits to validate the data at each centre now include checks of all hospital-reported deaths against the patient’s medical records.
- 7.10 In this second case, we saw a letter from NICOR to the family concerned explaining these matters. It was sent by NICOR as the result of the family writing to NICOR, asking about the fact that their child’s death had not been included in the tables relating to Bristol’s results. But in the first case, it was NHS England rather than the family concerned which asked for information. Thereafter, NHS England do not appear to have provided the family concerned with a clear explanation about what had happened.

8 ‘Diagnostic’ vs ‘Interventional’ Procedures

- 8.1 In relation to the concerns of another family, the Review asked NICOR why a death of a child following a cardiac catheterisation procedure in 2013 was not reported to NICOR by the Trust. NICOR investigated at our request. We were told that, in this instance, a serious complication arose in the catheter laboratory before the planned interventional procedure had begun and, as a result, the intervention never took place. Because of this, the case was correctly recorded by the Trust as a diagnostic, rather than an interventional procedure. It was therefore not counted within the mortality statistics, as at that time the data-set only included outcomes within 30 days of a completed interventional cardiology procedure.
- 8.2 The Review’s Expert Panel, having reviewed the history of this child’s care, agreed that the manner in which the procedure had been classified by the Trust was correct. In particular, the experts confirmed that the classification of the procedure as ‘diagnostic’ was accurate. Although an intervention was planned, the adverse event occurred before any part of the planned interventional procedure had taken place and therefore the intervention had not occurred, for the purpose of the audit. As a result, the fact that the death had not been reported to NICOR and was not shown in statistics was

procedurally correct. They agreed that it could seem surprising that a death in hospital associated with undergoing a procedure would therefore fall outside the mortality statistics. But this was a reflection of the audit criteria, and was not unique to Bristol.

- 8.3 In discussions with NICOR, the Review heard that this situation has now changed. Diagnostic procedures are now (with effect from April 2015) included in the information collected from Trusts. Results published in 2016 (2013-16) will include the number of diagnostic procedures, together with any deaths within 30 days.

9 **Validation of Data**

- 9.1 General questions were asked by families about whether the information contained in the National Audit could be relied upon. As a result, we set out below what the Review saw and heard about the process of validating data used to make sure the underlying information is reliable.
- 9.2 NCHDA undertakes an annual process for validating data for all the cardiac centres to confirm that all major procedures for congenital heart disease have been submitted and that the quality of the data is appropriate. The process includes visits to sites by a clinical data auditor and a volunteer clinician, from another centre, to check the accuracy of the data submitted. The hospital records of 20 patients are randomly selected by NCHDA's data auditor for review. The data that the centre has previously submitted to NICOR for these 20 patients is checked against their hospital notes.
- 9.3 In addition, logbooks from theatres and the catheter laboratory are examined to ensure that all appropriate cases have been submitted, with correct procedure and diagnosis codes. Finally, the records of all cases where the child has died in the audit year are examined to ensure the accuracy of diagnoses, procedure(s) undertaken and any additional co-morbidity, again comparing against the data submitted.
- 9.4 The submitted data is also signed off and verified by each Trust as being accurate by cross-checking in reverse the data held in NCHDA's database against the data held by the Trust.
- 9.5 As part of the feedback to the Centre, the Centre receives a quality score (the Data Quality Indicator (DQI)) on the validation of the case notes. The DQI is a measure of the accuracy and completeness of data entered (across four domains: demographics, pre-procedure, procedure and outcome) into NICOR's outcomes software when compared to actual patient records during a visit to the site. Typically, NICOR would expect the DQI to be greater than 90%. Above 95% is considered excellent.

- 9.6 Bristol’s scores were at, or close to, the ‘excellent’ threshold for quality of data in all years except 2013. That year’s score was however still within the acceptable range, as seen below:

Year	2010	2011	2012	2013	2014	2015
Score	95.25%	95.25%	95%	91.75%	96.5%	94.5%

- 9.7 The report in 2013 recorded that, on the whole, NCHDA’s data was accurate, well documented, good quality and appropriately recorded in the Theatre and Cath Lab logs books at BRC. However, there were concerns about the data entered in the Bristol Royal Infirmary (BRI). The report recommended that ‘Urgent consideration should be given to reviewing and creating roles of clinical audit and data managers for both the paediatric congenital and the ACHD data collection to support the current individual in post.’ These points were picked up in the Cardiac Clinical Governance Group in September 2013, which noted the need for ‘A full time data manager ... to facilitate the CCAD audit’, as well as the need for a new consultant audit lead.
- 9.8 Thereafter, actions about the quality of data submitted to NICOR were picked up as part of the Composite Cardiac Action Plan developed after the CQC’s inspection of Ward 32. A Data Manager was appointed, and steps taken to pick up promptly any issues highlighted by NICOR as part of their validation process.
- 9.9 We confirmed at our meeting with NICOR that this appointment had been made by the Trust; however, it was felt that staff entering the data were still overburdened.

10 Internal Procedures to monitor mortality and morbidity.

- 10.1 In addition to the national audit, there are also local procedures in place to review mortality and morbidity. It is routine practice in each children’s cardiac centre that a regular multidisciplinary mortality and morbidity meeting (M&M) is held to discuss patients’ care and to take forward any resultant lessons or actions to improve quality at a local level. In Bristol this meeting takes place on a weekly basis.
- 10.2 The monitoring of outcomes became more sophisticated during the period covered by the Review. At the beginning, in early 2010 it was generally recognised that the NCHDA could not provide meaningful contemporaneous analysis of data on mortality due to retrospective reporting and the time taken to validate data satisfactorily. As set out above, in April 2013 software known as PRAiS became available which enabled all centres routinely monitor their short-term surgical outcomes. The software enables users to generate estimates of risk for all episodes of care 30 days after the procedure and produce from this a Variable Life Adjusted Display (VLAD chart). The VLAD charts allow centres to examine their outcomes and quickly identify any trends that might warrant further investigation. This allows each unit to examine its own performance in real time. It has the advantage of allowing earlier ‘alerts’ if there is a

potential concern (although it also risks overreacting to statistically random change). It is still only partially risk-adjusted, however, and its use is under continuing evaluation.

- 10.3 From September 2013, every centre has been required to report to specialist commissioners on a monthly basis whether they have undertaken this monthly in-house real-time reporting and whether there is anything of concern to report. BRHC has reported that this analysis has been undertaken and there were no concerns to report each month since December 2013 to March 2015.²¹
- 10.4 The Review examined the minutes of the M&M meetings which are called Performance Meetings in Bristol. The approach shown there was in line with expected practice and we did not identify any areas of concern from this documentation.
- 10.5 In addition, after a death of any child there is a formal process of child death review. This is a statutory national process. We have set out more detail in Chapter Sixteen.

11 Numbers of surgical procedures

- 11.1 It was noted in the minutes of the Risk Summit in October 2012 following CQC's inspection of Ward 32 that 'there had been an increase in the number of Fontan [procedures] being completed in the last two years'.²² There were suspicions voiced by parents that these numbers had increased as part of an effort by staff at the Trust to increase the numbers of surgical procedures performed, in anticipation of a need to meet the proposed Safe and Sustainable standards for surgical activity.
- 11.2 The Review was told that the number of children requiring cardiac surgery is related to the birth rate. A relatively stable proportion of babies are born with congenital heart defects. The birth rate nationally has changed little in recent years, although there has been a sixteen percent increase over the period 2014-2104 in the number of children aged 0-15 living in Bristol and an increase in the number of births from 4,600 live births in 2001/2 to 6,400 in 2013/14. Across the Southwest and Wales, the number of births has increased from 79,363 in 2001 to 91,947 in 2014. Consistent with this, the Expert Panel advised the Review that the number of Fontan procedures performed by any Centre in a particular time period is a factor of the rate of presentation of the condition requiring this procedure from amongst the catchment population of the Centre. In addition, the introduction of a new surgical option for hypoplastic left heart syndrome (HLHS), the Norwood procedure, will increase the number of children needing cardiac surgery (as there was previously no surgical option offered in Bristol) including Fontans, as this is the third stage operation for these patients. Since Bristol started their HLHS programme in around 2009/10, there would have been an increase in Fontans relating to this programme from about 2011/13.

²¹ Latest data sought or supplied.

²² The information reported was that over the period April 2007 to March 2012. The Trust performed 42 Fontan procedures with a notable increase in the volume of procedures in the period 2011/12 having done 19 cases in that year. In the report to the Risk Summit it was noted that this was on the lower end of activity undertaken within the existing centres.

11.3 More generally, what we saw was evidence of a service acutely aware of the ‘bottlenecks’ in its ability to admit children for surgery. There was a desire to manage waiting lists and to increase capacity by (for example) adding to the numbers of operating sessions. Consistently with this, we saw efforts to manage throughput more efficiently. We did not see any evidence of some form of manipulation of either the timing of procedures, or anything that would suggest that there was a failure to refer children to other centres when appropriate. In particular, experts did not consider that there was a need to have referred children requiring a Fontan procedure to another centre.

12 Improving information available through the National Audit

12.1 The New Congenital Heart Disease Review noted that improvements are needed to the accessibility and ease of understanding of the information on NCHDA’s website for patients and families. We were told by NICOR that had undertaken a survey of patients to gain feedback on the quality and content of the current online portal, and that further work is in progress.

12.2 It had been intended to make information on 90-day mortality available alongside 30-day mortality from April 2016. However, the Review was informed that this work had encountered some technical difficulties relating to obtaining accurate and timely data in relation to deaths. Nearly all children will have gone home within 90 days, and those children who die may die for reasons unrelated to their cardiac condition. The hospital may well be unaware of these deaths. Work is underway to assess the scale of the challenge in obtaining accurate and timely information regarding deaths. At present, the timeframe for reporting on 90-day mortality is not yet known.

12.3 The Review also noted the work to increase the range of the procedures against which data on activity is reported on NCHDA’s website and those included in the analysis of mortality. The audit now reports overall survival at 30 days for 72 major surgical and transcatheter cardiovascular interventions covering 84% of all procedures²³.

13 Improving information about morbidity

13.1 Some families were concerned about the level of morbidity post-procedure in Bristol and whether this was comparable to the results in other centres. By ‘morbidity’ we mean post-operative complications, whether after surgery or after catheterisation.

13.2 The Review discussed this issue with its Expert Panel, with NICOR and with specialised commissioners. We heard that at present, it is not possible to estimate accurately the true scale or impact of such complications. This is because there is little solid information on how often such events occur, which patients are most at risk and what the precise impacts are. There are no agreed sources of data or means of reliably comparing rates of complication from centre to centre.

²³ National Congenital Heart Disease Audit Report 2012-15 4th April 2016

- 13.3 At present, a research project is underway, led by the Clinical Operational Research Unit (CORU). It seeks to identify paediatric morbidities which could be gathered and studied, and to test the quality and usefulness of the information collected. The research is due to be published in September 2018.
- 13.4 After consultation with both families and professionals, CORU has decided to measure nine complications:
- a new problem with the brain or nervous system
 - unplanned re-operation
 - mechanical support for the heart (ECLS/ECMO)
 - necrotising enterocolitis (NEC)
 - prolonged problems with fluid around the lungs / chylothorax;
 - problems feeding
 - major adverse event (eg, a cardiac arrest in intensive care)
 - kidney problems
 - hospital acquired infection
- 13.5 In addition, the study will seek to examine poor communication between the clinical team and the family.
- 13.6 There are five participating hospitals, including the BRHC: Great Ormond Street, the Evelina Children’s Hospital, Bristol Children’s Hospital, Birmingham Children’s Hospital and the Royal Hospital, Glasgow.
- 13.7 Families included in the study will be assessed 4 times in the 6 months following a procedure. The study will follow up those who have experienced a complication after surgery but also an equal number of children who did not, in order to separate out the significant impact of the very fact of undergoing surgery from any additional impact of having a complication. After the study ends in 2018, the next task will be to help all hospitals to monitor these complications and to undertake further research on how to reduce rates of complication.
- 13.8 The Review noted that this work should provide much improved information for patients, families and clinicians. The Review noted that the NCHDA too has been collecting data on post-operative complications since April 2015, mirroring the indicators recommended by the CORU study.
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14 Conclusions

- 14.1 There is a fundamental difference between the circumstances revealed by the Bristol Public Inquiry (where systemic weaknesses in the management of two procedures²⁴

²⁴ Operations on AVSDs (Atrioventricular septal defect) and the arterial switch operation.

were revealed by the Inquiry), and the situation now. The work of the NCHDA in monitoring and comparing activity and outcomes across surgical centres, should ensure that such a situation would now not go undetected.

- 14.2 The value of the NCHDA, as a single reliable source of information upon activity and outcomes, is considerable. Those who manage it are aware that improvements are needed to the accessibility and ease of understanding of the information on NCHDA's website for patients and families.
- 14.3 The data available from the NCHDA shows that the outcomes of surgery and other interventional procedures at BRHC were comparable with those in other centres within the UK, from April 2010 – March 2015. There is no evidence of an 'excess death rate' following paediatric cardiac surgery or interventional catheter procedures at the BRHC during the period of this Review. The paediatric cardiac services in Bristol responded appropriately to requests for information about its outcomes and action taken in 2013 and 2014 when an 'alert' was triggered, regarding one procedure.
- 14.4 Concerns raised by parents that the data submitted by Bristol was inaccurate or incomplete were understandable, and have led directly to changes and improvements in the national audit. But we have set out why, ultimately, those concerns about poor submission of data were not justified. Any gaps in the data were not the result of incomplete or inaccurate information returns from Bristol, but were caused either by how the NCHDA checked those returns using information from the Office of National Statistics; or from the scope of the National Audit which did not, until recently, include the results of diagnostic catheterisation.
- 14.5 NICOR's data validation (checking) process has not identified concerns with the information recorded or submitted by the Bristol paediatric cardiac services. There are concerns that Trust staff remain over-stretched. The Review considered that, given the importance of the integrity of the data returned, this requires attention.
- 14.6 It is not possible at present to make robust comparisons of rates of morbidity between centres. A major research project on this topic is in hand which, together with data collected by the NCHDA, should secure improvements in the information available over the next few years.

15 Recommendations

15.1 In the light of the above, we recommend:

- (1) That any review of the Department of Health's Outlier policy (the policy followed by the NCHDA when its audits trigger alerts or alarms) should give specific attention to the need for publication of the responses to outlier alerts, and of any actions taken as a result.
- (2) The Trust should review the adequacy of staffing to support NCHDA's audit and collection of data.

CHAPTER FIVE: NETWORKS, DIAGNOSIS AND OUTPATIENT CARE

1 Networks, and the Safe and Sustainable Review

- 1.1 The draft Safe and Sustainable Standards (2010) set out a series of aims for Networks that would be led by Tertiary Centres providing active leadership in their clinical networks.²⁵ In relation to the BRHC, the assessment of the Expert Panel in December 2010 was that the CHD service had further work to do. If designated as a Tertiary Centre, action would be required to transform good working practice and strong individual relationships with trusts and clinicians within its network, into documented protocols and agreed governance arrangements.²⁶ Further development of the Cardiac Network was the aim of one of the sub-groups established as part of the Paediatric Cardiac Programme Board. The Board aimed to secure progress in meeting the Safe and Sustainable standards.
- 1.2 We set out below what we heard and saw, from parents and clinicians, about the delivery of care across the network served by the BRHC, both across the South West and into Wales, and about any developments in developing agreed pathways across those regions.

2 Ante-natal diagnosis

- 2.1 The University Hospital Bristol (UHB) NHS Foundation Trust's Fetal Cardiology Service provides a tertiary level screening and diagnostic service to the 19 maternity/obstetric ultrasound departments in the South West region. A diagnostic service is also provided in support of the fetal cardiology services in Wales.
- 2.2 A significant number of parents who contacted the Review indicated that their child had been diagnosed with congenital heart defects antenatally.
- 2.3 The majority of these parents reported that they felt well prepared for what to expect when their child was born and were positive about the fetal cardiology service. The offer to visit the Children's Hospital to see where their child would be cared for was universally appreciated. However, a few families reported that they felt there was a lack of information and support at this time.
- 2.4 We note that from its recent clinical case note review, the CQC found good evidence of well documented parental counselling in cases of antenatal diagnosis, with shared care and the use of telemedicine in one case.
- 2.5 A small number of families expressed concern or distress when staff raised the option of terminating the pregnancy at the time of diagnosis. The Review noted this is routine practice, but needs to be conveyed very sensitively. This is not only because of the

²⁵ Standard A1. Further details of the integrated care pathways were set out within Section A.

²⁶ Report of the Independent Expert Panel, December 2010.

- possible religious, moral or cultural beliefs and values of the parents, but also because the ability to consider options at the same time as absorbing the information about implications of the diagnosis can be limited by the shock of receiving that information.
- 2.6 Some families from Wales felt that they were given different expectations during antenatal counselling about the implications of the diagnosis by clinicians in Wales and those in Bristol and felt they were presented with a less positive outlook by clinicians in Bristol.
 - 2.7 The Review asked clinicians in both Bristol and Cardiff about this perception. It was not possible to identify precisely why this should be, but there was awareness amongst the clinicians that for some families this had been a concern. Both sets of clinicians were agreed on the need to align communication in a way that is received consistently by parents in the various centres.
 - 2.8 The Review's Expert Clinical Panel considered that this perceived difference in approach between clinicians was perhaps understandable in the context of a discussion at the time of diagnosis; presenting a stark prognosis at this time can seem harsh. In addition, the diagnosis and outlook may change in response to the development of the foetus, over the term of the pregnancy. There are also difficulties imposed by the uncertainty of the changes occurring in the transition between the prenatal and postnatal circulation, as well as the inability to 'see all' prior to birth. There is a degree of inherent uncertainty in any prenatal diagnosis, and the ability of any one individual to impart this uncertainty effectively is inevitably variable.
 - 2.9 All that said, the Review felt that there were real challenges in aligning communication across all the 'levels' within a network, such as previously envisaged by the Safe and Sustainable Review and now developed by the New Congenital Heart Disease Review.
 - 2.10 The Review was told that the fetal cardiology service in Bristol had experienced an increase in referrals and this had resulted in significant pressures on the service for a period of time during 2012 and 2013. A bid was made to commissioners for an additional consultant in fetal cardiology and further support staff. Increased consultant sessions along with increased support from sonographers and the Cardiac Liaison Nurses and more dedicated administrative support were provided in 2014.
 - 2.11 The Review heard from clinicians in Cardiff and Bristol that the fetal cardiology service in Wales was poorly resourced and was not able to meet the standards set out in the relevant British Congenital Cardiac Association Standards.²⁷ Clinicians in Bristol also felt that the necessary integration and communication with the fetal cardiology service in the surgical centre in Bristol was also underdeveloped. They had concerns about disparities in service for families and babies across the network. Variations in standards are a significant issue not least because around 40% of the patients treated

²⁷ The British Congenital Cardiac Association Standards' for Fetal Cardiology and Fetal Anomaly Screening standards (2010) were those referenced in the Safe and Sustainable draft Standards: see Section B on prenatal diagnosis.

by the service in Bristol come from Wales. Consistency of standards across the network is a requirement of the New Congenital Heart Disease Review.²⁸

- 2.12 The Review noted that the service in Cardiff was currently provided by one fetal cardiologist, serving a catchment area with a population of approximately 2.2 million. The fetal cardiologist worked with limited access to support staff such as a specialist sonographer or liaison nurse. Access to fetal Medicine is not always possible on the same day as the patient attends the clinic. The Review was told that referral to the fetal cardiology service in Wales operated on severely restricted criteria and that the service was unable to meet the New Congenital Review Standard - that all women with suspected or confirmed fetal cardiac anomalies should be seen within three working days and preferably two. The Review was told that the fetal cardiology service in Cardiff aimed to see women within two weeks, and had recently had difficulties in meeting even that criterion.
- 2.13 Despite this, the ante-natal detection rate in South Wales for babies who required surgery or therapeutic catheterisation during the first year of life (excluding those with conditions not diagnosable antenatally), was amongst the highest in the UK at 53.8% in 2013/14 and was slightly higher than that in the South West Region. Clinicians in Cardiff felt that this excellent performance in detection of anomalies had been an impediment to recognition of the need for investment in the fetal cardiology service. The good detection rates had also resulted in increased referrals to the fetal cardiology service, compounding the challenges for the service in Cardiff. The Review was told that referrals to the fetal cardiology service in Wales have increased around three fold in recent years.
- 2.14 The Review noted that this trend is evident across the country, as anomaly detection improves.
- 2.15 The Review discussed the issue of commissioning to consistent standards with the team leading the New Congenital Review and was told that discussions have taken place with the WHSSC who are the commissioners of the service in Wales.
- 2.16 The Review heard from WHSSC that an investment was made during 2015/16 to fund the time of a consultant, nurses in the clinics and a co-ordinator, to allow for the provision of 55 additional clinics to reduce waiting times. In addition, the Review was told that WHSSC's Commissioning Plan for 2016-19, approved in March 2016, included further additional recurrent investment in fetal and paediatric cardiology. The funding is to provide three additional clinics for fetal cardiology a week, a dedicated fetal ultra-sonographer and dedicated support for families from a nurse/counsellor. It was anticipated that this would also help support the appointment of a fifth Paediatric Cardiologist. We were told that additional clinics for paediatric cardiology were planned to provide sufficient capacity to meet long-term

²⁸ Which includes standards relating to fetal diagnosis: Standards K2(L1) and K3(L1).

demand from 2016/17. The funding commitments would ensure that the fetal cardiology service would be able to meet the standards laid down in the New Congenital Heart Disease Review. More broadly, the WHSSC was working with the NHS England Congenital Heart Disease Review Team, the new Congenital Heart Network and providers of services to ensure the coordination of plans to improve services.

3 Pathways Across Networks

- 3.1 Across the period examined by the Review, there were challenges in establishing clear pathways of treatment across the network, with clear and consistent communication to parents. This was particularly so with regard to the management of transfers between the service provided by paediatric cardiologists from UHW (where there was what would now be regarded as Level 2 centre – i.e. a Specialist Children’s Cardiology Centre as defined by the NCHDR) and the BRHC.
- 3.2 An example of this was the difficulties raised with the Review about the management of patients transferred from Wales to undergo a surgical procedure called patent ductus ligation (PDA ligation) to resolve a condition called patent ductus arteriosus. This is a congenital heart defect where the duct fails to close after birth. One family told the Review that they understood that their baby was being transferred to Bristol from Wales for PDA ligation. However, when they arrived in Bristol they were told that their child would be assessed by the neonatologist and paediatric cardiologist and a decision would then be made about whether the child would be treated medically or surgically. This caused great anxiety and distress to the family who felt their very young baby should not have been transferred long distance if surgical intervention was not required. This was particularly significant for the family concerned as the child subsequently died in Bristol. Poor management of the parents’ expectations seriously damaged parental trust.
- 3.3 The Review was told that the approach to the management of PDA ligation has changed over the years. In the mid 1990’s it would be common practice to undertake a surgical ligation. But new drugs became available which created the option of using medical approaches to treatment and avoiding surgery. The Review was told that surgical ligation in premature babies was a controversial issue and there were different opinions amongst neonatologists on whether PDAs should be ligated. Many neonatologists have a conservative approach to PDA ligation and refer for ligation only as a last resort. The decision to refer for duct ligation is that of a neonatologist, but the decision to undertake the ligation resides with the surgeon and cardiologist.
- 3.4 It was accepted by clinicians in Bristol and Cardiff that there had been some confusion about the process for clinical decision-making in the management of babies with patent ductus arteriosus and that this had resulted in parents having expectations which were then not in line with what, in practice, followed.

- 3.5 The Review heard that as a result, the neonatology and cardiology teams in Bristol and Cardiff developed a joint PDA ligation protocol which was put in place across the whole network in 2013. A new leaflet for patients was also developed which explained that referrals to Bristol would be for assessment and possible ligation. We also saw evidence of liaison and information-sharing between the Bristol and Welsh paediatric cardiologists in the latter's annual audit and reviews of their services.²⁹
- 3.6 Clinicians reported that there was now clarity about the pathway and they were now better placed to give consistent information to parents. The Review noted the importance of such consistency, in circumstances where there had been significant confusion or distress to parents.

4 Information for Families

- 4.1 We noted that one of the observations of the CQC's recent clinical case note review was that 'The reviewers felt that there was not as much evidence of families being given appropriate written information about to diagnosis and management as they would expect, although more evidence that written material was provided was seen in later cases and in relation to bereavement support.'
- 4.2 The Review considered that there was further scope for reviewing information given to families at the point of diagnosis (whether antenatal or post-natal), to ensure that it covered not only diagnosis but the proposed pathway of care.
- 4.3 Any such review should consider both the content of the information, and the means by which it is conveyed.
- 4.4 The recommendations of the Kennedy Inquiry included a number of recommendations on improved information, including that:
- Patients should receive a copy of any letter written about their care or treatment by one healthcare professional to another (we note that this has now been implemented by the Trust and nationally).
 - Information about treatment and care should be given in a variety of forms, be given in stages and be reinforced over time.
 - Information should be based on the current available evidence and include a summary of the evidence and data, in a form which is comprehensible to patients.
 - Various models of conveying information, whether leaflets, tapes, videos or CDs, should regularly updated, and developed and piloted with the help of patients.

²⁹ Audit meetings were held annually by the cardiac clinical team from University Hospital of Wales (Cardiff). The meetings were also attended by representatives of WHSSC and the Bristol cardiac team. The audit meetings provided the opportunity to review the performance of the service, including in-depth scrutiny of outcomes. These audits covered patients referred to Bristol. They also provided the opportunity to discuss individual patients and identify at any emerging patterns.

- 4.5 In 2003, one of the observations of the Report on the Work of the UBHT Paediatric Cardiac Surgery Inquiry Stakeholder Group had been:

‘The provision of information in other formats, e.g., tapes, videos is an under developed process in the Trust. The overall development of the patient communication and information work is to be commended, but the provision of information in other formats would require additional investment.’

- 4.6 Discussing the implementation of the Public Inquiry’s recommendations, the Trust referred to leaflets used to support verbal information and noted that ‘Work is being undertaken in Children’s Cardiac services to complete the full range of leaflets relating to communication of risks and complications with regard to the various local procedures and interventions carried out.’³⁰ In addition, it was apparent that further efforts were being made to sign-post families to internet resources, as well as using computer or smartphone apps in work with children and young people.
- 4.7 Tapes, videos and CDs have now been largely replaced by a demand for internet resources. The Review felt that there was further scope for ensuring that information about diagnosis, treatment and care was delivered electronically, and that parents were directed towards information and resources which they could explore at their own pace. We have discussed the work done on the process of seeking consent to surgery in Chapter Six; we were told that the surgical team were seeking to adopt such an approach. The Review felt that the same need existed at all stages of the pathway journeyed by patients and their families.

5 Out-Patient Services

- 5.1 The majority of families who commented on their experience of the outpatient service at the Children’s Hospital were generally content with the service. Many praised the staff.

‘During [outpatient] appointments we were encouraged to ask questions and on several occasions I would text [the consultant] with my concerns which he would reply to within the hour.’

‘The appointments process has been well managed and we have never had to wait too long in the waiting room to see the consultant.’

‘We often speak about the excellent quality of care, the professionalism of the hospital staff and the remarkable provision we experienced during all our outpatient appointments.’

- 5.2 A number of families did, however, report that clinics seemed rushed and pressured and they did not have enough time to ask questions. A few families reported a lack of information ahead of attending the clinic about such matters as how long they would

³⁰ Trust assessment of UHB compliance with the recommendations of the Public Inquiry (2014).

be there, the tests that would be undertaken and practical details such as the need for the child to wear suitable clothing to undergo an exercise test.

- 5.3 A small number of families felt that staff did not deal appropriately with their children's distress and anxiety when undertaking procedures and tests in out-patients. There were also concerns voiced by a family who had been away from Bristol when a crisis affected their child, about the extent of the expertise available to manage congenital heart defects at a local hospital within the South West; it was vital to be able secure quick access to advice back in Bristol, as well as emergency retrieval services. To the Review, this indicated the importance of strong networks, with clear and well-known procedures to ensure specialist advice and help could quickly be obtained.
- 5.4 The most consistent theme from those families who reported any aspect of poor experience regarding out-patient care was in relation to appointments. A number of families reported that appointments were not forthcoming in the timeframe that the consultant had indicated for follow-up and it was difficult to get this resolved when they tried to get appointments arranged. Some reported multiple phone calls and high levels of concern and frustration before a resolution was arrived at.
- 5.5 A small number of families had experienced delays in follow-up out-patient appointments which they were concerned had adversely affected their child.
- 5.6 The quotes from parents below express the nature of the concerns conveyed to the Review:

'As a parent I have learned and firmly believe that you need to be proactive in chasing up appointments, passing information about [my child] between doctors etc. Ideally this is not how it should be but it seems to be the reality.'

'Our observation is that there seems to have been miscommunication within the administrative areas, resulting in unnecessary appointments, a missed appointment we were not aware of and some long delays in actions being taken following consultations.'

'We did not receive an appointment from the Children's Hospital and had to chase this up on several occasions. It was only after contacting the manager of cardiac services that we finally received an appointment. This was not a one off and for each of the subsequent appointments our child had with the consultant Cardiologist at the Children's Hospital, we had to chase up the appointment.'

- 5.7 A number of different factors were highlighted by these comments from parents and by our own reading of documentation. In discussing them it is necessary to distinguish between outreach clinics outside Bristol, and those held at the BRHC itself. We discuss both below.

6 Cardiac Outreach Clinics

- 6.1 As set out at Chapter Three, cardiac outreach clinics were held in district general hospitals across the South West by the consultant cardiologists from UHB. The systems for booking appointments and the referral letters back to UHB which might sometimes follow, were the responsibility of the relevant hospital concerned. They were not the responsibility of the UHB, although there might be co-ordination between a consultant's secretary at the UHB and the bookings team at the district general hospital concerned.
- 6.2 The comments that the Review received from families about these clinics were largely positive.
- 6.3 That said, there were serious concerns raised by one family. It was clear what lay behind them were failures in the booking system of a hospital where an outpatients' clinic was held. The Review heard of difficulties relating to the introduction in a District General Hospital of a patient administration system, 'Millennium', in 2011. A follow-up appointment that was due in early 2012 was not promptly booked. It was repeatedly 'chased' by the child's parents and nurse before an appointment was made. As recorded subsequently in a Coroner's verdict: 'Due to the failure of the hospital outpatients booking system there was a 5-month delay in [the child] being seen and receiving necessary treatment. [His] heart was disadvantaged and he died following urgent surgery.'
- 6.4 The problem was investigated by the Hospital Trust concerned, which noted that problems had been identified with the process for recording requests for follow-up appointments; clinic's letters and outcome forms were not always being uploaded into the system for scheduling appointments. Action was taken by the Trust concerned to remedy this.
- 6.5 This was a tragic case. But the Review noted that, in relation to the delay in re-scheduling the clinic, the systems concerned were not managed by the UHB. In addition, it was apparent that the Bristol cardiologist who provided the outpatients clinics had made several attempts to highlight risks and to clear any backlogs.
- 6.6 The Review discussed with clinicians the implications of providing clinics across a network whilst relying on the administrative systems of the hospitals concerned. It was recognised that there were both strengths and weaknesses in such a model.
- 6.7 The Review heard from some cardiologists that if the District General Hospital where there is an outreach clinic has a Paediatrician with an interest in Cardiology (a PEC), the arrangements worked well. There was a local clinician who understood the needs of the child and the frequency of follow-up required. Working with the PEC meant that the skills of the tertiary consultants could be used to best effect, and families received consistent information. In the absence of a specifically commissioned network, however, the presence of a PEC was ad-hoc and dependent on the priorities of

individual Trusts. The absence of a PEC could result in increased referrals to the tertiary cardiology service, placing further pressure on this group of clinicians and their clinics.

- 6.8 The NCHD Review model of care now requires local cardiology centres to employ a PEC to provide monitoring and care, and run outpatient clinics alongside specialists from the Specialist Surgical Centre. Standards set out in the NCHD Review should also help to strengthen and improve outpatient services across the network by requiring improvements in telemedicine and IT.³¹ At present, there are a number of unsatisfactory ad hoc arrangements for the transfer of images following outpatient appointments.
- 6.9 Requiring all local children's cardiology centres to employ a PEC can be expected to reduce some of the demands on the BRHC cardiologists. Currently, in the absence of a PEC, there is no appropriate 'filter' for referrals to the tertiary centre.
- 6.10 The requirement from the NCHD Review to appoint a network manager is also anticipated by the Review to be a helpful move to build up the communication across managerial and administrative teams in hospitals where outreach services are provided.

7 Scheduling of Outpatients' Clinics at the Children's Hospital

- 7.1 The quotes set out above reflected frustrations on the part of a number of parents about the systems for scheduling outpatient appointments in Bristol's cardiology clinics.
- 7.2 The Review was told by cardiologists at Bristol that there had been some errors in managing appointments which had resulted in some children being seen later than intended.
- 7.3 The Review was told that, at least in 2009, there had been insufficient guidance given to administrative staff about the timeframe within which patients needed to be seen when re-booking appointments when the parents cancelled or the consultant had to cancel a clinic. In those circumstances, patients might be slotted into the 'next available' appointment. This could mean a delay, or rescheduling without regard for the time by which the child was meant to be seen again. This problem was a Trust wide problem. The system was subsequently changed to ensure that the patient would be re-booked within the appropriate time frame, or efforts made to find time of a clinic time.
- 7.4 The Review's examination of documents showed an awareness on the part of staff of continued concerns about the robustness of booking procedures, prompted by a

³¹ NCR standards A16L1 and A17L1, page 72.

number of documented incidents, some of them serious. During the course of 2010 and 2011, analyses arising out of such incidents highlighted the need to:

- strengthen the referral pathway from the Neonatology Unit at St Michael's;
- eliminate delay or error in the entry of referrals or requests for appointments received by the administrators of outpatients;
- ensure that children whose appointments were cancelled, whether by the hospital or by the patient or parents, were re-booked in a timely manner;
- ensure proper follow-up of those who did not attend an appointment. Such patients were commonly referred to as a 'Did Not Attend' or 'DNAs'. Failure to attend an appointment could have many causes, but, at least if repeated, could raise concerns about the care and welfare (safeguarding) of the child.

7.5 It was apparent that, as a result of concerns about reported incidents, work was carried out in mid-late 2011 to strengthen processes. The 'DNA' policy and the training in safeguarding of the cardiology team were reviewed to see that they were up to date. There was reference to a 'mini-audit' of case notes to review the handling of out-patient clinic bookings, as part of a process of analysing gaps and seeking to put fail-safe procedures in place. A new form was developed for use if a child did not attend a clinic to ensure proper follow-up.

7.6 In April 2012, the BRHC introduced a new patient administration system, Medway. We heard from a consultant cardiologist that a problem with the use of the system used for booking out-patient appointments followed, in that some patients were discharged from the system who had not been discharged by the consultant. The consultant told us that the problem had, however, been resolved through the process of governance.

7.7 We sought to establish further details and noted that, despite the work on strengthening processes undertaken in 2011, in late 2012 a further two incidents were recorded which raised questions about the robustness of the system for bookings and follow-up. One related to a situation in which a referral had been made to the cardiology team and the child given an appointment. The appointment did not take place, but the patient was nonetheless taken off the system. A review of a further incident noted that the Trust's DNA policy was not followed completely, with non-attendance at an appointment followed up with GP and referring consultants but not with the family or health visitor. Problems also arose about sharing information about missed appointments across more than one team of specialists.

7.8 Actions to be taken as a result of the review included a 'DNA policy audit', as well as steps to develop the use of the Medway system to ensure that non-attendances were flagged up and could be recognised if they occurred in more than one department. There was also a recognition that a new system for cancellations was required.

7.9 It is apparent that by early 2013, about 12 months after the switch to the new patient administration system, there were concerns being raised about the management of outpatient appointments under this system, as well as co-ordination between teams of

specialists and children being 'lost to follow up'. In the Quality Assurance Group meeting held in January 2013, the Lead Doctor for Paediatric Intensive Care and Paediatric Cardiac Service asked for a risk assessment of cardiology outpatient services as a result. The work done as a result of the flagging of these matters is discussed further at 10.7, below.

- 7.10 We also saw evidence of two cases where the handover from a consultant who was leaving to a colleague resulted in referrals for procedures being left without action for a period of weeks, with referral letters being left unopened.

8 Pressures on the Outpatients Clinics

- 8.1 As we have set out above, a part of some parents' feedback to the Review was that clinics could be rushed or that they felt that they had inadequate time to ask staff questions about their children.

- 8.2 We heard from cardiologists that there had been pressures on out-patient services, particularly for the clinics held in Bristol, rather than elsewhere across the network. The schedules for outpatient had been very busy at certain points.

- 8.3 Cardiologists highlighted that they did take steps to run extra clinics from time to time, or 'over-booked' to fit in additional patients urgently, in order to manage these pressures. They also told us that steps were implemented to improve the efficiency of clinics.

- 8.4 In late 2012, one consultant wrote graphically about the problem of overbooked clinics:

'I was attempting to start my clinic (13.45) which had a large number of patients booked. Not able to get into my room, since the morning clinic was overrunning as usual (due to end at 13.00).' Once that room was vacated: 'I then had 2hrs and 45 minutes to see, ECG and echo 15 patients. This led to some patients not being able to have their investigations, the technicians have to leave soon after 5pm. This is a recurring theme, with patients waiting long times for investigations and not even being able to find a seat. Dr Y has a clinic at the same time, which makes it rushed and intolerable for staff and patients. Many times I am then on call for the cardiology service at 5pm.'

- 8.5 An analysis which was completed by March 2013 noted that the 'outpatient clinics are at times overbooked often in response to clinical need; the booking process does not currently comply with trust standards and at times patients need to be added on because of their clinical situation. This can result in overbooking and a difficult working environment for doctors and support staff.' It was unstated, but clearly, the results were equally unsatisfactory for families.

8.6 The actions identified in response were:

- the cardiac outpatient process and pathway were to be reviewed. ‘Sufficient support staff, echo facilities, time and space must be available to sustain a high standard of patient care. A regular commitment to service delivery should be balanced by spreading the workload and if necessary increasing capacity.’
- risk assessment to be completed
- patient satisfaction surveys to be completed
- DNA policy audit
- a new system for cancellations was required

8.7 A risk assessment was placed on the Divisional Risk Register on the 2nd of February 2013. It recorded that ‘A local review by the lead doctor for cardiac services suggests that there are issues relating to outpatient capacity for the cardiology service. The issue can be summarised as:

- referral and booking processes
- clinical sessions being changed with minimal notice impacting on OPD function
- cardiology clinic capacity.’

8.8 The risk was rated as ‘moderate’. The controls listed relate to improving clinical capacity and efficiency.

8.9 In autumn 2013, the problem was addressed in a letter in the following fashion, in response to a patient’s complaint about delay in receiving a follow-up appointment in the spring. The letter noted that the consultant’s appointments in clinics:

‘... were in high demand during this period of time, and as a consequence some of his patient’s follow up appointments were booked later than originally anticipated. The main contributing factor to this was insufficient capacity and the consultants and managers have been working hard to resolve this issue over the spring and summer.

I am pleased to report that the wait for clinic, for both new and follow up patients, is now much less. The consultants have all undertaken extra clinics and this further injection of capacity is planned to continue until December this year. The managers at BRHC have also acknowledged that clinic waiting times have been too long and there is now a clear plan to move forward with the appointment of an additional consultant post to focus primarily on the outpatient service and the reduction of waiting time.

The managers are also completing a piece of work around the mix of new, follow up, and urgent appointment slots, to make sure that every clinic has the appropriate mix of each to enable more urgent patients to have easy access as and when required. For urgent patients currently an appointment can be offered within four days.’

8.10 In summer 2014 improvements were made to the out-patient facilities with larger rooms and the provision of three rooms in the place of two where echocardiography could be undertaken. Support staffing was subsequently expanded, with the appointment of another echo technician and cardiac physiologist.

9 The scrutiny by the West of England Child Death Overview Panel

9.1 When child deaths were reviewed, any incidents which had occurred during the child's treatment were included in the review, irrespective of any direct link to the cause of death. Such matters could include failures in the appointments systems (e.g., delayed or missed appointments). Evidence of the actions taken to improve out-patient services was presented by the Trust to the West of England Child Death Overview Panel (CDOP), as part of the Child Death Review process. The Review noted that in 2010, 2011 and 2012 CDOP was satisfied that the action plans prepared by the Trust in response to serious incidents addressed the issues about appointments that had arisen.

9.2 In 2014, CDOP sought further specific assurance that problems relating to cancellations of clinics and 'DNAs' were being addressed. Those issues have been outlined earlier in this Chapter. The Clinical Chair of the Division of Women's and Children's Services responded to enquiries in April and June 2014. She stated that actions to strengthen the current systems had included:

- adherence to the Trust's policy to follow up Did Not Attends;
- weekly validation of both new and follow up waiting lists by clinic co-ordinators who worked with the specialty concerned;
- twice weekly monitoring of outpatient performance, particularly length of wait for appointments.

9.3 There had also been work to develop systems further, including:

- the introduction of 'partial booking', a new process aimed at arranging an appointment suitable to the family over the telephone, to reduce DNA and cancellation rates;
- the introduction of a text reminder system with reminders sent via mobile telephone;
- full review of the DNA policy by the safeguarding team;
- introduction of 100% adherence of stamping all referrals on day of receipt and of putting referral letters in front of records for first appointment.

9.4 The letter outlined plans to develop the case for two further Consultant posts, 'supported for this coming year', to support the introduction of more outpatient clinics.

9.5 In the letter of the 14th April 2014, the waiting list time for outpatients was said to be 13 weeks (having improved from 22 weeks, some 9 months previously). 94.62% of new patients were seen within 13 weeks (up from 74%, 9 months previously). Extra clinics were in place, 'ongoing'. The correspondence also included data to show that the DNA rate for cardiology clinics had fallen from 16.9% in April 2013 to 6.8% in 2014/15 for the year to date from March 2014. No complaints had been received regarding

contacting the Out Patient Department's booking team for 4 months, whereas previously this had been a 'regular theme'.

- 9.6 Further work continued. The Review noted, for example, evidence of audits of DNAs developed across 2014. The Composite Cardiac Action Plan of March 2015 noted extensive work on policies to be followed when patients did not attend for appointments.

10 Adequacy of cardiologist staffing

- 10.1 In 2001, the Kennedy report wrote:

'There was also a national shortage of paediatric cardiologists. In the late 1980s, the British Cardiac Society and the Royal College of Physicians of London regarded this shortage as 'very worrying'. This national shortage was starkly reflected in Bristol. For the early part of the period of our Terms of Reference there were only two senior paediatric cardiologists. A third was appointed in 1989. There were no trainees who could support them. They bore an extremely heavy workload involving not only their patients in Bristol but the need to visit 'outreach' clinics throughout the South West and South Wales.'³²

- 10.2 Compliance with the draft Safe and Sustainable Standards (2010) would have required the employment of at least one paediatric cardiologist per half million population served.³³ By 2010, the numbers of Consultant Paediatric Cardiologists in Bristol had increased to six, with two further appointments imminent; in addition there were four Consultant Paediatric Cardiologists at the University Hospital of Wales.³⁴ But the demands upon these individuals had increased too. It is apparent from the discussion of the outpatients clinics above that, by 2012 or earlier, the capacity of the consultant cardiologists in post at the BRHC to cover the workload placed on them was a cause of concern. The Review was told that benchmarking of cardiologist staffing at Bristol compared to other centres in 2013 had indicated that the numbers were 'at the lower end'.

- 10.3 The Review noted two new consultant cardiologists took up post in April and July 2015 and that a further appointment was expected.

- 10.4 Some clinicians we spoke to thought that the outpatient service was still under pressure. The Review heard from consultants in other disciplines in the children's cardiac service that there was a view that the cardiologists were stretched and that further support was required from paediatric cardiologists to, for example, NICU.

³² Report of the Bristol Royal Infirmary Public Inquiry (2001), page 60, paragraph 46.

³³ Standard C8. The Report of the Independent Expert Panel (December 2010) did not comment on compliance with this draft Standard. It has been carried forward into the NCHD standards: standard B13(L1) now requires that 'Each specialist Children's Surgical Centre must be staffed by a minimum of one consultant paediatric cardiologist per half million population served by the network, working flexibly across the network'.

³⁴ Information contained in the self-assessment return to the Safe and Sustainable Review, 2010.

- 10.5 The Review's overall impression was that the service remained under-resourced, in terms of the cardiologists available to meet local demand.
- 10.6 Furthermore, there was a need for a review of the outpatient facilities and resources. The Review heard of gaps or inadequacies in the physical space available for clinics, the time available for cardiologists to plan their clinics, the absence of equipment to enable the viewing of echocardiograms in the consulting rooms, and in the availability of cardiac physiologists or technicians to support clinicians.
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11 Conclusions

- 11.1 In December 2010, the Safe and Sustainable Review's Independent Expert Panel had concluded that arrangements across the network were based on strong individual relationships rather than documented protocols.³⁵ The Review noted limited change to that position in the course of the Review, with development of the PDA protocol between clinicians in Bristol and Wales an exception to this picture. But it felt such limited development was not surprising, given how the Safe and Sustainable process came to a halt. The Review noted the recent appointment of a Network Manager by the UHB, and the plans for future development as a result.
- 11.2 There were challenges in ensuring consistent information was given to families, particularly when care was shared or passed between referring clinicians outside of the Bristol service, and those based at the UHB. The difficulties in managing communication and expectations in the treatment of patent ductus arteriosus, between Wales and Bristol, was one example of those challenges.
- 11.3 The matters most frequently raised by families concerned recurring problems with the robustness of systems for booking outpatient appointments, for re-scheduling missed or cancelled appointments and, we add, for following up those who did not attend. There were also concerns about the capacity of the service, given the demand for outpatient clinics, and the need to systematise the procedures in the outpatient clinic, such as observations of patients, review of observations by medical staff, and procedures for escalation of abnormal observations.
- 11.4 The causes of these difficulties appear to have been many and varied.
- 11.5 Our experience of appointments systems is that they are frequently the source of patient frustration and complaint, and that it is difficult to eliminate occasional error or instance of poor communication. There is evidence³⁶ that, as might be expected,

³⁵ The Report of the IEP, p53, noted that the documented clinical governance framework for UHB was not matched by the existence of documented frameworks for the network. The network was dependent on strong individual relationships rather a strong formalised structure. Good working practices with other Trusts were not formally documented. There was a lack of clarity over Bristol's role as leader of a network and the impact that it would have on governance arrangements.

³⁶ See the report of the CQC's inspection of the Trust, December 2014.

issues in the management of outpatient appointments were not limited to the paediatric cardiac department, but were a Trust-wide. Without suggesting that the situation described was an acceptable one, the Review's Expert Panel felt that the challenges in the management of paediatric cardiac outpatient appointments were likely to be similar to those faced not only more generally in the UHB, but in many hospitals across the country. Moreover, the Review considered that there had been a 'step change' in the response to these issues from early 2013 onwards, when it appeared that more vigorous action had been initiated.

- 11.6 Cardiac children are, however, a vulnerable group. Their condition can change and deteriorate quickly, with potentially life-threatening consequences. This highlighted both the general need for stringent adherence to planned appointment timescales and the importance of the issue of those children 'lost to follow-up'. The Review felt that this was an issue of real importance throughout the course of a child's life, and not only at the stage of transition to adult services.
- 11.7 The standards developed by the NCHD Review should enable the development of an effective network, with consistent standards to be met by all centres within the network, including in the planned deployment of professional expertise (e.g., the appointment of 'paediatricians with an interest') at local hospitals. Without underestimating the challenges that will be faced in meeting those standards, their development nevertheless represents an important step towards achieving equitable access to services.
- 11.8 The process of commissioning in Wales stood outside the NCHD Review. This Review felt that there was an urgent need for the effective implementation of standards designed to ensure consistency of services for patients/families across the network, including in fetal medicine, maternity and neonatal services both within Wales and between Wales and Bristol.
- 11.9 The Review noted the commitment given by the WHSSC to working with the NHS England Congenital Heart Disease Review Team, the new Congenital Heart Network and providers to ensure the coordination of plans to improve services. It endorsed the importance of ensuring the consistent provision of services, to a uniform standard, across both England and Wales.

12. Recommendations

- 12.1 In the light of the above, we make the following **recommendations**, addressed respectively to those named:

<p>(3) That the Trust should review the information given to families at the point of diagnosis (whether antenatal or post-natal), to ensure that it covers not only diagnosis but also the proposed pathway of care. Attention should be paid to the means by which such information is conveyed, and the use of internet and electronic resources to supplement leaflets and letters.</p>

- (4) That the Commissioners and providers of fetal cardiology services in Wales should review the availability of support for women, including for any transition to Bristol or other specialist tertiary centres. For example, women whose fetus is diagnosed with a cardiac anomaly and are delivering their baby in Wales should be offered the opportunity, and be supported to visit the centre in Bristol, if there is an expectation that their baby will be transferred to Bristol at some point following the birth.
- (5) The South West and Wales Network should regard it as a priority in its development to achieve better co-ordination between the paediatric cardiology service in Wales and the paediatric cardiac services in Bristol.
- (6) There should be explicit recognition that children are 'lost to follow up' at points in time other than transition and transfer to other centres, which are the points explicitly reflected in the NCHD's current standard. The standard should be broadened by NHS England, to recognise the issues of safeguarding which can arise for vulnerable children.
- (7) The paediatric cardiac service in Bristol should carry out a periodic audit of follow-up care to ensure that the care is in line with the intended treatment plan, including with regards to the timing of follow-up appointments.
- (8) The Trust should monitor the experience of children and families to ensure improvements in the organisation of outpatient clinics have been effective.
- (9) In the light of concerns about the continuing pressure on cardiologists and the facilities and resources available, the Children's Hospital should benchmark itself against comparable centres and make the necessary changes which such an exercise demonstrates as being necessary.
- (10) NHS England should gather and/or publish, to the extent possible, the data necessary to assess the implementation of the NCHD standard, that tertiary centres should employ one consultant cardiologist per half million people served, working flexibly across the Network.

CHAPTER SIX: ADMISSIONS TO HOSPITAL

1 Pre-operative and pre-interventional cardiology care - Decisions regarding treatment plans

- 1.1 The first stage in the patient journey towards any operative or cardiology intervention is joint decision-making by the team of clinicians involved in the child's care.
- 1.2 It is a longstanding expectation that every Specialist Children's Surgical Centre will have a dedicated specialist multidisciplinary team (MDT) that meets weekly to consider the management of cases. In many centres, including Bristol this is called a JCC meeting. This expectation is set out in the standards set by NHS England arising from the New Congenital Heart Disease Review and was also set out in the Safe and Sustainable Review Standards published in 2010.
- 1.3 It is expected that patients undergoing complex cardiology interventions or any surgical interventions must be discussed in an appropriate MDT meeting. The MDT meetings are considered to be pivotal to the quality of clinical decision-making and associated outcomes for patients. All rare, complex and innovative procedures and all cases where the treatment plan is unclear or controversial are expected to be discussed at the MDT.
- 1.4 The overarching principles of an MDT meeting are that the key members of the team are present, the frequency is sufficient to meet the demands of the efficient running of a service and that the wishes of the patient or family are taken account of. An effective MDT seeks to discuss all matters relevant to the management of patients and should include a minimum core group of members with the necessary range of expertise (including surgeons, interventional cardiologists and non-interventional cardiologists). Together they should be able to reach a consensus that has incorporated all the factors required to achieve optimal management of the patient's care. It is considered good practice to have members of other medical specialties (e.g. cardiac anaesthetists, nurses and allied healthcare professionals) present as well, although this may not always be practicable.
- 1.5 The Review asked clinicians about the functioning of the JCC meetings in Bristol. Some of the clinicians the Review spoke to felt that meetings had not been well organised and it had been difficult to timetable and to cover all the cases that should be discussed each week. One cardiologist expressed frustration about the lack of resources available to 'run a very complex surgical interventional MDT'. The Review heard that a persistent concern had been lack of adequate administrative support for the JCC. In July 2012 the report on a serious incident recommended administrative support be made available for the JCC, after questions were raised about the depth of involvement of Welsh cardiologists. No action was taken immediately as no funding was judged to be available. An appointment was finally made in May 2013. The Review was told that the meetings were much better planned and efficiently run once the JCC co-ordinator had been appointed.

- 1.6 Improvements to the JCC were linked to the work on team-building carried out in 2013, in the wake of various investigations in 2012 and the CQC inspection in September 2012. We were told that as a result senior representatives from the Theatre Nursing Team joined the meeting, thus facilitating the scheduling of operations and enhancing communications between theatre and ward nursing staff.
- 1.7 The Review heard from paediatric cardiologists in University Hospital Wales that it was difficult for them always to participate in the meetings because of clinical commitments and scheduling clashes. It had become more difficult over time to participate as a result of increased workload. This was felt to be disadvantageous by clinicians in both Bristol and Cardiff, as well as contrary to best practice.³⁷
- 1.8 Some clinicians told the Review that they felt parents sometimes got different information about their child's condition and treatment plan because communication across the cardiology teams was not always as good as it could be.
- 1.9 The Review was told that the poor facilities available for the JCC meeting and an outdated image archiving system had hampered the efficiency of the JCC. 'The imaging equipment, the archiving system, all those things are essential for a cardiology department to run and they just didn't happen. I saw those as being major issues', said one. There were, and we understood still are, also difficulties due to separate systems for managing records in Wales and Bristol.
- 1.10 The Review was told that in some other centres the clinicians had worked, the cardiologists would have time in their job plan in advance of the JCC to prepare the cases and identify the key images to support discussion of the case. Although there was also time in job plans at Bristol, the cardiologists in Bristol nevertheless felt that they did not get sufficient time to prepare and time was wasted as the team had to run through multiple images to find the key ones.
- 1.11 Clinicians told the Review that recently they had audited the echocardiograms and had demonstrated that improvements were needed to support JCC discussions. This work was in progress in spring 2015. The Review was told that the service had secured funding for an improved data archiving system that will enable all echocardiograms, MRIs and cardiac catheter data to be integrated into one system across the hospital so that if an echocardiogram was carried out in the neonatal intensive care unit it could be looked at in the cardiac unit. It was reported that the new system would be in operation 'fairly soon'. The Expert Panel felt that Bristol was an outlier, in not having such a system in place during the period of the Review.

³⁷ See, for example, the Safe and Sustainable draft standards (A27), which stated that staff from across the network should be encouraged by the Tertiary Centre to attend MDT meeting when, for example, an individual's care is complex or involves more than one speciality team. In the alternative, participation could be secured by video or teleconferencing.

- 1.12 The Review noted that in at least one of its case reviews it had seen evidence of the limited involvement of clinicians from Wales in the JCC, and felt that this had affected the quality of pre-operative planning. Problems of communication were also evident in the history of the questions concerning PDA litigation, referred to in Chapter Five.
- 1.13 The Review felt that the matters outlined above were real impediments to the creation of a network that functioned as effectively for Welsh patients as for others from the south west of England.

2 The Process of Seeking Consent

- 2.1 The pathway following a decision by the JCC is to schedule an operation and contact the parents. The parents and child, if appropriate, would then have a meeting with the surgeon to discuss the operation, its benefits and risks.
- 2.2 A number of parents raised questions or concerns about the process that was followed to inform them about their child's proposed operations or procedures, and the obtaining of consent that followed.
- 2.3 They covered a broad range of topics. They included:
- a sense that the family concerned had struggled to understand the information that was being conveyed, and, at times, had felt rushed into agreeing to procedures;
 - concerns about the accuracy or completeness of the information that was given, including about the nature or extent of the risks involved;
 - in a small number of cases, concerns about the identity of the person who carried out the procedure, such that the person who obtained the consent was not the person who carried out the procedure.
- 2.4 It is right to acknowledge that we heard also from a number of families who felt that the process of obtaining consent was thorough and they were well informed about the procedure, the reasons for it and the risks.

'Arguably the most important conversation of our son's life was the one held between my wife, myself and [the consultant] when he came to take informed consent for the surgical repair of the aorta. We found him to be clear, to the point and honest. He fully explained the risks and benefits of the operation and was entirely professional.'

'The surgeon fully explained the risks and benefits of the proposed surgery . . . he spent some time with us and explained everything fully and I was very impressed with him.'

3 Conveying information about procedures: recordings

- 3.1 We heard from a number of families who felt that the information which they had been given was difficult to understand, incomplete or failed properly to address their

questions. The Review has commented on these issues, so far as it is able, in some of the individual family reports. There are real difficulties in seeking to ‘reconstruct’, at a later point in time, discussions between clinicians and families. It is an inevitable feature of the emotions and anxieties which attend the care of a sick child that not every word of a discussion about procedures and risks is heard and there is scope for misunderstanding even when all are well-intentioned.

- 3.2 We have noted, below, the improvements made to the process of seeking consent prior to surgery, in cardiac services at the BRHC. We have sought to examine what further scope for improvement may exist.
- 3.3 The Bristol Public Inquiry gave great emphasis to the importance of communication with children and families and particularly to the notion of partnership between patients and professionals. Good communication provides the bedrock for effective and informed consent.
- 3.4 Recommendation 24 stated: ‘The process of informing the patient, and obtaining consent to a course of treatment, should be regarded as a process and not a one-off event consisting of obtaining a patient’s signature on a form.’
- 3.5 Recommendation 26 stated: ‘As part of the process of obtaining consent, except when they have indicated otherwise, patients should be given sufficient information about what is to take place, the risks, uncertainties, and possible negative consequences of the proposed treatment, about any alternatives and about the likely outcome, to enable them to make a choice about how to proceed.’
- 3.6 Recommendation 10 stated that: ‘Tape-recording facilities should be provided by the NHS to enable patients, should they wish so, to make a tape recording of a discussion with a healthcare professional when a diagnosis, course of treatment, or prognosis is being discussed.’
- 3.7 The recommendation about ‘tape recording’ was one that was not accepted nationally and, in common with all other similar institutions, was not implemented by the Trust.
- 3.8 The Review asked about perspectives on the issue of recording now, particularly given how technology has moved on. The Trust reported that they did not do this but they encouraged families to bring someone else with them and take notes. They had not as yet found a practical and cost effective method to provide recordings and/or transcripts of the discussion to families. More information was also now provided in written form, after an appointment.
- 3.9 In feedback from families and at least one of our expert case reviews, we noted the existence of disputes about what had been said at consultations before a planned procedure, and whether risks had been accurately conveyed. For example, there was a dispute as to whether or not information recorded on the written consent form had

also been conveyed orally in discussion. In another case, a surgeon had not noted, in writing, a statistical estimate of the risk that he had quoted to the family. These are precisely the sort of circumstances that the recommendations of the Bristol Public Inquiry were intended to address. It is at best disappointing that they can still occur. They were important here, not because it was difficult for the Review to reach firm conclusions about what might have been said, but because confusion or differing recollections of such important discussions was a potential source of distrust between clinicians and families.

3.10 We further noted the CQC's comments, in its clinical case note review:

'Two particular aspects of preparation were not well documented in the records reviewed. Firstly, in the majority of cases the risk of surgery was not expressed in numerical form in the documentation of consent. This does not mean that it was not discussed, but the reviewers regard it as good practice for the surgeon to record the percentage risk of mortality or other major complication that they have discussed with the parents or carers in the record or on the signed consent form. This ensures that there is no ambiguity when a procedure is described as high risk or low risk. In two examples reviewed features of the individual child's condition meant that the surgical procedure would carry a higher risk than would normally be expected for this operation. It was unclear from the case notes whether this was discussed during the consent process'.

3.11 Plainly, in understanding what passed between clinician and parent or patient, the patient's records are an important source of information. The Review noted that the GMC's Guidance states: 'You must use the patient's medical records or a consent form to record the key elements of your discussion with the patient. This should include the information you discussed, any specific requests by the patient, any written, visual or audio information given to the patient, and details of any decisions that were made.'³⁸

3.12 However, clinical notes or consent forms will only ever contain a summary. Moreover, they are not available for the family when thinking about what they have recently heard at an appointment.

3.13 The Review felt that most if not all families would now readily be able to record discussions with clinicians by using their mobile phones. This fact, and the ease with which recordings can now be made in any event without the knowledge or consent of clinicians, means that it is time to re-visit the recommendation about recording made in 2001. If families are encouraged to take notes (which would not necessarily be shared and agreed with the clinicians), they can equally be assured that it is permissible to record a conversation. We take the view that there needs to be an open

³⁸ GMC Good Medical Practice; Consent Guidance, Part 2 para 51.

dialogue between patients and clinicians about this issue, and that discussion should include explicit mention of the option of recording and the benefits to understanding that it could bring.

- 3.14 Support for this approach is provided by the GMC's guidance 'Consent: patients and doctors making decisions together' (2008), which states:

'21. You should check whether the patient needs any additional support to understand information, to communicate their wishes, or to make a decision. You must make sure, wherever practical, that arrangements are made to give the patient any necessary support. This might include, for example: using an advocate or interpreter; asking those close to the patient about the patient's communication needs; or giving the patient a written or audio record of the discussion and any decisions that were made.'

4 Support for parents and carers: consent to surgery

- 4.1 The need for support for parents and carers in making difficult decisions about the care which their children needed was evident to the Review. We heard families describe how difficult they had found it to understand the complexities of what was being proposed, as well as how little they felt prepared for admission to hospital.
- 4.2 The Trust told us that it had recognised this as an area needing further improvement and in response had established a programme of work concerned with consent in children's cardiac services. It held an event for parents in February 2015 to discuss how to best meet families' needs and expectations.
- 4.3 Clinicians from the Trust described how in 2010, the Trust had formal guidelines for consent and its documentation. After the child was discussed in the JCC, parents were sent an invitation to attend the surgical clinic so that they could meet the surgeon undertaking the operation, and discuss the planned procedure, its risks and benefits. Time was left for the families to ask any questions of the surgeon. The cardiac nurse specialists (CNS) would also meet the families, give them their contact details, and start to prepare them for the forthcoming operation. Following the clinic, a letter was sent to the families in which the details of the meeting were documented and the parents were told they could contact the CNS team whenever they wished if they were worried or if they had any questions.
- 4.4 Thereafter there was little formal contact between the cardiac services team and the parents until an appointment was sent to them to attend a pre-admission clinic, shortly before the operation.
- 4.5 The CQC's clinical case note review recorded that 'There was evidence in some cases that families received information and support from the Cardiac Liaison Nurse in the pre-operative period, but this was not recorded in all cases.'

- 4.6 The Trust told the Review that as a result of the feedback from families at the event in February 2015, it has been recognised that families were not fully prepared for what they were going to go through, and anxieties remained.
- 4.7 Accordingly, the letter inviting the families to the surgical clinic has been changed to provide additional information. The surgical clinic has been changed to be more multidisciplinary in approach, with the cardiac nurse specialist present at the consultation so they know exactly what the surgeon has said to the family. They then have a meeting with the family, answering any further questions. Families are now given more written information and greater attempts are made to check the family's understanding of what has been said.
- 4.8 The Review was told that developments have taken place to expand the psychology service. With the appointment of a further psychologist on a full-time basis from April 2015, psychologists are now involved in the surgical clinic and introduced as members of the team. This allows a relationship to be built up between the psychologists and the families, and the psychologist may actively identify any families who are likely to need additional support. We were told this had dramatically increased the take-up of psychological support; there had been 1280 contacts in the first 10 months. Information packs for families about coping with coming into hospital had been developed. In addition, the psychology service, the clinical nurse specialists and the surgical co-ordinator between them aimed to maintain communication with families in the period between the surgical clinic and pre-admission clinic. Previously some families had reflected that they had felt somewhat abandoned between these two stages.
- 4.9 The written information provided to families about procedures and risks had also been re-designed following the feedback received at event for families in February 2015.
- 4.10 We were told by the psychology team that early evaluation of these changes was showing that they were helping to reduce anxiety and stress and also time spent in contact with families in hospital, as the preparatory work had already been carried out. *'An evaluation of all these changes is now underway. We believe we are the first children's hospital analysing our consent pathway in so much detail.'*
- 4.11 The Trust is planning to test the new approach to consent by seeking further feedback from families after a period of time and is seeking views through surveys on a monthly basis.

5 Gaps or Limitations

- 5.1 We were told by members of the psychology team that its resources were limited. As a result, the input of the psychology team, as described above, was restricted to surgical patients. Resources did not allow for it to be extended to patients undergoing catheterisation, to pregnant patients requiring fetal scans and patients in transition from child to adult, except in exceptional cases. This gap was reported via the

Divisional risk register. This challenge was not unique to Bristol; psychology services were stretched nationally and would be a challenge for commissioners.

- 5.2 It follows that the process of consenting to catheterisation had not been subject to the same overhaul and development.
- 5.3 The Review noted that a number of the standards set by the New Congenital Review are intended to support improved consent processes. In particular, standard H23 (L1) requires a Children's Cardiac Nurse Specialist to be available to support parents and children/young people throughout the consent process. Discussions with the Royal College of Surgeons also suggested that exemplary practice would involve the offer of a visit by the Cardiac Liaison Nurse at home, after the surgical clinic, on the basis that the nurses were in an excellent place to check on the family's understanding of planned treatment.

6 Safeguarding and the Vulnerable Parent

- 6.1 Following its review of individual cases and the Trust's Consent Policy, the Review further concluded that there was a particular situation which could arise when a parent (or carer) was expected to give consent to treatment for their child, but that parent's capacity to make such decisions was questionable. No doubt, this was a rare situation. But it was not one explicitly considered in the Trust's Consent Policy, even though the policy did refer to questions of capacity that could arise in the case of adults giving consent to their own care and treatment. From its review, the Expert Panel felt that, in the case of concerns about the capacity of the parent, there was a need to ensure, not only measures to support the family concerned, but to ensure that consent was validly given. The issue was one of safeguarding and all staff needed to be alert to it.

7 Consent and the Identity of the Clinical Team

- 7.1 Amongst the families who approached the Review were a number who made serious complaints arising from the identity of the person performing the procedures in question. One family told us:

'We were unaware that [the consultant] was [our child's] first surgeon until after [our child's] death when we viewed his medical records.'

- 7.2 The parents of another child told us that they had particular confidence in a surgeon, and indeed had agreed to come back to Bristol for their child's operation because they expected this surgeon to carry it out. They were deeply upset to find out at a later date (after the death of their child) that surgery had been carried out by another of Bristol's three paediatric cardiac surgeons. The two surgeons had been present together, both scrubbed up and with the senior surgeon supervising his more junior colleague; but the family felt that this was not what they had expected or agreed to.
- 7.3 We heard from the surgeon that, as a result of what had arisen, he had changed his practice. Now, if there was any suggestion that anyone else may be doing the operation he would specifically say this to the parents. Furthermore, if that information had not

been given, he would not let the other person be involved in the operation. He was plainly upset and distressed by the situation that had arisen.

- 7.4 In another case, a family told us that they had not been informed about the fact that a part of the catheter procedure for their child would be performed by a Specialist Registrar, a trainee under the supervision of the consultant cardiologist. They told us that, had they known, they would not have agreed to the involvement of the less experienced doctor. There was a dispute as to whether they had been informed in advance of this fact. The clinical team told us that they felt that the information had been given to the family. In particular, the team stated that there had been a pre-operative visit to the child and parents by the trainee concerned. The family did not agree that this was so.
- 7.5 In none of the cases raised with us was there evidence that the procedure or that part of it performed by the second surgeon or trainee cardiologist had been performed less than competently. Appropriate supervision was given to the trainee.
- 7.6 The Review noted that the usual progression in the career of a consultant paediatric cardiac surgeon is lengthy. A surgeon will increase the scope and complexity of the surgery he or she is undertaking, supported by an experienced senior colleague. Reaching the stage of clinical competence to be a single operator across the full range of paediatric cardiac procedures takes many years, even after reaching the status of consultant cardiac surgeon. In addition, a number of surgical interventions always require two surgeons to operate and a two-consultant operation is in some circumstances considered good practice.
- 7.7 The same circumstances apply to cardiologists undertaking catheter procedures where they may supervise more junior colleagues and, in a teaching hospital, trainees. Particularly in a teaching hospital such as the Children's Hospital, a proportion of the staff will be receiving teaching, supervision and mentoring to develop their clinical skills.
- 7.8 At a national level, there is no clear guidance about what information should be given about who will be involved in a procedure, when there may be more than one person involved. The General Medical Council's guidance 'Consent: patients and doctors making decisions together' (2008) states that a doctor must 'must give patients the information they want or need about' matters such:
- a. the diagnosis and prognosis
 - b. any uncertainties about the diagnosis or prognosis, including options for further investigations
 - c. options for treating or managing the condition, including the option not to treat
 - d. the purpose of any proposed investigation or treatment and what it will involve

e. the potential benefits, risks and burdens, and the likelihood of success, for each option; this should include information, if available, about whether the benefits or risks are affected by which organisation or doctor is chosen to provide care

f. whether a proposed investigation or treatment is part of a research programme or is an innovative treatment designed specifically for their benefit

g. *the people who will be mainly responsible for and involved in their care, what their roles are, and to what extent students may be involved* (para 9, italics added).

- 7.9 However, the ‘Reference guide to consent for examination or treatment’ published by the Department of Health in 2009 gave limited attention to these ethical dimensions, or the relationship between family and clinician when it stated:-

‘It is particularly important that a person is aware of the situation when students or trainees carry out procedures to further their own education. Where the procedure will further the person’s care – for example taking a blood sample for testing – then, assuming the student is appropriately trained in the procedure, the fact that it is carried out by a student does not alter the nature and purpose of the procedure. *It is therefore not a legal requirement to tell the person that the clinician is a student, although it would always be good practice to do so.* In contrast, where a student proposes to conduct a physical examination that is not part of the person’s care then it is essential to explain that the purpose of the examination is to further the student’s training, and to seek consent for that to take place.’ (paragraph 14, page 12, italics added).

- 7.10 The Trust’s Consent Policy referred to the DH Reference Guide, and had extensive information about who might be authorised to take consent on behalf of another clinician, but did not discuss the issue of team-working, training or the involvement of students.

- 7.11 We noted that in 2014 the Royal College of Surgeons published further guidance, ‘Good Surgical Practice’ (2014). This requires practitioners to provide information on the procedure and its implications:

‘In particular, you should discuss information about:

- The patient’s diagnosis and prognosis
- Options for treatment, including non-operative care and no treatment
- The purpose and expected benefit of the treatment
- The likelihood of success
- *The clinicians involved in their treatment*
- The risks inherent in the procedure, however small the possibility of their occurrence, side effects and complications. The consequences of non-operative alternatives should also be explained.
- Potential follow-up treatment’ (paragraph 3.5.1).’

- 7.12 The Expert Panel noted that in the cases they reviewed the process of taking consent was led by a consultant cardiac surgeon (for cardiac surgery) or a consultant cardiologist (for catheter procedures). It observed that, in its experience, this was by no means universal in the UK. Indeed, it was common to pass the obtaining of consent even for relatively complex operations to a more junior figure such as a Specialist Registrar.³⁹
- 7.13 The practice in children's cardiac services in Bristol,⁴⁰ involving as it did the lead consultant, went further and is to be commended.
- 7.14 We noted that the Trust's Consent Policy,⁴¹ after stating that 'Trust Policy recommends that the person carrying out the procedure should obtain consent from the patient or parent of a child patient', added that 'Where written consent is sought in advance of a planned procedure e.g. in a pre-admission surgical setting, consent may be obtained by a different health care professional to the person who undertakes the procedure.'
- 7.15 Moreover, the Parental Agreement or consent form used by the Trust, based upon a national (Department of Health) model contained the statement, to be signed by parents:
- 'I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience'.
- 7.16 It seemed to the Review that whilst as a matter of form these processes and procedures covered in principle the situations which were the subject of the complaint referred to above, there were underlying difficulties.
- 7.17 First, both the form and the Trust's Consent Policy tended to assume that there would be only one person 'performing the procedure'. Whilst it was true that in every case there was a leading surgeon or operator who had overall responsibility, it was also the case that more than one person might be involved in the procedure, or parts of it. Second, there was also the matter of parents' wishes and expectations. At times, parents not only considered that they had met the person who would be carrying out a procedure, but many attached a great deal of faith in the relationship built up with those whom they had met. It seemed to the Review that there was a conflict between this and the reality of both 'team-working' and the need to enable training and learning within paediatric cardiac surgery and cardiology.

³⁹ Such delegation would not be contrary to GMC guidance on consent, provided that the person who sought consent was suitably trained and qualified, had sufficient knowledge of the proposed investigation or treatment, understood the risks involved and understood and followed proper guidance on consent; see GMC Good Medical Practice Consent Guidance Part 2 para 26

⁴⁰ This is not to say that all procedures in the Children's Hospital followed this process. In April 2013, a 'Clinical Audit of Guidance for consent to examination or treatment in Children's Services' was carried out by the Audit Department. It demonstrated that in approximately 77% of cases, consent was sought and obtained from the patient/parent by a person either performing the procedure, or in a small number of cases, supervising it or assisting at it.

⁴¹ Undated, but the 'review by' date suggests a date of 21/3/12 and the clinical audit carried out in April 2013 refers to the Trust's Consent Policy as dating from March 2012.

- 7.18 The Review noted that this matter had not been resolved. The Root Cause Analysis (RCA) into the death of the child whose parents' experience was set out at paragraph 7.2 above stated that the Trust would review parental and professional understanding of the process of obtaining consent, the forms used and the literature designed to inform parents and patients. However, the review of the consent pathway that had undoubtedly taken place had not addressed this issue.
- 7.19 We noted that there was potential for inconsistent practice; it was not clear that the approach of the first surgeon outlined above (paragraph 7.3) was universally followed throughout the department.
- 7.20 The need to review policies on consent has been underlined by recent developments of the law in this area, emphasising the rights of patients to be treated as partners by doctors, and to be properly informed about the risks which they are likely to consider material.⁴²

8 Consent to Anaesthesia

- 8.1 The Trust's Consent Policy required specific discussion of anaesthesia in advance of a procedure (ideally in a pre-assessment clinic rather than on the day of the procedure), and that the anaesthetist should ensure that the discussion with the family and, where relevant, the patient, and their consent are documented in the anaesthetic record or in the patient's notes.⁴³
- 8.2 The Expert Panel commented that it would not generally be the practice in the UK to obtain a specific additional signed consent to anaesthesia (at least for paediatrics where the options of undertaking procedures under local anaesthesia are very limited). It was nevertheless very important that the practicalities and procedures of administering anaesthetics were explained to parents/patient, including all invasive monitoring lines, etc., that carry risks of complications.
- 8.3 Pure anaesthetic risk (i.e. cardiac arrest or death as a consequence purely due to the anaesthetic) is exceedingly low, but where the risks of these are higher due to the underlying condition (usually cardiac in origin) it is essential that these are made known to the parents. The Panel commented that in practice they had never encountered a case where surgery has been refused because of the anaesthetic risks in children.
- 8.4 The Review was of the view that greater clarity was needed, to ensure that between them, the person who sought consent for the cardiac procedure (whether surgical or involving a catheterisation) and the anaesthetist, had outlined and explained all risks, including those associated with the use of anaesthesia.

⁴² See *Montgomery v Lanarkshire Health Board* [2015] UKSC [11 March 2015]. "The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it."

⁴³ See policy at Appendix E, paragraph 12.2.

9 Pre-operative assessments

- 9.1 The Review received a few comments about pre-operative procedures. One family reported a poor experience and felt the process was chaotic, poorly managed and that they had not been given sufficient information ahead of the hospital appointment. Some families reported that there had been no pre-operative assessments, in cases where surgery or catheter procedures were scheduled at relatively short notice.
- 9.2 The Review was told by clinicians that the pre-admission clinics are arranged so that the junior medical team from the cardiac service could assess the patient. Generally, an echocardiogram is performed and the child is checked to see if there are any reasons they might not be able to have the surgery or if any further tests or checks are needed.
- 9.3 At this appointment the family have a further opportunity to meet the team, particularly to meet the Cardiac Liaison Nurses and more information is provided if the family have questions. They also, at this time, have the opportunity to visit the cardiac ward and PICU so that they could see the environment in which their child was going to be admitted in the near future.
- 9.4 The service has taken steps to improve the pre-admissions process as part of a Cardiac Development Programme, which was set up in spring 2014. A new screening tool has been developed for the cardiac nurse specialist to identify better any children who may not be fit for surgery. The booklets on key types of surgery have also been updated. Additionally, the cardiac surgery pathway coordinator will make at least monthly telephone calls to the families that are on the waiting list to keep them updated on progress and to answer any questions.
- 9.5 The Review heard that some families are unable to attend the hospital three times for the surgical clinic, pre-admission clinic and admission, because of problems with transport or distance. In this case they would meet the surgeon and have the pre-operative tests on the day of admission.

10 Admission

- 10.1 The Review heard a number of accounts of the stress and anxiety experienced by families associated with admissions for surgery or interventional cardiology.
- 10.2 Several families reported that they felt somewhat abandoned after the paperwork for admission had been completed and said they had no contact with a nurse after that until the morning of the surgery.
- 10.3 The Review was told that when a child is admitted for cardiac surgery the usual pattern is for them to be admitted the day before. The surgeon and the anaesthetist would see them and formal written consent would be taken at that time. The aim is to ensure that they have time to settle in to the ward.

11 Conclusions

- 11.1 We saw evidence that during the period of the Review, that on occasion the ability of clinicians at Bristol and Cardiff to co-operative effectively in planning operations and interventions at the Children's Hospital was constrained by the difficulties in securing the consistent involvement of Cardiff clinicians in Bristol JCCs, in person or remotely. The difficulties were a product both of the limits upon the ability of Cardiff clinicians to attend meetings in Bristol, and of the limited technology available to them to share images and other clinical resources.
- 11.2 We recommended in the previous Chapter that achieving better co-ordination between the paediatric cardiology service in Wales and the paediatric cardiac services in Bristol should be recognised as a priority in the development of the South West and Wales network. We make further recommendations related to this, below.
- 11.3 We heard a range of concerns expressed by some families regarding the process of obtaining consent to their child's treatment. These included concerns about the completeness of information provided and the manner in which it was conveyed and the support provided to parents during the process.
- 11.4 We note, and **endorse**, the recommendation from the CQC's clinical case note review, of the need to review the 'Recording [of] the percentage risk of mortality or other major complications discussed with parents or carers on consent forms.'
- 11.5 We noted that improvements had been made to the arrangements for obtaining consent from 2015 onwards, in response to parental feedback.
- 11.6 The Review considered that most if not all families would now readily be able to record discussions with clinicians by using their mobile phones. In the light of this, we have recommended further consideration of the option of recording discussions with clinicians.
- 11.7 We also heard of concerns about knowledge of the identity of the clinician who performed the procedure. There was, at times, a lack of transparency about who would be performing an operation. We noted that guidance on information to families about the identity of clinicians involved in procedures or treatment lacks clarity and consistency.

12 Recommendations

12.1 In the light of the above, we **recommend:**

(11) That the paediatric cardiac service benchmarks its current arrangements against other comparable centres, to ensure that its ability, as a tertiary 'Level 1' centre under the NCHD Standards, to communicate with a 'Level 2' centre, are adequate and sufficiently resourced. Benchmarking would require a study both of the technical resources underpinning good communication, and the physical capacity of clinicians to attend planning meetings such as the JCC.

(12) That clinicians encourage an open and transparent dialogue with patients and families upon the option of recording conversations when a diagnosis, course of treatment, or prognosis is being discussed.

(13) That the Trust review its Consent Policy and the training of staff, to ensure that any questions regarding the capacity of parents or carers to give consent to treatment on behalf of their children are identified and appropriate advice sought.

(14) That the Trust reviews its Consent Policy to take account of recent developments in the law in this area, emphasising the rights of patients to be treated as partners by doctors and to be properly informed about material risks.

(15) That a national protocol be agreed explaining the role of individuals and teams in paediatric cardiac surgery and cardiac catheterisations. Such a protocol should be shared at an early stage of the pathway of care, to ensure that all families are clear about how teams work and the involvement, under supervision of junior members of staff.

(16) As an interim measure pending any national guidance, that the paediatric cardiac service in the Trust reviews its practice to ensure that there is consistency of approach in the information provided to parents about the involvement of other operators or team members.

(17) That the Trust carry out a review or audit of (i) its policy concerning obtaining consent to anaesthesia, and its implementation; and (ii) the implementation of the changes to its processes and procedures relating to consent.

CHAPTER SEVEN: SURGERY AND THEATRES

1 Capacity and Waiting Lists

- 1.1 The Review's Terms of Reference require consideration of 'the demands on the service, and the capacity to meet those demands in a manner which was safe and of an appropriate quality.' Surgical capacity was an issue which was prominent in many sources of information, along with pressures on waiting lists and the cancellations of surgery that resulted from such pressure.
- 1.2 The heavy emotional impact of cancelling surgery on children and parents was clearly conveyed in the accounts that the Review received from families. It was also recognised by the clinicians whom we spoke to. Some parents of older children talked about how hard it was to break this news to their child and the evident distress it caused. A few families experienced multiple cancellations which they found hard to bear, even though they understood the need for the surgeons to respond to emergencies. Cancellations took a particularly heavy toll on families who travelled significant distances to get to the Hospital.

'Explaining to a 13 year-old that his surgery has been cancelled is the hardest thing I have ever had to do. It is a heart breaking position for a parent to be put in.'

- 1.3 One family reported that their child's operation was cancelled each day for a week in early January 2013 and on a further two occasions before it took place. They were told that this was due to a lack of beds in PICU and HDU. They described the strain on the family caused as a result.
- 1.4 The Review noted that this experience occurred when the Trust had taken action to reduce the number of beds on Ward 32 following the CQC's inspection in September 2012, thereby affecting the Trust's ability to admit children for surgery.
- 1.5 Clinicians too spoke eloquently of their distress in having to cancel operations. They acknowledged that it damaged the trust between clinicians and parents: *'So I remember cancelling a family coming from far away, I can't recall where exactly but three times. By the time you go to tell them that we cannot do your operation, you can tell immediately that they've lost faith in you because you're seen as the patient's advocate and you have to be that and we all try to do this.'*

2 Managing Demand

- 2.1 The Review asked clinicians about how they managed the demands on the service and ensured that there was sufficient capacity.
- 2.2 Two key factors affected the programme for cardiac surgical operations: emergency cases and the availability of beds on the paediatric intensive care unit (PICU).

- 2.3 We understood that one of the major difficulties for any cardiac surgical centre is balancing emergency and planned surgery. The commonly accepted level of emergency or urgent cases for cardiac surgery is about 40 per cent. Each operation takes on average four or five hours and therefore two cases fill an entire day of operating. If an emergency case arises, the options are to operate into the evening or to cancel a less urgent case.
- 2.4 The surgeons told us that to the extent that any urgent cases were potentially predictable, they would try to build this into the planning for the week. They also described how they tried to plan for reduced capacity for surgery in the winter, when all PICUs tended to have additional demands placed on them because of children with respiratory illnesses.
- 2.5 The Review was provided with information on the number of cancellations that had taken place as a result of the lack of a bed on PICU. The data was as follows:

Paediatric cardiac surgery cases cancelled due to lack of bed on PICU

2010/11	2011/12	2012/13	2013/14	2014/15
1	4	22	24	12

- 2.6 The Review asked about the reasons for the high levels of cancellations in 2012/13 and 2013/14. We were told that they related to the changes made immediately after CQC's inspection of September 2012. For a period, there were fewer beds on Ward 32 and children were staying longer in PICU. The Review was also told that around this time there was an increasing number of children with non-cardiac conditions who required long-term ventilation and who stayed for a long time in PICU. At this point, when the number of available beds was reduced, the whole waiting list was reviewed and re-prioritised based on clinical urgency.

3 Management of waiting lists

- 3.1 The Review heard that the paediatric cardiac service had taken steps to improve management of the surgical waiting list in 2013 with the appointment of the cardiac pathway co-ordinator. Prior to this appointment the waiting list was regularly reviewed, examining each child's underlying condition and the urgency of the treatment. Since 2013 the process of review has been more systematised and also contains information about any cancellations or delays, as well as matters that the family want to be taken into account in terms of timing of surgery, such as examinations or a family event. The data also includes information about any families who are willing for their child to undergo surgery at short notice.

4 Management of Operating Lists

- 4.1 Efficient use of the operating theatre's capacity, availability and resources relies upon effective communication and co-ordination of cases. Theatres need as much notice of forthcoming cases as possible to plan the mix of skills required and to secure required equipment.
- 4.2 The Review received accounts from three families where the surgery or catheter interventions were cancelled or delayed as the necessary equipment was not ready in theatre. One said:

'After the initial date being postponed (which meant going through all the pre-op checks for a second time) we were prepared for the op on the new date and after waiting from 7am until 5.30 pm we were told, as my daughter was in her gown on the operating trolley, about to go under anaesthetic, that they couldn't do the op. We were told that a piece of equipment had not been cleaned properly, and also that there were staff shortages. So we had to head home, quite stunned, my daughter confused and upset, and very hungry!!! She wasn't allowed to eat from 9.30am onwards.'

- 4.3 It was apparent from what we heard and saw from documentation that there were problems with the co-ordination of surgical lists in the early part of the period covered by the Review period: 'there was a perception that the theatre lists were never organised .. people didn't respect the list that had been organised and agreed and locked so to speak.' But the Trust ran a 'transformation project' focused on the surgical pathway in 2014 to address a number of issues, including ensuring effective organisation of theatre lists.

5 Increasing Capacity

- 5.1 Steps were taken to increase the number of surgical operating sessions over the period 2010-15.
- 5.2 In 2010 there were three days of operating, each running two sessions per day: one on the morning and one in the afternoon. These were extended to longer working days of three sessions to reflect the length of operating time needed and to prevent unscheduled over-running. But the service still had to balance the impact of emergency cases which disrupted the planned cases and resulted in cancellations. The surgical operating programme was extended by a further day to four days in 2010.
- 5.3 A Cardiac Development Programme was set up in spring 2014 to seek improvements in quality across the service. As part of the work initiated by it, the surgical service moved to operating on five days a week in May 2015, increasing both capacity and flexibility.
- 5.4 From September 2013 cancellations on the planned day of surgery were monitored through the 'transition dashboard'. This information is provided each month by each

centre to the specialist commissioners as part of the process of monitoring quality. The information showed that despite the improvements in organisation and capacity in 2013 - 2014, cancellations could still not be avoided.

- 5.5 For example, the rise in the waiting list in the winter of 2014/15 had caused concern. This was caused by a surge in the number of children with respiratory illnesses, which in turn reduced the ability to operate due to lack of PICU beds. The surgeons had considered not taking referrals, but that option was not pursued due to similar pressures in other centres. The numbers on the waiting list has subsequently fallen due to the increase in operating sessions to five days, by undertaking some extra time limited operating sessions and by providing an additional bed in PICU.
- 5.6 The Review's Expert Panel's impression was that the pressures on Bristol were matched by, and typical of, those experienced by units across the country. But good comparative data is in short supply. The development of comparative measures through the quality dashboard should, in the future, enable commissioners to make more effective assessment of the pressures and comparisons between units, to assist in assessing whether there are unacceptably high rates of cancellation in any centre.

6 The effect of delays on outcomes

- 6.1 Some families asked whether delays in surgery or catheterisation had had an impact on the outcome for their child. It was plain to the Review that there were examples of great stresses caused by cancellations, sometimes on more than one occasion. But the question was whether cancellations or delays meant that procedures took place at a time when risks to a child's health had increased.
- 6.2 The children who were scheduled for surgery and whose cases we were asked to review were not, in general, ones in which delay caused by cancellations appeared to have such an effect; when procedures were needed urgently, provision was made to fit them in. The extensive documentation that we reviewed showed that clinicians and staff were, as might be expected, highly conscious of the need to ensure that surgery or other interventions took place at the appropriate time. That was the main concern behind the frequent review of the waiting lists managed by the surgeons, as well as decisions to cancel one procedure in favour of another that was more urgent.
- 6.3 That said, there was some evidence that when surgery was extremely urgent - a matter of days only - limits on the availability of surgeons and theatres in the earlier period of the Review were capable of causing difficulties and were not easily managed. The Review is aware of a limited number of situations in which it would not be possible to say with any confidence whether or not children were affected by cancelled surgery. If a 'window' during which surgery is needed is a matter of days only, it will not be difficult or impossible to say whether delaying procedures for 2 - 4 days when beds or operating slots are not available has an adverse impact, or not. The Review also saw evidence of a situation in which surgery was needed urgently by the time delayed follow-up appointments had been scheduled by a district general hospital.

6.4 We have focussed on the surgical waiting list in the discussion above. But as the section on the cardiology service in Chapter Six makes plain, there were also pressures on the resources available to the cardiologists, both in relation to the numbers of cardiologists available to perform interventional catheter, and the laboratory space available for them to do so. One child death reviewed by the Review involved a child whose catheterisation was cancelled; he died outside hospital, before the re-scheduled procedure could take place. Whilst we cannot generalise, from one case, upon the robustness of the process for assessing the risks of any cancellations, we have included this matter in the recommendations below.

7 Waiting for Surgery to be rescheduled

7.1 Some families reported to the Review that during the period when they were waiting to hear if surgery could be rescheduled for later that day or the next day, inadequate consideration was given to food or drink for their child. One family reported that their child had no food or drink for 16 hours pre-operatively.

7.2 A few families told us about the stress and anxiety they experienced if a procedure was taking longer than they had been led to expect, particularly in the absence of any communication about what was happening:

'... we were told the surgery would only take 4-5 hours. After 8 hours of surgery, we had still heard nothing. You can imagine how distressing this was for us. In the end, we returned to the hospital to find out what was going on.'

7.3 We also heard accounts from families who felt they were kept very well informed.

7.4 The Review discussed these matters with clinicians at the Trust. We were told that the 'nil by mouth' guidelines have been reviewed. It was also part of the new pathway co-ordinator's role to ensure that families are kept informed of any delays in theatre or if the operating time has been extended.

8 Surgery and Incidents in Theatre

8.1 The incident reports that were examined by the Review relating to unplanned events in theatres did not reveal systemic weaknesses relating to the capabilities of the consultant unit (that is, the consultant and the team of doctors and other professionals who work under his or her supervision in theatre). The same conclusion was drawn from the Expert Case Reviews, which did not reveal that the management of cases in theatre fell below accepted standards. We have seen also that the CQC's clinical case note review noted, in relation to surgery, that: 'There were many examples in the cases reviewed of excellent surgical care. There were examples of highly complex procedures that were performed well with good outcomes. The case reviewers were not critical of the standard of surgery in any individual case.'

8.2 We were conscious of the serious incident which had occurred in an operating theatre in 2005, when an error in perfusion led to the death of a child. It was apparent that

this had been a deeply traumatic event first and foremost, to the parents and family of the child who died. We also spoke to staff about the event, the investigation which followed and the actions taken to ensure that lessons were learned, in order to understand the impact of these events on the service that we reviewed, from 2010 onwards.

- 8.3 We noted that more than one report was commissioned, to investigate the issues and identify the actions necessary to prevent a recurrence. The most significant of these investigations was conducted by Mr Gritten, in 2008. The Review saw evidence that the Trust had taken steps to implement the recommended action plan and to monitor progress, over a number of years. In April 2013, the Trust Patient Safety Group received a further review of implementation of the recommendations from the Gritten Report and accepted that the action plan could be closed. Whilst this was some considerable period of time after it had been completed, the report had included wide-ranging recommendations and the regular monitoring represented good practice.
- 8.4 A significant issue in what had happened in 2005 related to the availability of perfusionists. The Review sought assurance on the numbers and expertise of perfusionists now available. We learned that the Trust encountered difficulties recruiting perfusionists and felt that it was much easier to recruit trainees and take them through a training programme; it felt confident that they had sufficient resources locally to make the training possible and appropriate. The availability of perfusionists remains a matter of national concern, particularly in stand-alone children's trusts, where the option of drawing on perfusionists practising in adult services to be does not exist.
- 8.5 Perfusionists remain regulated by voluntary, professional societies rather than by statute. The Society of Clinical Perfusion Scientists maintains a voluntary register. An application for statutory regulation was made in the past. But the Government will only consider extending statutory regulation, including to groups in healthcare, where there is 'a compelling case' on the basis of a risk to public safety and where voluntary registers are not considered sufficient to manage this risk. In 2007, the Government published a White Paper 'Trust, Assurance and Safety – the Regulation of Health Professionals in the 21st Century' which identified healthcare scientists (which includes clinical perfusionists) as a priority group for future regulation. So far no action has been taken.
- 8.6 The Review did not see evidence of incidents in which the availability of perfusionists, or their skills, was at issue, during the period of its terms of reference. As things stand, the professional skills and competence of perfusionists are a matter for their employers: they are able to draw upon the work of the professional associations in setting appropriate standards.
- 8.7 More generally, it was apparent that the death in 2005, coupled with the inquest that followed and the retirement of Mr Ash Pawade, the paediatric cardiac surgeon who

come to the Children's Hospital in 1995, had a serious effect on the morale of staff in the years immediately prior to the start of the Review.

- 8.8 In early 2011, there was a further serious incident in the operating theatre. A child died two days later. The incident was reported to commissioners and the SHA in line with the Trust's Serious Incident Policy. An inquest was held and a narrative verdict was recorded.
- 8.9 The Review examined the RCA and the subsequent Serious Incident Review Panel Report. We felt that the Trust's RCA was a thorough investigation. It proposed a wide range of actions. These included a review of the induction and mentorship programmes for new consultants, as well as measures to enhance team-working, improve the use of a surgical checklist, improvements to scheduling surgery and a review of the capacity of operating theatres to deal with the volume of cases.
- 8.10 A Serious Incident Review Panel was also convened in relation to this incident at the request of the Medical Director. Its report was presented to the Chief Executive and the Trust's Board. It concurred with the findings of the RCA. It noted, consistently with the RCA, that the limitations on the allocated time for the use of theatres for paediatric cardiac surgery was a source of considerable pressure on the surgical and anaesthetic team, who were required to prioritise patients.
- 8.11 As is not uncommon in such circumstances, a programme was developed to provide additional support for the surgeon concerned, to improve the team's dynamics and to provide assurance that there were no concerns over surgical practice. The surgeon retained the confidence of the senior surgeons, and support was delivered by the other surgeons working alongside him. The Review was told that, throughout the period of additional support, the surgeon continued to lead discussion about operations with the families concerned and to obtain their consent, as the surgeon responsible for the procedure. The Review felt that this was good practice.
- 8.12 The Review saw evidence that the actions following from this incident were carefully followed up within the Cardiac Governance Group and Women's and Children's Division Quality Assurance Committee, as well as being reported to the Trust Patient Safety Committee.

9 Governance and Power Supplies

- 9.1 Concerns were raised with the Review about the power supply to BRHC and whether the Trust had failed to secure it properly. Following interruptions in power in November 2010, which had affected the BRHC (amongst other areas), the Trust had installed new generators which, it was said, would ensure that the Trust did not suffer power failures in the future. Yet the BRHC subsequently experienced two interruptions to its power supply in November and December 2013. It was suggested that this showed that there were underlying weaknesses in the Trust's system of risk

assessments and safety or in the process of learning from and taking action in response to such events.

- 9.2 The matter was discussed with staff from the Trust. The interruptions in November and December 2013 had separate, unrelated causes. The Review saw documentary evidence regarding the serious incident and root cause analysis reports that were prepared. There was further investigation of the risk analyses that had been carried out for these systems in the external report on Risk Management from Ms Utley in 2014. Opportunities to improve procedures were identified from these investigations. We also saw evidence of implementation of the action plan developed in response. We were not persuaded that there were systemic issues linked to the events in 2010 which the Trust had failed to address.
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10 Conclusions

- 10.1 A number of parents were concerned that their children had not received proper care; at times this included concerns or questions about the management of operations or procedures in the operating theatre or catheter laboratory.
- 10.2 Reviews of individual cases which were carried out by this Review did not point to flaws in the management of cases or failures in the technical ability of the teams involved.
- 10.3 We have always borne in mind the cases before us in which children, tragically, died. They include children who did not recover after surgery or other interventions, or whose operations were unsuccessful. In other parts of this report, we have set out occasions when aspects of their care either fell short or could have been improved. But we have concluded that there is no evidence to link these cases to specific or systemic failures in the conduct of individuals carrying out procedures, whether in the operating theatre or the catheter laboratory.
- 10.4 The CQC's clinical case note review noted that: 'The case reviewers were not critical of the standard of surgery in any individual case.'
- 10.5 During the period of this Review, there were serious pressures on the capacity of the cardiac surgical service, caused both by the limited operating slots available and the finite number of beds available in PICU. As a consequence, heavy strains were placed upon parents and children by the resulting cancellations of operations. There were times of particular pressure, e.g. in late September 2013 or during the winter of 2014/15. At times, surgeons considered not taking referrals but did not do so because of similar pressures in other centres.

- 10.6 There is very limited evidence that cancellations affected outcomes, as opposed to causing serious stresses on the parents and children affected. The review or ‘juggling’ of surgical waiting lists that took place was aimed at ensuring that children were operated upon at an appropriate time, and clinicians were plainly highly aware of seeking to achieve this.
- 10.7 Steps were taken both to increase the number of operating sessions over time and to improve the management of the surgical list in 2013. The recent appointment of the cardiac pathway co-ordinator should also assist.
- 10.8 Cancellations cannot be avoided, despite these increases in capacity. Rates of cancellation are now monitored through the transition dashboard. Data which would allow comparison with other sites are not yet publicly available.

11 Recommendations

(18) We recommend that steps be taken by the Trust to review the adequacy of the procedures for assessing risk in relation to reviewing cancellations and the timing of re-scheduled procedures within paediatric cardiac services.

CHAPTER EIGHT: THE PAEDIATRIC INTENSIVE CARE UNIT

1 The Paediatric Intensive Care Unit

- 1.1 The Paediatric Intensive Care Unit (PICU) in the Children's Hospital serves the whole of the South-West Region. It is responsible for the care of all children who need critical care services within this area. During the period 2010 to 2014 there were 15 funded beds on the PICU at the Children's Hospital. This increased to 17 beds in 2014-15 when services for burns, neurosurgery and plastic surgery were transferred to the Children's Hospital from Frenchay Hospital in May 2014. The unit had physical space for 18 beds and would on occasions operate above or below the funded number of beds.
- 1.2 Experience of the Paediatric Intensive Care Unit figured in a significant number of the accounts that the Review received from parents.
- 1.3 A number of families expressed high levels of appreciation for the care they received on PICU. Accounts spanned the years covered by the Review.

'The nurses in ICU were amazing and really made me feel that [my child] was in safe hands. I would say that the time spent both in ICU and on Ward 32 was an emotional rollercoaster and I can only offer my utmost praise for the staff.'

'[Our child] received exceptional care whilst in PICU and the nurses and Drs there are truly outstanding. We were kept constantly updated, our expectations were always well managed and I wouldn't hesitate to highly praise the staff at Bristol Children's Hospital.'

- 1.4 A number of families did however have concerns that their child had been prematurely discharged from PICU. Again these accounts spanned the time period covered by the Review:

'.....We were uncomfortable with the speed of transfer to Ward 32, particularly given the staffing issues that then seemed evident on Ward 32 – [this] can be anxiety provoking for parents, particularly when your child is so soon post surgery and doesn't seem well to you.' (this from a family receiving care in 2010).

'After the operation [our daughter] was moved to PICU but she was only there for less than 24 hours before she was moved to Ward 32. I felt that she wasn't in PICU for long enough at this time and that she was moved too quickly because there was a pressure for beds in PICU. There was no HDU at this time.' (2011).

'Intensive care beds appeared highly pressurised and we felt that our daughter was moved out of this unit too soon in order to make way for another patient. In fact we were left in limbo on the edge of a care space, in ITU, whilst staff cleaned around us to prepare it for the next patient, for 2 or more hours, which was an uncomfortable (awkward) experience and a cause for concern actually. It felt like [we] were in the

way and that [our daughter] was no longer a priority despite her still being, in our view, very unwell. It felt as if the staff were distracted away from her and that there was potential for missed interventions, e.g, medications including pain relief, if we weren't advocating for her.' (2014).

- 1.5 Others outlined the anxiety they felt at the transition from PICU with 1:1 nursing care to the environment of a busy ward.

'I was relieved when [our child] was moving from ICU to the ward as this meant that he was getting better but it was hard and stressful on the ward as it was completely different to ICU.' (2010).

- 1.6 The most common concern that we heard from parents was a concern about capacity. This was linked to concerns about access to PICU and the timing of discharge from it. It was widely appreciated by parents that a bed in PICU was a 'scarce resource'. We heard both about difficulties in accessing beds, which influenced the ability to schedule operations and, at times, led to their being cancelled and the concerns that pressures on beds might influence decisions to discharge children from PICU.

2 Quality of Care in PICU

- 2.1 The most common tone of the comments from families who contacted the Review and who had experienced care on the PICU was positive. As set out above, appreciation of the 1:1 care offered in PICU did, however, translate into a concern about the timing of discharge from that environment.
- 2.2 We acknowledge that there were families who were more critical of the management of their child's care in PICU, or who were worried that care and communication with them about their child had fallen short of what they expected.
- 2.3 For this reason, complex cases were reviewed by the Expert Panel. The Panel did not detect systemic flaws in the management of the PICU or the delivery of care in those cases reviewed. By contrast, it saw evidence of complex cases being well managed. This included evidence of appropriate liaison and transfer of children to other centres, e.g. for ECMO.
- 2.4 This overall assessment of the delivery of care on PICU was supported by other material. The Review noted that the Safe and Sustainable's Independent Expert Panel had noted that the PICU was 'already compliant' with standards. The CQC's inspection of cardiac services in September 2012 included an inspection of PICU. No adverse comments were made. In the CQC report of December 2014, no specific issues about the PICU were noted. We also had regard to the information published annually by the Paediatric Intensive Care Audit Network (PICANet). Since 2013, this has presented data about standardised mortality rates in PICUs. Whilst this related to the

outcomes for all children admitted to the PICU, and not just those with cardiac conditions alone, we noted that the Children's Hospital was not an outlier.⁴⁴

- 2.5 This positive assessment of the delivery of care on PICU does not imply that, at times, errors were not made, in a complex environment involving multiple caregivers and clinicians. We looked at the record of serious incidents for cardiac services; at times they involved incidents in PICU. We noted, first, that incidents which had occurred appeared to be recognised and logged as such by PICU staff. Serious incidents were also investigated conscientiously. For example, a serious incident in August 2011, involving error in the use of an infusion pump, had led to both a detailed root cause analysis and a report by the Serious Incident Review Panel at the request of the Medical Director. The Expert Panel did not consider that the records of incidents and child death reviews it examined suggested that there were systemic flaws in the management of PICU.

3 Pressures on PICU

- 3.1 Paediatric intensive care services in England were, and remain, under significant pressure, and this intensifies during the winter months or if there is an outbreak of an infectious illness. All PICUs have a very high level of emergency demand, with around 50 per cent of admissions being emergency driven. On occasions, units will be asked to accommodate patients from outside their region and transfers between units also take place.
- 3.2 Long-term trends have increased the demand for beds.⁴⁵ Intensive care clinicians described how the case mix of children cared for in PICU has changed over the past 15 years. At the start of that period, they told us that many children coming into intensive care had a serious illness but were otherwise well before the infection; they would stay for a relatively short time. But now, around 50 per cent of beds are occupied by children with complex needs, with very prolonged lengths of stay. This period had also seen significant technological advancements which not only increased the need for care in PICU but its complexity.
- 3.3 One example of these changes was the increased use of long-term ventilation. Prior to the development of a medical HDU in the Children's Hospital and of a programme to support care at home, these children might have stayed in PICU for periods running into months. Quite apart from the impact on the PICU's capacity, clinicians noted that PICU was not an appropriate environment in which to care for them.
- 3.4 Until designated high dependency beds were commissioned in the Children's Hospital outside the PICU, it also had to care for children from the local Bristol area who needed high dependency care. By contrast, children from other areas in the South-

⁴⁴ See the PICANet Annual Report 2013 (analysing information from January 2010 – December 2012), Figures 47 – 49 (information about 2010, 2011 and 2012), and the PICANet Annual Report for 2014 (pp67 – 71).

⁴⁵ The PICANet Annual Report 2013 'Bed Census' (noting the number of children present in a bed at 10 minutes past midnight on a given date) noted an increase from 10 children in 2010 to 13 in 2011 and 2012. See Table 35.

West who did not need the specialist care provided at the Children’s Hospital could be transferred to their local District General Hospital, if they were able to provide high dependency care.

- 3.5 The Review looked at the data on the levels of occupancy on PICU. The accepted maximum recommended level of occupancy for PICU units across the country is regarded as 85 per cent.⁴⁶ It was apparent that, in the BRHC, there were periods of very high demand for beds in PICU. For example, a paper submitted to the Divisional Quarterly Review’s meeting in August 2012 showed the proportion of days when the PICU had maximum occupancy of 100% or more at some time during the day.⁴⁷ This latter occurs when one bed is used twice, i.e. someone leaves and it is reoccupied, or when more beds are occupied than are ‘funded’.

Jun 11	July 11	Aug 11	Sept 11	Oct 11	Nov 11	Dec 11	Jan 12	Feb 12	Mar 12	April 12	May 12
37%	0%	19%	53%	23%	37%	61%	42%	83%	58%	87%	35%

- 3.6 We received data from the Trust regarding the number of discharges from PICU to Ward 32, readmissions to PICU within 48 hours from Ward 32 and all discharges from PICU to all destinations after 6pm.

Year	Discharges to Ward 32 from PICU	Re-admissions from Ward 32 to PICU within 48 hours	Number of children discharged from PICU after 6pm [all destinations]
2010	326	1	78
2011	317	2	102
2012	335	1	90
2013	328	2	79
2014	328	5	56

- 3.7 Re-admission can be an indicator that children were discharged too soon. The data shows very few readmissions. This information, assessed together with the comparative information collected nationally by PICANet on rates of emergency readmissions within 48 hours, did not identify cause for concern.

⁴⁶ This is the level set out in the Service Specification for the NHS Standard Contract for Paediatric Intensive Care, 2013-14.

⁴⁷As a result of these pressures, the PICU bed occupancy levels frequently triggered ‘red ratings’ on the ‘Health of the Children’s Hospital’ performance indicators dashboards which were presented at the Divisional Quarterly Review meetings from October 2012.

- 3.8 Discharging a patient from PICU after 6pm is considered not to be ideal due to the reduced level of nursing and medical staffing elsewhere in the hospital overnight. But the number of discharges after 6pm (shown above) were considered by the Expert Panel to be within a normal and acceptable range.
- 3.9 We asked why the rate of readmissions had increased in 2014 after the opening of the cardiac HDU. The clinicians told us that they felt the explanation was that prior to the opening of the HDU children would move from PICU care to HDU care within PICU if they deteriorated. Once the HDU was in place they would leave PICU for HD care and require readmission to PICU if they deteriorated.

4 **Nursing Staff on PICU**

- 4.1 PICU's services have the benefit of well-established standards for levels of nursing staff levels, set out by the Paediatric Intensive Care Society (PICS), with detailed calculations for the staff required. These were the standards referred to by the Safe and Sustainable Review in its requirements for paediatric intensive care.⁴⁸ We were told that the PICU Matron, Mr Booth, was a member of the national group that developed these standards. The standard in the PICS' guidance in 2001 was that there should be 6.4 whole time equivalents (WTE) per bed. In 2010, this guidance was revised to 7.01 WTE per bed, taking account of the uplift needed to cover factors such as annual leave, study leave and sick leave. The Review was told that, by contrast, there are no standards stipulating the mix of skills and that there is substantial variation in this mix across the country.
- 4.2 The Safe and Sustainable Review's standards were based on compliance with the PICS standards.
- 4.3 We heard that nationally it is difficult to recruit sufficient nurses with the necessary skills to work in PICU. The Children's Hospital had focused on offering very comprehensive educational programmes as a way of attracting and retaining staff. The Unit aims to develop staff so that they progress through the grades.
- 4.4 The difficulty in recruiting nurses was identified in the Bristol Public Inquiry's Report, which noted⁴⁹ 'there was a national shortage of paediatric intensive care nurses which affected Bristol such that while the bedside establishment was recommended by the Paediatric Intensive Care Society at 6.4 whole-time equivalents (WTE), the staffing level at the BRI was 5.4 WTE'.
- 4.5 The 'Report of the Workforce Benchmarking Project of Tertiary Children's Services' ('the Williams Report') was commissioned by the Trust in spring 2012 and undertaken

⁴⁸ See, in particular, Standard C15 which referred to the need to have a Paediatric Intensive Care Unit: Level 3 / Level 4 paediatric critical care services, capable of multiorgan failure support (delivered in accordance with Paediatric Intensive Care Society Standards). The Standard also referred back to other applicable guidance such as the RCN (2003)'s 'Defining Staffing Levels for Children's and Young People's Services'.

⁴⁹ Page 60 paragraph 45.

between October and December 2012. It reported that the level of staffing in place was then 5.7 WTE nurses per bed.⁵⁰ The report set out how a reduction in the allowance for paid time lost, introduced in April 2012, had resulted in a loss of flexibility and an inability to have available 15 beds in ICU consistently. ‘Paid time lost’ relates to changes that the Trust made in April 2012 to reduce the allowance in nursing budgets from 23 per cent to 21 per cent. The Williams Report described the ‘annualised hours’ contracts which had been in place for PICU’s staff; these had met their objective of deploying staff flexibly throughout the year and enabled the unit to function largely without Bank or agency staff, until this change came into place. PICU was using Bank and agency staff at the time of Ms Williams’ review. She stated that numbers of Bank and agency staff required had been difficult to meet due to ‘recent changes to Bank pay rates and timings’ and the lack of suitably qualified nurses available by this route.

- 4.6 The Williams Report noted that compared to other large units, the PICU at BRHC had the lowest ratio of nurses per bed and also a flatter structure, with fewer Band 6 and 7 nurses (the more senior nurses). This was thought to present potential difficulties to career progression for, and hence the retention, of Band 5 nurses who might wish to advance their career.
- 4.7 The Review looked at the staffing figures for the Children’s Hospital held on PICANet; it conducts a survey in November of each year. The surveys showed that the number of clinically qualified staff in post (WTE) per bed fell consistently below the lower recommended level of 6.4 WTEs in every year from 2010 – 2014. Numbers were just a little below 6.4 in November 2010 and 2011 but fell sharply in 2012. The figure was substantially the same in November 2013, before recovering somewhat in 2014, but still to a level below 6.0 WTEs.
- 4.8 Whilst there was some suggestion that a survey based on one week’s data might not be representative (and a survey in November may reflect a time when units may face winter pressures), the information provided to the Review by the Trust on the PICU’s establishment confirmed a reduction in the funded establishment during 2012/13, before it climbed back in 2013/2014.⁵¹
- 4.9 The Review was told that during 2011 the Women’s and Children’s Division was under significant financial pressure and controls were in place in relation to recruiting to vacancies and the use of Bank and agency staff. The limitations on Bank and agency staff had a lesser effect on PICU than on the wards, as PICU tended not to use these

⁵⁰ Page 25.
⁵¹

PICU	2010 – 2011	2011 – 2012	2012 - 2013	2013 - 2014
	Funded Establishment (wte)	Funded Establishment (wte)	Funded Establishment (wte)	Funded Establishment (wte)
Total Registered (excluding Matron)	93.46	91.99	86.14	93.06
Total unregistered	4.47	4.46	4.7	4.74
Total	97.93	96.45	90.84	97.8

mechanisms. However, the Review was told by PICU staff that the controls on vacancies resulted in the fall in the staffing numbers reflected in the PICANet data. Posts could not be recruited until staff had given notice which was a problem for PICU as it took around 6 months to get a new member of staff in post. Previously the PICU would recruit on a pro-active basis to maintain the staffing numbers.

- 4.10 PICANet's Annual Reports are also a source of comparative information. The inability of PICUs to meet the recommended staffing levels was widespread and common in other Trusts. The 2015 Annual Report summarised the position, in the Executive Summary: 'In 2014 only 5 (15%) PICUs met the nursing establishment levels currently recommended by the Paediatric Intensive Care Society', which was that of at least 7.01 Whole Time Equivalent (WTE) nurses per critical care bed.⁵²

5 Children with CHD in the PICU

- 5.1 The Paediatric Intensive Care Unit is central to the provision of children's cardiac services. The availability of a bed in the PICU is crucial to whether surgery, or some forms of catheterisation, can take place. Around 50% of the admissions to PICU were cardiac cases. Ward 32 in turn received about 330 discharges from PICU each year between 2010 and 2014.

- 5.2 The length of stay in PICU was affected by where high dependency care was to be provided; within PICU or on Ward 32. It was not until April 2013 that the first dedicated high dependency beds opened on Ward 32. When we spoke to a number of members of the nursing staff working on PICU over the period 2010 to 2014, they told the Review that children requiring high dependency care were cared for in PICU until such high dependency beds opened. Returns to PICANet from the PICU confirmed that a reasonable percentage of the care delivered on PICU from 2010 – 2012 was high dependency care.⁵³ The question of whether a number of the children requiring high dependency cardiac care were also, at times managed on Ward 32 before the opening of dedicated HD beds on the ward is discussed in Chapter Ten.

- 5.3 The complex interrelationship between beds on Ward 32 and in PICU was apparent from the effect of the changes made immediately after the CQC's inspection, when all high dependency care on Ward 32 ceased and the numbers of beds in the ward was reduced. The Trust opened two high dependency beds in PICU instead, but closed one bed in PICU to secure the numbers of nurses to achieve this. We heard that the effect was to increase the pressure on beds in PICU.

⁵² 'PICS standard 164 details the qualified nursing establishment levels required. In November 2014 Figure 4 showed that 14.3% (n=5) of the UK PICUs met the standard of at least 7.01 Whole Time Equivalent (WTE) qualified nurses required to staff one critical care bed. A total of 28.6 % (n=10) units met the previously defined PICS standard (2001) of 6.4 WTE per bed. This compares to November 2013 when 5 units reached the target of 7.01 WTE per bed and 13 were equal to or above 6.4 WTE per bed'. See pages 7 and 24.

⁵³ The Annual Report for 2013 shows that a little under 30% of the care delivered on PICU represented 'high dependency' or 'advanced' high dependency care: Figure 1 page 102.

6 Discharge from PICU to Ward 32

- 6.1 The Review spoke to a number of staff about the process for deciding whether a child was ready to be discharged from PICU to Ward 32.
- 6.2 We were told that the nature of PICU services is such that difficult decisions have to be taken by the medical staff as to whether to admit or refuse critically ill children from across the region. In so doing, the clinicians were constantly assessing children currently in PICU to see who could be discharged safely to the wards or back to their referring hospital to ensure that space for new admissions was available.
- 6.3 We heard consistently from clinicians that the decision to discharge a patient from PICU rested with the consultants and was always a clinical decision. For example, the Matron for PICU and Cardiac Services told the Review that the decision to discharge a child from PICU would be taken following a multidisciplinary ward round on PICU which would include a PICU nurse, a PICU consultant and a cardiologist or a surgeon who would all have to agree that the child was ready for discharge. This process was confirmed by a number of the medical staff whom the Review spoke to.
- 6.4 We were told that after the decision that the child was ready for discharge, the Clinical Site Manager worked to ensure that the receiving ward was appropriately staffed. If they had concerns, they would refer this to the Duty Matron or Manager during the workday or the Trust's on-call manager out of hours. In addition, the nurse in charge of the receiving ward would review any children who are ready for discharge and would refuse the admission if they judge staffing levels are not adequate.
- 6.5 We heard about the day-to day realities of arranging discharges and managing beds, from both nursing and medical staff. One cardiologist told us:

'I must admit, there were some days when you felt like a bed manager yourself and you'd go up and say, well hang on a second, I'm being told that we can't go to surgery because we don't have a bed and the reason we can't have a bed, because this patient who's ready to go to the ward, can't go to the ward. I said, well hang on a second, I'll go up and do a ward round.being the consultant on call, I know the flow of traffic, I know the expectation. ... So I think that the cardiologist going on the rounds and creating the capacity was a not uncommon theme.'

- 6.6 It was apparent that, although some parents worried that their children might have been discharged too early, from the point of view of PICU the difficulties could relate to the availability of beds on the wards. If no bed was available, that could delay a discharge from PICU.
- 6.7 Audits of 'delayed discharges' were undertaken in 2010 and 2014. The audit in 2010 covered the period February to July 2010. During this period there were 164 discharges from PICU to Ward 32 of which 106 were delayed, 49 by more than four hours. 27 children stayed in PICU for extra nights as a consequence (16 because there were no

- beds and 7 because the ward was short staffed). Of other delayed discharges, 12 per cent were due to shortages of staff and 12 per cent because staff were too busy.
- 6.8 The audit of delayed discharges from PICU from November 2013 to December 2014 showed that delays in discharging patients from PICU resulted in a loss of capacity in PICU of just over one bed per day. This meant that other patients could not be taken into PICU. The audit stated that ‘the number of refused admissions to PICU and cancelled surgery remains unacceptably high’. It reported that 91 patients had their surgery cancelled or were refused admissions to PICU in 2014 due to the lack of a bed on PICU. The solution proposed was to: ‘increase capacity in general but in particular on Ward 30 and Ward 32 HDU. Ward 32 HDU requires the ability to flex to 6 beds when there are longer stay patients in HD.’ (Chapter Fourteen covers the changes made to the HDU provision on Ward 32 in 2013).
- 6.9 The Review was concerned that the process of movement from PICU to Ward 32 lacked sufficient safeguards for children.
- 6.10 We accept that the decision to discharge was a clinical one, taken by a multidisciplinary team which included cardiologists familiar with the environment on Ward 32, and staff on Ward 32 were able to refuse to take a patient if they felt that they would be unable to deliver proper care. But still, decisions about discharge were taken against the background of pressures on PICU or the known fact that a bed in PICU was a ‘precious resource’.
- 6.11 For example, the Minutes of the Children’s Governance Committee on the 5th April 2012 record: ‘Cardiac and PICU – There has been a high amount of both pressure and dependency over the last month. There have been sick children being moved back to the wards from PICU which has led to a higher number of incidents being reported. This has been due to a high demand on PICU beds’.
- 6.12 The Review noted that the information submitted by the Trust to the CQC in August 2012 stated:
- ‘As a result of the continued pressure on beds, and with patient safety as a priority, Mr Booth, in his role as Matron/Lead nurse communicated to the PICU and Cardiac team in April 2012 that *patients would not be discharged from PICU to Ward 32 without collaborative working between PICU and Ward 32 to clearly identify the nursing needs of infants and children on discharge from PICU.* The impact of moving the more highly dependent child from PICU to Ward 32 must be viewed in light of the impact of both areas and this may result in delayed transfers and impact on the elective cardiac surgical programme.’ (*italics added*).
- 6.13 The Review takes the view that such ‘collaborative working’ and, in particular, the aim to ‘clearly identify’ the nursing needs of infants and children on discharge from PICU should have been in place prior to April 2012. Indeed, it was stated in the April 2011

Inotrope Guideline a year earlier, in April 2011, that ‘For a patient to be transferred to the paediatric cardiac ward on inotropes, they must: ... have nursing staffing levels sufficient to support 1-to-3 patient care ratio’. This implied express consideration of the nursing support available in Ward 32, prior to discharge. But this did not appear to be a formal or documented part of the clinical decision-making process.

- 6.14 The Review considered that its assessment, that in practice arrangements for transfer had been more ad-hoc and informal, was consistent with the fact that the needs of children for more complex care were increasing over the period of the terms of reference, and that there was scope for confusion about what level of care was available on Ward 32. We were concerned that the practical effect of these developments had received insufficient attention, until spring 2012 at least.
- 6.15 The onus appeared to be on Ward 32’s leadership to refuse a patient who had been declared to be fit for discharge. The Review acknowledged that nursing staff told them that they felt able to do so, and that cardiologists also told the Review that they would back the judgment of nursing staff if this happened. But a more formal process, involving the ‘clear identification’ and documentation of nursing needs would, in the Review’s opinion, have supported this.
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7 Conclusions

- 7.1 Viewed overall, there was a good standard of care provided in PICU throughout the period of our Terms of Reference. This was achieved despite significant pressure on beds. High rates of occupancy were, in turn, a reason why planned operations could not always proceed.
- 7.2 The PICU has effectively managed staffing constraints, which in common with many other PICUs across the country, have been consistently below recommended levels.
- 7.3 PICU staff were active leaders in the reporting and investigation of clinical incidents.
- 7.4 During the period prior to the creation of dedicated High Dependency facilities, the multi-disciplinary procedure for agreeing discharges from PICU to Ward 32 would have benefitted from the explicit identification and documentation of the nursing needs of infants and children, when transferred to the ward.
- 7.5 Clinicians were frustrated at the absence of dedicated beds for their patients in PICU. They felt that they would be able to provide a higher quality service, with fewer cancellations, if such beds were available, and also that PICU’s staff could further specialise in the needs of children with CHD. On the other hand, it was apparent that the current arrangements provided greater flexibility.

7.6 Changing practice against this background is a complex challenge, with changes to one part of a system (e.g. by the creation of a HDU) affecting others, both inside and outside a hospital serving a wide area.

8 **Recommendation**

8.1 We were conscious of the heavy strains placed on families by the limitations on the capacity of the Bristol PICU, during the period of this Review, and consider that this is likely to be a national issue that requires proper attention.

8.2 In light of the above, we **recommend:**

(19) That NHS England should commission a review of Paediatric Intensive Care Services across England. We were conscious of the heavy strains placed on families by the limitations on the capacity of the Bristol PICU, during the period of this Review, and consider that this is likely to be a national issue that requires proper attention.

CHAPTER NINE: END-OF-LIFE CARE, BEREAVEMENT AND PSYCHOLOGICAL SUPPORT

1 Background

- 1.1 We have discussed the transition from PICU to Ward 32 in the previous chapter. Tragically, for a number of families, their child did not recover and leave hospital, but died in hospital. All of the children whose deaths were examined by us and who died in hospital had been in the PICU immediately prior to death (sometimes having been transferred back there from Ward 32). Consistently with this, it was the staff based on PICU who most often needed to help and support families either when their child was unlikely to recover, or immediately after death. We looked to see what services were available to support families in these situations.
- 1.2 A small number of families who contacted the Review and whose child had died commented on the end-of-life care offered leading up to or immediately prior to the death of their child. Specifically, some families reported that in their experience end-of-life plans were either non-existent or were not communicated adequately to them. Some families told us that they were not warned about the seriousness of the deterioration of their child, so that in some cases a death was unexpected.
- 1.3 We heard a number of complaints that staff had lacked sensitivity when speaking to parents immediately after the death of their child. But equally, we also heard the opposite, with one account, for example, of sensitive and caring support from staff in 'saying good-bye'.
- 1.4 We noted that in its clinical case note review, the CQC examined six cases in which a child died:

'It was not clear from the records what information the families received after a child's death in all of these cases. However, there was evidence of an increasing focus on effective bereavement support of families in the latter part of the period of the review, with excellent practice observed in these later cases.'

2 End-of-life Care and Bereavement Services

- 2.1 The recommendations of the Bristol Public Inquiry had included the following:

'20. The provision of counselling and support should be regarded as an integral part of a patient's care. All hospital trusts should have a well-developed system and a well-trained group of professionals whose task it is to provide this type of support and to make links to the various other forms of support (such as that provided by voluntary or social services) which patients may need.

21. Every trust should have a professional bereavement service. (We also reiterate what was recommended in the Inquiry's Interim Report: 'Recommendation 13: As hospitals

- develop websites, a domain should be created concerned with bereavement in which all the relevant information concerning post-mortems can be set out in an appropriate manner.)’
- 2.2 In the years since that recommendation appeared, further attention has been given to the issue of end-of-life care and palliative care. Thus, the Safe and Sustainable standards required that ‘The Tertiary Centre should have a paediatric palliative care service able to provide good quality end-of-life care in hospital and with well-developed shared-care palliative services with the community’ (A14).
- 2.3 We noted that there was overlap between end-of-life care and bereavement support and counselling, and have discussed them together, below.
- 2.4 The Trust’s submission to the Safe and Sustainable Review regarding palliative care described a range of services provided in the community in the West of England, such as the Lifetime Service (which provided nursing and psychological support to children, including palliative care), as well as local hospices. It was apparent that there was an absence of in-hospital provision.
- 2.5 Dr Fraser, Consultant in Paediatric Intensive Care, was involved in developing a case for the funding of a specialist palliative care team from 2009 onwards. The need for such a team in the Women’s and Children’s Division was mentioned in the Child Death Review Action Log of May 2010. It was classified as an ‘ongoing’ action, with mention of a proposal submitted to specialised commissioners. However, the funding bid was not successful.
- 2.6 The process of child death reviews did not include responsibility for bereavement counselling, but a bereavement nurse specialist was appointed by the West of England Child Death Overview Panel (CDOP) and was based in the Children’s Hospital to work with families in PICU in 2011, on the basis of a two day week. In 2014, the West of England CDOP report also noted that the Child Death Enquiries Office had arranged two well-received training sessions on communicating with bereaved parents for a wide range of professionals and office staff who may have contact with families.
- 2.7 The Trust turned from its attempt to get funding from commissioners to seek support from its hospice partners. When this too was unsuccessful, it renewed its proposals to commissioners, and was successful in 2014 – 2015. In January 2015, the part-time palliative nurse specialist was able to begin full-time work. In addition, by June 2014 a palliative care consultant had been appointed by Children’s Hospice South West to work 2 days per week, with a ward round at BRHC on 1 day a week.
- 2.8 We saw evidence of valued long-term support given by the palliative nurse to at least one family involved in the Review, and we were impressed by the quality of the care, compassion and expertise now available within that team. We also saw guidance developed to support professionals in using the ‘Child and Family Wishes: Discussion

Record' (containing agreed plans to be followed when a child's condition's deteriorates), as well as leaflets and information designed to assist parents after a death. We felt that the findings of the CQC's clinical case note review supported our impression of the recent developments to the service, which were of a high quality.

- 2.9 The Review heard from staff that further development of the service was planned. Increasing the team from three to a team of six⁵⁴ will enable patients and their families to receive more consistent contact and support throughout their care.
- 2.10 The Trust acknowledged that an improved website for bereaved families could still usefully be developed.
- 2.11 Whilst recognising that the provision of this area of care was challenging nationally, the Review noted that there were weaknesses in the scale and scope of provision for bereavement and palliative care services until their expansion in 2014. The Trust acknowledged that it was unusual amongst children's hospitals, in not having a dedicated palliative care service until 2014. The Review felt that this recognition helped to provide a context for some of the parental comments summarised above.
- 2.12 The ability of the hospital team to provide end-of-life care which respected the wishes of families could depend on the availability of services in the community as well as in hospital services. We noted how in one situation in 2011 there were delays in discharging a child because no palliative care teams in the community were available on weekends to provide community-based palliative care, and there was no regional co-ordinator for community-based palliative care.

3 Psychology Support and Services

- 3.1 For ease of reference we have addressed the topic of support from psychology services here, although the input of psychologists is relevant at every point along the pathway of care and we have already noted in Chapter Six, the involvement of the team in supporting the process of obtaining consent.
- 3.2 We noted that this was an area of weakness, with regards to the implementation and reinforcement of the recommendations from the Public Inquiry.⁵⁵ The Report of the Work of the UBHT Paediatric Cardiac Surgery Inquiry Stakeholder Group (January 2003) commented:

'Clinical Psychology Services in the Trust are under resourced and their development through additional investment would underpin many of the recommendations of Kennedy as well as improving the overall quality of care provided.'

⁵⁴ The Trust told us that developments in early 2016 include additional palliative care nursing resources, a new palliative care consultant role, a new palliative care psychologist role and a family support worker.

⁵⁵ For example, the Public Inquiry noted that 'Patients should be supported in dealing with the additional anxiety sometimes created by greater knowledge.'

3.3 Without purporting to assess any changes from 2003 – 2010, it was apparent to the Review that in 2010, weaknesses were again evident.

3.4 The Safe and Sustainable standards required psychology support to be available to families, but did not define minimum staffing levels for its provision. The British Psychological Society (BPS) produced its own recommendations for standards in 2013.⁵⁶ The BSS commented that:

‘Historically, the psychological issues affecting children with CHD and their families have been less well researched than other paediatric specialties. This dearth of information may have contributed to the limited development of psychological services within Paediatric Cardiology.

The focus within Paediatric Cardiology has been on improving mortality and morbidity rates, and thus on medical and surgical improvement. As mortality and morbidity rates have improved there is a growing interest in, and need to, develop appropriate psychological provision for CHD children and their families’.⁵⁷

3.5 The importance of such support was well-summarised by an observation that we received from a parent:

‘The journey of a child who is a cardiac patient (and the journey of parents of those patients) are long, filled with anxiety and can be intensely lonely. I am pleased to see that the clinical psychology input to cardiac services is at last being increased and taken seriously. They are not ‘heart children’ they are children who just happen to have cardiac conditions. Services must recognise this and be able to work closely with school settings and families in recognition of this.’

3.6 The psychology service at BRHC came into being in 2005 when Dr Garrett was appointed. She provided three sessions per week for the cardiac service up until December 2011 when it was reduced to two sessions (she also had 5 sessions for HIV services). A benchmarking exercise conducted by the BSS in 2012/13 identified that psychology staffing in the ten centres treating CHD in England ranged from none to 4 full time posts. At that time, four units in England had similar or lower provision than Bristol.

3.7 In Bristol, the limited level of support from the psychology service was noted and a risk assessment was undertaken in December 2013. In April 2014, a decision was made by the Trust to invest further in psychology services. The principal psychologist’s allotted time increased to 0.4 wte from September 2014. Funding was also provided for a full-

⁵⁶ The BSS’s Children Congenital Heart services psychology standards (2013) recommended:

- 1 WTE psychologist with experience of working with paediatric cardiology services per 400 surgical patients in the heart surgery centres, to include consultation and CPD for the network;
- 1WTE psychologist per 5000 children with congenital heart disease in Cardiology Centres or DGHs where there is a Paediatrician with a Special Interest in Cardiology (PECs).

⁵⁷ Children Congenital Heart Services Psychology Standards – British Psychological Society – 2013

time appointment at Band 7. A post-holder took up this role on April 2015. This enabled the psychology service to move away from supporting families in the PICU to a broader involvement, for example playing a greater part in the process of obtaining consent to surgery. The service had recently been reviewed to obtain feedback from families, which had been positive. It was most effective when families were able to communicate and seek support from psychologists without having to formally 'opt-in' to receive services.

- 3.8 The New Congenital Review has paid particular attention to the psychological needs of children and families in its standards. The recommended staffing levels set out by the BSS have been embraced in the standards, along with standards regarding access to the service and its integration into the broader range of services. The staffing standards are required to be met by April 2017. The Review saw evidence of planning underway to meet these standards. However, the proposals had not yet secured funding and this had been re-entered onto the risk register. The register noted that the Trust was still unable to provide a psychology service for children and families at a number of stages including fetal diagnosis, transition from child to adult care and patients undergoing catheterisation.
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4 **Conclusions**

- 4.1 There were weaknesses in the provision made by the Trust for end-of-life care and bereavement support, particularly in the early part of the period covered by this Review. More recently, services had been strengthened and there were examples of excellent practice.
- 4.2 The need for psychological support for patients and families is a crucial part of the service that should be offered. Although there has also been some improvement in the provision of psychological support for patients and families, it remains under-resourced and is not able to meet the needs of all those who could benefit from it.

5 **Recommendations**

- 5.1 In light of the above, we **recommend**:

(20) That the Trust should set out a timetable for the establishment of appropriate services for end-of-life care and bereavement support.

(21) Commissioners should give priority to the need to provide adequate funds for the provision of a comprehensive service of psychological support.

CHAPTER TEN: WARD 32

1 Introduction

- 1.1 Ward 32 was the 'cardiac ward' in the Children's Hospital. It contained 16 funded beds, of which 8 were single-bedded cubicles. It had the capacity to admit up to 19 patients, if necessary. Children might be admitted to Ward 32 prior to procedures and remain there until discharge; or they might come to Ward 32 after a period of care in PICU. The Trust explained that that all children under the care of the children's congenital cardiac service who required to be admitted as in-patients would be cared for on Ward 32, except in some rare cases where due to co-morbidities they were better cared for on another specialist ward in the Children's Hospital.
- 1.2 At times, Ward 32 might also admit 'non-cardiac' patients, if pressures on beds in the Children's Hospital made this necessary.
- 1.3 Ward 32 ran a 'ward attenders' service, whereby patients and families could come directly to the ward for a variety of clinical reasons ranging from blood sampling to ECG's. This was predominantly through the week and more occasionally at weekends. According to a draft risk assessment dated January 2011, 'The ward attenders can significantly add to the patient numbers and further dilute the staffing and increase the demands on nursing staff.' A later draft of this document was more cautious, suggesting that 'ward attenders' did not usually have a significant impact on nursing time as they generally attended for a medical review. However, there were some incidences when the patient required sedation for a procedure, which would require additional nursing and the use of an inpatient bed. The experience of the Review's nursing experts was that 'ward attenders' would require nurses' time, even if they attended for medical review as they would need to be observed, blood taken or height and weight measured.
- 1.4 The needs for care and nursing of children on the ward varied, depending on how ill they were. During the period of time with which the Review is concerned, there was a clear recognition in the Division that the acuity of the patients on the Cardiac Ward in the Children's Hospital was increasing (as, for example, surgical programmes for complex conditions such as hypoplastic left heart syndrome were initiated). The term acuity refers both to the seriousness of the child's illness or condition, and the level of the need for care. The experience of increasing acuity was one common to most Children's Hospitals at the time.⁵⁸
- 1.5 Concern expressed about the quality of the care on Ward 32 was a reason why the CQC decided to inspect the ward in September 2012, and why the Review was later set up in 2014. We therefore spent a considerable amount of time investigating care on the ward.

⁵⁸ See the report by Carol Williams – 'A background report on nurse staffing in children's and young people's health care'.

- 1.6 This Chapter, together with the next Chapter, examines:
- families' accounts: summary of material gathered from the families who contacted the Review;
 - guidance concerning levels of nursing staff;
 - the Trust's information upon how the ward was organised and its staffing;
 - the history of any expressed concerns about the ward.
- 1.7 We comment more generally on the adequacy of systems of assurances and the responses to concerns expressed in subsequent chapters.

2 The Experience of Families

- 2.1 The Trust aimed to measure the experience of patients during this period by conducting surveys. After parents and children left the ward, a sample received a questionnaire through the post. The survey, conducted quarterly, contained three questions, one asking families to rate the quality of the care received, one asking whether they had been treated with respect and dignity and the third asking them to rate the cleanliness of the ward. The survey's methodology was designed at a national level.
- 2.2 The picture gained from these surveys was a favourable one. That is, of those who responded to the surveys between April 2011 and June 2012, between 86 and 88% of respondents said that care was excellent or very good, between 88 and 91% of respondents said that they were always treated with respect and dignity and between 58 and 72% of respondents rated the ward as 'very clean.' We did note, however, that in comparative terms, these results for Ward 32 were slightly lower than that for all wards in BRHC in terms of quality of care and markedly lower for the rating for cleanliness.
- 2.3 The information gathered from families by the Review painted a more mixed picture. As set out in Chapter One, the Review was contacted by over 200 families after its call for evidence in summer 2014. The information reported below relates to families whose experience of care was during the period from 2010 – late 2012. That is, we have tried to separate reports of the care received before changes were made following the inspection by the CQC, from reports relating to the later period.
- 2.4 It is important to bear in mind that, as we set out in Chapter One, we heard a range of views and also that the information received in this way cannot be regarded as 'representative' of every family's experience.
- 2.5 We should say, first, that many of the families who contacted the Review echoed the positive picture painted, in broad terms, by the Trust's surveys. For example, one family - which twice experienced admission to hospital - reported no concerns about the care on Ward 32. Staff were 'competent, caring and hard-working'; they 'went out of their way' to make things easier for the parents as well as the children they cared for. 'I have cried and laughed with a number of the nurses over the years.' Another said

that they thought that their young child, who was rushed to the BRHC in autumn 2011 received 'outstanding' care, in the three weeks in PICU and Ward 32. In Ward 32 'there were always nurses available' and the majority of the time the baby had a nurse who cared for him. The family found staff 'informative'. Another family commented that 'At every stage the staff were patient, kind and explained everything that was going to happen. Staff, the parents said, were on hand whenever they had queries or thought that the child needed pain medication.

- 2.6 When parents or carers gave more negative reports, a key perception was that nursing staff were spread too thinly. Some families reported that whilst on the ward they received 'good care but it was apparent that the staff were very stretched and relied on parents.' One of these families felt that the ward was understaffed.
- 2.7 Another mother reported how rushed the healthcare assistant was who admitted her and her child to the ward in 2010. They were left alone in a side room until 11pm, seeing no-one until a night sister came and helped them to settle in. After the child's operation, she said that although the nurse had promised that he would be seen every 15 – 30 minutes, no one came in or checked the child's wound site for over 3 hours. His oxygen monitor came off many times and still no one came in to check, she said.
- 2.8 The complaint that there was no response to alarms was a theme for a number of parents; more than one family said that they were told to 'silence' a monitor. There were concerns that medication was not delivered in a timely fashion, or as needed by children. One family told the Review that they made allowances for the fact that their child, a teenager, was a 'low priority' since she was getting better and had a parent caring for her, but still noted that the staff did not come to check on her. This was so even when nursing intervention was needed and requested, e.g. to measure urine output. The parents learnt to do this themselves and 'fell into a routine' of caring for their child.
- 2.9 Some parents told us that they understood that, out of PICU, a child would not be 'watched all the time'. One commented: 'It is normal as a parent to want more support than is there and if money was no object then there could have been more support.' But 'the nurses would always find a doctor if we needed one and there was never a point when I thought they should be doing more than they were.'
- 2.10 By contrast, some families were more critical. Some criticised the ward's ability to care for those who had recently been discharged from PICU. They told us that they felt the lack of high dependency provision was appalling and that very sick children did not get the level of nursing care they needed when they were discharged from PICU. They felt a higher level of nursing care should have been available for a period of 2 or 3 days after discharge from PICU.
- 2.11 Others suggested that the issue was not merely the nurse:patient ratio but staff who lacked a caring attitude. For example, a family with experience of operations in 2008

and 2009 regarded nursing staff on Ward 32 as ‘uncaring and inconsiderate with what can only be described as a ‘couldn’t care less’ attitude. They had little or no regard for families or patients at a time that was filled with uncertainty, distress and fear” Another family reported nurses chatting in the central area rather than checking on patients: ‘They seemed to have no interest in the patients and I never saw them walk around the ward to check on things.’

- 2.12 There were a few comments on the availability of medical staff, particularly out of hours. One family said that they themselves detected that one of their child’s legs was cold but found it difficult to contact any doctors during the evening and the night to respond to their concerns. The junior doctor on duty had to call a colleague at home to get advice and to start the child on Heparin (although the Review noted that such out-of-hours arrangements were standard). The parents stayed awake through the night to massage the child’s leg. They felt that their child was not a priority as she was not as ill as other children, and felt that they were not being taken seriously when they voiced their concerns (in contrast to their experience of the local hospital).
- 2.13 A few parents suggested that the ward was dirty or that cleaning was inadequate: cleaners would ‘clean around’ you.
- 2.14 We have noted that a number of the concerns reported by those who gave information to the Review echoed the experience of the two families who complained to the CQC in 2012. They set out similar themes about the availability of nursing staff, and suggested that there was inadequate response to the needs of seriously ill children who, it was suggested, required augmented levels of nursing care. They questioned the skills of staff on the ward, and the extent of the review that could be provided by the ‘Outreach’ team of PICU-trained nurses who were asked to support Ward 32 staff by reviewing children recently discharged from PICU. They gave an account of parents whose anxieties and distress about their children were not taken seriously and of children who, it was suggested, should not have been cared for on the ward in the absence of dedicated high dependency beds, properly staffed with nurses equipped to deal with the more seriously ill child.
- 2.15 It can be seen that the adequacy of staffing, and whether nurses and medical staff were in a position to care for seriously ill children in need of high levels of supervision, or to detect and respond to the condition of deteriorating children, lay at the heart of matters that we were asked to examine.
- 2.16 Against that background, we turn to the subject of levels of staffing on the ward, prior to the creation of a dedicated HD unit.

3 Applicable Guidance

- 3.1 There were no mandatory requirements for levels of nursing staff at this time. The most widely used guidance for children’s services at this time was found in the Royal College of Nursing (RCN)’s ‘Defining staffing levels for children’s and young people’s

services' (2003).⁵⁹ This set out what the RCN viewed as appropriate levels of staffing for various children's services, including intensive care, high dependency and specialist and general wards.

- 3.2 For general wards, the guidance set out an indicative baseline ratio of registered nurses to children/young people, taking into account distinct requirements for care:
- For under 2 years: 1:3
 - For other age ranges: during the day 1:4, and during the night 1:5
- 3.3 The RCN's guidance also looked at appropriate staffing for specialist wards and departments:
- 1:3 in specialist wards;
 - 1:2 for high dependency patients;
 - 1:1 for children in intensive care.
- 3.4 The guidance however stressed that on a daily basis nursing staff must reflect the needs of the children and families on the unit, rather than being pre-determined by the number of beds, or the level of care each bed was designated as providing.
- 3.5 The RCN's guidance stated that the nursing establishment should allow for a shift supervisor who would co-ordinate the operational and clinical management of the ward alongside delivering care to a small caseload. Healthcare assistants educated to the level of S/NVQ3 with additional specific skill and competence-based training could provide support to registered nurses as part of the nursing team.
- 3.6 Ms Carol Williams (an Independent Healthcare Consultant) identified all wards in BRHC as 'specialist' in the benchmarking report that she completed for the Trust in October 2012. In a literature review⁶⁰ previously written for the RCN in January 2012, Ms Williams wrote:

'Specialist hospital services

There is a range of guidance available relating to specialist children's nursing services, including children's oncology and cardiac nursing. However, little of this evidence is specific about the number of nurses required. In the case of oncology and cardiac guidance, readers are referred to the RCN staffing guidance of 2003 (NICE, 2005, NHS Specialised Services, 2011). This specifies the following, using oncology as an example:

- thirty-three per cent of patients require 1:2 ratio of nurses to patients (HD care)
- the remainder require one nurse to three patients
- a shift supervisor and nurse practitioners/specialists are additional to the bedside establishment.

⁵⁹Royal College of Nursing, 2003. Revised in 2013.

⁶⁰Williams, Carol (2012): 'A background report on nurse staffing in children's and young people's health care'.

Evidence from discussion with senior and specialist nurses suggests that these figures may now be insufficient with a higher number of children in specialist hospital wards falling into the HD category, in some cases up to 50 per cent. This information is not always supported by evidence gained from using workload and dependency tools, but is often based on professional judgement and feedback from staff. Due to the requirement for a nurse to patient ratio of 1:2 for children falling into the HD category, there is a need for objective workload measurement to support professional judgement, especially where staffing requirements are increasing in specialist services. Therefore, it is recommended that further workload measurement is required in specialist services over a period of time (minimum four weeks) to demonstrate the need for higher nurse: patient ratios where acuity is high. Tools such as Paediatric Acuity and Nursing Dependency Assessment (PANDA) tool may prove useful in this setting.....’

..... The information above demonstrates the lack of clear guidance relating to nurse staffing which is applicable to all of the services providing children’s health care.’

- 3.7 The Review’s Experts on Nursing agreed with the conclusion that there is a lack of clear guidance on levels of nursing staff.
- 3.8 The RCN’s conclusions were refreshed but not radically revised in 2013. The updated guidance further emphasised that the level of dependency of the patient was equally important and should be determined as part of the process of setting the level of nursing staff required.

4 Nursing Staff on Ward 32

- 4.1 The Review asked the UHB’s Chief Nurse how she assured herself that nursing staff levels were appropriate in the Trust and on Ward 32 in particular. She told the Review that, broadly speaking, assurance relied upon:
- the RCN guidance;
 - an annual review of the funded establishment and staff in post (called re-basing the budget)⁶¹;
 - guidance on minimum levels of staffing for each ward;
 - feedback from the Heads of Nursing on a regular basis;
 - reporting on ‘quality indicators’ such as pressure sores or infection control;
 - feedback from patients/families through surveys and complaints;
 - reporting of incidents;
 - visiting the wards herself and feedback from other Directors through their visits to check on the safety of patients.

⁶¹ The Chief Nurse told that the Review that the budgets had been re-based in late 2009. The Conroy review had then taken the place of rebasing in 2011.

- 4.2 The Chief Nurse told the Review that establishing minimum levels of staff for each ward was one of the recommendations of a report of the Audit Commission in 2009, which benchmarked staffing against other hospital trusts.⁶² The minimum levels of staffing for each ward, which included Ward 32, were set by the Ward Sister, the Matron and the Head of Nursing Women's and Children's Division.
- 4.3 The Head of Nursing Women's and Children's Division highlighted the fact that there were no mandatory levels for nursing staff for the care of children in England over the period of the Review. We have already referred to the RCN's 2003 guidance; she commented that it had a number of limitations. Setting a ratio of nurses to patients was a relatively crude approach as it did not necessarily reflect the number of hours of nursing that each child actually needed. She noted that there were no nationally accepted tools to measure acuity and dependency, to aid decisions about levels of nursing staff levels for children over the period 2010 to 2014. This led to a reliance on the professional judgement of the senior nursing staff, from Ward Sister to Matron to Head of Nursing, to ensure that appropriate numbers of staff were in place or to raise concerns when called for.⁶³
- 4.4 We looked at the data regarding the funded establishment⁶⁴ for Ward 32 in 2010/11, as well as information provided by the Trust to the CQC in August 2012. During 2010 and 2011, the funded establishment for Ward 32 was:
- three registered and one unregistered member of staff during the day on Monday to Friday; and
 - two registered and one unregistered member of staff overnight and at weekends.
- 4.5 A Trust-wide Review of staffing was carried out in 2011 by Ms Margaret Conroy. For Ward 32, this Review recommended a small increase in the level of staffing to enable the Ward sister to be supernumerary or supervisory (but a very small decrease in the skill mix from 82.7% to 81.3% registered nurses). We were told that in 2012 following this review, changes to the shift patterns were introduced, the 'uplift' to allow for such

⁶² The main findings from this report by the Audit Commission were that in comparison to group of similar Trusts, UHB's nursing staff establishment was 'fairly generous,' there were high levels of bank staff deployed and the sickness rate of 6% was above the national average. The report suggested that there was potential to achieve £5m of efficiency savings by revising the trust's nursing staff establishment. The Report was influential in triggering the further review of levels of nursing staff carried out in 2011.

⁶³ In the 'background report on nurse staffing in children's and young people's health care' (2012) Ms Williams noted 'the need for triangulation of methods when undertaking workforce planning', including:

- professional judgement of experienced nurses
- benchmarking with other services; and
- the use of tools to measure patient dependency or acuity and nursing workload.

She noted that guidance provided a useful summary of these tools, 'but few of these have been developed for children's nursing and senior nurses have reported that to date few of the tools used have been suitable for children's services....'

⁶⁴ That is, the numbers of each band of Registered Nurses, Health Care Assistants and Ward clerks that are considered necessary to run a particular hospital Ward.

matters as leave and sickness cover was reduced from 23% to 21%, the nursing establishment on Ward 32 was increased by 0.74 whole time equivalents (WTEs) and a post of supervisory Ward Sister was introduced, i.e., a nurse in a leadership role who would not be expected to have direct responsibility for the care of patients on the ward.

- 4.6 On 18th April 2012, an email was sent by the Matron of Ward 32 which indicated an intention to increase the staffing with 'immediate effect' to:
- four registered and one unregistered member of staff during the day on Monday to Sunday; and
 - three registered and one unregistered member of staff overnight.
- 4.7 Shift patterns were said to have been changed to free nursing resources.
- 4.8 A timeline provided to the Review by the Trust suggested that these changes were implemented earlier, in January/February 2012. The submission made by the Trust to CQC in August 2012 also recorded that this pattern of staffing was in place by that date. We questioned whether these changes were in place as early as January / February 2012, given the date of the Matron's email (April 2012). See Chapter 11, paragraph 1.14 – 1.16, where we suggest that the picture was, rather, one of a gradual increase in the nursing numbers during the first part of 2012.
- 4.9 Further changes in the nursing establishment took place following the CQC inspection and the creation of dedicated HD beds. These developments are considered further below, in Chapter Fourteen.

5 The Model of Care on Ward 32: The Outreach Team and 'Flexing' Staff

- 5.1 The discussion of nursing numbers above relates to the funded establishment on Ward 32. However, the Trust pointed out that it also supported nurses on the ward by means of the Outreach Team, and by 'flexing' numbers as needed (i.e., responding flexibly to the needs for nurses).
- 5.2 The Trust told us that the discharge of a child from PICU to the children's cardiac ward followed a clinical decision by the PICU's team, including a consultant cardiologist, and agreement by the ward. For a further 48 hours, the child would be monitored by a specialist Outreach Team and, for the remainder of the child's stay, there would be additional review by the Outreach Team, if requested to attend. Children would be re-admitted to PICU if required.
- 5.3 The Nurse Consultant (PICU/HDU), Ms Haines, told us that the Outreach Team consisted of experienced middle-grade nurses who had a background in intensive care and qualifications in intensive care, emergency care or high dependency care. The Matron for Paediatric Critical Care, Mr Booth, told us: *'I think we recognised that on the wards there were children with a higher acuity and more junior nursing staff or inexperienced nurses and doctors, junior doctors, needed the support of somebody who was more au fait with nursing children with the higher acuity or dependency.'*

- 5.4 The Outreach Team served the whole of the Children's Hospital. There would be one member of staff on duty for the site for 24 hours, 7 days per week. So the word 'team' referred to staff who performed this function generally; it was not a reference to there being a number of staff on duty at any one time.
- 5.5 The Review was advised by its Expert Panel that it was common for hospitals to have an Outreach Team, or use the Outreach model. The model was developed in hospitals in response to reductions in junior doctors' hours. It was thought to be an appropriate method of supporting ward staff through the use of those with specialist skills and expertise. Furthermore, in the relatively small environment of the Children's Hospital, there should have been an opportunity for the members of the Outreach Team to forge effective relationships with ward staff.
- 5.6 We were told that the staffing on the ward was also 'flexed' upwards according to the number of children and levels of acuity on the ward, by bringing in additional members of staff to supplement the basic nursing establishment. Additional nurses could be drawn from other wards, if less busy, from the pool of 'Bank' nurses⁶⁵, or from agency nurses. This process was managed by senior nursing staff on a day-to-day basis. The aim was to ensure that additional skills and capacity were brought to bear when acuity or activity on the ward required.
- 5.7 The Head of Nursing explained that rosters were planned six to eight weeks in advance so that if there were gaps these could be addressed by the use of agency or Bank staff. All rosters were signed off by the Ward Sister and the Matron. Although the funded ratio of nurses to patients was on average one-to-four on Ward 32 (see above), on a day-by-day basis the level of patient acuity and dependency was actively assessed by the Ward Sister. If those ratios needed to change due to patients' needs and occupancy of beds, this would happen in discussion with the Matron and the Site Team.
- 5.8 Nursing staff described how the Trust had a day duty team (comprising a clinical site manager, duty matron and duty manager) and a night duty team (comprising a clinical site manager and on call manager). Twice a day, the clinical site manager, the duty matron and duty manager would meet to discuss the occupancy of beds, nursing staff levels, activity on the ward and the acuity and dependency of patients. Various ward rounds and scheduling meetings enabled them to assess needs and gaps in staffing. If there was a gap, the site team expected the ward staff to take responsibility for addressing it in the first instance. The next step was for the sister to refer it to the clinical site team manager and duty matron. If it could not be resolved by redeploying appropriate staff from across the Children's Hospital, Bank or agency staff would be used. The Review was told that Bank staff are generally nurses employed part-time by the Trust who will work occasional extra shifts through the Bank. The Trust also aimed to use the same agency nurses consistently.

⁶⁵ Bank nurses are staff registered with the Trust on their staff bank to provide temporary cover where there is a short-term increase in work or a short term shortfall due to vacancies. Many bank staff are already employees and register with the bank if they are willing to do additional shifts.

- 5.9 It was apparent to the Review that the funded establishment for Ward 32 before the changes noted in April 2012 contemplated a nursing ratio of one nurse (registered or unregistered) to four patients during day time hours, and a little under one nurse to five patients overnight and at weekends, *if* all 16 beds were occupied. As regards registered nurses only, and again on the basis that all 16 beds were occupied, the ratio would have been one nurse to 5.3 patients during day-time hours and one nurse to eight patients overnight and at weekends.
- 5.10 If three registered nurses had been present (during the day), this would have meant that the RCN guidance was adhered to only if:
- no more than 12, rather than 16 beds were filled;
 - there were no children under the age of 2. The RCN's guidance suggests that children under 2 need care at the ratio of 1 nurse to 3 patients, rather than 1 to 4;
 - there was little or no use of the cubicles on Ward 32. Cubicles require higher levels of nursing attendance, because the 'walk by' oversight of nurses is lost and the patients are more isolated (even if linked by monitors to the central nursing station, as were patients in Ward 32); and
 - staff were not over-stretched by meeting the needs of the 'ward attenders'.
- 5.11 Overall, and even leaving aside the question of whether some children on the ward had higher dependency needs or presented additional challenges to nurses because they were not cardiac patients, it appeared that the extent to which the RCN's guidance would be met must have depended heavily on the ability of the ward to supplement or 'flex' its staffing on a daily basis. Heavy reliance on increasing the number of staff through deployment of Bank and agency staff to meet routine needs (rather than to address vacancies, absence or sickness) is not consistent with providing an appropriate quality of care.

6 High Dependency Care

- 6.1 Staffing levels of 1:4 or 1:3, recommended in the RCN's guidance in 2003, applied to 'general' wards. But children may require closer nursing attention because of their particular needs (for example, because their fluid balance needed careful attention and recording). Or they may fall within a more formal category, that is, children who need 'high dependency care'.
- 6.2 Such children were defined in the guidance produced by the Paediatric Intensive Care Society in June 2010, 'Care of the Critically Ill Child'.⁶⁶ The PICS guidance set out a range of circumstances in which children might require close monitoring and observation, while no longer needing to be nursed in an intensive care environment. If children required what was described as 'Level 1'⁶⁷ care, the guidance recommended that 1 nurse should be allocated to 2 patients; or 1 nurse to every patient nursed in a

⁶⁶ As well as in the RCN's 2003 'Defining Staffing Levels'.

⁶⁷ Quality Standards for the Care of Critically Ill Children – Paediatric Intensive Care Society 5th Edition December 2010

cubicle. Thus, if any children falling within the terms of that element of the guidance were to be on Ward 32, a greater level of nursing staff was required.

- 6.3 As with the other publications, PICS' guidance was just that - guidance only. The fact is that there were no nationally mandated standards for levels of nursing for children.
- 6.4 Some parents in contact with the Review said that they were told that their children would receive high dependency care on Ward 32. This was in the period before a high dependency unit was established on the ward in 2013.
- 6.5 We heard from patients that there was mention of a high dependency unit, and they were given assurances by staff that their child would be cared for in a high dependency bed but that their experience was that on return to Ward 32 the provision of nursing care was not enhanced.
- 6.6 Support for the suggestion that parents could have been told that high dependency care would be provided on Ward 32 was provided by two members of staff. In particular, the Nurse Consultant (PICU/HDU) told us that it was a 'likely scenario' that parents would be told this:

'...because I think that when a child is getting to the stage where they are ready for transfer (from paediatric intensive care unit), they are less acute in their illness. They are likely or possibly likely to be cared for by a slightly less experienced nurse. Therefore, that slightly less experienced nurse may not understand the nuances of using terminology like high dependency. Although in their minds they're not incorrect in what they're saying, because from an intensive care point of view they have been in intensive care and they've moved, stepped down to a high dependency level.'

She considered that the use of the term was wrong when referring to the acuity of a child who is ready for transfer to a ward area, however, as it did not necessarily mean that these children were highly dependent patients who fell within the PICS guidance:

'This is one of the real concerns that there is nationally about this terminology of high dependency. So they were not wrong in using that terminology, but how that is interpreted by those families would be perhaps very different to the way I would interpret it because of my deeper understanding of those terms.'

- 6.7 During the period of the Review's Terms of Reference, we heard that there were consistent attempts made to secure a dedicated high dependency unit for the Children's Hospital as a whole.
- 6.8 A number of factors lay behind this. There was a plan for the centralisation of specialist paediatric services (CSP) in Bristol with the Children's Hospital. The plan was for neurosurgery, burns and trauma services to transfer from Frenchay Hospital. There was already a high dependency unit in Frenchay and this would need to be re-

provided in the Children's Hospital. This would have thrown the absence of similar provision as regards the other paediatric services into sharp relief.

- 6.9 In addition, clinicians at the Children's Hospital were conscious of the pressures on the PICU, particularly in the absence of a HDU. The PICU in the Children's Hospital had to care for seriously ill 'local' children, who in other parts of the region might be cared for in high dependency units in District General Hospitals. The absence of such a unit at the Children's Hospital meant a reduced capacity on the part of PICU to care for critically ill children from across the region. As a result of these concerns, the Clinical Director of the PICU sought agreement that the working group looking at the provision of high dependency care associated with the CSP should be extended to cover all the needs for high dependency in the Children's Hospital.
- 6.10 In its response to the Safe and Sustainable self-assessment, the Trust had referred to plans to develop a dedicated HDU, if the children's services for cardiac care expanded.
- 6.11 There were, therefore, attempts to persuade commissioners to fund a HDU for the Children's Hospital, prior to the CQC inspection of September 2012. That history is considered in Chapter Fifteen.
- 6.12 Here, we consider what happened prior to that point: the extent to which children with higher care needs were cared for on Ward 32.
- 6.13 In their review of cardiac services carried out in March 2008, Dr Michael Godman (paediatric cardiologist) and Mr Roger Mee (Cardiac Surgeon) noted that the extent of the cardiac ward's capacity to provide high dependency care needed assessment.⁶⁸
- 6.14 The Trust accepted that children needing 'higher levels of care' or with 'higher care needs' were, at times, nursed on Ward 32. However, there was debate about the extent to which children who would have been recognised as requiring 'Level 1 care' within the meaning of the PICS guidance were nursed on the ward, i.e., children needing nursing care at the ratio of 1:2 or even 1:1 in a cubicle. We were told that if children needed 'high dependency they were still in the intensive care unit', i.e., in PICU. Nurses in PICU told us that they provided high dependency care in PICU, referring to children who were no longer ventilated but remained in PICU.
- 6.15 We accept that PICU did provide high dependency care⁶⁹, but the question is whether it provided *all* such care. The suggestion that all children who needed high dependency care remained on PICU was not consistently reflected in the contemporaneous documentation provided to us, including:

⁶⁸ The review of cardiac services by Mr Godman and Dr Mee noted that: 'Additional work is required to determine whether high dependency non-ventilated patients can be accepted from the PICU without compromising the admission of patients for cardiac catheterisation or pre-operatively'.

⁶⁹ This is supported by the data supplied to PICA Net, which showed that a substantial proportion of the care provided on PICU was high dependency care, or advanced high dependency care, under the PCCMDS' criteria.

- The self-assessment submitted in April 2011 by Dr Davis on behalf of the Trust, to the South West Specialised Commissioning Group's Review of High Dependency Care. This declared non-compliance with two nursing standards for HD care. There was a recognition by the authors that children requiring HD care could at times be nursed on general wards rather than remaining in PICU; and that, if so, the levels of nursing care could fall below that mandated by the South West standards.
- A paper to the Divisional Quarterly Review of July 2011, which described 'a strong view from the clinical teams within Children's Services that the absence of a High Dependency facility, and, as a result, the amount of high dependency care that is being provided on the general wards is a key clinical and financial issue.' A finance paper submitted to the same meeting referred to 'Increasing patient acuity requiring 1:1 and 1:2 nursing support on general wards e.g. ...long term ventilated children expected to stay at least 6 months each; earlier cardiac discharge from PICU e.g. inotrope therapy; and more inpatient chemotherapy ...'. It linked high expenditure on the cost of Bank and agency nurses to the fact that 'the dependency of patients on the ward areas is potentially well above the levels of dependency that the wards are staffed for.'
- Information collected by Dr Caroline Haines regarding the levels of patients' dependency while on the children's wards, in 2011;
- The Standard Operating Protocol for children in receipt of inotropes on the cardiac ward (April 2011). This set out the need for augmented care when children receiving such drugs were on the ward and specified a nursing ratio of 1:3.

6.16 In relation to the information gathered by Dr Haines, we were told that the Trust had been seeking to document the extent to which children with a need for higher dependency care were present on its wards. Staff began work in 2008 to develop systems for collecting data for the 'Paediatric Critical Care Minimum Data Set' (PCCMDS).⁷⁰ By 2011 this work had progressed to allow a pilot study across the Children's Hospital. The work yielded evidence of patients needing high dependency care being nursed outside PICU.

6.17 For example, on the 14th July 2011, a 'snapshot' of the levels of all inpatients' dependency was undertaken at the Children's Hospital. This snapshot captured the number of inpatients and categorised their levels of dependency. It noted the patients who, variously, required 1:1 nursing, 1:2 nursing, 1:3 nursing or 1:4 nursing. On this date, over 30% of all inpatients (excluding patients in PICU) required 1:1 or 1:2 nursing.

6.18 The data indicated there were 17 patients on Ward 32 on that day. Of these, 2 were said to require 1:2 care and 15 to require 1:3 care.

⁷⁰ Paediatric High Dependency Data Collection – Health Related Groups (HRGs) – Report on Pilot Study At Bristol Royal Hospital for Children, July to September 2008, Haines, C. & Marriage, S. (2008)

- 6.19 A more lengthy process of collecting data took place between March and October 2011. A report was produced on the 9th of December 2011. The overall findings were that Ward 32 had the highest percentage of admissions that had, for more than four hours during the admission, required interventions that met the PCCMDS criteria. The figure for Ward 32 was 46%; the next highest was 36% (with the remainder of wards below 14%). Ward 32 also had the highest proportion of days of care of children under the age of one year who fell within the PCCMDS by a substantial margin: 810 days over the period, out of 1265 days across all age groups on the ward. This compared to the next highest ward with 160 days for under one year olds, out of 518 days across all age groups.
- 6.20 The Review was told that the Paediatric Critical Care Minimum Data Set's (PCCMDS) definitions of high dependency that were used were, in fact, those used to inform Health Related Groups (HRG) whereby patients' conditions were coded. This data set was aligned to the PICS' standards for Level 1 care, but had within it two categories, HRG 1 and 2. These HRG codes were accounting-based standards, used by the Department of Health for financial payments to Trusts.
- 6.21 As such, the Trust considered that the codes were not designed to provide a definitive clinical statement that a child needed high dependency care. An example provided by the Trust was of a patient on oxygen and oximetry and, specifically in relation to cardiac services, monitoring through an ECG. Such a child would fall within the HRGs definitions for high dependency care, but his or her inclusion would not in all cases be supported by the medical assessment of the child as being acutely unwell or requiring high levels of nursing care. Thus, when the Trust reported this data to the CQC in August 2012, it commented: 'It is worth noting that the biggest proportion of triggered high dependency activity on the cardiac ward relates to continuous ECG monitoring. It is estimated that 50% of this activity within the cardiac ward relates to 'normal' level of care that is part of the day to day speciality work rather than high dependency.' The Review was told by medical and nursing staff in the PICU and cardiac service that many of the children identified by these criteria would be considered to have 'higher acuity needs' and not as 'high dependency.' The Trust's view, therefore, was that the data referred to in 6.19 above had to be treated with some caution.
- 6.22 The Review heard from a number of clinicians that some of the definitions within the PCCMDS also changed over time because it became apparent that there were groups of patients who were being identified as high dependency when they were not.
- 6.23 It was further suggested that this view of the ill-defined nature of high dependency care was confirmed by the Royal College of Paediatrics and Child Health (RCPCH) report's 'High Dependency Care for Children – Time to Move On' (October 2014). The report stated:-

'The term HDC [high dependency care] has historically been used to mean different things in different hospitals. A child who is not critically ill may have been classified as

requiring HDC based solely on a requirement for additional nursing resources. Whilst many of these children will continue to require enhanced nursing supervision they should be differentiated from the group of children who are critically ill'.⁷¹

- 6.24 The RCPCH's report advocated a change in terminology: i.e., moving away from the term high dependency care or HDU to a description of different levels of critical care. Levels 1 and 2 would be used to describe activities which would previously have been described as high dependency care. For the child who requires a considerable input from staff but who is not critically ill, the term 'high nurse dependency' should be used.
- 6.25 We accept that there was confusion surrounding the term 'high dependency' or 'high dependency care' during this period. It could be used widely, including to describe children who were not critically ill but needed considerable input from staff. We consider that the reported use of the term to parents by staff probably did, at times, reflect that confusion, and led to parents being confused.
- 6.26 We also accept that a large part of the activity described by Dr Haines on Ward 32 referred to patients receiving continuous ECG monitoring, which was not the most challenging category of patient from the point of view of a specialist cardiac ward. Nevertheless, 'the child undergoing close post-operative observation with ECG and pulse oximetry and receiving oxygen' is one of the general examples given in the 2010 PICS' standards of a child needing 'Level 1' care. The Review considered that the inclusion of such a child in the standards carried some weight when assessing the level of nursing need on the ward.
- 6.27 Furthermore, the 2010 standards included 'post-operative patients who need close monitoring for more than a few hours' as within its definitions, as well as those on 'CPAP or non-invasive ventilation' or those who needed 'vasoactive drugs to support arterial pressure or cardiac output'.
- 6.28 In its Expert Case Review, as well as in its more general review of evidence from the Trust, the Expert Panel saw examples of patients whose needs, after surgery, plainly required 'close monitoring' for more than a few hours. Indeed, this was acknowledged on the ward, since they were generally subject to hourly observations. Dr Haines' work logged a high number of patients in receipt of vasoactive drugs or inotropes. Incident reports were a further source of evidence on this matter.
- 6.29 The Review also took note of the development of the programme to operate on hypoplastic left heart syndrome at this time. Whilst the numbers of patients operated

⁷¹ Section 1.1.5. see, equally, section 2.6: 'HDC is a term which is used correctly to describe the child who is critically ill requiring enhanced observation, monitoring and intervention but also is used to describe the child who is not critically ill but requires additional nursing care for other reasons. An example would be the combative child after a head injury requiring close supervision, or the child who is receiving a number of intravenous medications which require preparation and checking. Whilst these are situations which will impact on the staffing levels required on a Ward they are not relevant to a discussion about care of the critically ill child outside PICU, and need to be considered using a different approach.'

upon was low,⁷² these were challenging procedures on very young babies who would need prolonged post-operative care. A small number of such patients were capable of having a disproportionate effect on the levels of nursing care required.

- 6.30 The Review was told by a number of members of staff that at this time the only patients on inotropes and vasoactive drugs who might be cared for on Ward 32 were neonates on low levels of a vasoactive drug called-prostaglandin, and the 'occasional patient' with cardiomyopathy who was 'stable' on a single inotrope; they might remain on it for weeks or months. It was said that the understanding that these were the children who were suitable for transfer was well-understood and embedded in practice on Ward 32. In relation to the care of babies on prostaglandin, it was pointed out that the ward had long experience of these children.
- 6.31 Notwithstanding such views, as a matter of principle, the Review's Expert Panel was not persuaded that these were good reasons for arguing that such patients were not 'high dependency' patients. The Panel considered that a child on inotropes was a very sick child and, furthermore, one who was always potentially unstable or whose clinical state could change very rapidly. Prostaglandin carried with it a risk of apnoea. Such children were reliant on the drugs given, and any failures in their delivery could have rapid and devastating effects. Staff would need to check infusion pumps every hour and blood pressure taken at least every 2 - 4 hours. Children on vasoactive infusions were defined as needing high dependency care under the 2010 and 2014 PICS standards, without further categorisation, and the Review felt that this was the appropriate approach.
- 6.32 A copy of the Trust's clinical guideline, 'Inotrope Guidelines for Paediatric Cardiac Ward' dated April 2011 was made available to the Review. We noted the reference to the need for patients transferred from PICU to have been 'haemodynamically stable with no escalation of cardiovascular or respiratory support in the preceding 48 hours', to 'have definitive central venous access and if required, additional intravenous access for other IV drugs' and 'not be on more than two inotropic agents'. This suggested that a wider category of patients than those described to the Review (paragraph 6.30) could be approved for transfer. We recognise that we were not in a position to carry out checks such as a comprehensive check of clinical records to resolve this point. But we did see evidence in incident reports or CDRs of the presence of at least a small number of patients on inotropes who were not 'stable' or who were in receipt of more than one inotrope.
- 6.33 The clinical guideline also referred to the need to 'have nursing staffing levels sufficient to support 1-to-3 patient care ratio'. The Review noted that this represented a departure from the PICS' guidelines and that in early 2012, when it was reviewed by the Clinical Lead for PIC, Dr Davis, he amended it to specify levels of 1:2. The Review

⁷² According to the NCHA data, there were 3 Norwood procedures in 2014-15; 3 in 2013-4; 7 in 2012-13; 2 in 2011-12; and 3 in 2010-11, in the BRHC.

considered that this later approach was better supported by the available professional standards. Furthermore, it seemed more realistic in the light of the significant requirements for monitoring patients set out in the Guideline, including hourly observations. Patients admitted to the ward under this Guideline needed, in the judgment of the Expert Panel, high dependency care.

- 6.34 More generally, the debate about whether patients were ‘high dependency’ or had ‘higher nursing needs’ at times had an air of unreality to it. Both sets of patients clearly demanded a higher level of nursing attention, such that levels of staff based on the needs of patients on a general ward would be too low. The Review’s nursing experts considered that, for example, a child on vapotherm would not necessarily be considered a high dependency patient. But the use of vapotherm suggested at least a degree of heart failure or respiratory compromise, and the need to monitor the child carefully during a period of recovery from surgery. Furthermore, as the Panel saw in one of its Expert Case Reviews, using vapotherm meant that staff had to monitor and maintain another piece of equipment, all of which took time.
- 6.35 We noted also the views of medical staff, as reported to the CQC in September 2012, that they ‘currently believed that Ward 32 could cope with one child on inotropes but not several’. There were 11 or so occasions of recorded incidents, from October 2010 to August 2012, when more than one patient on inotropes was noted to be on the ward. This can reasonably be expected to be only a proportion of such instances, given also the numbers of patients on vasoactive infusion recorded in the HRG data collection exercise.

7 Clinical Leadership of High Dependency Care

- 7.1 The standards set in the South West Specialised Commissioning Group’s review of High Dependency Care in the region also included a standard requiring ‘a dedicated lead clinician for HD care’, with responsibility for ensuring, for example, the availability of trained and suitably skilled staff. In the self-assessment in response to these standards, the authors identified the fact that this standard was not met in UHB (although clinicians from PICU were actively seeking to develop HD services).
- 7.2 The self-assessment of compliance with standards for the Children’s Hospital and the findings from the SW’s Review of High Dependency Services did not require formal acceptance through the process of governance within the Division, although Dr Davis gave a presentation upon the work to the Children’s Executive Group. It is plain that the self-assessment then fed into the work done to develop the bid for HD facilities that was presented to Commissioners in early 2012.
- 7.3 It appeared to the Review that fuller consideration should have been given to this self-assessment by the Children’s Executive Group, followed by the appointment of a dedicated lead clinician, as the standards required. More fundamentally, the Review was concerned that the fact that declared non-compliance with standards was not

linked to any need to assess the risk presented by the existing arrangements nor to any specific action to be taken.

8 Professional Discretion and Objective Measures

- 8.1 We have set out at some considerable length the information which we received about numbers of patients and levels of acuity, numbers of staff and the ability of staff to respond to patient needs. We have done so partly because there appears to be no consensus as to whether the ward's staffing was adequate to meet the needs of all its patients, even though well over three years has elapsed since the CQC made its judgment on the care delivered on Ward 32 in September 2012.
- 8.2 We have reflected on the difficulties of reconstructing a definitive picture of the staffing on the ward, and its adequacy, given the absence of mandatory minimum levels of staff and the complex variables at play: that is, the constantly changing mix of patients, their age and acuity, which had to be set against not merely the numbers of staff present but their experience and skills.
- 8.3 It was apparent that, against such a background, there was a heavy reliance on professional judgment and discretion. We do not doubt the sincerity and good faith of all those staff made those judgments. But we do consider that they needed better tools to be developed, so as to make them. When a system is operated solely on the basis of responding to the needs of the moment and on the use of discretion, there are no objective criteria by reference to which performance can be measured and staff held to account. Indeed, what is operated is an 'ad hoc' approach rather than a system.
- 8.4 The national nursing leaders to whom we spoke stressed that research strongly pointed to the fact that good care was not merely a product of 'the right numbers' but teamwork (with staff feeling supported), an open and learning culture, and good leadership. It was important to recognise that the 'numbers' could be adequate but care still poor; if, for example, there was an over-reliance on Bank and agency staff with limited knowledge of the ward and its regular staff, or the specialty in question.
- 8.5 We sought to explore the extent to which tools or information had become available, since late 2012, to assist in determining and meeting the needs of patients on a paediatric ward.
- 8.6 It was apparent that nationally there has been much focus upon the issue of levels of nursing staff, from around that point in time. December 2012 saw the publication of 'Compassion in Practice', the Chief Nurse's national strategy for nurses, midwives and care staff. The Report of the Public Inquiry into Mid-Staffordshire NHS Foundation Trust (the Francis Report) was published in February 2013. The RCN's guidance on levels of staffing was refreshed in 2013. In November 2013, the National Quality Board (NQB) published an 'Overarching Guide' to ensuring safe staffing, which set out 10 core expectations for providers and commissioners. One of those expectations was that 'evidence-based tools are used to inform nursing, midwifery and care staffing

capacity and capability'; tools were to be used in conjunction with professional judgement and scrutiny. We learnt that the NQB's guidance is currently being refreshed, to include the implementation of the new 'care hours per patient day' approach to recording levels of staffing, which is to be put in place from May 2016 with further testing and review over the summer.

- 8.7 From April 2014 all hospitals have been required to report and publish the numbers of nurses, midwives and care staff working on wards. This requirement follows the recommendations of the Francis Report, which called for greater openness and transparency in the Health Service. Levels of staffing on wards are now recorded daily. The information is not merely available to providers and commissioners but is published online. Trusts' Boards are required to review levels of staffing and their adequacy in public meetings every 6 months.
- 8.8 Clearly, there is now thus a much greater level of transparency about whether or not wards can deliver the planned nursing establishment. Systems for measuring and reporting are still evolving. Currently a system of measuring 'care hours per patient day', as a single consistent way of recording and reporting the deployment of staff in in-patient wards or units, together with the outcomes of care provided to patients, is being implemented.
- 8.9 Information about levels of staffing alone does not, of course, address the question whether or not the planned levels are adequate, given the mix of factors determining the need for care that we have described above. We noted that the RCN's updated guidance on levels of nursing staff (2013) does not define the levels in a prescriptive fashion. The guidance stresses the importance of the use of evidence-based tools combined with professional judgment and refers to a number of sources of standards and tools. In relation to specialist wards, such as cardiac wards, it notes that at least a third of patients on specialist wards should be classified as requiring high dependency care, although in some areas of a ward this may be as high as 50%. If children meet the criteria for high dependency care, the relevant standards should be met⁷³; if they do not, the minimum standard is 1:3 registered nurse: child. The professional assessment of standards for specialist wards must be supported by use of a suitable tool for measuring acuity.
- 8.10 Nationally, a validated tool for measuring acuity has been developed for adult wards, the Safer Nursing Care Tool. It was based on the work of the Association of UK University Hospitals (AUKUH). At a national level, work is close to completion on a paediatric version of the Safer Nursing Care Tool. It has been validated through work with 10 hospital trusts over the last 18 months. We heard that the publication of this tool was expected by summer 2016. It will be available for use by hospitals to support the assessment of staffing needs on paediatric wards, using data from surveys to be collected in each ward about the patients' acuity/dependency.

⁷³ I.e., the Paediatric Intensive Care Society Standards (2010)

- 8.11 Health Education England has been developing special courses, based on e-learning, to support Ward Sisters in (for example) the proper use of tools such as those discussed. Given the key role in leadership of Ward Sisters, we felt that such courses would be an important resource. We were also told that work was being carried out to strengthen professional networks through which advice could be sought. Given the continued emphasis placed on professional judgment, this too seemed important.
- 8.12 We noted that, despite some earlier work in this field by bodies such as NICE, the trend had been away from seeking to define 'minimum' safe levels of nursing levels. There were a number of reasons for this. There was limited research to support the work. Furthermore, there was a concern that 'minimum' numbers could become 'maximum' ones; also, that an emphasis on numbers alone might shift attention from factors such as training, teamwork and leadership. As a result, work continued to refine sources of information that help to measure outcomes (i.e., whether good care is being provided), such as surveys of the experiences of both patients and staff.

9 Staffing Data from UHB

- 9.1 The Review noted that as a result of the requirement to publish levels of nursing staff, monthly data from UHB is now available online and shows the 'fill rate' (the level of staffing) of individual wards such as Ward 32, measured against the planned establishment, together with comments from the Trust's Chief Nurse when required. See further Chapter Fourteen.
- 9.2 In relation to tools relating to acuity, the Review was told that from 2013, staff at the BRHC had been developing a Care Levels Tool for children with cardiac conditions, based on the Association of UK University Hospitals Acuity/Dependency Tool which was first launched in 2007. As the original work was based on adult critical care, further work and adjustments were made to ensure that the BRHC's Care Levels Tool was appropriate for infants, children and young people. As a result of this work, we were told that the Children's Hospital now has two years of data to support the planning of future requirements for nursing. Such a tool may, of course, be replaced by the national tool described at paragraph 10.10 above.

10 Conclusions

- 10.1 We have set out a picture of the patient numbers and needs on Ward 32, together with staffing levels, prior to the CQC inspection of September 2012 and the changes which followed it.
- 10.2 There is evidence to suggest that Ward 32 was potentially the ward with the highest level of patient acuity, compared with others in the Children's Hospital. The Trust's own data collection shows that there were a significant number of children who required augmented levels of nursing care on Ward 32 during this period.

- 10.3 There was confusion surrounding the term ‘high dependency’ or ‘high dependency care’ during this period. It could be used widely, including to describe children who were not critically ill but needed considerable input from staff. On occasion, staff use of the term probably reflected that confusion. We accept that because of this, it is likely that, on occasion, the term was used to describe the care on Ward 32, as some parents reported to us.
- 10.4 The demand for nursing care on Ward 32 was further increased by the fact that a large percentage of its patients were babies or very young children with cardiac problems, who needed high levels of attention, and the fact that there were a large number of small rooms or cubicles on the ward. Nurses and medical staff also had to respond to the needs of the ‘ward attenders’, and ‘non-cardiac’ patients whose needs were, therefore, more diverse and less familiar.
- 10.5 Overall, there was evidence that suggested that Ward 32 was under heavier pressure than other wards, because of the circumstances of its patients.
- 10.6 At the time, there was a heavy reliance on professional judgment and discretion in order to assess the numbers of nurses needed. We do not doubt the sincerity and good faith of all those staff made those judgments. But we do consider that they needed better tools to be developed, to support them to make them.
- 10.7 In recent years, much work has been done on ensuring safer nursing levels. Validated tools for measuring patient acuity have been developed, with a tool for paediatric patients soon to be available. Trusts are now required to put information in the public domain about staffing levels in each hospital ward.
- 10.8 We **endorse** the importance of this work. We emphasise the importance of the early use of, in particular, a nationally recognised paediatric staffing tool for acutely ill children. When available, this should be utilised, together with the professional judgement of senior nurses responsible for the care of the patient, to review the basis of the current nursing establishment on the cardiac ward.

CHAPTER ELEVEN: MANAGING LEVELS OF STAFFING

1 Matching Numbers of Nurses and Patients' Needs, 2010 - 2012

- 1.1 The Matron and the Consultant Nurse for Critical Care and High Dependency told the Review that it was recognised that Ward 32 was a very busy ward. This was due to the numbers of admissions for day cases, admissions from PICU, 'ward attenders' and children who did not require cardiac care, as well as the proportion of children who were under two. It was also, the Review would add, due to the acuity of patients, as discussed above.
- 1.2 Against that background, it is apparent that managing and 'flexing' nursing staff were complex matters. There was a considerable number of variables that affected the need for nursing cover, as has been set out above. They would have required constant, daily attention and 'juggling' by the ward's team and the site managers, through the mechanisms described in Chapter Ten.
- 1.3 Staff were asked about the ability to 'flex' the Ward 32 staffing. They were adamant that it worked effectively. Mrs Hazel Moon, Head of Nursing Women's and Children Division, told the Review that staffing was 'taken into account on a day by day basis'. She explained that 'some of the children that would be on the wards could deteriorate by the nature of their condition' and the best way to deal with this on a day to day basis 'would be determined by the site manager, the matrons, the nurse in charge as to what needed to be flexed in terms of staffing, in terms of patient acuity changes. That's when nurses from other wards may have been drafted in to give that level of support'. A nurse on Ward 32 was able to tell the Review that if it was necessary due to pressures on the ward, 'we'd flex our staffing and we'd look at what else we'd got going on' and this was a manageable system.
- 1.4 The Review sought to examine all the evidence in its possession to assess whether the staff's views were justified; that is, the extent to which the system which we have described above worked in practice. There was no straightforward source of evidence. Whilst examination of ward diaries and staffing rotas gave a reasonable picture of staffing, there was no consistently available information regarding occupancy of beds numbers and the age and acuity of each patient in each bed. Furthermore, these were factors which would have altered from hour to hour.
- 1.5 However, the examination of ward diaries and rotas, matched when possible with information about reported incidents, did convey an overall impression of patterns of staffing on the ward. The Review conducted a detailed study of the period from 16 December 2011 – 30 April 2012. It also looked at data in March 2010, April and 14 July 2011, by way of comparison.

- 1.6 As set out in Chapter Ten, during this period the funded establishment consisted of:
- three registered and one unregistered member of staff Monday to Friday daytime; and
 - two registered and one unregistered member of staff overnight and at weekends
- 1.7 It was apparent that these levels were generally achieved, sometimes with the assistance of Bank or agency staff.
- 1.8 At night-time, there were usually either two registered nurses and one healthcare assistant, or three registered nurses on duty. There were a few nights in which the levels at night were lower. For example, in the period from 16 December 2011 – 20 April 2012, there was one occasion when the two registered nurses present needed help from PICU. There was a number of occasions when there were only two nurses present; or one nurse and an HCA; or a nurse and HCA helped by a member of Outreach. There was evidence of what appeared to be long-term sickness affecting the continuity of staffing at night in February and early March 2012, in particular.
- 1.9 During the day shifts, again there were usually three registered nurses and quite frequently four (and, very occasionally five) on the ward, including at weekends. If there were three nurses, they were usually supported by a healthcare assistant, but this was less likely when there were four nurses. Again, there were a number of gaps, or exceptions or occasions when there was reference to support from another ward, but these were relatively infrequent.
- 1.10 Some of the occasions when there were gaps were the subject of incident reports which gave an insight into the levels of need on the ward. For example, one in mid-February recorded that the levels of staffing at night were ‘unsafe’. There were two trained and one untrained member of staff for a night shift. One of the trained members of staff was new and the second was meant to be supernumerary (not having specific duties), for the purposes of training. Only one member of staff was trained to give intravenous medications. There were 13 patients on the ward; 2 on Vapotherm requiring hourly observations, 2 on nasal cannulae oxygen requiring hourly observations, and two others requiring observations as a result of other needs.
- 1.11 Another incident report related to a day shift, when levels of staff were said to be ‘unsatisfactory for the dependency level of patients and amount of patients on the ward.’ A description of the acute needs of the children on the ward was set out, together with the information that: ‘For a period of the day the ward was at full capacity of 18 beds filled when the ward is meant to only open to 16 beds, for the rest of the day all 16 beds were filled. In the afternoon a junior staff nurse was in charge alongside 2 Bank nurses as the staff rostered to work were off sick. The shifts had gone out to agency but had not been filled.’ As a result, there were said to be failures in the ability of nurses to carry out duties such as observations, timely medication and feeds, as well as responding to parents’ concerns.

- 1.12 It appeared to the Review that, overall, scrutiny of nursing numbers to April 2012 showed that the ward's leaders were generally able to maintain the numbers at the level of its funded establishment (using Bank or agency staff to make up numbers when there was sickness). Furthermore, the ward was moving towards having four, rather than three, registered nurses on duty during the day, on a fairly regular basis.
- 1.13 However, these numbers had to be set against the background of both numbers of children and their needs on the ward. The concern raised by the Expert Panel related to the fact that, when the level of staffing were set in the context of the information about numbers of patients, their age and acuity, as well as factors such as ward attenders and the use of cubicles, the levels of staff appeared consistently low. The Panel took the view that this was not merely a busy environment, but a pressured one.
- 1.14 Analysis of the ward diaries for January to April 2012 suggested that just over 25% of shifts across this period were staffed at the higher levels set out in Mr Booth's email of 18 April 2012 (4 nurses plus 1 health care assistant (HCA) on Early and Late shifts and 3 nurses plus 1 HCA on the nightshift; see paragraph 5.3 of Chapter 10).
- 1.15 From the rotas for Ward 32 provided to the Review, there appeared to a marked increase (about one-third) in the numbers of shifts which met the augmented ratios in April 2012 when compared to March 2012, with the caveat that the increase was almost completely in Early and Late shifts rather than at night. There were further increases in the number of shifts being staffed at the specified ratios in May and June. But despite these increases, in May, June and July a reasonable proportion of shifts did not meet the staffing ratios which were to be put in place 'with immediate effect' from mid-April 2012.⁷⁴
- 1.16 We were told that the role of Ward Sister was supervisory from April 2012. However, rotas and ward diaries at the time show that the Ward Sister was still doing regular clinical shifts in July 2012. Establishing a supervisory Ward Sister was one of the recommendations that the CQC made following its unannounced inspection of Ward 32 on 5 September 2012. We therefore doubt whether this change was fully implemented earlier, notwithstanding what we were told.
- 1.17 The Review's terms of reference required it to consider whether 'the demands on the service, and whether the service had the capacity to meet those demands in a manner which was safe and of an appropriate quality.'
- 1.18 The most appropriate sources of guidance or recommendations appeared to be the RCN's guidance of 2003 and the PICS standards of 2010. Even looking only at the

⁷⁴ We recognise that there is scope for argument upon the exact position from day to day. But we note that the CQC commented as a result of its inspection: 'During our visit on 5 September 2012 we asked for the staff rotas for the four weeks commencing 12 August 2012. These rotas showed a number of occasions when the number of registered nurses on duty was below the trust's planned number. There were nine early shifts i.e. 7.30 am - 2 pm when the staffing level was three registered nurses and one health care assistant. On a number of late shifts i.e. 1.30 pm - 8 pm there were recorded to be two registered nurses and one health care assistant on duty.'

RCN's guidance for general wards, it appeared to the Review that there was evidence that, on a reasonably regular basis, these standards could not have been met on the cardiac ward, in the period to April 2012. We were concerned that, for example, three registered nurses were not adequate to cover a 16-bedded ward which, even when not full, would have had many patients under the age of two. When additional factors such as the effect of higher acuity are also taken into account, the Review felt that the nursing levels would have fallen below the recommended appropriate levels, on a reasonably frequent basis, and that there was a clear risk of harm as a result.

- 1.19 The picture of a ward under pressure was consistent with the picture formed from the Expert Case Reviews. It was apparent that staff worked hard to ensure that (for example) hourly observations were generally carried out. There was concern, however, that they lacked the 'time and space' to reflect on trends; see for example the concerns expressed, in spring 2012, about the staff's ability to identify children who were deteriorating.

2 Documented Events from March 2010 to September 2012

- 2.1 We examined the documents provided by the Trust to see whether what they described was consistent with the impressions about levels of staffing formed from the ward diaries and staffing rotas discussed above.

3 Autumn 2010

- 3.1 An untoward incident took place on Ward 32 in autumn 2010. A child on inotropes⁷⁵ was given the wrong rate of infusion for 24 hours. The child was not harmed, but an incident report acknowledged the potential for harm. It stated 'Poor staffing and skill mix *regularly place* patients and staff in potentially vulnerable situations' (emphasis added).
- 3.2 The incident was fully investigated, including a root cause analysis. The immediate cause of the incident was a failure to follow the Medicines Code, but low staffing and the high acuity/dependency of patients, thereby increasing the workload were said to be contributory factors. It appears that, at the time, there were 13 inpatients on the ward. There were four patients receiving inotrope infusions (two of whom were described as 'unstable') and two patients on vapotherm. There were three registered nurses present, but one of them had only been a team member for 4 months and one was a newly qualified staff nurse who had not completed an 'intravenous study day' and was not authorised to administer intravenous medications. Both junior nurses required support.
- 3.3 As a result of this incident, the need to update the clinical guidelines concerning inotropes and to carry out a risk assessment of arrangements for staffing was identified.

⁷⁵ These are medicines which change the force of a heart's contractions, administered intravenously.

- 3.4 Four more incident reports were made during December 2010 that related to low levels of staffing. Two of these stated that levels of staffing were 'unsafe'. They described a high level of acuity on the ward, nursing staff unable to perform hourly observations and drugs given late. A further 7 incident reports were filed in January 2011. Thereafter there were no further reports until 24th of April 2011.
- 3.5 We were told by the Trust that the procedure was that any event relating to safety and staffing was followed up by a Matron and discussed with the Ward Sister/Charge Nurse to ensure that referral to the appropriate person took place.

4 Ward 32 - Draft Risk Assessment

- 4.1 A draft risk assessment was produced in January 2011. It noted that its origins lay in the incident in autumn 2010. It discussed the needs by way of nursing for those children on inotropes or on Vapotherm. It stated: 'Patients receive inotropes post operatively to increase the blood pressure and support the heart; inotropes are commonly used in intensive care units where patients are nursed with 1:1 ratio. Patients are more likely to be nursed using Vapotherm which allows the delivery of high flows of gas at body temperature with close to 100% relative humidity.... Both procedures require a higher level of nursing care. The recommendation is that patients being nursed with inotropes and/or Vapotherm should be nursed on a 1:3 ratio. Currently the nursing staffing provision for Ward 32 means that nurses are not able to monitor patients being managed using inotropes safely. It also means that the ward is not in a position to comply with Royal College recommendations of nursing children under the age of 2 on a 1:3 ratio.'
- 4.2 The draft also recognised that 'outlier' patients with non-cardiac conditions and the 'ward attender' services further increased calls on staff. 'The ward attenders can significantly add to the patient numbers and further dilute the staffing and increase the demands on nursing staff.'
- 4.3 Various controls were said to be in place to reduce the risk to patients. They included actions such as the review of patients on a weekly basis in meetings regarding admissions; weekly reports on nurse staffing provided to the Head of Nursing Women's and Children's Division and encouraging Bank staff to work on Ward 32. The next steps in relation to staffing were listed as: recruiting new staff; filling deficits in staffing which had been identified; bed meetings to include planning for increases in workload and booking Bank staff in a timely manner to reduce the risk of their not being available if late requests were made. In addition, there was reference to seeking to improve the nurses' competence by rotating nursing staff from PICU to increase their knowledge and experience, 'as planned for in April 2010' and for 'Clinical nurse specialist nurses to support Ward 32 staff'.
- 4.4 The risk assessment referred only the one incident of October 2010. It did not refer to the other incident reports filed between from December 2010 - January 2011.

5 The Trust-wide Review of Nursing

- 5.1 During the course of 2011 a Trust-wide review of levels of nursing staff across UHB was commissioned. It was carried out by Margaret Conroy of Conrane Consulting. At the same time the Trust also carried out analysis of shift patterns across the Trust.
- 5.2 The Conroy review formed a 'backdrop' to events in 2011. It was apparent that there was an expectation that it would address the various areas of difficulty. While it was being conducted, there was an understandable reluctance to tackle any but minor issues.
- 5.3 Mrs Hazel Moon told us: *'any changes to any nursing establishment across the Trust [were] put on hold until that review was completed. It was anticipated, at the time, that there could be many nurses that might need to be redeployed.'*⁷⁶
- 5.4 Mr Booth spoke in similar terms: *'So Conroy came in and then I think every time you alluded to talking about staffing and skill mix it would be well the trust is engaging this external Conroy to do a skill - so we need to see what the outcome of that is.'* Mr Ian Barrington, Divisional Director for Women's and Children's Services, told us that there was recognition that there was an increasing level of dependency on the wards across the Children's Hospital and it was expected that the Conroy Review would consider that. In the event, it did not.
- 5.5 We felt that, from the perspective of children in the Children's Hospital, the Conroy Review was a 'missed opportunity'. There was, from the start, a clear need to ensure that its findings were properly informed by professional nursing advice and capable of commanding support and acceptance from the nurses' leaders within the Children's Hospital. Judging from the reactions to the Conroy Review's recommendations in respect of PICU (where recommended reductions in staff were not accepted nor implemented) and by the fact that it did not engage with the case for higher levels of nursing staff to recognition of the specialist care in children's wards, this did not occur. The result was that at an early stage, staff at the Children's Hospital begun to seek a further review of nursing, designed specifically for the Children's Hospital.
- 5.6 The reasons for the failure to ensure that the perspective of paediatric nursing was clearly reflected in the Review are not wholly clear. We heard that Ms Conroy was advised by a steering group, on which the nurses' leaders from the Children's Hospital, as well as financial officers, were appropriately represented. So there was a structure for these matters to be debated. Yet, given the outcome of the Review, we can only conclude that the voice of the Children's Hospital in it was comparatively weak.

⁷⁶ This perspective was reflected in the minutes of the Cardiac Clinical Governance Group meeting on the 6th of September 2011 where it was stated 'Ward 32 Risk Assessment (update): No change to establishment and waiting on Trust recommendation for standardised shifts'.

- 5.7 We recognise that in response to the need for more specialist assessment of the Children's Hospital, a further review of nursing for the Children's Hospital was subsequently commissioned, and reported in late 2012 (the 'Williams Report').

6 Progress of the Risk Assessment of Ward 32

- 6.1 The Review saw from the minutes of the Cardiac Clinical Governance Meeting on the 8th of March 2011 that Ward 32's Ward Sister (Ms Middelburg) had met the Head of Nursing of the Children's Hospital, to discuss staffing. The minutes record that the 'department' was 'currently underspent on staffing. As they haven't requested staffing, the Head of Nursing assumes that the department is running at its appropriate benchmarked status'. It was anticipated that the draft Risk Assessment would go to the Divisional Management Board in March 'for a decision on whether it would go on the risk register.'

- 6.2 In the event, the draft Risk Assessment was first presented to the Divisional Management Team's Meeting. We were told that this was the first stage for consideration of any risk assessment. The team would consider if the document was completed to the necessary standard and ready for submission to the Divisional Board. The minutes of the Divisional Management Team's meeting on the 16.03.11 record that the issues raised were regarded as complex:

'Ward 32 Staffing – HM. Patient Safety incident – RCA – staffing levels cited as part of the RCA. Increase patients on complex treatment regimes. 1:3 staffing level recommendations, currently 1:4 and 1:5/6 at weekends. Long debate – need for strategic view regarding steer for this type of issue.'

- 6.3 The minute noted that the Head of Governance (Ms Sherriff) was to seek the opinion of Ian Barrington and Dr Jacqueline Cornish, Head of Division for Women's and Children's Services.
- 6.4 Mrs Sherriff and Mrs Hazel Moon, Head of Nursing Women's and Children's Division, told the Review that following the discussion, it was felt that further work was needed on the Risk Assessment, e.g. to quantify the impacts of the 'outlier patients' and 'ward attender service' and to detail measures regularly taken enhance staffing and influence the care of patients. Mrs Sherriff said that she explained, by email, to Dr Alison Hayes, as Governance Lead for Cardiac Services, the need for further work. She also told us that she discussed the risk assessment with Dr Cornish and Mr Ian Barrington, to ensure that they were aware of the concerns being raised and its current status. Mrs Sherriff recollected that the responsibility for taking forward the draft risk assessment was delegated to the Patient Safety Team, whose members attended the Cardiac Clinical Governance Group.
- 6.5 The Review was given undated information with no named author that set out further information in relation to this risk assessment. It contained information about the level of dependency of patients when the incident of autumn 2010 occurred, together with

information on non-cardiac patients and the 'ward attenders'. It set out the number of occasions in the period October to January 2011 when the ward's requests for additional staffing were not filled (20 requests for trained staff were unfilled and 15 for untrained staff). Finally, it referred to the CQC's standards regarding staffing, indicating that compliance was at risk.

- 6.6 Dr Cornish noted that if any risk assessment was judged to be incomplete or needed further work, it would be sent back for further work. This assessment was not returned for further consideration. Her perception was that Ward 32's needs were less pressing than others in the Division and she highlighted pressures on other services. 'I knew that in one month on my own unit in stem cell transplants we had more low staffing incidents logged than cardiac had had in the whole year.' In the first place, the onus was on a service to manage the risk, in conjunction with the site team, as her own unit had done.
- 6.7 Mr Ian Barrington told us that it was recognised that there was an increasing level of dependency on the wards across the Children's Hospital and that it was expected that the Conroy review would consider that, although in the event it did not. He also told us that he accepted that, with hindsight, the risk assessment should have returned to the Divisional Management Team. He added that that he felt the risk may have been thought to be mitigated by virtue of the Trust-wide review of nursing being carried out by Ms Conroy; perhaps because of that it might not have been included on the risk register.
- 6.8 Like Dr Cornish, he was of the opinion that 'there were no concerns about Ward 32 that stood out from the general concerns about how hard everyone was working in the clinical areas.'
- 6.9 Dr Hayes told us that she sent an email to Mrs Sherriff referring to Caroline Haines's work logging the acuity of patients and the fact that this work could be built upon for the risk assessment. But she remembered being told at a later date by the Head of Nursing Women's and Children's Division, Mrs Hazel Moon, that the risk assessment was closed, or that it had been dealt with, and that she queried this.
- 6.10 The perspective that the risk had been 'closed' was reflected in the minutes of the Cardiac Clinical Governance Group on the 7th of August 2011⁷⁷. In relation to Ward 32, the minutes stated: 'Not getting any more staff. Went to divisional board but won't put on the risk register as all wards could have this risk. The group are not happy with this as there is a real risk and are disappointed at the escalation procedure. Caroline Haines is collecting data but dependent on people filling out forms. Trying to standardise shift patterns; may have to change to release more staff without recruitment (5 on days, 3.5 at night and 4 on weekend).'

⁷⁷ The Review noted that there had been no meetings or no notes of meetings of the Cardiac Clinical Governance Group between April and August 2011.

- 6.11 Mrs Hazel Moon said that she met the Ward Sister regularly and supported her in identifying how best to manage the ward. Her view was that mitigating the risks relating to Ward 32 relied on the whole hospital's working as a team to manage the daily workload, with nurses being moved as required. Her view was: *'My recollection was that there wasn't risk in terms of on a day to day running of the ward. The risk was more around the changing needs of patients and the desire, I think, to develop with the high dependency unit which I believe was being recognised at the time or was certainly talked about at the time, around those requirements. On no - it was busy, there were challenges sometimes but on no account do I recall it being unsafe.'*

7 **Cardiologists' concerns regarding staffing of Ward 32**

- 7.1 The Review noted that incidents regarding low levels of staff continued to be logged in 2011, with 2 incidents logged in April, 4 in May, 1 each in June and July and 3 in September. These reports indicated that there were children with higher than usual needs in the ward when staff were short.
- 7.2 The incident report for the 16th of September 2011 was particularly concerning. It stated:

'Arrived for shift as Outreach Nurse for the Children's Hospital. Advised by the Site Manager for the day shift that I would have to work on Ward 32 for the night shift as there was only 1 nurse and one HCA working for the night shift. On arrival to Ward 32 handover was given ... The acuity on the ward was extremely high with 3 patients with chest drains, 1 patient on inotropes, 2 patients on Vapotherm, 3 patients requiring facemask oxygen and a number of patients having been discharged from PICU within the last 48hrs. At this time there were 15 patients on the ward ... From the start of the shift it was very difficult to provide a safe and satisfactory standard of care to the patients on the ward. Not all patients who required hourly observations had these carried out and some of the basic care needs were not met such as the changing of a patient's nappy when this was waiting to be done. Also some patient medications were not given at their prescribed time. I had been informed that a request for agency has been refused by the duty manager saying that the back-up plan of using the Outreach Nurse was an acceptable one. the remainder of the hospital was left without the delivery of an Outreach service and the patients on the Outreach service list had not been reviewed overnight'

- 7.3 Dr Tometzki, Consultant Cardiologist, told the Review that he had raised the issue of staffing on Ward 32 with Dr Cornish and Mr Ian Barrington. He sent an email to them on the 19th of September 2011. It read as follows:

'Ward 32 is brimming with complex patients despite having a quiet week of cardiac catheter admissions. ... I am not sure how much you get to hear about these alerts but the cardiologists are very nervous that the nursing levels are simply too low. There appears to be long term staffing issues of those with cardiac skills (maternity and sick leave I understand) such that the situation is not likely to change in the near future.'

Last week I met with the cardiac liaison nurses and ward nursing staff who raised concerns directly with me. Add to that it appears that [Dr] Garrett continues to provide psychological support to the nursing staff. We have instituted a short weekly ward meeting on Fridays to discuss the previous week's activity and issues plus try to look ahead at workload for the ward in the coming week(s). I hope that will help since we might be able to jiggle day cases in particular.

I have had a parent in the last few weeks mention that when they were in Ward 32 they constantly had to chase staff to give medication. They appreciated they were busy but felt the level of staffing was inadequate though they were appreciative of their care all the same. These incidents with the term 'Low/Unsafe Staffing Levels' are difficult to defend if and when a failure occurs. Do you agree?

- 7.4 We asked Dr Tometzki what happened as a result of his email. He said that he was told that people had been working on addressing the matters raised and that there had been meetings earlier in the year to review the concerns. He was also told that there was work to improve systems such as improving the processes of discharge to strengthen the capacity of the ward to admit patients.
- 7.5 Mr Ian Barrington told us that he asked Mrs Hazel Moon to investigate the matters raised in the email and to talk to Dr Tometzki, after which Dr Tometzki told him he was much clearer about the situation. Dr Cornish also noted that the Head of Nursing had been asked to look into the matters and that, as reported back to her, Dr Tometzki appeared satisfied with the actions being taken.
- 7.6 Mrs Hazel Moon told us that there was only one occasion throughout the whole period of time when one of the senior staff nurses contacted her about levels of staffing on Ward 32 on a particular shift. She said that discussed the issues with the nurse. She also referred to the meeting with Dr Tometzki. They *'talked through what we had been doing. That seemed to satisfy [him] but I don't recall at any other point it being escalated to me as being unsafe. And had it I would have done something about it'*.

8 Appointment of the Matron of Cardiac Services

- 8.1 In September 2011 Mr William Booth took on the role of Matron of Cardiac Services as well as continuing in his role as Matron of Critical Care. Mr Booth told us that prior to taking on this additional responsibility, he was unfamiliar with Ward 32 and did not know the staff in depth. He therefore chose to work clinical shifts on Ward 32 to enable him to observe the care on the ward and gain a picture of the profile of patients. Mr Booth said he felt very aware of the expectation that the Conroy review would consider skill mix and establishments but he wanted to form a view as Matron.
- 8.2 The Trust noted that Mr Booth acted as the Ward Sister's mentor, when he took the role of Lead Nurse for Cardiac Services (see Chapter Twelve). From the information available to the Review, it does not appear that Mr Booth was briefed on the draft Risk Assessment of early 2011, or included in the discussions that arose as a result of Dr

Tometzki's email of September 2011. Mr Booth's appointment represented an opportunity to examine the management of discharges from PICU to Ward 32 (and any necessary readmissions), as well as what support PICU could provide to Ward 32 for complex cases. But, in our view, the absence of a full discussion of the concerns that had been raised meant that he was not as aware of the demands on the ward as he could have been.

9 Reviews of Incidents and Deaths, Winter 2011 – Spring 2012

- 9.1 Between the latter part of 2011 and April 2012, the Review identified four deaths of children and one serious incident in respect of which the Trust's child death reviews (CDR) and or other investigations subsequently identified levels of staff and a failure to spot a deterioration in a child's condition on Ward 32 as contributory factors. The earliest initial investigations into these children's care took place in late March 2012, followed by Child Death Reviews or other forms of investigation between April and October 2012.
- 9.2 The Review noted that this period coincided with the winter pressures on PICU and reduced staffing on PICU due to the controls on vacancies in place during 2011. In Ward 32, a number of incident reports related to the dependency of patients and levels of staff were logged during these months. Two were logged in December 2011 and three in February 2012. A further three were generated in March 2012, albeit all related to the same day.
- 9.3 On the 2nd of February 2012, the minutes of the Children's Clinical Governance meeting record that the risk assessment relating to Ward 32 was discussed. The following day, the Head of Governance emailed the patient safety officer, asking her to revisit and 'revive' the risk assessment in the light of recent developments, including the appointment of the Matron for Ward 32 and the new Ward Sister. If concerns were still identified, the Head of Nursing should be involved.
- 9.4 On the 7th of February 2012 the minutes of the Cardiac Clinical Governance Group's meeting recorded 'Ward 32 Staffing - HDU Report from CH flags that Ward 32 at risk'. This was a reference to the report of the pilot study regarding high dependency care completed in December 2011. The minutes also refer to taking forward the development of the cardiac HDU with commissioners, alongside further work on the risk assessment relating to staffing in conjunction with the Matron and Head of Nursing. They record that a recent bid to the Vacancy Control Panel for additional staffing was rejected. The Ward Sister was to take action to reduce workload by reducing the 'day attenders.'
- 9.5 The Ward Sister told us that she met the Matron and Head of Nursing in February 2012 to discuss her concerns about levels of staffing. She told the Review that the levels were increased to four trained and one untrained members of staff during the day and three trained and one untrained overnight, seven days per week from the middle of February 2012.

- 9.6 However, the minutes of the Cardiac Clinical Governance Group on the 3rd of April 2012 reported that funding had been ‘verbally’ agreed but not yet made available:

‘Staffing –The Ward 32 nurses feel that the site team do not always listen to them when they are talking about transferring patients back from PICU. JH is trying to get the site team to be proactive about requesting second line agency when Ward 32 staffing is unsafe. JH and SB are to meet with William Booth to discuss staffing concerns and develop an action plan. SB confirmed that funding had been verbally agreed for additional staff but she had not received the funding in her budget; and also that amendments to the shift pattern should also help in the resolution of the problem.’

- 9.7 We commented more generally at 1.14 and 1.15 above about the timing of the implementation of the changes outlined in Mr Booth’s email of 18 April 2012.

- 9.8 The minutes of the Children’s Governance Committee on the 5th of April 2012 at which the Head of Nursing referred to a planned meeting about staffing on 17 April stated:

‘Cardiac and PICU – There has been a high amount of both pressure and dependency over the last month. There have been sick children being moved back to the wards from PICU which has led to a higher number of incidents being reported. This has been due to a high demand on PICU beds. We have also been asked to take patients from London and Liverpool. All of the beds are being staffed. The staffing levels are right for normal patient dependency. The higher dependency levels are still to be decided. These concerns have been raised. Ward 32 has vacancies available which can hopefully go to advert quickly. A staffing risk assessment for Ward 32 was completed following a high risk incident in October 2012 [this was a typographical error and should read 2010] and has been ongoing since that date.’

- 9.9 Child Death Reviews for two children whose deaths had taken place in winter/spring were written in April and May 2012. One CDR identified as a concern the recognition of a child’s deterioration on Ward 32; another noted that the patient was discharged to the ward requiring a ‘very high level of support’ and shortly needed to be re-admitted to PICU. Only as regards one of the deaths was a question of staffing identified as possibly contributing to the outcome, but both CDRs had identical entries in relation to concerns over staffing:

‘The following measures have been implemented with immediate effect to address these concerns:

- It has been agreed to staff the ward during the seven days period to 4 Registered Nurses (RN’s) and 1 Unregistered practitioner (NA), and at night a ratio of 3 (RN’s)+1 (NA)
- Short falls on the off duty will be put out to the Nurse Bank and Agency well in advance to increase fill rate success
- Changes to shift times have been made to the nursing rota which will utilise the available nursing resource more efficiently

- The ward nursing staff rebasing exercise, findings to be released shortly, will hopefully address some of the shortfall
- As long term high dependency children are identified e.g. on long term inotropes or complex fluid regimes, an additional request will be made to enable 1:2 nursing for HDU patients (PICS Standards June 2010)
- Improved communication and collaborative working between PICU and Ward 32 to clearly identify the nursing needs of infants and children on discharge from PIC. The impact of moving the more highly dependent child from PICU to Ward 32 must be viewed in the light on the impact of both areas and this may result in delay transfers and impact on the elective cardiac surgical programme
- Patient data will be collected to identify levels of dependency on Ward 32 and feed into work being undertaken across the hospital to look at the future provision of high dependency care
Action: Monitor and audit Ward 32 staffing....'

9.10 These actions were identical to those recorded in an email sent by Mr Booth to the ward's staff on 18 April 2012 (presumably as a consequence of the meeting held on 17 April).

10 Identifying the Deteriorating Child

10.1 An important element of the retrospective analyses of incidents or child deaths in winter 2011 – spring 2012 was the theme of 'failures in the identification of the deteriorating child'.

10.2 The analyses contained a number of threads, including weaknesses in systems for defining 'Early Warning Scores' for the individual child and in identifying signs of deterioration and the need for review by senior doctors. Even when such review was requested, there were concerns that it was difficult to trigger or secure prompt review from doctors in response to any concerns that were identified, or that doctors did not take heed of the nurses' concerns. The weaknesses identified were in our view serious and persistent. They cut across nursing and medical teams, involving a failure both to 'voice' and to 'hear' concerns that were being raised. Ultimately, they led to the development of a substantial programme of work, both to improve the Paediatric Early Warning System (PEWS) and communication between medical and nursing teams on Ward 32. This work is further described in Chapter Fourteen.

10.3 The Review's experts' study of individual children's records led it to identify two further dimensions to the situation described above:

- The numbers of specialty trainees in cardiology were limited (as they were in any cardiac centre in the country). Medical cover was also provided also by those who were attending in cardiology as part of a more general paediatric training, who might need greater levels of support and oversight by the on-call consultant paediatric cardiologists who retained overall responsibility for medical decision-making on the ward. Whilst acknowledging the demands on those consultant cardiologists who provided cover, the Review felt that there was a need for

- greater presence or oversight by senior cardiologist decision-makers on the ward.
- The most common response to concerns about a child's condition, including in response to Early Warning Scores suggesting a need for review, was to seek the advice of a nurse from the Outreach Team. An Outreach Team was a proper person to contact, under the PEWS system. But the Review felt that the choice of adviser had not helped to integrate nursing and medical care, or to foster closer communication between the two teams.

11 The benchmarking study of the provision of high dependency care

- 11.1 During the period 2010 to January 2012, the Operational Manager for Cardiac and Intensive Care Services, Ms Hernandez (who was a formerly a Ward Sister on Ward 32) obtained a scholarship from the Florence Nightingale Foundation to undertake a benchmarking study of the provision of high dependency care in a ward environment for children with congenital heart disease. The aims of the study were to critically evaluate the current pathway for cardiac children requiring high dependency (HD) care in Bristol, benchmark and compare the approach to such care in other centres in the UK and USA, as well as assessing the resources required to implement any changes to the pathway in BRHC. The intention was to use the information gathered to inform the development of services in BRHC.
- 11.2 The context for the work was the impact of HD care on the throughput of the PICU and planning for a potential increase in the number of procedures to be undertaken in Bristol, if selected to provide services following the Safe and Sustainable Review.
- 11.3 The work reviewed six hospitals in the UK including the BRHC and six in the US. The study found variable approaches to the provision of HD care across the UK and the US.
- 11.4 We were told that the Report was completed in January 2012. It described current arrangements and issues regarding the provision of HD care within BRHC. It stated:

'There are currently no specific high dependency areas available within Bristol Royal Hospital for Children and Paediatric high dependency care and care for chronically ill children requiring Long Term Ventilation (LTV) support is often provided at the expense of other services because members of staff are moved from the area they are working in to care for high dependency/LTV patients.

There are children who require high dependency care for general paediatric/surgical conditions, in addition to specialist services who because of the lack of appropriate facilities are admitted to the Paediatric Intensive Care Unit, the only area within the hospital where such care can be currently provided safely.

At times there is the potential that these high dependency admissions may adversely affect PICU bed availability for children elsewhere in the region who require intensive care, and potentially impacts specialist service provision such as the cardiac programme.'

- 11.5 The study noted that ‘children who require higher levels of care in a general ward environment do not currently attract an increased tariff relating specifically to high dependency, and as such the current management of enhanced acuity is unfunded’ and referenced the proposal put to commissioners for a 6 bed medical HDU to be funded from April 2012.
- 11.6 It also made reference to the current level of pressure to move patients through PICU quickly, ‘leaving the ward managing a variable but nonetheless significant proportion of cardiac children with HD requirements, with a nursing workforce that is not currently properly resourced to do so’.
- 11.7 The statement that the Paediatric Intensive Care Unit was the only area within the hospital ‘where such care [i.e., high dependency care] can be currently provided safely’ raised serious concerns with some of the families who contacted the Review. They felt that the care of children needing such care had been compromised and that the position was one which was known and acknowledged within the Trust.
- 11.8 The Review discussed the report with Ms Hernandez and the intention behind these statements. She told the Review that the statements reflected the position that those children who met the commissioned criteria for high dependency care, were cared for in PICU; that this group of patients were distinct from those who had increased nursing needs or ‘higher’ dependency or greater acuity; some of these might be on the wards, outside PICU. We have previously discussed the confusion around these terms in the previous Chapter.
- 11.9 We felt that the report was further evidence of the fact that there was ‘a variable but nonetheless significant proportion of cardiac children with HD requirements’ on a ward that was not resourced to provide care on such a basis. But we noted, more generally, that the work on this report was not finished until early January 2012. It appears to have been used, if at all, to inform the thinking around the bids for a high dependency unit which were pursued at that time. It does not appear to have been presented or discussed in any formal governance structure. Overall, the report seemed to the Review to add little to the information contained in material such as the further risk assessment which is discussed below.

12 A Further Risk Assessment – ‘Higher Dependency Needs’

- 12.1 A further risk assessment (numbered Risk Assessment 1901) concerning the model of care across the whole of the Children’s Hospital was set out on the 9th of February 2012. This noted the ‘Risk of a reduction in the quality of care for patients in children’s hospital when the number of children with higher dependency needs exceeds the level planned and staffed for.’ The document stated that children ‘with highly dependent needs’ (a broad term) are currently managed across the whole hospital ‘with the nursing staff supported by outreach team. Whilst this model is functional for a small number, when the ratio of highly dependent patients increases nursing resources are pulled in from other areas ... This results in an adhoc system of delivering care to a

cohort of patients who have high dependency requirements and who require a high level of monitoring, intervention and nursing ratio. This results in frequent reductions in total bed base, reliance on temporary staffing and an inherent risk of compromised care.’ The risk was said to be ‘high’, although steps to manage it were set out, both by deploying staff and through discussions with commissioners.

12.2 The risk was included in the risk register for the Women’s and Children’s Division dated 28 March 2012.

12.3 The Review was told that Risk Assessment 1901 was put in place to support the bid to commissioners for a high dependency unit. It was set out at the same time as the steps to strengthen the provision of care on Ward 32, discussed above, were being developed.

12.4 In March 2012, the Divisional Management Board noted that the bid for high dependency funding had not been successful. In early May, it noted that Dr Fraser had proposed ‘a short life working group, to model our beds against current pathways. Over the next 2 years this will form our discussion with local/Welsh commissioners.’ The next meeting, in early July noted the ‘Changing picture of patient complexity - long stay complex patients prevalent in hospital. Longer term planning needs to acknowledge this changing picture. Short term pressure remains the issue.’

12.5 Placing this issue on the Divisional Risk Register was an important step forward in raising the profile of the concerns. It is plain that the issue of securing commissioned high dependency care was receiving much attention, in spring 2012. What we saw less of, was evidence of rigorous scrutiny of the risk assessment within the Divisional processes of governance. Specifically, we did not see discussion of the efficacy of the steps being taken to mitigate the known ‘short term pressures.’ In our view, the need for discussion and assurance upon these steps was increased when it became clear that the bid for high dependency funding would not be successful in the 2012/2013 funding round.

12.6 At a Trust level, the risk was listed as one of six ‘risks newly escalated to the Corporate Risk Register’ in the paper upon the Corporate Risk Register for the Board meeting on 30 April 2012. In this paper, it was described as ‘Risk 1901 – Lack of sustainable model of service delivery for children with high dependency needs.’ The minutes of the meeting do not record any specific discussion of this risk, although others were the subject of detailed discussion by the Board. It was discussed by the Trust’s Quality and Outcomes Committee in March 2012⁷⁸ and the Management Executive in June 2012.

12.7 So far as we were able to see, it was not picked up for further or more detailed discussion by the members of the Trust Board before September 2012. With the

⁷⁸ In response to a query relating to Risk 1901, the Assistant Director of Governance and Risk Management directed the Committee to the action being taken by the Women’s & Children’s Division.

benefit of hindsight, it is easy to see that as a result Board members were unprepared for the findings of the CQC's inspection. But there was nothing in the papers which would have signalled that Risk 1901 needed closer scrutiny and attention at Trust Board level.

13 Conclusions

- 13.1 The most appropriate sources of guidance or recommendations on levels of nursing staff were the 2003 RCN's guidance and the 2010 PICS' standards. As regards the nursing establishment in the light of numbers of patients, their ages, their need for specialist care and the increasing acuity of patients, the Review felt that the levels of nursing care would have fallen below the recommended appropriate levels on a reasonably frequent basis, and that there was a clear risk of harm as a result.
- 13.2 The picture of a ward under pressure was consistent with the picture formed from the Expert Case Reviews. It was apparent that staff worked hard to ensure that the children received proper attention, so that (for example) hourly observations were generally carried out. There was concern, however, that they lacked the 'time and space' to reflect on trends in the clinical status of the children they were caring for, as illustrated by the concerns expressed, in spring 2012, about the extent of the nursing staff members' ability to identify children whose condition was deteriorating.
- 13.3 There were a number of opportunities to take stock and assess the adequacy and safety of the model of care on Ward 32, prior to the CQC's visit of September 2012. In both early 2011 and 2012, there were attempts to secure funding for high dependency beds in the BRHC. But the focus of the Review was on whether there had been attention paid, not only to the desirability of improvement, but to the adequacy and safety of the existing model of care, whilst awaiting the support of Commissioners and before any changes could be introduced.
- 13.4 By late 2011, there was information available in the form of the draft risk assessment for Ward 32 (January 2011). This, together with details of incidents relating to 'low' or unsafe staffing on the ward, and the expressions of concern voiced by members of the Cardiac Clinical Governance Committee, and in Dr Tometzki's email of September 2011, further suggested the need for review.
- 13.5 By April and May 2012, a number of incidents had prompted further consideration, both of the staff's ability to recognise children whose condition was deteriorating and of the adequacy of levels of nursing staff. Steps to increase these levels were outlined in an email from Mr Booth in mid-April 2012.
- 13.6 Critics of the hospital might ask whether the steps set out in this email were 'too little, too late'. As to whether or not too little was done, it seemed to us that the steps set out in the email were reasonable ones, particularly when linked to the further steps outlined in the investigations or CDRs which followed shortly thereafter. The Review

noted, however, that the intention had been to audit these changes. This does not appear to have occurred. The Review considered that this should have taken place at the time, as planned. In its absence, there was a dearth of information about exactly when the changes described took effect, and their efficacy. We felt that this mirrored the lack of attention, at a Divisional level, to assuring the effectiveness of steps to manage the risks detailed in Risk 1901.

- 13.7 Perhaps more complex was the issue of whether such steps were 'too late', i.e., whether they could or should have been taken more quickly. We have noted events of concern in late 2011/early 2012. But it took a few months for clinicians to gather together the relevant information, and for a review to take place; post mortems might also need to be carried out. We felt that, rather than focussing on this period of time, our primary concern remained the failure to complete a proper risk assessment in late 2011. It was at this point that an effective evaluation of the risks on Ward 32 could, and in our view should, have been carried out.

CHAPTER TWELVE: GOVERNANCE AND LEADERSHIP

1 Management and Governance of the Women's and Children's Division

- 1.1 Clinical governance is the system of assurance and scrutiny in relation to clinical quality and safety in NHS organisations.
- 1.2 The systems of clinical governance in the children's cardiac service, the Women's and Children's Division and upwards to the Trust's Board were a significant focus of the information requested from the Trust and our discussions with the Trust's staff. Our terms of reference required us to consider 'the operation of reporting and the use of information within the Trust at, and below, the level of the Board'.
- 1.3 The Division of Women's and Children's Services was one of six Divisions in the Trust. Managerial and clinical responsibility for each Division rested with the 'Head of Division', who reported directly to the Chief Executive. The Head of Division led the executive management of the Division and was accountable for the clinical, operational and financial performance of the Division.
- 1.4 Dr Jacqueline Cornish was Head of Division for the Women's and Children's Division from 2005 until March 2013. Dr Cornish maintained a clinical position as Consultant in Paediatric Stem Cell Transplant and was additionally Director of its Transplant Unit. Her role as Head of Division was allocated four sessions per week (the equivalent of 2 days per week).
- 1.5 The Head of Division was supported by a team of staff in various clinical and managerial disciplines who reported to her. Those most relevant to the Review were the posts of Head of Nursing, Divisional Manager, Clinical Governance Lead and the Lead Doctor for Paediatric Intensive Care and for Paediatric Cardiac Services.
- 1.6 In summer 2013, the structure of all the Trust's Divisions was changed following an external review of their efficacy. New posts of Clinical Chair and Divisional Director were created. The Clinical Chair had responsibility for the governance, maintenance and improvement of standards of clinical quality and professional leadership throughout the Division and chaired the Divisional Board, while the Divisional Director had responsibility for business planning and operational delivery.
- 1.7 Dr Bryony Strachan was appointed Clinical Chair and Mr Ian Barrington Divisional Director.
- 1.8 The role of Lead Doctor was replaced by that of Clinical Director.
- 1.9 Throughout the period covered by the Review, the business of the Division was overseen by the Divisional Management Board, chaired by the Head of Division and

latterly by the Clinical Chair. Relevant Committees reporting to the Board were the Children's Executive Committee and the Quality Assurance Committee.

2 Leadership of Clinical Governance at the Level of the Children's Cardiac Service

- 2.1 The business and governance of each service was carried out through a 'business meeting' and a 'governance meeting' of each specialty. The Governance Group for children's cardiac services was the Cardiac Governance Group.
- 2.2 There were four medical roles with responsibilities for governance below the Head of Division. These were:
 - Lead Doctor of PIC and Paediatric Cardiac Services
 - Clinical Lead for Cardiac Services
 - Clinical Lead for Paediatric Cardiac Surgery
 - Governance Lead for Cardiac Services
- 2.3 The 'Lead Doctor' was Dr Fraser, Consultant in Paediatric Intensive Care, from 2010 until May 2013. He was succeeded by Dr Sale, Consultant in Paediatric Anaesthesia (in the new role as Clinical Director), until July 2014, when Dr Jenkins, Consultant in Paediatric Anaesthesia and Intensive Care took up the role.
- 2.4 We note that the Lead Doctor/Clinical Director played a prominent role in developing the structures and the methods of clinical governance whereby key incidents in the Children's Hospital were scrutinised. In particular, Dr Fraser was a key figure in ensuring detailed investigation of all deaths of children, through the Child Death Reviews. Furthermore, in April 2011, he and Dr Sale produced substantial new guidance (the 'Risk Management Protocol'), defining the responsibilities of the groups with responsibility for clinical governance in the Children's Hospital.
- 2.5 The Clinical Lead for Paediatric Cardiac Surgery was Mr Parry. This was a role created in June 2011, and was subordinate to the Clinical Lead for Cardiac Services.
- 2.6 There was inconsistent information regarding who held the other roles over the period 2010 to 2014. We were initially told that the Clinical Lead for the Cardiac Service was Dr Tometzki, from 2006/7 until January 2012, when the role was transferred to Dr Hayes, a fellow Consultant Cardiologist. But the minutes of the Cardiac Programme Board in July 2011 record that Dr Tometzki had resigned from the role of Lead Clinician; the role was handed over to Dr Hayes by mid-October 2011.
- 2.7 However, the Trust also told us that Dr Hayes was absent due to ill-health from February to September 2012 and that during that time Dr Tometzki covered the role informally, until Dr Hayes resumed it and continued in post until December 2014 when, once again, Dr Tometzki took it on from January 2015.

- 2.8 The Trust told the Review that the Governance Lead for Cardiac Services from 2008 until January 2012 was Dr Hayes. From January 2012, it passed temporarily to a newly appointed consultant cardiologist, Dr Walsh, until Mr Parry, Consultant Cardiac Surgeon, took it up from June 2012 onwards. Mr Parry was also the Clinical Lead for Paediatric Cardiac Surgery, from June 2011, from when the post was established, onwards.
- 2.9 Documents examined by the Review indicate that there was, however, a gap in filling the role of Governance Lead in late 2011 – early 2012, and concerns about the ability of the Cardiac Governance Group to function effectively as a result.⁷⁹
- 2.10 Despite the absence of a Governance Lead, the Review noted that meetings of the Cardiac Governance Group did take place in September and November 2011 and in February, April and May 2012. That said, the meeting in May 2012 had no medical staff in attendance and there was, in general, no consistent attendance by any member of medical staff.
- 2.11 The Review has drawn attention to this situation in some detail because the period from late 2011 – mid 2012 appeared to it to be a key period, during which the cardiac service was under great pressure.
- 2.12 We note that in his review of risk management and the safety of patients produced in May 2011, Mr Derek Hathaway commented that challenges remained in getting medical staff to participate fully in the reporting and investigation of incidents and RCAs; he noted comments by staff about the time taken to carry out such work. Dr Hayes told us that the work of Governance or Clinician Lead often took up more time than the session allocated to it in her job plan, or that of Dr Tometzki. The Bristol Public Inquiry had recommended that ‘Where clinicians hold managerial roles which extend beyond their immediate clinical practice, sufficient protected time in the form of allocated sessions must be made available for them to carry out that managerial role.’ It was apparent that securing ‘sufficient’ time, in a busy and complex service, was a challenge.
- 2.13 Challenges in securing medical engagement and leadership in clinical governance were not, and are not, unique to the Children’s Hospital in Bristol. We further accept that medical staff ‘pitched in’ and sought to address emerging issues. But it appears to the Review that there was an absence of clear or sustained leadership at this important point in time.
- 2.14 In 2013, the Trust took action to support clinicians in cardiac services and to develop skills in leadership. In 2011, it is apparent that as Lead Doctor, Dr Fraser was aware of gaps in the structure of governance and tried to take steps to cause them to be filled.

⁷⁹ See the minutes of the Cardiac Governance Group on the 7th of August 2011, and the minutes of the Quality Assurance Group on the 20th January 2012 and the minutes of the Cardiac Programme Board of the 21st February 2012 and 13th March 2012, which document concerns.

Dr Cornish also offered mentoring and informal support to leaders in the Cardiac team over this period; proportionately more than to any other of the 35 clinical services in the Division, she told us. It was apparent that, therefore, the problems of engagement and leadership were recognised and attempts made to address them. But the Review remained concerned that there was a heavy reliance on the Patient Safety Team, in the absence of more consistent clinical engagement.

3 Team-working and clinical leadership

3.1 The Review heard that the Trust's leadership were aware of concerns about how well those providing cardiac services operated as a team, and about the strength of clinical leadership. These concerns were noted following investigations into events which took place across 2012. They led to the development of a formal plan to develop the team and team-working in April 2013.

3.2 The matters identified were, in summary:

- an absence of strong clinical leadership, both nursing and medical;
- insufficiently robust or systematic methods of communication and handover between clinicians, for example in ward rounds or at the night-time handover;
- poor standards of clinical documentation;
- weaknesses in the systems for referring on or escalating clinical concerns;
- weaknesses in team-working and support for colleagues, whether between members of the medical team (senior or more junior), or between nurses and members of the medical staff.

3.3 These concerns related in the main to the cardiology team and Ward 32 although there were some matters regarding handover from PICU to Ward 32, the functioning of the JCC and the relationship between the cardiology service overall and the hierarchy in the Women's and Children's Division.

3.4 The observations contained in these investigations are consistent with the Review's analysis of the position from 2010 – 2012, based on its review of documents and discussions with staff. We referred at in section 10 of Chapter 11, for example, to the support that the Review perceived was needed by specialty trainees providing middle grade staff cover on the ward.

3.5 It is, however, important to place the concerns in the context of the pressures on the service as whole. These pressures included:

- the high demands placed on the cardiology team, who were described by a senior clinician from PICU as 'under resourced and over-stretched', and having to manage a number of departures and additions to their number;
- pressures on the nursing team;
- turnover in nurses' leaders;
- the financial pressures on the Women's and Children's Division.

- 3.6 As indicated above steps were taken, starting in 2012 and continuing into 2013, to address these matters.

4 Leadership of Nurses on Ward 32

- 4.1 The Review heard from a number of members of staff that Ward 32 had not had stable leadership over the period 2010 to 2014, and this was felt to have had an impact on the care provided.

'I don't think that's been helpful at all because there's been a lack of continuity of a stable senior nursing figure on Ward 32'. (Mr Booth)

'I think one of the problems on the ward was that the nursing leadership did vary quite a lot through this period and that had its issues, I think.' (Dr Hayes)

- 4.2 The usual structure for staff is to have a Ward Sister who reports to a Matron who has responsibility for a number of wards. The Matron then reports to the Divisional Head of Nursing.
- 4.3 The Review was told that the Matron who was in post from June 1999 left in September 2010 and the Ward Sister left in July 2010. Ms Middelburg, who was until then, a Sister on PICU was then appointed as 'lead nurse for cardiac services and sister for Ward 32'. She held this post until January 2012.
- 4.4 The Review found that it was unclear who filled the role of Matron from September 2010 until September 2011. The outgoing Matron believed that she handed over to the Matron for Critical Care, Mr Booth. He told us that Ms Middelburg went to Ward 32. She was promoted up to an 8A post, a matron post: '... she would run Ward 32, have responsibility for the cardiac nurse specialists and there wouldn't be a matron covering her but I would support her from a distance.' Mr Booth therefore was her mentor.
- 4.5 In September 2011, Mr Booth himself took up the role of Matron for Cardiac Services and Critical Care.
- 4.6 In January 2012 the role of Ward Sister was taken over by Sarah Britton until August 2012 when the role reverted to Ms Middelburg. In August 2013 Sarah Britton returned to the post after a period of leave. The post-holder changed again in July 2014 with Zoe Trotman taking up post.
- 4.7 The inescapable impression was that Ward 32 had suffered from the lack of strong and stable leadership for some time.
- 4.8 The changes in the leadership of nurses on Ward 32 weakened the relationship between medical and nursing staff. In addition, the absence of a Ward Sister whose

role was supervisory rather than 'hands-on' until a point during 2012⁸⁰ meant that that it was more difficult to attend the ward rounds and to ensure close working with the medical team. This coupled with the busy nature of the ward, inconsistency in the timing and approach to ward rounds by medical staff, meant that there was limited input from nursing staff to ward rounds during the period 2010 to 2012, as well as reduced feedback to nurses from other members of the care team.

- 4.9 The availability of a senior nurse to meet senior medical colleagues and regularly discuss care of the patients is critical for developing the team and sharing accountability for setting and maintaining standards.

5 Oversight by the Cardiac Clinical Governance Committee

- 5.1 The terms of reference of the Cardiac Governance Group⁸¹ set out that it was expected of this Committee:

- to reflect on governance and patient safety issues as they arise within cardiac services
- to provide encouragement and leadership with regard to clinical governance in cardiac services
- to regularly review and discuss the patient safety incidents in cardiac services
- to risk assess issues that are assessed as being a risk to safety within cardiac services
- to ensure that lessons are learnt and disseminated to all staff
- to monitor compliance with all of the above.

- 5.2 In April 2011, alongside the review of corporate governance in the Trust, new guidance entitled the 'Risk Management Protocol' was issued by the Women's and Children's Division. This set out the responsibilities of the groups charged with governance along with a recommended standard agenda and terms of reference.

- 5.3 The document set out the expectation that that each clinical governance group would be the primary forum for all discussion and action relating to clinical governance, the safety of patients and risk management within a speciality. It would take over the work previously undertaken in the 'patient safety forum', which would cease in its current form. Clinical governance groups were expected to meet on a planned and regular basis. Specific objectives were to ensure that clinical teams took responsibility for all risk assessments and RCAs relating to their speciality, including responsibility for actions arising from risk assessments and RCAs.

- 5.4 At the beginning of the period covered by the Review, documents showed that the Cardiac Governance Group met 5 times in 2010 and 4 times in 2011. Regular monthly meetings were in place from June 2012 onwards. From such minutes, it was clear that

⁸⁰ See the discussion in section 1, Chapter 11.

⁸¹ Document presented to the Group in February 2010.

the Group did discuss incidents, risk assessments and RCAs at most meetings, and followed up whether required action was taken.

- 5.5 However, the Group struggled to push the draft Risk Assessment for staffing on Ward 32 (January 2011) to an effective conclusion. It failed, for example, to pull evidence together from a variety of sources to inform the assessment of risk.
- 5.6 The draft Risk Assessment was prompted by an error with an inotrope infusion in October 2012. The risk assessment referred only to this one incident.
- 5.7 The next meeting of the Governance Group was on the 8th of March 2011; the minutes record that the risk assessment is discussed. However, no reference was made to the eleven incident reports raising concerns over staffing, made between October 2010 and the meeting in March 2011. Nor was information presented to analyse the level of risk relating to unfilled shifts, after the service had requested, but not secured additional staffing.
- 5.8 Further incident reports concerning low levels of staffing continued to be made: two in April, three in May, one in June and three in September.
- 5.9 We appreciate the difficulties of later relying on short written minutes as a source of information. But, on their face, the minutes give no assurance that consideration was given to the 'full' pattern of events on the ward. It may be the case that all present were well aware of the situation and discussions were not recorded. However, the issue was, at least in part, how the risk was presented to the Divisional Management's team. Ensuring that all the available information on the ward's level of staffing was gathered together and formally recorded formed part of making that case.
- 5.10 In addition, the Review noted that the classification of risk in the draft risk assessment was questionable. The risk assessment for Ward 32 records the residual risk score after the impact of mitigating actions is taken into account as 'low' based on 'high effectiveness of controls'. But it is arguable that the residual risk was higher, because the section of the form relating to the 'effectiveness of controls' stated that the effectiveness of the mitigation was 'low'. Plainly, this was a draft document only and subject to review and correction. But it needed to be properly finished.
- 5.11 The Review felt that our observations were consistent with the findings of a review of the culture of patients' safety in the Children's Hospital commissioned by the Clinical Chair and Divisional Director in May 2013. This recorded, amongst other things, comments that staff were put off reporting risks because they were unsure about what should be reported, and in categorising and grading risks.
- 5.12 The next meeting of the Governance Group after the 8th of March did not take place until 7th of August 2011 when the notes of the meeting record that incidents report were 'not discussed'. The minutes of the meeting on the 6th of September 2011 record only

one incident being discussed, this was an incident from July concerning the competence of a health care assistant sent to support the ward who had only been in post a short time.

- 5.13 Whilst the Review found the incident report for the 16th of September 2011 particularly concerning, see Chapter 11, section 7.2, it was shortly after this that Dr Tometzki wrote to the Head of Division and Divisional Manager regarding his concerns about staffing levels. We have set out in Chapter Eleven, sections 7.3-7.6 what staff have told us of what followed.
- 5.14 Apart from these exceptions regarding reporting incidents and risk assessment relating to Ward 32's staffing, once the regularity of the meetings was addressed, along with a better level of attendance from mid-2012, the information received by the Review suggested that the Cardiac Governance Group fulfilled its function properly.

6 Divisional Consideration of Ward 32's Risks

- 6.1 At the Women's and Children's Divisional level, there were, broadly, three routes by which concerns relating to the standard of care on Ward 32 might have reached the Divisional leadership of the Women's and Children's Division, judging by the written information seen by the Review relating to the period from late 2010 – early 2012. One route was the draft Ward 32 risk assessment, another was through the incident reports relating to shortages in staffing or poor skills-mix on Ward 32, and the third was through the concerns raised directly by clinicians. We have described each of these. We also noted that the issue of risks related to high dependency care was raised by a paper, 'High Dependency Care in the Children's Hospital', considered by the Divisional Quarterly Review in July 2011.
- 6.2 We consider now what happened as regards the information which reached the Divisional Management structure through each of these routes.

7 Ward 32 – The Draft Risk Assessment

- 7.1 We reflected that the history of the draft Ward 32 Risk Assessment showed that systems of governance were under-developed. Once a draft Risk Assessment had been presented to the Divisional Management Team, it should have been followed up. There was a clear failure on the part of that Team to ensure that the draft document was brought back for further discussion, and that a clear and properly documented decision relating to it was taken by the Divisional Management Board.
- 7.2 The minutes of the Divisional Management Team's meeting suggest that it was thought that the issues raised by the draft Risk Assessment were complex. Yet, despite the recognition that a 'strategic view' was needed, the issue did not receive the direct attention of the Head of Nursing nor the Head of Governance, but was delegated to the Patient Safety Officer to pursue with the Ward Sister. The delegation was on the basis that the draft needed 'further work', but the issue identified in the minutes of the discussion was of a different order.

- 7.3 Even accepting the need to develop the draft further and the fact that the Patient Safety Team were in a good position to liaise with the Cardiac Clinical Governance Group to do this, there was an absence of clear guidance or leadership on the steps that needed to be taken, and by whom. At the time, there was work being done on the changing patterns of need in the Children's Hospital, e.g. by Dr Haines. This should have been used to strengthen the Risk Assessment. If the level of risk was in doubt, it could have been further assessed, with closer scrutiny of incidents on the ward and of the levels of requests for staff that had gone unmet. As it was, supplementary information to support the risk assessment was provided and the risk of not complying with CQC's regulatory framework was raised, but the draft was not re-presented nor discussed by the Divisional Management Group or Board.
- 7.4 The absence of explicit follow-up or a clear decision on the draft Risk Assessment created a situation in which staff at the level of the ward, including those sitting on the Cardiac Clinical Governance Committee felt 'rebuffed' and perceived the signal that no changes would be made to the underlying establishment of staff; whilst those with positions of leadership assumed that the Cardiac Group had not pursued the assessment as they were satisfied with the current steps being taken to review and support nursing staff.
- 7.5 We noted that in the report of the review of risk management in the Children's Hospital in June 2014 carried out by Ann Utley, it was observed that 'There is not a strong discipline around risk assessments and there is a sense that when risks are too tricky or an owner can't be identified then the natural default setting is to delay or abandon the risk assessment.' (page 15). This seems an apt description of the fate of the risk assessment for Ward 32.
- 7.6 The Trust told us that, since 2012, a new risk management and reporting system has enabled the tracking of draft risk assessments at all levels, and there is regular review of such 'pending' risks by the Divisional patient safety team.

8 Concerns by Staff

- 8.1 We have noted how Dr Tometzki raised concerns about levels of staff in Ward 32 in September 2011. The Head of Nursing Women's and Children's Division was asked to speak to him.
- 8.2 The Review felt that the email from Dr Tometzki should have prompted re-consideration of the earlier draft Risk Assessment and its progress, or lack of progress. The email was, in part, an expression of concern about the message received by the Cardiac Clinical Governance Group's meeting, that 'Ward 32 would not be getting any more staff'. It appears to us that the response to the email focussed on providing reassurance to Dr Tometzki, rather than any real analysis of the concerns that he had raised or the adequacy of the current 'mitigation' in place on the ward.

- 8.3 Such a review, at this point, could have provided the opportunity to react before late 2011, and before the likely effect of ‘winter pressures’ on PICU made spaces on PICU a yet more precious resource.

9 The Case for High Dependency Care in the Children’s Hospital

- 9.1 In July 2011 a paper regarding High Dependency Care in the Children’s Hospital was presented to the Divisional Quarterly Review Meeting with the Trust Executives. The Chief Nurse and Director of Corporate Development attended the meeting along with the Head of Division, Head of Nursing and Divisional Manager. In the paper the position regarding high dependency care is described as follows:

‘For some time, there has been a strong view from the clinical teams within Children’s Services that the absence of a High Dependency facility and, as a result, the amount of high dependency care that is being provided on the general wards is a key clinical and financial issue. High dependency care on ward areas requires greater nursing intervention, consumes more resources and can impact on length of stay. This is currently not recognised, except for the high dependency outreach team funded through a block contract.’

- 9.2 The report goes on to say ‘On the 14th July 2011, a ‘snapshot’ of the patient dependency levels of all inpatients was undertaken at the Bristol Royal Hospital for Children (see attached). This snapshot captured the number of inpatients and categorised dependency as those patients who required either: 1:1 nursing, 1:2 nursing, 1:3 nursing or 1:4 nursing. On this date, over 30% of all inpatients (excluding PICU patients) required 1:1 or 1:2 nursing.’
- 9.3 The data indicated that of the 17 patients on Ward 32 on that day 2 required 1:2 care and 15 1:3 care. The recommendation was to pursue with commissioners a local tariff uplift for high dependency care. The papers for the October meeting show that a decision was made to put forward a bid for a 4 bed HDU.⁸²
- 9.4 It appears that the discussion at the meeting focussed on securing funding for development. As set out in the minutes circulated in October 2011, a decision was made to put forward a bid for a 4-bed High Dependency Unit. This resolution was followed through in the commissioning bids for the financial year that followed.
- 9.5 This step was clearly an important one. But what appeared to us to be missing, were questions about how the existing risks revealed by the paper were being managed, or whether such mitigation would be affected by the further decisions taken at the meeting, to manage costs. The papers implied that, to the extent that higher dependency care was being provided, it was being achieved through the increased use of Bank and agency staff. But it was also apparent that the Division faced a challenging

⁸² There was wide attendance, including from Ms Lee, Ms Alison Moon, James Rimmer, Paul Mapson (Director of Finance and Information), Dr Cornish, Mr Barrington and Mrs Hazel Moon

- financial situation. In response, a number of initiatives aimed at financial recovery were approved in principle.⁸³ These included a ban on agency staff, with exceptions to be approved by the Head of Nursing or Head of Division.
- 9.6 In those circumstances, the Review felt that, first, there was a need for formal assurance that existing levels of care provided for children with higher dependency needs were sufficient and safe, and second, that they would be not compromised by the financial measures agreed at the meeting. The mechanism for both would have been a formal risk assessment. Without such an exercise, there was a danger that the effects of the financial initiatives which had been agreed would not be properly assessed or understood.
- 9.7 In making this assessment, the Review bore in mind that the discussion at Divisional level followed closely on the presentation of the draft Ward 32 Risk Assessment. Its existence was known to the leadership of the Women's and Children's Division (although not to those of the Trust's Executive who were present).
- 9.8 The Review felt that there was a failure on the part of those attending this meeting to identify or address these wider issues. It felt that the course of events at this meeting was an illustration of a theme later noted in the Utley report, which records: 'A more proactive approach to risk management is required ...' and later: 'The commonly held view is that the hospital is not good at proactively recognising clinical risks.'⁸⁴
- 9.9 Concerns regarding acuity were highlighted again in December 2011, when the results of the study on high dependency care were reported. This showed that Ward 32 dealt with particularly heavy demands. There were poor rates for meeting the needs for Bank staff across the Division.⁸⁵ Reports on the reasons for using Bank and agency staff were showing an increasing proportion of use was due to clinical needs, rather than sickness or short term cover, between November 2011 and June 2012.
- 9.10 Overall, the Review considered that the information available should have prompted a re-assessment of risk associated with the model of care both for the cardiac service and for the Children's Hospital as a whole. Instead it appeared that the response, at least until spring 2012, focussed on the development of a bid for funding to local commissioners.
- 9.11 We have seen how, in February 2012, a risk was formally noted with regard to the absence of high dependency care in the Children's Hospital; this was the risk assessment numbered 1901. (See Chapter Eleven). We have commented that this risk assessment did not generate further scrutiny of the adequacy of the mitigating steps that were in place.

⁸³ Trust staff pointed out that cardiac services were protected from a number of these measures, which we accept. However, our concern was the potential effects of the constraints on the use of bank and agency staff on the Ward.

⁸⁴ BRHC Risk Management Review (2014), pages 4 and 15.

⁸⁵ See the workforce report to the Divisional Quarterly Review meeting in January 2012.

10 Monitoring 'Low risk' and 'No Harm' incidents 2010-2012

- 10.1 The third source of documented information about levels of staffing on Ward 32 were the electronic incident forms filled in by staff which mentioned low levels of staffing, poor skills-mix or a lack of safety on the ward. One feature of these reports was that they were classified as 'low risk' or 'no harm' incidents. They stood in contrast to reported 'high risk' or serious incidents, which were automatically reported to the Divisional Quality Assurance Committee and to the commissioners (as set out in Chapter Three, para 4.7). We saw evidence of extensive investigations of such serious incidents (see, e.g. the discussion of the error in theatre in 2011 at Chapter Seven, para 8.8), as well as of systems for monitoring matters on the Divisional and Trust Risk Registers.
- 10.2 We sought to establish the systems for looking at 'low risk' incidents.
- 10.3 We were told that the immediate response to unsafe events would be that each was followed up by a Matron and discussed with the Ward Sister or Charge Nurse to ensure that appropriate reference up through the system took place.
- 10.4 The Hospital's Chief Nurse (Ms Alison Moon) told us that the review of 'low risk' and 'no harm' incidents was an important aspect of quality assurance; it enabled any trends or patterns to be identified. She told the Review that the policy regarding incidents which was in place from 2008 - 2011 required each patient safety lead at Divisional to review all its 'low risk' and 'no harm' incidents on a quarterly basis, and to present this to the Divisional Board. These patient safety leads were also members of the Trust-wide Clinical Risk Assurance Committee (subsequently the Patient Safety Group), chaired by the Medical Director.
- 10.5 The Head of Governance told us that monitoring 'low risk' and 'no harm' incidents was a responsibility delegated to the Clinical Governance Group for each service. A monthly report was prepared by the Patient Safety Team and circulated to the Governance Lead for each specialty. She told the Review that the Divisional Quality Assurance Committee would review serious incidents. In addition, there was a standing item on the agenda for the monthly Children's Governance Group to receive reports on incidents and a rotational requirement for the Governance Lead from each service to report their key findings or concerns.
- 10.6 The final level of oversight in the Division was the Divisional Board. Meetings of the Divisional Board were held roughly bi-monthly during 2011 but fell away in 2012 with only 4 meetings being held, in January, May, July and November. From 2013 onwards meetings were held monthly with very few exceptions.
- 10.7 The Divisional Board received a 'Governance and Performance Report' at each meeting, which included a report on incidents. However, the reports prepared during 2010 and 2011 were high-level reports at Divisional level, indicating matters such as the number of incidents according to their severity (e.g., 'near-misses' across the

Division). There was detailed information only about serious incidents. The cardiac service attracted the Divisional Board's attention only when there were high risk incidents and RCAs.

- 10.8 The Review examined the report to the Divisional Board on the high risk incident reported in October 2010 which initiated the risk assessment of Ward 32. The concerns recorded in the incident report regarding levels of staff were not included in the information which reached the Divisional Board. In essence, no matters were highlighted regarding staffing on Ward 32 prior to the CQC's inspection in September 2012.
- 10.9 After examining the minutes of the Women's and Children's Quality Assurance Committee and monthly Children's Governance Group, it seemed to us that the most accurate summary of the position in 2010 – 2012 was that responsibility for assessing 'low risk' or 'no harm' incidents was delegated to the Clinical Governance Group for each service, assisted by the Patient Safety Team. However, we have commented elsewhere on the weaknesses in the Cardiac Clinical Governance Group at the time.
- 10.10 We noted that in late 2010, the Trust commissioned Mr Derek Hathaway to undertake a review of systems for ensuring the safety of patients. In May 2011, Mr Hathaway presented a report entitled 'Patient Safety and Risk Management'. This described the system of electronic reporting of incidents. He noted a risk 'that in some areas staff are losing faith in the system and are not reporting the low risks and the near misses. As it was pointed out by others however they need to understand that most serious incidents are the result of several much less events happening in line.' He added that the Trust was talking to Divisions to encourage them to follow up on such trends, and noted a campaign by the Chief Nurse on pressure ulcers.
- 10.11 It is fair to say, therefore, that the risk of insufficient attention being paid to 'low risk' incidents, if reported, was not something highlighted to the Trust's leadership, in Mr Hathaway's report. The emphasis was on the need to ensure that staff reported all incidents, rather than concerns about the subsequent use of the information.
- 10.12 However, in the light of our review of the incident reports from Ward 32, we take the view that there were weaknesses in the systems for the review of 'low risk' or 'no harm' incidents. Attention was concentrated on higher risk incidents, coupled with high-level reports. If the delegation of responsibility to consider 'low risk' incidents to the Patient Safety Team and clinical governance groups of the various services was to be effective, then it depended on those groups, in turn, discharging their responsibilities rigorously. It also depended on effective oversight from the Divisional leaders, who needed to detect and then challenge any failings or weaknesses at that level. We were not satisfied that this occurred.

10.13 We would also concur with the assessment in the Utley report⁸⁶ that there is a risk that staff may place undue reliance on the Patient Safety Team and do not themselves take responsibility for risk management.

10.14 We understand that following the CQC inspection of Ward 32, the Trust changed its policy and incidents of low or unsafe staffing were reported to Divisional and Trust level governance committees. Heads of Nursing were required to review personally all of the 'low risk' and 'no harm' incidents. In addition, following the recommendations of the Mid Staffordshire NHS Foundation Trust Public Inquiry, there are now national requirements for reporting on any shortages in the nursing establishment.

11 The Reporting of Incidents

11.1 We have discussed the use made of incidents reports that related to staffing on Ward 32 or the skills-mix on the ward. But some parents also questioned the adequacy of reports of more serious events involving their children. We heard concerns from a small number of parents that particular events relating to their children's care were not reported as 'patient safety incidents' under the Trust's reporting policy, and were not, therefore investigated as they should have been. These parents had seen traumatic events such as a cardiac arrest on the ward and were concerned that these were not reported properly.

11.2 In relation to events on Ward 32 in early 2012, the Review saw evidence of:

- a cardiac arrest on the ward requiring CPR and recourse to IV adrenaline. The arrest followed shortly after the central venous line had been removed from the child. There had also been an error, a little earlier, in the manner in which drainage pots had been changed. No incident report was filed, whether in relation to the error regarding the drain pots, or in relation to the cardiac arrest;
- a cardiac arrest on the ward leading to emergency CPR and surgery reported as a 'patient safety incident', under the category of 'clinical assessment and review'. The incident was not reported by staff on Ward 32 (medical or nursing). It was one of the PICU's consultants who took action to report it, when she was concerned that no incident report had been filed after three days had passed. Thereafter, a root cause analysis was performed.

11.3 In relation to the first event, because the child had, sadly, died a few weeks later, a Child Death Review followed. One action that was agreed arising from that review was to:

'Launch systematic cardiac arrest audit with resuscitation led Root Cause Analysis (RCA) of cardiac arrest calls in Bristol Children's Hospital. Ensure resuscitation form is completed for all arrest calls and emergencies in the hospital, to ensure that all cardiac arrests are fully reviewed and investigated.'

⁸⁶ Bristol Royal Hospital for Children, Review Of Risk Management System – April- May 2014, Ms A. Utley

11.4 The Trust's minutes of a meeting with the family concerned in August 2012 recorded that:

'... after every unexplained collapse, there should be an automatic review and an incident form completed. To date this had only happened on an ad-hoc basis, but is now expected to be standard practice that this will occur.'

11.5 The minutes of the PICU clinical governance meeting of September 2012 record that 'Any crash calls or cardiac deaths [*this may have intended to refer to arrests rather than all deaths*] should be being put on as clinical incidents.' A log of the actions arising out of CDRs in August 2012 noted the need to 'Ensure patient safety critical incident form is completed for all ward cardiac arrests, to ensure all ward cardiac arrests are fully reviewed and investigated.' By March 2014, this action was said to be 'closed', with reference to all cardiac arrests in BRHC being reported via the critical incident reporting system. We also saw evidence of a PICU led audit of resuscitation documentation at the BRHC.⁸⁷

11.6 In another death of a child brought to its attention by parents that occurred in autumn 2013, the Review saw the incident reports that were completed when the child suffered a cardiac arrest, first in a catheter laboratory and then in PICU. In both cases, an incident report was filed by staff, consistently with the policy set out above.

11.7 The Review was conscious of the fact that it saw only a small number of cases and it did not carry out a general review of reporting on incidents relating to patients' safety. With that in mind, we make the following comments:

- We noted the evidence of action by PICU to improve the recording of crash calls and arrests.
- On the other hand, it was not clear how action had been taken to ensure that the ward's practice of logging clinical incidents had been strengthened.

11.8 We note that the Trust commissioned a number of external reviews aimed at strengthening systems to assure the safety of patients and strengthen risk management in the BRHC in 2013 and 2014. In particular:

- A review of the BRHC's 'Patient Safety Culture' was commissioned by the Divisional Manager of the Children's Service in May 2013; and
- A Review of the BRHC Risk Management Systems took place in April – May 2014, led by Ms Utley.

11.9 In the review of the BRHC's 'Patient Safety Culture', one of the themes noted was that although staff were 'patient focused', they were 'were unclear about what type of incident should be reported as a PSI' (i.e., patient safety incident). In June 2014, the

⁸⁷ Clinical Audit Annual Report, 2013/14.

review of Risk Management⁸⁸ reported that ‘Limited understanding of what constitutes a Patient Safety Incident and how these incidents should be graded’ was still ‘relevant’.

- 11.10 In the report from Ms Utley, it was also noted that: ‘There is confusion around the risks related to safe staffing levels not helped by a difference of opinion in what constitutes safe staffing. It is not clear if incident forms should be raised every time staff levels fall below the safe level or, if appropriate action had been taken to mitigate the risk, should these incidents simply be reported to management. Similarly it is not clear where the ownership for such risks lies. If for example the risk relates to a generic nursing shortage should this risk be carried by the wards where the gaps exist or is this a corporate risk that requires a corporate solution.’⁸⁹
- 11.11 Given the focus on safe levels of staffing since the Mid Staffordshire Public Inquiry, the Review found it somewhat surprising that this confusion existed in 2014. More pertinently, it felt that concerns lay behind some of the debate that it had heard, about the weight that should be placed by it on incident reports relating to low levels of staffing, and whether they showed or did not show that action had been taken to mitigate the risk. The Review felt that if more sustained attention had been given either to reviewing ‘low risk’ or ‘no harm’ incidents, or to developing the draft risk assessment of Ward 32, these matters could well have been detected and received attention earlier.

12 The Voice of the Children’s Hospital within the Trust

- 12.1 Despite the strides that had been made by the establishment of the Children’s Hospital, the Review felt that there were weaknesses in ‘hearing’ the voices of children, or the Children’s Hospital, within the wider Trust. We have noted, for example, that the review of nursing carried out by Ms Conroy did not succeed in addressing the needs of the Children’s Hospital.
- 12.2 The survey of material about the care of children on Ward 32, and the effectiveness of the mitigating steps intended to ensure the safety of children with higher dependency needs on the wards, has demonstrated that there were relatively few points at which the concerns about these issues were brought to the attention of Trust executives or leaders.
- 12.3 We formed the view that the paper about securing funding for high dependency care for children’s services, discussed at the Divisional Quarterly Review of July 2011, did raise questions about the management of existing risks.
- 12.4 We have also noted the existence of ‘Risk 1901’, which was placed on the Trust corporate risk register. So far as we were able to see, it was not picked up for further or more detailed discussion by the members of the Trust Board before September 2012.

⁸⁸ Review of Risk Management Systems (April – May 2014), p10.

⁸⁹ Page 12.

With the benefit of hindsight, it is easy to see that as a result Board members were unprepared for the findings of the CQC's inspection. But there was nothing in the papers which would have signalled that Risk 1901 needed closer attention at Trust level. Without a fuller appreciation of the material that we surveyed in Chapter Eleven, we can understand that there seemed little reason to question the 'action being taken by the Women's and Children Division' (to which the Quality and Outcomes Committee was referred, when it inquired about the risk in March 2012).

- 12.5 We have considered how such a gap could have been bridged, and have discussed issues such as review of low-harm or low-risk incidents.
- 12.6 The Report of the Bristol Public Inquiry included a recommendation that 'All trusts which provide services for children as well as adults, should have a designated executive member of the board whose responsibility it is to ensure that the interests of children are protected and that they are cared for in a paediatric environment by paediatrically trained staff.'
- 12.7 The Trust told us, in relation to this recommendation, that the Chief Nurse is the defined executive lead for children and young people. In addition, the Head of Division held a seat at the Trust Board, as well as having access to the Chief Executive when needed.
- 12.8 The Review considered that the original recommendation had embraced a wide vision, looking to see that the voice of children, and now of the Children's Hospital, were heard within a large and complex organisation. We considered that the effective implementation of this recommendation should be revisited and reviewed.
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13 Conclusions

- 13.1 We heard that when the CQC raised concerns about the quality of care on Ward 32 in September 2012, this came as a surprise to the senior leadership of the Trust. The review of the information that was reported upwards does not suggest that reports or warnings were ignored by the Trust executive. Rather, the Review's opinion, the information that was suggestive of the need to review existing risks remained at the level of the Division.
- 13.2 The fact that concerns about the staffing of Ward 32 were not referred to the Board until after the CQC's visit demonstrates clearly that they were not taken sufficiently seriously. There was a continued need to strengthen the voice of the Children's Hospital within the Trust as a whole.
- 13.3 The Review noted evidence of, first, greater focus upon the study of 'low-risk' incidents since 2012, and, in addition, a number of reviews examining patient safety and risk management within the BRHC, in 2013 and 2014. It appeared that action had been

taken to review the mechanisms by which matters to do with the safety of patients were identified and reviewed throughout the BRHC hospital.

13.4 However, the evidence of the Review of Risk Management in 2014 was that work remained to be completed to develop staff's understanding of the nature of patient safety incidents and how such incidents should be graded.

14 **Recommendations**

14.1 In light of the above, we **recommend**:

(22) That the Trust review the implementation of the recommendation of the Kennedy Report that a member of the Trust's Executive, sitting on the Board, has responsibility to ensure that the interests of children are preserved and protected, and should routinely report on this matter to the Board.

(23) That the BRHC confirm, by audit or other suitable means of review, that effective action has been taken to ensure that staff possess a shared understanding of the nature of patient safety incidents and how they should be ranked.

CHAPTER THIRTEEN: THE CQC'S INVOLVEMENT

1 The Care Quality Commission's Inspection

- 1.1 In summer 2012, the Care Quality Commission (CQC) was contacted by two families whose children had died following cardiac operations carried out in the Children's Hospital earlier in 2012. They expressed concerns about their children's care.
- 1.2 The CQC made initial inquiries of the Trust about the cardiac service and the delivery of care on Ward 32 in particular. The CQC sent an email to the Trust on the 15th of August 2012, seeking information. On the 16th of August further discussion by email and telephone took place to clarify timescales for the return of the information.
- 1.3 The Trust submitted a written response on the 20th of August 2012 with further information submitted on the 24th of August 2012. These set out how Ward 32 functioned from day to day and the model of care for providing high dependency care. The staffing establishment on Ward 32 was set out, along with the ratio of registered to unregistered staff. Information was also provided on the use of Bank and agency staff over the preceding 7 months and on incident reports over the same period. There were 10 incidents reported of low/unsafe levels of staffing, with 3 of the reports using the word 'unsafe' in the description of the incident. The document set out data on children on Ward 32 who triggered a clinical score relating to high dependency during their stay on the ward over the period from March to October 2011.
- 1.4 The document went on to state that the need for a cardiac high dependency unit was part of the plans submitted under the Safe and Sustainable Review which would have been taken forward should the catchment area for the Bristol Centre have been extended because of the closure of other Centres. As that review had been delayed, 'the Trust was working with commissioners to propose funding for a 4 bedded cardiac high dependency unit on Ward 32. A proposal would be submitted as part of the next commissioning round'. The Trust's document continued:

'We have recognised that an interim solution is required. The senior members of the team have been working on a virtual bed model, which would see a flexible group of PICU trained nurses open a PIC bed for a child requiring cardiac surgery and then transfer that patient to the ward, managing them at the benchmarked high dependency staffing levels. This model is in development, and has not yet been implemented, however funding required to invest in the trial of this model has been identified'.
- 1.5 The document stated that high dependency care was on the Division's risk register and was graded as one of the Divisions 'top risks'. As a result of this grading an appointed member of the Trust's Executive Team was responsible for addressing the risk. A copy of the risk register was included in the report.
- 1.6 The Trust highlighted the pressures on PICU and the Children's Hospital from winter 2011 onwards which, unlike previous years, had not abated. It recorded, in part, the

changes instituted by Mr Booth in April 2012 (as set out in his email of the 18th of April), in relation to the need for collaborative working between PICU and Ward 32, to identify clearly the nursing needs of children prior to transfer back to the ward.

1.7 The Trust acknowledged that concerns had been raised by the clinical team 'regarding the levels of acuity experienced at times on Ward 32. In combination with the clinical incident reporting system, these concerns have been acknowledged and prompted a number of changes'. The following changes were listed:

- review of high dependency activity across the hospital
- improvement to ward funded nursing establishment and changes to shift patterns
- review of patients/ward acuity levels prior to discharge from PICU
- improved monitoring capability within the ward
- development of virtual bed model to include staff managing post PICU care on the ward at Paediatric Intensive Care Society staffing recommendations as required
- commissioning negotiations in progress for formally funded cardiac high dependency unit
- High Dependency Operational Group developed
- highly graded Divisional risk register entry for high dependency care
- implementation of supervisory ward sister model
- joint appointment of Matron for PICU and Lead Nurse for Cardiac Services to improve communication and relationship between PICU and Ward 32.

1.8 Viewed overall, this was a reasonably full and comprehensive outline of the key issues relating to Ward 32, and was supported by data on incidents, staffs' rotas and the work by Caroline Haines on patients' acuity. The Review had some concerns that developments which were, at the time, embryonic were given a rather more definitive shape.⁹⁰ However, it is apparent that the document enabled the CQC to decide whether or not further investigation was needed.

1.9 On the 30th of August 2102 CQC requested a copy of the risk register and also whether the operation policy for high dependency care dated 2 July 2012 was in place. The Trust responded to this request on the 3rd of September and also to a verbal request for information about an incident which occurred in November 2010 on Ward 32.

1.10 Then, the CQC carried out an unannounced inspection of Ward 32 and PICU on 5 September 2012.

⁹⁰ For example, the document stated: 'A High Dependency Operational Group is in place, chaired by Dr PD, Paediatric Intensivist, and the draft Operational Policy has been included for information.' The Review was told that the first meeting of this group, in fact, took place on 7 September 2012.

2 CQC's Inspection of Ward 32, 5th September 2012

- 2.1 We heard some concerns from parents that the inspection was not 'unannounced' or that staff were able to prepare for it. However, there was no real evidence to support this suspicion and there seems little doubt that staff were shocked both by the fact of the inspection and its findings. The CQC told us that under the methodology in place at the time, Trusts were not normally given notice of any inspection. Inspectors would however declare themselves once they arrived on site. Providers could however infer from the Commission's conduct when an inspection was likely. For example, if a warning notice had been issued, a further inspection would be likely to take place to check whether compliance had followed.
- 2.2 It was true, therefore, that the Trust could reasonably have expected that follow-up inspections would take place at a later date. But the Review received no evidence that would have tended to suggest that, when it inspected, it received anything other than an accurate picture of the ward.

3 The Private Meeting of the Board

- 3.1 After preliminary, informal feedback from the CQC about its inspection, a private Meeting of the Board was held on 21 September 2012. One of the topics of discussion was the CQC's inspection. This was the first occasion at which the Chief Executive had been fully involved; he had been on leave when the CQC attended. A full briefing was given to the Board's members.
- 3.2 We examined the minutes of the meeting with some care, given the importance of the information that was presented to the Board. There was an extensive and detailed discussion of the care given to the children whose deaths had triggered the CQC's involvement, as well as of the immediate measures that the Trust had taken to support the ward. These included:
- agreement with commissioners to bring forward plans for establishing a high dependency unit for post-operative cardiac children;
 - as the Ward Sister was on maternity leave, a new senior experienced nurse with experience of cardiac services and intensive care had been put in place;
 - the nurse consultant for intensive care and high dependency and the matron with responsibility in this area would have a timetabled presence every day on Ward 32 to support staff and take skills training forward;
 - a process had been started to map the dependency of children against the experience and training of staff.
- 3.3 Plainly, there was limited time between the CQC's inspection and the Board's meeting, such that there was a focus on practical action. However, the Review noted that at a Divisional level, quite extensive information already existed to show the scale of the pressures on Ward 32 which included acknowledgements of occasions when there had been failings in the care provided. The material was recent, gathered together in a composite CDR Action Log in August 2012, as well as in a key RCA written in June 2012. Although at the time, CDRs sat somewhat outside formal processes of

governance, there was still a widespread knowledge of these investigations at a Divisional level. Yet only a part of this material was identified and reviewed by the senior leadership prior to the private meeting of the Board of 21 September and then the subsequent response to the CQC. The focus was on the material relating to the two families who had contacted the CQC. Further relevant material was not identified.

- 3.4 The Board was assured that its executive officers did not believe that levels of staffing had contributed to poor care or to poor outcomes for families, as opposed to, on occasions, a poor experience of care. This was not, however, the conclusion reached in some of these documents. The CDRs and the RCA which have been referred to painted a complex picture, but at a minimum they raised questions about the contribution of low levels of staffing, as well as the ability of staff to identify deterioration in children, to the events which occurred. It seems to us that a more thorough discussion and review of the history of concerns about staffing in Ward 32, and of the most recent investigations into deaths or untoward incidents in the ward, would have contributed to a fuller and more complete understanding of the pressures on that service and the effectiveness of the measures taken to mitigate risks. It would have led to a more qualified or nuanced discussion with the Board, and, thereafter, in the representations to the CQC. It could also have better informed communication with some of the key families concerned.

4 Trust's Response to the CQC

- 4.1 The CQC followed its usual procedures by sending its draft findings, warnings and notices to the Trust's Chief Executive, together with an opportunity to make representations upon them.
- 4.2 The Review examined the Trust's response to the CQC's draft findings with care. It was a robust response. But the Review reflected that critical comment on draft findings was a legitimate part of the process established by the CQC. The Trust was entitled to challenge any factually inaccurate statements and to seek to persuade the CQC to change its language or conclusions. Provided that it took care to ensure that its response was also candid, accurate and complete, there was nothing unusual or objectionable in exchange, however much others might have disagreed with its perspective. A good number of the points made were, indeed, accepted by the CQC.
- 4.3 In addition, there was limited time available between the date of receipt of documents, and the time needed to respond.
- 4.4 The Review did have concerns, however, about the following aspects of the Trust's response.
- 4.5 First, the letter from Mr Woolley of 10 October 2012 argued that the CQC was wrong to give 'significant weight' to staffs' reported concerns about levels of staffing on Ward 32. It attributed the comments made by staff to the pressures that they were under at the time. Mr Woolley repeated this theme in the letter he subsequently wrote to Sir Ian

Carruthers of NHS England when he set out concerns about the methodology of the inspection; there was objection to reliance on 'random staff comments on the day'.

- 4.6 We acknowledge that Mr Woolley's letter to the CQC did balance the concern he raised, with an acknowledgement of the 'importance of staff feedback and the benefits of frank and open exchanges of views and concerns.' Steps were also taken at this time to support staff on the ward (and also families), and this led to further feedback being provided. But we were troubled by a sense that, viewed overall, the reported views of Ward 32's staff were not given sufficient weight in the Trust's determination of its response to the CQC's inspection and findings. We have previously noted that concerns expressed in documents such as the 'low risk' incident reports, in the draft risk assessment of Ward 32 and in the email of September 2011, did not rise beyond the level of the Divisional management. We were struck by the fact that, when concerns from nursing and other staff were clearly reported to the Trust's leadership for the first time, commentary upon them, admittedly to third parties, was dismissive.
- 4.7 Second, although we do acknowledge the limited time that was available before a response had to be made to the CQC, the limitations in the research undertaken which we discussed at paragraph 3.3 above persisted.
- 4.8 Finally, the Trust also protested about the CQC's reference to inotrope infusions on the ward 'as if they are of themselves a high care intervention...'. It argued that 'An inotrope infusion is not of itself a marker for high dependency care.' That was a matter of professional judgment, and we make no comment on that judgment. However, the letter continued: 'As part of the current service model, the Trust operates a protocol for the management of inotrope infusions which requires enhanced staffing according to the acuity of the patient receiving the infusion.' The use of the word 'requires' implied that this protocol of 'enhanced' staffing was observed. Yet incident reports (6 in the period from May 2011 – August 2012) recorded occasions when it was not. The Review felt that a franker or fuller response would have acknowledged that the protocol could not be observed at all times. The issue was not whether the Trust had put 'mitigations' or safeguards in place, but their effectiveness.

5 The CQC's Findings

- 5.1 The CQC published its findings and Warning Notice(s) on 29th October 2012. It found the following breaches of the Regulated Activity Regulations:
- Non-compliance with Regulation 9: Care and welfare of people who use services.
 - Non-compliance with Regulation 22: Staffing.
 - Non-compliance with Regulation 23: Supporting workers.
- 5.2 The Commission had already issued a warning notice on 26 September 2012 in respect of Regulation 22 (Staffing). The warning notice required the Trust to comply with the Regulation by 18 October 2012 or face further action.

- 5.3 The Commission also issued compliance notices in respect of the additional breaches found. It asked the Trust to send the Commission a report setting out the actions it would take to achieve compliance.
- 5.4 The Review concurred with the findings of the CQC that there was inadequate provision of staff with the level of competence required for the care of highly dependent children with CHD.
- 5.5 Following the inspection, the Commission approached the Strategic Health Authority to organise a risk summit. Further discussion regarding the risk summit is set out below.
- 5.6 Thereafter, the Trust began a programme of substantial change in order to meet the requirements of the CQC. The following steps were taken:
- the number of beds on the cardiac ward was reduced from 16 to 12 with two beds to be used for patients with higher care needs (not High Dependency Unit) on a 1:3 nurse ratio;
 - admissions to Ward 32 were restricted to cardiac patients only;
 - high dependency cardiac care was provided in the paediatric intensive care unit only;
 - cardiac operations on Fridays were restricted for a period of time;
 - action began to recruit nurses to allow the creation of a dedicated high dependency unit on Ward 32 by spring 2013.
- 5.7 The CQC received an action plan which it judged was acceptable. It inspected again on 19 November 2012 to check that improvements had been made and found that the Trust complied with Regulation 22, regarding staffing.
- 5.8 There was a further inspection of Ward 32 on the 26th of April 2013. As a result of this inspection CQC was satisfied that the Trust had taken action to ensure that children on Ward 32 received care and treatment that met their needs, and the Trust complied with the relevant regulatory requirements.
- 5.9 Whilst the Trust took action to make changes to the provision of care on Ward 32, its leadership continued to hold the view that the judgments reached by the CQC in its initial inspection were unjustified, and that the existing model of care on Ward 32 had not failed, or delivered unsafe care. This view, however, did not act as an impediment to the implementation of the changes required, which were the subject of a comprehensive Action Plan (see further Chapter Fourteen).
- 5.10 It appeared to the Review, however, that the Trust's assessment of the adequacy of the care previously provided on Ward 32 did affect the way in which it communicated, particularly with families whose children had been affected by this care.

6 Progress of a Root Cause Analysis

- 6.1 Within the Trust, a reassessment of a key investigation took place.
- 6.2 In May – June 2012, a major root cause analysis (RCA) of one of the deaths which occurred earlier in the year was completed. The history of this RCA was an unhappy one. It was drawn up following a meeting of clinicians'; a draft was circulated for review and comment by the clinicians. The draft report was then forwarded to the Lead Doctor and Head of Governance and sent to the Trust's legal department. According to the later Child Death Review's report, the legal department agreed that it could be passed to the family concerned. Others who spoke to the Review, including the Patient Safety Officer, were also clear that the Trust's Medical Director knew that a meeting was taking place with the family. At that stage it appeared that the RCA was regarded as a good and comprehensive piece of work.
- 6.3 We noted that, although the family concerned voiced criticisms of the RCA and pointed out inaccuracies, the analysis contained a full and open discussion of failures in the care provided and of any possible impact on the outcome for the child.
- 6.4 Later in the year, after the CQC had visited the Trust, the contents of the RCA became controversial. Both its methodology and conclusions were subject to further investigation and, ultimately, to criticism by an internal review.
- 6.5 We were driven to conclude that, when it was first produced, the RCA received inadequate attention from the senior officials with whom it was shared, including the Trust's Medical Director and Chief Nurse, both of whom had seen a copy prior to the CQC's inspection. The Medical Director had seen it before the meeting with the family. Although it was a lengthy document, the wide-ranging nature of the RCA and its candid discussion of systemic weakness were evident on its face. Yet no 'alarm bells' rang, either to check that the criticisms and actions it contained were justified, or to seek assurance that the weaknesses identified were being addressed vigorously.
- 6.6 Key staff involved in producing the RCA then found themselves being questioned about its contents by members of the Trust's Executive team in a manner that they found difficult and intimidating. One clinician was asked to attend what was described to her as an 'understanding' meeting. Whilst she was supported by other members of the clinical teams, the Review felt that the questioning of her should not have occurred in this fashion. The Patient Safety Officer also described being questioned about the RCA, probably at the Patient Safety Meeting held in November 2012.
- 6.7 Perhaps inevitably, views about these meetings were polarised. We were told by the Trust's leadership that they considered that any questioning had been appropriate, professional and necessary. The Review felt that the perspective which was more valid, however, was that of the more junior members of staff who had been questioned.

6.8 The Review considered that the Trust's senior leadership should have taken much greater care to avoid giving the impression that documents which set out critical comments, such as this RCA, were not welcome. Their behaviour was crucial in setting the tone or 'culture' of the organisation, so as to ensure that the Trust was a 'listening' organisation. But in our view, neither of these sessions demonstrated a commitment to achieving that aim. Staff associated with the RCA required support in a fraught atmosphere. They did not receive it.

7 The Report of the Serious Incident Review Panel

7.1 The outcome of the challenges to the RCA was that the Medical Director commissioned a Serious Incident Review Panel (SIRP) to review and report on the key RCA in late 2012. This was a part of the Trust's procedures, introduced by the Medical Director, for ensuring a thorough consideration of serious incidents.

7.2 This SIRP stood apart from others seen by the Review, in that a major focus of its work was a review of the earlier RCA, rather than of the underlying care and treatment which the RCA had sought to examine. The patient's clinical notes were not reviewed, and there was a focus on the procedures followed to produce the RCA. Despite this being the focus, the RCA's authors were not interviewed. The Review felt that the SIRP failed to establish fair and proper mechanisms for a balanced review of the RCA. A lack of consensus about its conclusions resulted, which was ultimately reflected in the Division's response to the SIRP.

7.3 The family whose child had died were not informed of this further review. It was treated as an 'internal' review. There were a number of interviews of staff but no involvement of parents. The SIRP was made available by the Trust to HM Coroner, in the course of preparation for the subsequent inquest. The family were also not informed of the response to the SIRP's report produced by the leadership of the Women's and Children's Division. After legal advice had been taken by the Trust, this response was not disclosed as part of the evidence made available by the Trust at the inquest. However, a copy was sent anonymously by an unknown person to the family as the inquest was drawing to a close.

7.4 The Review considered that the failure to involve the family in the SIRP was a serious lapse of judgment. Involving the family, not whether but how to, should have been discussed and agreed at the highest level, as part of setting the SIRP's terms of reference. This was a family who had contributed to both the RCA and CDR, and had received copies of both. They plainly wanted feedback and answers to the questions they had about their child's death. If either the death, or a review into it (i.e., the RCA), was to be subject to further investigation, their perspectives should have been sought. This obvious need became plainer yet when the SIRP proceeded to criticise the RCA. In the event, the fact that both the SIRP and the Division's response to it only came to the family's attention in the course of the inquest, contributed further to an atmosphere of suspicion and distrust.

- 7.5 The Review recognised that the procedure for instituting a SIRP was relatively recent. It appeared that engaging the family in such a review had not been considered (and the issue perhaps had not previously arisen). But as a matter of principle, it was difficult to see a reason for treating such reviews differently from either RCAs or CDRs, in terms of parental involvement. Each required a recognition of the role of patients, parents and carers, both in contributing information, and being given the opportunity to discuss the results of an investigation in a candid fashion.
- 7.6 Moreover, had the family been told about the SIRP as it happened, and involved if they wished, it seems unlikely that their first awareness of the Division's response would have been through an anonymous delivery.

8 Engagement with Parents

- 8.1 Efforts were made initially to involve the family concerned in the process of implementing the measures set out in the RCA's Action Plan. The suggestion that they should work with clinicians to implement the steps set out in the Plan was, we understand, made at the meeting in which the parents were given a copy of the RCA.
- 8.2 The Review understands that the family initially responded to the offer by saying that they would think about it. The Trust's response to the CQC (August 2012) records that they were pleased to be asked and that this was regarded by the Trust as 'the way forward'. Thereafter, this offer appears to have got 'lost'. We have seen no evidence that it was clearly repeated in writing or expressly kept open, such that the family could take it up as they worked through the questions which they had about their child's death, and their complaints about the care that he received.
- 8.3 We appreciate that, from the Trust's perspective, the relationship with the family became strained, with (for example) serious criticisms about the cardiac service being made in public and a complaint filed. However, the offer having been made, it should have been followed up. As it was, it seemed to us that the Trust retreated into a closed and defensive stance. It did not seek to reach out to these bereaved parents and clearly signal its commitment to continue to work with them. In its initial response to the CQC's questions, the Trust had written that: 'This approach [to involving the family] is recognised as the way ahead for the RCA process and adheres to the May 2012 Health Foundation 'Thought Paper' which recommends this action.' This apparent enthusiasm for the approach does not seem to have led to sustained efforts to put it into practice.
- 8.4 What we have described as a 'closed' stance was evident in the failure to update the parents with the progress of the steps set out in the RCA's Action Plan. This could and in our view should have been done, at least in writing if communication was strained and difficult.

9 The Progress of the RCA's Action Plan: Review of the most recent 50 deaths of children receiving cardiac care

- 9.1 The issue of information about the implementation of the Action Plan was most sharply evident in the concerns about the fate of the RCA's recommendation that the Trust should carry out a review of the last 50 deaths of children receiving cardiac care. We heard repeated criticism by families of the fact that the Trust had never done so.
- 9.2 From the Trust's perspective, the Action was discussed by the Divisional Quality Assurance Group and then at the Trust's Patient Safety Group, in November 2012. The minutes of the latter meeting state that Dr Steven Sale 'reported [that] the [Women's and Children's] Division felt it was unnecessary to complete a review of the last 50 cardiac paediatric deaths ... as all child deaths are subject to a child death review panel.'
- 9.3 It is accepted that the Trust had a thorough process - probably an unusually thorough one - for considering children's deaths and reporting on them to the CDOP. (See Chapter Fifteen). Given this, the Review can understand the reaction of clinicians that a review of the most recent 50 deaths was not required.
- 9.4 On the other hand, the Trust's former Patient Safety Officer told us that the reason for the recommendation was, first, to enable the use of a structured tool (the Institute of Improvement's morbidity review template), to ensure a consistency of approach; and, second, to see whether there were links between cases, or 'themes' to be identified. These points were not wholly addressed by referring to the existence of the CDRs.
- 9.5 More seriously, it does not appear that the issue of maintaining public confidence, or communication with the family concerned received any, or sufficient, attention when this decision was made. The family expected the actions set out in the RCA to be carried out, and the decision not to do so does not appear to have been explained to them. They continued to press for the work to be done.
- 9.6 The failure to explain the Trust's perspective further contributed to the atmosphere of distrust and suspicion which grew up between the Trust and bereaved families.
- 9.7 For these reasons, it seems to us that the issue of carrying out a further review of mortality was not given sufficient care and attention by the Divisional leadership who recommended that it should not to be carried out, and the Trust's Medical Director who had overall responsibility. There was a 'failure to embrace these opportunities to just stand back a little' or to consider the family's or the public's perspective.
- 9.8 Lest a one-sided impression be left, we acknowledge that the failure of this attempt to engage with parents in the implementation of the Action Plan was not the only example of interaction between the Trust and parents that the Review saw. Indeed, we also saw much more successful work, including the involvement of a family in the development of systems to record parental concerns. The Trust also carried out

consultations with interested parties on such issues as the process of obtaining consent to treatment.

- 9.9 But we felt that there needed to be greater commitment to sustain a commitment to work with families even if there were strains; or, at the least, continue clearly to 'hold the door open'.

10 **Candour and Defensiveness**

- 10.1 We have described above the journey from what we perceive to have been reasonably candid discussions with one family in the immediate aftermath of their child's tragic death and following the clinical investigations into that death, to a more defensive and 'closed' stance on the part of the Trust following the public airing of concerns about care on Ward 32 and the CQC's inspection.

- 10.2 This contrast was also apparent from the course of meetings with the first family who had approached the CQC, whose child had died in the early part of 2012.

- 10.3 The family had met clinicians in June and August 2012, when the Trust had acknowledged failings in line with the contents of the CDR into their child's death. Following further correspondence, there was a meeting with the Chief Executive and the Medical Director in March 2013. By this point, the Trust was committed to a defence of the model of care in Ward 32, as it stood prior to the CQC's inspection. Those attending on behalf of the Trust at the meeting with this family in March 2013 were inadequately briefed on previous communications with the family, and in particular, on a meeting between clinicians and the family in August 2012. For the family, there was a sharp contrast between what had been said in August 2012 and what was being said in March 2013. Had those from the Trust fully appreciated, as they should have done, the nature of the previous discussions, they would have realised that various observations that they made, whether on issues such as staffing on the ward or the recording of a cardiac arrest as a clinical incident, would be interpreted as defensive and lacking in candour, given that they did not reflect what had been said previously.

11 **The Risk Summit**

- 11.1 To follow up the CQC's findings, a risk summit was held on the 29th of October 2012, attended by representatives from the Trust, CQC, Monitor, NHS South of England, the Specialised Commissioning Group, the BNSSG PCT⁹¹ cluster and a representative from the Safe and Sustainable Review Team. The meeting was preceded by extensive discussion and communication between these various bodies, exploring the matters raised and steps taken.

- 11.2 At the meeting, each of the organisations set out whether the information that they held about the service had indicated any concerns prior to the CQC's inspection.

⁹¹ Bristol, North Somerset and South Gloucestershire Primary Care Trust

- 11.3 On behalf of commissioners, it was stated that there had been no cause for concern, having reviewed the available information, and that no concerns regarding staffing had been identified at either a specific or general level. It was evident from the notes of the meeting and our discussions with staff from commissioning organisations that the extent of information available to commissioners regarding the performance of the cardiac service was limited to the annual child death overview panel's reports (which deal with all deaths of children), reports of serious untoward incidents, the NCHDA data on outcomes and data on activity in the service. None of these would have signalled staffing concerns.⁹²
- 11.4 It was confirmed at this meeting that the Safe and Sustainable Team, the Primary Care Trust and Specialised Commissioners were aware of the model of care on Ward 32 (see Chapter Two for the information given to the meeting).
- 11.5 Those attending the meeting considered the actions set in place by the Trust and whether they were assured that they were adequate and whether any concerns remained.
- 11.6 The meeting considered the following questions:
- Outcomes – did recent deaths of children change the apparent position of the Trust as a high performer in paediatric cardiac care?
 - Governance - did fact that staffing appeared on the Trust's risk register without adequate action taken signal a more systemic failure of governance?
 - Staffing – were patients being safely cared for as of this time?
- 11.7 In relation to outcomes, the meeting concluded that there were no indicators raising concern. But it was agreed that the Medical Director for NHS South of England would seek further assurance based on the latest data on mortality from NICOR and would identify someone to undertake a clinical review 'to assess case mix and its relevance to the issue,' given that there appeared to be an increase in Fontans procedures. The difficulties in analysing small numbers of procedures were discussed.
- 11.8 In relation to governance, the meeting indicated a degree of satisfaction with what it had heard from the Trust's Executives at the meeting but sought further details for Monitor to assess.
- 11.9 Finally, in relation to staffing the actions put in place by the Trust were acknowledged and it was agreed to monitor the position.
- 11.10 At the meeting, it was noted that the RCA for a child's death had recommended a review of the last 50 deaths (see section 9 above). The Trust's perspective on why this was not needed was explained.

⁹² The topic of bids for high dependency care is considered at Chapter Sixteen.

12 Second Risk Summit

- 12.1 A follow-up meeting was held on the 6th of December 2012 to review the progress made regarding the actions agreed at the previous meeting.
- 12.2 It was noted that the CQC's re-inspection had taken place and had been positive. It was noted that a number of actions had been completed but it was reported that no-one had been identified to take forward the review of case-mix and that NICOR's data would not be available for a further 3-4 months.
- 12.3 In relation to staffing, it was recorded that the PCT would continue to monitor staffing and that data received had indicated a fall in unfilled shifts and in the use of Bank and agency staff. It was felt that the arrangements for continuing monitoring were robust.
- 12.4 Outstanding actions in relation to the review of data on outcomes were to be taken forward by the Medical Director of NHS England South. It was agreed that the monitoring of the Trust's implementation of the action plan was to be the responsibility of the PCT and that no further meetings of the risk summit group were necessary.
- 12.5 The responsibility for further follow-up passed to the newly established Quality Surveillance Groups, from March 2013 onwards.
- 12.6 In relation to the families, the minutes stated that the 'SHA will organise a meeting with the parents to summarise issues covered and the outcomes of the risk summit into paediatric cardiac surgery at UBH'. The SHA in this context was a reference to NHS South of England.
- 12.7 We have seen comments by the parents on these minutes. It is clear that they felt that there were inaccuracies or misleading comments made by the Trust. In particular, the minutes recorded that Mr Woolley had said that 'The Trust had met with the parents on many occasions since the death of their child; the most recent time was in front of the coroner for a pre-inquest hearing when they were accompanied by their lawyer.' The family commented that they had not met 'many times'. They had met clinicians at the Trust on only two occasions. Only a lawyer and not staff from the Trust had attended the meeting with the coroner and it had not been an opportunity for general discussion.
- 12.8 We note there had been extensive written communication between the family and the Trust. We can appreciate that, from the perspective of those who attended the meetings of the risk summit, the difference between two or three meetings, and 'many' meetings, might not have seemed significant and was believed to be accurate. But the family were not present or represented. They were outside this process. We can understand their frustration and distress about even small inaccuracies. It seems to us that they helped to erode trust, not only because the family's experience was not accurately reported but also because it would be easy to conclude that similar

inaccuracies could creep into the reporting of matters of which the family had no direct experience.

13 Reporting to Local Bodies

- 13.1 The Trust reported the fact of the CQC inspection and its response to Bristol City Council's Health Wellbeing and Adult Social Care Scrutiny Commission.
- 13.2 Two families also contacted the local Independent Safeguarding Board themselves to highlight their concerns about care on Ward 32. When they did so, they were informed that the Safeguarding Board not been made aware of any such issues; the information had not been relayed to it, from the Scrutiny Commission. As chair of the Safeguarding Board Professor Jones sought confirmation from the Trust that any issues raised in the CQC's report were receiving an appropriate response. A meeting was held with senior executives from the Trust in March 2013 and reassurance was given that these matters were being appropriately dealt with.
- 13.3 During the course of 2013, concerned parents sought to use local mechanisms such as public meetings of the Scrutiny Commission to highlight their concerns about cardiac services and the need for investigation. The Review examined this history. From its point of view, it appeared that, first, local democratic bodies had not been in a position to hear additional information about, or scrutinise the performance of, specialised services for children with congenital heart defects, until after the CQC carried out its inspection. Second, local bodies were concerned to ensure that appropriate steps had been taken by the Trust but did not consider themselves able to carry out independent investigations of parents' concerns.

14 Follow-up meetings with families

- 14.1 The CQC arranged a meeting with the families who had helped to prompt the CQC's inspection on 1 November 2012, to give them feedback about the results of that inspection.
- 14.2 The CQC's Compliance Manager for the SW Region subsequently asked Mr Leslie Hamilton, Consultant Congenital Cardiac Surgeon at the Freeman Hospital in Newcastle, to review documentation to see if there were any significant matters which had not been highlighted and of which the CQC should be aware. In March 2013, Mr Hamilton noted that questions about the size of centres were being considered by the Safe and Sustainable Review, but felt that there was no indication of matters that needed further specific investigation by the CQC.
- 14.3 After the second risk summit, a feedback meeting was also held in December 2012 with one of the families concerned. It was attended by Liz Redfern (Chief Nurse for the SHA), Lindsey Scott (Director of Quality and Governance, NHS Bristol), and Andrea Young (NHS Commissioning Board). The parents were seeking help at that point from bodies outside the Trust, including NHS England, in exploring further what had happened to their child.

15 NHS England's involvement with families

- 15.1 We were told that one of the families which had contacted the CQC wrote to Sir Bruce Keogh (the NHS Medical Director) on 26 September 2012. Further contact with various officials from NHS England, as the body soon to take over responsibility for commissioning specialised services followed. We have noted how the family was asking for help in exploring the issues raised by the death of their child. The family also wrote directly to the National Congenital Heart Disease Audit, setting out their concerns about the accuracy of the information from Bristol on NICOR's database.
- 15.2 We have noted that the Risk Summit of December 2012 had recorded that the 'SHA [i.e., NHS South of England] will organise a meeting with the parents to summarise issues covered and the outcomes of the risk summit into paediatric cardiac surgery at UBH'. It had also been agreed that Dr Durkin (Medical Director for NHS South of England) would seek further assurance about outcomes of care at Bristol, based on the latest data on mortality from the CCAD, when it became available. He would also identify someone to undertake a clinical review to understand the pattern of service in Bristol and across other systems taking account of case-mix.⁹³
- 15.3 Following extensive contact between the family and a number of officials from NHS England (South), a letter was sent to them by Sir Bruce Keogh in March 2013, advising that a meeting would be arranged by Dr Mike Durkin with Mr Bill Brawn of Birmingham Children's Hospital. Mr Brawn was to be asked to examine their child's care. The scope of the work was subsequently widened to make it clear that it was intended to encompass the concerns of both of the families who had approached the CQC in summer 2012. This enlarged scope represented, potentially, a shift away from a clinical review of such matters as case-mix, to a clinical review of all aspects of the treatment of these two children.
- 15.4 On 13 June 2013, a meeting was held between both families and Dr Mike Durkin, now Director of Patient Safety at NHS England. Dr Durkin wrote to them afterwards, explaining that he had asked Mr Bill Brawn, Consultant Paediatric Surgeon and Dr Tony Salmon (Consultant Cardiologist) to carry out a review of the children's care. Their work would now be co-ordinated by the Chief Nurse (Liz Redfern) and the Medical Director for the South of NHS England (Nigel Acheson), following Dr Durkin's new appointment. Dr Durkin acknowledged the time that it had taken to arrange matters and hoped that there would be no further delays. He expressed the hope that 'the learning from Mr Brawn's findings' could be used to inform the new NHS England's Congenital Heart Disease Review.
- 15.5 As a result, Mr Brawn and Dr Salmon met two sets of parents on 23 July 2013 and discussed with them the concerns that they had about their children's care. Also present was Professor Brian Toft, a consultant on safety who had been supporting the families. The parents' experience was outlined and discussed, and there was further

⁹³ Minutes, Risk Summit meeting of 6 December 2012.

discussion about the potential scope of any work by Mr Brawn and Dr Salmon. It is apparent from the parents' communications afterwards that, although they were pleased at the involvement of the two senior clinicians, they wanted a review of the service that ranged more widely than their own children's deaths and hoped to be involved in determining the terms of reference to enable this. For example, a review of the most recent 50 deaths of children receiving cardiac care was mentioned.

- 15.6 In the event, a debate on terms of reference did not take place and it does not appear that formal instructions, setting out a defined task, were ever drafted for Mr Brawn and Dr Salmon. Ultimately, a note was sent by them to Ms Redfern in early November 2013. It was shared by her with the families, the Trust and HM Coroner (who by then was convening an inquest into the death of one of the children concerned). The note discussed the families' concerns about the care received, whilst noting that the reviewers had not heard from the professionals involved. It discussed mechanisms for a wider review, such as the Royal College of Surgeons of England's mechanism for an Independent Review. The note did not set out to address questions of case-mix or data on outcomes more generally. It was followed up with a further meeting between the report's authors and the families in early December 2013.
- 15.7 NHS England initially took the view that it would be appropriate to pursue the outstanding issues by seeking to involve the Parliamentary and Health Service Ombudsman (PHSO). However, further representations from the two families, together with reports from other families who had joined them in expressing concerns about the care received by their children, led to a revised approach. On 14 February 2014, Sir Bruce Keogh met a number of the families who had expressed concerns and agreed to set up an independent review.
- 15.8 In a letter sent much later, in November 2014 to one of the families who met Mr Brawn, Mr Farnsworth, Area Director, NHS England Area Team, on behalf of NHS England, reflected:

The relevant history starts with the risk summit dated 29th October 2012 where the following action was agreed and attributed to pursue. The task was to undertake a clinical review to understand the pattern of service, i.e. case mix in Bristol and make comparisons with relevant comparators. This in itself is a complex task and from what I know as a lay person, the method for doing this in a meaningful way was not obvious. It is very difficult to make retrospective judgements about the comparative case mixes between units in order to draw a conclusion over variations in outcomes such as those shown by NICOR.

Bill Brawn was subsequently asked to begin this task. As you know he interviewed some parents during the summer of 2013 and produced a summary of parents' views and concerns before his work ceased. This does not go far enough in answering the question of whether there was quantifiable evidence of poor outcomes. It is with regret that we now understand that no further action was taken to progress this which

precipitated your and others approaches to Sir Bruce Keogh resulting in the current review announced in February 2014.'

15.9 Mr Farnsworth's letter continued:

'I need to accept that it took too long to undertake this work and to deal with the fact that there no conclusions were drawn. I think this is in part due to the inherent difficulty with the task and not helped by staff changeover due to NHS reorganisation. As you know this was when the Strategic Health Authority was being abolished, individuals were being given new responsibilities and responsibility for patient safety was handed over to the emerging new body, NHS England. It is clear that these changes created a loss of momentum in following through on answering the question and responding to parents.'

15.10 The Review endorses these observations. A number of potential topics for investigation were being proposed in late 2012: the study of case-mix and outcomes in Bristol proposed at the Risk Summit; an investigation of the care and treatment of the two children who had undergone the Fontan procedure; and, possibly, a more general review of the service. The process for commissioning Mr Brawn and Dr Salmon did not succeed in clarifying which of these was to be followed up. Ultimately, their work fell short of its intended outcome.

15.11 It appears that there were failures:

- to grapple with the potential topics set out at the Risk Summit, and to map out the work that would be needed. This would have included an assessment of whether it was in fact feasible to study the case mix and outcomes, or whether the best evidence available was actually provided by NICOR's data. As it was, the Review felt that Mr Brawn and Dr Salmon were never equipped for this task, however valuable their clinical insights into the children's cases and the model of care at the Children's Hospital undoubtedly were.
- to maintain consistent contact with the families concerned, updating them about what was happening (or not happening) and why.

15.12 In addition, although NICOR's data was reviewed by NHS England, there was no clear mechanism for feedback to concerned families about the conclusions reached as a result.

16 Conclusions

- 16.1 There was effective co-ordination between commissioners, regulators and the Trust in the wake of the CQC's inspection, with a view to sharing information and agreeing on the actions needed. Decisions were taken on funding for additional beds for high dependency care and there was effective monitoring of the Trust's action plan to effect widespread changes, as discussed further in the following chapter. The Risk Summit as a mechanism worked well to bring key organisations and individuals together.
- 16.2 The exception to this picture of communication and inclusion were the families who had first gone to the CQC. They were left largely outside this process and were not satisfied that proper action was being taken.
- 16.3 In relation to communication between families and the Trust, the Trust failed to continue attempts to involve one family in the actions agreed as a result of a RCA and to share information about continuing investigations. More generally, we perceived a sharp contrast between the early acknowledgement of either failings or areas for improvement in CDRs or RCAs shared with families, and the Trust's subsequent defence of the model of care in Ward 32 prior to September 2012, after the CQC had found that the Trust had not complied with certain of its standards.
- 16.4 While there were some meetings with families, held by the CQC and by representatives of NHS Bristol, the SHA and the NHS's Commissioning Board and, in due course, NHS England, during the course of late 2012 and 2013 families were not only preparing for their children's inquests, but seeking support or help from a very wide range of bodies in the NHS and elsewhere to answer further questions which they had. Their experience was of a lack of progress or action.
- 16.5 The Review concluded that organisations within the NHS, and more particularly NHS England, failed to engage consistently with families throughout 2013, and to develop and deliver a strategy for reporting on what had been done to investigate or to address concerns. These failings played a part in creating the situation which eventually led to the commissioning of this Review.

17 Recommendations

- 17.1 In light of the above, we **recommend**:

<p>(24) That urgent attention be given to developing more effective mechanisms for maintaining dialogue in the future in situations such as these, at the level of both the provider and commissioning organisations.</p>

CHAPTER FOURTEEN - THE TRUST'S ACTION FOLLOWING THE CQC'S INSPECTION

Introduction

- 1.1 The CQC's inspection and its findings triggered agreement that dedicated beds for patients needing high dependency (HD) care should be commissioned, on Ward 32 and ultimately in respect of other medical wards more generally.
- 1.2 The immediate response of the Trust to the CQC's inspection focussed on ensuring that patients were cared for safely on Ward 32. Four beds were closed and an instruction was issued that all high dependency care should take place on PICU. Operating on a Friday was restricted. Steps were taken to support families with children on the ward and staff. The Nurse Consultant for PICU was asked to make sure that she was present on the ward on a daily basis and the Matron also increased his presence.
- 1.3 An extensive programme of work was set in motion to address both the beds for HD care and the wider issues which had been noted by the CQC. The work was set out in the 'CQC Action Plan'. Weekly meetings to report on action were held.
- 1.4 In parallel, work was also taken forward in response to the Trust's own investigations and reviews carried out in 2012 in respect of four major RCAs, the Child Death Reviews for the two families who were instrumental in prompting the CQC's inspection, the response to the complaint made by one of these families, NICOR's clinical audit action plan⁹⁴ and the plan for the team-working arising out of the incident in the operating theatre referred to in Chapter Seven of this report. Ultimately these action plans were consolidated into one document called the 'composite paediatric services action plan'. It ran to thirty-three pages and addressed the issues and the actions in response in detail. We have summarised main themes only here.
- 1.5 Progress was monitored by the Divisional Quality Assurance Committee and was ultimately agreed to be completed in April 2015.
- 1.6 Some of the matters on which the Trust took action have already been set out elsewhere in this Review, namely improving the process of obtaining consent, improving arrangements to support the JCC and focussing on measure to improve team-building and develop leadership. A 'service transformation programme' was also established to improve the pathway of care for children with CHD and outpatient services. This programme of work was designed not only to improve services but also to improve working in multidisciplinary teams. In the sections that follow we set out the other key matters on which the Trust took action.

⁹⁴ See Chapter Four.

2 'Core Care Plans' and Care of the Deteriorating Child

- 2.1 One major theme in the Trust's investigations and reports of early 2012 had been failures to identify or to respond to the deteriorating child. The CQC's report also set out that there was an apparent lack of personalised planning of care and of clear evidence that parents were involved in such planning. The report noted the 'lack of detail about the child's needs making it more difficult for nursing staff to fully understand the needs of either the child or the parent'.
- 2.2 As part of the action plan, changes were made to ensure 'core care plans' and accompanying documentation were comprehensive and contained 'person/child centred' information. A new clinical protocol 'Recording Inpatient Paediatric Physical Observations, Pain and Early Warning Scores' was developed and put into place. It set out the expectations and standards to be applied when observing and recording a child's clinical condition, and explained the Paediatric Early Warning Scores (PEWS) system and the action to take in response.
- 2.3 A Paediatric Early Warning Scores (PEWS) system was already in use, but the chart used until November 2012 was basic compared to that subsequently developed. The earlier version included a recommendation to seek help if any parameters met the relevant criteria by contacting one or more of a list of staff. The list included the nurse in charge, Outreach, the medical team on the ward, or PICU staff, but there was no clear hierarchy as regards referring concerns. The general category E4 'any child whose condition is worrying' appeared to be the main category used on the charts that we reviewed.
- 2.4 In November 2012, the new improved PEWS was introduced, based on a numerical system of ascending severity. It used a standard method of communication called SBAR (Situations, Background, Assessment, Recommendation), which is a recognised mechanism for improving clinical communication by using 'prompt' questions to ensure that staff share concise and focused information. The line of communication followed when raising concerns about a patient and the referring of concerns was given a clear hierarchy: Nurse-in-Charge first, then Outreach and then medical staff. The new chart was more flexible in enabling changes to the parameters, something particularly important in children with CHD. To accommodate more personalised care, the charts were also modified into categories of 0 -12 months of age, 1 - 4 years of age, 5 - 11 years of age and 12 years plus.
- 2.5 One of the Outreach nurses commented about the differences: *'On the front of the [new] 2012 observation charts there's a clear escalation of what the nurse at the bedside is to do if the PEWS on the observation charts are above a certain level.'* Another commented, *'Even if the children are a low PEWS but if the nurse is worried or the parents are worried we can still get involved and get a call in as well.'*
- 2.6 Another addition was a box where nurses and parents could write their concerns. Discussing this, some of the Outreach Nurses commented that these concerns are now

more easily recognised and taken more seriously, enabling parents to express concerns where, although the clinical observations may appear to be fine, aspects of their child's physical presentation differs from the normal state.

- 2.7 The Paediatric 'Core Care Plans' were also reviewed and updated with final versions in use since March 2013.
- 2.8 We noted that the area of care of the deteriorating child was one in which significant national work has also been undertaken, by the NHS England's Patient Safety Team and the Royal College of Paediatrics and Child Health. This work has made it clear that there are many interlocking reasons why the deterioration in a child's condition can be missed, including weaknesses in systems for responding to physiological changes, limited engagement of parents or carers and gaps in healthcare professionals' training and education. A project was led by NHS England in 2015, called ReACT or the 'Respond to Ailing Children Tool', which has resulted in the production of a series of tools to aid the recognition of and response to ill children and young people. The tools include films for parents and families, expert talks, webinars and documents and presentations.
- 2.9 The Review noted the existence of this work, and that it was apparent that systems improvement in systems to ensure the effective identification and response to children whose condition was deteriorating remained an area of challenge and for improvement on a national level.

3 Enabling Parents to Raise Concerns

- 3.1 The Trust undertook work to develop a Standard Operating Procedure (SOP) entitled 'The Acutely Ill Child - Parental (Patient) involvement in Escalation of Clinical Care'. The aim of this SOP was to clarify the process of empowering parents to 'escalate' concerns if they were worried about the clinical condition or care being provided to their child. The Trust was particularly keen to ensure that the systems in place were effective throughout seven days a week, 24 hours a day, as it was recognised that previously there were weaknesses in the system during weekends and overnight in particular.
- 3.2 A number of parents whose children had received care on Ward 32 and volunteers from Bristol's parent/carers group were involved in this work. The Trust has involved families in subsequent audits of effectiveness.

4 Communication and Ward Rounds

- 4.1 Participation in ward rounds and the need to improve communication across the multi-disciplinary team, including between junior medical staff and senior medical colleagues and between medical and nursing staff, had been identified as a need for improvement (as it had been in the Bristol Public Inquiry).

- 4.2 A template for conducting Ward rounds was agreed in August 2012 and there was an audit in October 2012 and again in April 2013. These audits showed substantial improvement in participation. Between October 2012 and April 2013 there was an increase in nurses' presence from 52% to 90% at ward rounds in the morning and similarly from 66% to 100% at ward rounds in the evening. Compliance by medical staff was recorded as 100% for ward rounds and 85% for Board Rounds.
- 4.3 Meetings took place between the on-service consultant cardiologist and the ward manager at the conclusion of the ward round, to ensure that each child had an identified cardiologist, and to discuss potential discharges and admissions to the ward over the next 24 hours, as well as requirements for discussions by multi-disciplinary teams.
- 4.4 Arrangements for handing over responsibility between teams and shifts had been found to lack rigour. Arrangements were made to strengthen these arrangements and to ensure consistency, in relation to, for example, transfer of children from PICU to Ward 32 and the handovers at night from the specialist cardiology registrars to the specialty medical registrar.
- 4.5 A programme of training using clinical simulation was undertaken to improve the interpersonal dynamics of team-working. Specific measures to build teams and develop leadership were also undertaken.

5 Pathways of Care and establishing the Cardiac HDU

- 5.1 An HDU Operational Group was established to take forward the planning for the establishment of the cardiac and medical HDUs. This group undertook the work to establish a clear pathway of care from PICU to HDU and then to Ward 32 and to develop the model for the medical staff required for the Unit.
- 5.2 The 'Model of Care for the Cardiac High Dependency Unit - Ward 32' was ratified in February 2013. This document set out the protocol to be used for admission to the unit. A further document 'Levels of Care for Inpatient Children with Cardiac Conditions' detailed the criteria to be used to assess whether a child's condition requires intensive care, high dependency care, or specialist care on the ward. This was a clear practical tool to be used by all members of the multidisciplinary team.
- 5.3 This tool used the red/amber/green rating that is commonly used in health care and relates to the acuity of the child's condition, with red being intensive care. It was a tool that could also be understood by parents. We commented in earlier chapters upon the need for the development of tools to measure patient acuity, so as to assess nursing needs. As a result of implementing such tools, we were told that the Children's Hospital now has two years of robust data to support planning of future requirements for nursing.

- 5.4 A new high dependency area needed new arrangements for consultant leadership and cover. Clear expectations were set for the duties of the on-service cardiologist who provides senior clinical oversight of the service each week on rotation and twice daily, seven days a week. The ward round in the high dependency area is undertaken jointly by a cardiology consultant and the high dependency consultants, who are a group of the intensive care consultants who have developed this role. It was felt by the PICU consultants that it was important that intensive care expertise should be available on the ward, in high dependency areas.
- 5.5 The Review's experts commended this.
- 5.6 Two Cardiac HDU beds were opened on Ward 32 in April 2013. Although we heard some criticisms of empty beds by parents whose children were admitted at around this time, the number of beds available increased as the recruitment of nurses progressed. The Unit functions with a funded base of 5 beds but operates 4-6 beds depending on clinical need and levels of staffing.

6 Levels of Nursing Staff and Recruitment

- 6.1 As was set out in Chapter Eight, the 'Report of the Workforce Benchmarking Project of Tertiary Children's Services' ('the Williams Report') was commissioned by the Trust in summer 2012 and undertaken between October and December 2012. The Report recommended that staffing should be increased to reflect the complexity of tertiary/specialist services. The recommendation was accepted by the Trust Board of Directors and an investment of £1.6 million was made to increase the number of children's nurses.
- 6.2 In April 2013 the funded establishment of nurses for Ward 32 was increased to levels which support one nurse to three patients receiving care on the ward during the day and one to four at night, with one nurse to two patients in the Cardiac High Dependency Unit. The investment was focussed on all grades of nurses, but specifically on more senior nurses particularly senior staff nurses and those in Band 6, so that a Band 6 nurse was present on every shift. This provided greater supervision and greater guidance for the middle grade and the junior staff. This arrangement was complemented by the leadership of a supervisory Ward Sister who could direct the Band 6 nurses and the rest of the nursing team, as she was not engaged directly in the care of patients.
- 6.3 The Trust also undertook work to improve the recruitment of nurses across all specialties in the Children's Hospital to reduce the use of Bank and agency staff. Advertisements were placed and a new strategy for recruitment was implemented in 2013 to recruit potential paediatric nurses and to ensure that the Children's Hospital was an attractive employer, for a pool of staff in high demand.
- 6.4 The Review noted that as part of work nationally on safe levels of staffing following the Francis Inquiry, from April 2014, all hospitals have been required to publish levels of

staff on a ward-by-ward basis together with the percentage of shifts which meet the guidelines for safe staffing. The Trust displayed daily information on boards for patients and visitors inside every ward about the number of nurses and care staff present and planned on each shift. Information about levels of staffing was also published monthly on the Trust's website and on NHS Choices. Full details were also reported to public meetings of the Board of Directors.

7 Skills and Training

- 7.1 Following the CQC's inspection of Ward 32, the Trust set in place a 'Training Needs Analysis' which defined the qualification required by nurses working in Ward 32. An appendix to the document set out that, at November 2012, 49% of RCNs had undertaken a course in high dependency care and 65% of RNs had undertaken a paediatric cardiac course. The expectation was set that from December 2014, 80% of all RNs would fulfil the qualification for the speciality.
- 7.2 A record of paediatric clinical competency was also developed for ward nurses. The 'Report on External Assurance Exercise - Ward 32 Action plan' notes that by August 2013, 95% of all registered staff on Ward 32 had been assessed as competent against the core measures of clinical competence and 'the expectation is that by the end of December 2013 the same would be achieved within the cardiac competencies for all staff in post at January 2014'.
- 7.3 Investment was also made in a dedicated cardiac educator for PICU and Ward 32 to support staff in the development of clinical skills.

8 Follow up by NHS Bristol Clinical Commissioning Group

- 8.1 Responsibility for seeking assurance that the Trust's action plan following the CQC's inspection was properly implemented passed to the newly created Bristol CCG in April 2013. The CCG took this work forward through Integrated Quality and Performance Management Meetings (ICQPMs). Detailed discussions took place regarding the action plan, with the Trust reporting all actions completed at the ICQPM's meeting in June 2013.
- 8.2 The Chief Nurse, Ms Alison Moon, from UHB took up a new post at Bristol CCG from April 2013 as Director of Transformation and Quality. Since she had been the former executive responsible for the action plan for Ward 32, an external review of implementation of the action plan was jointly commissioned by Ms Alison Moon and Ms Lindsey Scott (Director of Nursing and Quality NHS England: Bristol, North Somerset, Somerset and South Gloucestershire Area Team).
- 8.3 The review was carried out by Liz Childs, a former Director of Nursing and a paediatric trained nurse. She had been recommended by the Director of Nursing, NHS England South, and the Review could see no conflict of interest or lack of independence in her role or work. She undertook this work during August 2013 and presented a report which was considered at the meeting of the CCG's Governing Body in November 2013. Her report concluded that all aspects of the CQC's action plan had been addressed

based on evidence from documentation and observed practice. She noted that attention continued to be needed to achieve full implementation at the time of her report and emphasised the importance of periodic monitoring, audit and review to ensure the effectiveness and sustainability of the changes. The Governing Body accepted her report and its recommendations and agreed that implementation would be monitored through the ICQPM's meetings and the question of assurance should be the responsibility of the Quality and Governance Committee.

- 8.4 The minutes of Bristol CCG's Contract and Performance Management Board Meeting on the 20th of November 2013 recorded that the Trust's Division Quality Assurance Group had accepted the external review's findings and that the resulting action plan arising from the recommendations would be reviewed by the CCG on a quarterly basis. Any low and unsafe levels of staff were also to be kept under review by the CCG.
- 8.5 At the next meeting in January 2014, it was recorded that Ward 32's action plan developed following the CQC's inspection had been closed; monitoring of the composite paediatric services action plan which replaced it would continue.
- 8.6 The Review noted evidence that implementation of this plan was taken forward by the Trust and the completeness and adequacy of the actions was reviewed by the CCG through the ICQPM.
- 8.7 On the 27th of January 2015, a paper was presented to the CCG's Governing Body giving the latest updated action plan which had been discussed at the November 2014 IQPMB's meeting. The Governing Body was asked to:
- accept that the CCG and NHS England have through the extensive monitoring and reviews of completed actions received assurance that the action plan is completed and improvements in services have been made;
 - approve the recommendation that the action plan is closed and paediatric cardiac services will be monitored through business as usual through the ICQPM and through meetings of the Trust and commissioners.
- 8.8 The Governing Body accepted the recommendations of the report.
- 8.9 The Review considered that there had been a thorough process for follow-up and assurance of the composite cardiac action plan by both the Trust and the CCG.

9 The CQC's inspection 2014

- 9.1 In September 2014 CQC undertook a comprehensive inspection of the Trust under CQC's new methodology. Under this, the Trust would be informed of the date of the inspection to allow them to submit relevant evidence in advance of the inspection and make sure that key staff are available to be interviewed by CQC on these days. These announced days may be followed by unannounced visits. The Commission undertook announced inspections on 10, 11 and 12 September and an unannounced inspection on 21 September 2014.

9.2 The CQC's findings in respect of services for children and young people were:

- Services for children and young people were found to be good. Children received good care from dedicated, caring and well-trained staff skilled in working and communicating with children, young people and their families.
- Outcomes for patients were routinely better than expected which was demonstrated through independent benchmarking. There was evidence of staff being involved in the development and review of policy, procedures and implementing a change practice, where improvements in outcomes were required. There was a strong commitment to the skills knowledge and competence of all staff. The Trust had developed a Paediatric Faculty of Education at the hospital to develop the skills, competence and knowledge of staff.
- Transitional care was outstanding, young people had been involved in the development of the service and planning occurred from an early stage.
- Children and their families were actively involved in their care and treatment and their feedback regularly sought and listened to.
- The arrangements for safeguarding were excellent and staff spoke about the open culture that encouraged them to report issues as they arose. Following a successful recruitment campaign, wards were staffed with well-trained and competent staff.
- The majority of comments from parents, children and young people were very positive. They told inspectors that they thought the staff were brilliant and the facilities excellent.

9.3 The Commission's ratings for services for children and young people were:

- Safe – Good
- Effective - Outstanding
- Caring - Good
- Responsive - Good
- Well Led – Good
- Overall - Good

9.4 In the Review's judgment, substantial lessons have been learnt within cardiac services, from the criticisms which had been expressed.

10 **Feedback from Staff and Families**

10.1 The nurses we spoke to recognised positive improvements once the Cardiac HDU beds were open and more recently and significantly now there was also a HDU Consultant.

10.2 We looked at the information that we had received from families, about their experience of Ward 32 following the creation of dedicated beds for high dependency care. We acknowledge that it was difficult to form a full and consistent picture, given the limited information which we had.

- 10.3 We received some positive comments about the new high dependency beds. One family reported that they were 'reassuring to us', as they seemed like a reasonable step down between PICU and being a 'general' patient on Ward 32. Another noted 'brilliant supportive nurses and doctors'; the child was also seen by the dietician. The family drew a contrast between a poor experience in early 2012 and one in mid-2014, when they had to return for a further operation. On this occasion, they had a few nights on PICU which went well and there was a higher degree of support and interaction on Ward 32, especially from the Nursing Assistants.
- 10.4 One family commented that more could be done to explain changes in care to families: *'The move from HDU to Ward 32 is not explained. The assumption is that the parents will just think it's good and will accept that. There is no recognition that parents will be anxious. The view seems to be that parents are going to be anxious when care changes and there is nothing that you can do about it.'* We heard some continued concerns about the management of infection on the ward.
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11 Conclusions

- 11.1 We accept that significant changes were made in the delivery of care on Ward 32 and in cardiac services more generally, in the wake of the CQC's inspection of September 2012. They went substantially beyond the establishment of dedicated high dependency beds, to improvements in areas such as triggering reactions to warning scores, listening to parents and improving team-working and communication. We have tried to sketch out the main areas where there was change and development.
- 11.2 In the Review's judgment, there had been substantial learning, within cardiac services, from the criticisms which had been voiced and the findings of the Trust's own reviews and investigations.

CHAPTER FIFTEEN: THE COMMISSIONING OF HIGH DEPENDENCY CARE AT BRISTOL CHILDREN'S HOSPITAL

1 Introduction

- 1.1 Some families and members of the public raised concerns about the decision by NHS Commissioners not to fund high dependency care at Bristol Children's Hospital before the CQC had found non-compliance with regulatory standards on Ward 32.
- 1.2 The Review obtained documentation, and held discussions with current and former staff from NHS commissioning organisations and the Trust, to investigate the history of discussions and decisions regarding the commissioning and provision of high dependency care at Bristol Children's Hospital.
- 1.3 We set out below the structure of commissioning arrangements and then the history of the commissioning of high dependency services at the Children's Hospital.

2 Documentation

- 2.1 The Review asked NHS England, as the current commissioners of specialised services, to provide documentation relating to the discussions of the former South West Specialised Commissioning Group (SWSCG).
- 2.2 The Review received the full support of NHS England's staff and they made significant efforts to trace documents. However, the documentary evidence was incomplete for the period 2009 to April 2013 due to organisational changes and the absence of a complete archive of documents. For example, minutes from all committees associated with SWSCG could not be made available for the entire time period.

3 Commissioning and organisational changes, 2010-14

- 3.1 Discussions regarding high dependency care in the South West region have their origins in discussions during 2008. The commissioning of healthcare services was at this time, the responsibility of Primary Care Trusts (PCTs). Where services being commissioned were part of a designated set of 'specialised' services, they discharged this responsibility through collaboration with neighbouring PCTs called the Specialised Commissioning Group (SCG). This was a formal constitutional arrangement through which a SCG was formed as a sub-committee (or committee in common) of the PCTs.
- 3.2 The thirteen PCTs across the South West of England formed the South West Specialised Commissioning Group (SWSCG). The services commissioned by the SWSCG were funded by a contribution taken from PCTs' budgets. The approval of funding for new developments was subject to the agreement of all the PCTs, agreed through meetings of the SWSCG.

- 3.3 The SWSCG had a team of officers who conducted the business of the SSCG. The Chair of the SWSCG was Deborah Evans, Chief Executive of Bristol PCT, and the Director of Specialised Commissioning was Ann Jarvis.
- 3.4 The responsibility for the joint planning of specialised services in Wales throughout the period was undertaken by the Welsh Health Specialised Services Committee (WHSSC) on behalf of Local Health Boards. There were close working arrangements between the two commissioners regarding the services in Bristol.
- 3.5 Bristol PCT was the co-ordinating commissioner for University Hospitals Bristol NHS Foundation Trust. This meant that it took the lead on behalf of all PCTs who commissioned all non-specialised services from the Trust in negotiating service agreements and monitoring quality. The Bristol PCT's officers would work with the SCG's officers on matters of quality and commissioning, given the inter-relationships between services.
- 3.6 After the passage of the Health and Social Care Act 2012, changes were made to the structure of the NHS in England from 1st April 2013. PCTs and Strategic Health Authorities were abolished and Clinical Commissioning Groups and NHS England were established. The responsibility for commissioning specialised services passed to NHS England on the 1st of April 2013. Across England, NHS England established four Regional teams; under these were twenty-seven Local Area Teams. The Bristol, North Somerset, Somerset and South Gloucestershire (BNSSSG) Area Team was responsible for commissioning all specialised services for the South-West and therefore became the leading commissioner for paediatric cardiac services at BRHC from April 2013 onwards.
- 3.7 In the period prior to the formal changes coming into effect various interim arrangements were in place. From February 2012⁹⁵, the SWSCG ceased to function and specialised commissioning was discharged by the South of England Specialised Commissioning Group chaired by Debbie Fleming, Chief Executive of the Southampton, Hampshire, Isle of Wight and Portsmouth PCT Cluster.
- 3.8 In the period prior to its abolition, Bristol PCT operated as a PCT cluster with North Somerset and South Gloucestershire PCTs. This was a transitional arrangement in which the three Primary Care Trusts retained separate arrangements as regards their Boards and governance but were supported by a single Chief Executive and team of staff.
- 3.9 In April 2015 NHS England changed its structure and Local Area Teams were removed. Responsibility for the commissioning of the paediatric cardiac service in Bristol passed to the South of England Region.

⁹⁵ Or a little earlier; its last meeting was in December 2011.

4 Review of High Dependency Services in the South West

- 4.1 In 2008 the South West SCG had conducted a review of paediatric surgery in the South West. This recommended a review of High Dependency Care (HD Care) in order to ensure appropriate capacity and links with other parts of surgical care. Commissioners wanted to understand the current configuration and capacity of existing high dependency services, their operating arrangements, strengths, constraints and challenges. This included how high dependency services related to PICU and the rest of the system of paediatric care.
- 4.2 In June 2010, a Project Initiation Document (PID) for the review was submitted to the SW SCG. The PID set out that SCGs were required to designate PICU services and in order to do so effectively they needed to understand other key elements of the pathway of care, including high dependency care. The work was commissioned and funded by the Strategic Health Authority (SHA).
- 4.3 A Project Board and a Project Team were established to take the work forward. The Chair was the Medical Director of the SW SCG, and the clinical lead was Dr Peter Davis, an Intensivist from Bristol Children's Hospital and Director/Lead Clinician for Paediatric Critical Care/Intensive Care.
- 4.4 Work was undertaken to identify and agree standards of good practice in the provision of high dependency care. The national guidance identified were:
- High Dependency Care for Children – Report of an Expert Advisory Group - Department of Health 2001
 - Tanner Report 2006
 - Paediatric Intensive Care Society Standards 4th Edition 2010.
- 4.5 In the report on their work, the Project Board noted that since 2001 the recommendation had been that all hospitals where children are treated should have arrangements in place for paediatric high dependency care. The recommendations set out that children requiring such care should be cared for by a children's nurse with training in paediatric resuscitation and competence in providing high dependency care. This care should be available in 'an appropriately designed and equipped area'.
- 4.6 In order to gain an understanding of compliance with standards each Trust providing acute hospital services for children was required to submit a self-assessment of their performance against the standards. We made reference to the submission from the Trust in the discussion of High Dependency Care, Chapter 10.
- 4.7 On the 15th July 2011, the report on the review of the paediatric high dependency services in the South West was presented to the South West Directors Group. This Group comprised Specialised Commissioning Group's staff and the Directors of Commissioning and Finance leads from the constituent PCTs. The involvement of leaders from the PCTs reflected the fact that specialised services are generally a part of a patient's pathway, starting out from and returning to the wider services which PCTs

commissioned. This made it vital for PCT's staff to be aware of the work of specialised commissioners.

- 4.8 The report set out that 'High Dependency services are not within the specialised definition set and are therefore commissioned by PCTs, but the efficient delivery of this service has immediate impact on specialised services, including PICU. There are also a number of specialties that have specialised HD services i.e. Burns. There is also inequity in the value and the method of the funding of HD services throughout the South West.'
- 4.9 The report presented what the Project Board considered to be the risks associated with the current service. It noted that 'Paediatric high dependency care is often provided at the expense of other services because members of staff are moved from the area they are working in to care for high dependency patients. This is not sustainable. In some cases this will continue until additional financial investment becomes available'.
- 4.10 In relation to UHB it stated: 'University Hospitals Bristol NHS Foundation Trust has particular issues related to high dependency given its dual role of providing both secondary and tertiary paediatric care, and being the provider of paediatric intensive care services for the region...There are currently no specific high dependency areas available within Bristol Royal Hospital for Children, although there are many children already receiving specialist tertiary care who have high dependency requirements and who would benefit from such facilities. Similarly there are also local children who require high dependency care for general paediatric conditions, who because of the lack of appropriate facilities are admitted to the Paediatric Intensive Care Unit, the only area within the hospital where such care can be currently provided safely. At times there is the potential that these high dependency admissions may adversely affect PICU bed availability for children elsewhere in the region who require intensive care.'
- 4.11 The Review noted that the emphasis was upon the pressures created for PICU by the lack of specific beds for high dependency care in the Children's Hospital. There was no recognition of, or discussion of, the point that had been made in the Trust's self-assessment; that children requiring high dependency care might at times be admitted to the wards rather than to PICU; and that, if so, 'on occasions nursing numbers may not allow for children meeting High Dependency criteria, to receive staffing levels as defined.' We note, however, that the Project Board for the Review of High Dependency Services for Children was strongly clinically led;⁹⁶ the approach to key findings presumably reflected their input.
- 4.12 In its recommendations the Project Board noted that the standards were 'recommendation rather than requirements', but it asked the Directors Group to consider the public's expectation and the 'litigious and constitutional risks' if standards

⁹⁶ It was chaired by the Medical Director at Taunton and Somerset NHS Trust and included seven Consultants and two senior nurses.

were not met. The Project Board's view was that providers and commissioners who were unable to meet the standards should have a 'comprehensive risk assessment' to consider the clinical, regulatory and reputational risks attached to non-compliance. The geographical area singled out as particularly needing a comprehensive risk assessment was the pan-Dorset health community, reflecting the widespread gaps in provision identified across the Region.

- 4.13 The minutes do not indicate the views of those present on any of the issues or recommendations. They record only that the report was presented and that, as paediatric HDU services were 'not in the Specialised Services National Definition Set, the responsibility for this service lies with PCTs.' No actions or agreements were recorded in the minutes.
- 4.14 At the meeting of the SWSCG on the 5th of October 2011, the SWSCG received the minutes of the SW Directors Group of 15th July 'for information'. Based on the minutes which NHS England was able to locate, through to October 2011 only, the report on the outcome of the review of HD care was not specifically reported back to the SWSCG meeting. We were concerned, if that was so, that a significant review of this nature was not reported back to the SWSCG. On the basis of the minutes of the SW Directors Group on the 15th of July 2011, they would have been unaware of the report's findings. We felt that this was a missed opportunity to highlight the relevant concerns to a senior and influential group.
- 4.15 On the other hand, the paper recorded that one of the next steps was to send the paper to PCT Cluster Chief Executives and Directors of Commissioning to follow up on individual Trust self-assessments, as well as presenting it to the SW SHA (the commissioners of the work).
- 4.16 The Review received a copy of the letter subsequently sent by the Director of Specialised Commissioning SWSCG to PCT Cluster Chief Executives. The letter did not highlight matters regarding non-compliance nor record the expectation set out in the report that action was required to review risks. However, the report itself was enclosed with the letter.
- 4.17 The initial targets that had been set out in the Project Initiation Document had included: 'Produce a draft action plan for consideration by Primary Care Trusts and the South West Strategic Health Authority.' It did not appear that a draft action plan was, in fact, drafted, and the SHA was no longer playing a visible role as leading the work. It seemed to the Review that there was an absence of clear action in response to the review. Responsibility for the development of HD services across the SW was divided between PCTs and the commissioners of specialised services⁹⁷; it seems that there was

⁹⁷ In transition from the SWSCG to the South of England Specialised Commissioning Group at the time.

no agreement reached as to how this work was to be carried forward in a planned fashion, involving all those with an interest.

- 4.18 The Review asked former PCT Cluster staff about the report and any actions following it. The Review was told that by this time, discussions were underway with UHB regarding bids for a high dependency unit and this was the basis on which the matters were taken forward.
- 4.19 We were further told by staff formerly involved in commissioning that the Trust did not allude to or report any concerns about safety in relation to the model of high dependency care. Commissioners understood the key concerns were about releasing capacity in PICU and recognising that 'flexing' the staffing to care for patients needing high dependency care on the wards had consequences for services across the hospital and was not in line with recommended standards. There was also an awareness that the Trust was an outlier in not having a dedicated HDU. In relation to cardiac services, the absence of any indications from data on mortality that Bristol was an outlier and its inclusion as a centre which would continue to provide services under the Safe and Sustainable proposals were also mentioned as providing assurance to commissioners.
- 4.20 The Review was concerned that the Project Board's view, that providers and commissioners who were unable to meet the standards should have a 'comprehensive risk assessment', was 'lost' or was never the subject of action. We accept that the Trust did not report concerns about safety in relation to its model of high dependency care, (certainly before February 2012, when it did prepare a risk assessment noting the 'Unsustainability of current model of service delivery' and 'an inherent risk of compromised care', although it is not clear how visible that assessment was to the commissioners themselves). But, that said, from mid-2011, the PCT Cluster and the SW SCG were in a position to seek assurance that the Trust had taken steps to carry out its own assessment of risk.
- 4.21 It was suggested to us that such a risk assessment was essentially a matter for the UHB, which was expected to have mechanisms for comprehensive risk assessment in place as part of effective arrangements for governance. We have commented on the UHB's approach in earlier chapters. Here, we note simply that the Project Board had identified the need to seek 'comprehensive assurance' that risks had been addressed; and that such a step could have been useful in enabling commissioners to reassess the importance of funding an HDU, having already turned down a bid in early 2011.

5 Trust's submissions seeking funding for a high dependency unit

- 5.1 We were told that the history of the Trust's submissions to Commissioners seeking funding for a high dependency unit in the Children's Hospital started in late December 2010, when UHB approached its commissioners to secure funding for dedicated provision of a medical HDU as part of the preparation for the 2011/12 contract. In early 2011, however commissioners notified the Trust that they were unable to make it a priority. Information about this bid was very limited, not least as it seems that the

- proposal never got past the initial discussion and no written proposal was developed.
- 5.2 At this point, the SW's review of the provision of high dependency care was continuing. We have seen that a report was produced in July 2011.
- 5.3 By late 2011/early 2012 it is apparent that the priority attached by the Trust to securing facilities for high dependency care had altered. In a written briefing from the Trust, it advised the Review that by this time benchmarking demonstrated the Trust to be an outlier in the provision of dedicated HDU, both nationally and regionally, and that the Trust had recognised that the sustainability of the current model was being compromised, particularly in regard of the ability to respond to peaks of high acuity and need. This essentially was how the risk was described in the entry on the risk register made in February 2012.
- 5.4 In late January 2012⁹⁸, at about the same time as the risk assessment for high dependency care was developed, the Trust approached its commissioners again and presented the development of medical HDU as a priority for investment in the 2012/13 planning round. At this stage there were no separate proposals for a Cardiac HDU on Ward 32.
- 5.5 The Trust stated that the bid for a medical HDU was presented as one of its highest priorities alongside the expansion of PICU. It told us that despite significant increases both in the demand for beds and the acuity of patients, the last investment in PICU had been in 2007.
- 5.6 After discussions between the Trust, the PCT and specialised service commissioners about the responsibility for commissioning HD care (which remained unresolved), commissioners advised they would not support the development of a dedicated HDU or the expansion of PICU. It was judged by commissioners that further work was needed before a commitment could be given to funding. We noted that additional funding for specialised commissioning was agreed for areas which included neonatal intensive care, paediatric oncology and haemophilia.
- 5.7 The Review was told that it was acknowledged that the issue of high dependency services had to be resolved before the transfer of burns, neurosurgery and trauma services from North Bristol Trust. Commissioners gave the Trust a commitment to do more work during the year.
- 5.8 A commitment was also given to try to resolve the issue of which commissioning body was responsible for funding HD care: specialised commissioners or PCTs. Discussions continued in March and April 2012. The difficulty arose from the fact that some elements of high dependency care could be seen as an aspect of specialised services

⁹⁸ There was some information suggesting that a bid was put forward in autumn 2011, but the better view seems to be that it was in early 2012 that this took place, at least at a formal level. The first clear documentation of the proposal was in the notes of a UHB/SCG Contracting Meeting (Full Group) taking place on 25 January 2012.

(such as paediatric cardiac services); others (such as care for the long-term ventilated patients, which was an element of the case for a medical HDU) could be seen as care that fell within the general commissioning responsibilities of PCTs.⁹⁹

- 5.9 The Review asked about the importance of this issue and its contribution to delaying agreement on funding. We were told that its importance should not be exaggerated. At the end of the day, all the funding for high dependency would come from the PCTs' budgets, whether it was drawn from that element which had been 'top-sliced' to support the specialised commissioning group or not.
- 5.10 Documentation set out that another meeting to discuss paediatric HDU was held in July 2012. Work progressed on a business case that was due to be presented in the autumn of 2012 for funding in 2013/14.
- 5.11 Following the CQC's inspection in September 2012, the priority attached to these discussions changed considerably, with urgent discussions with commissioners and proposals to develop HD in Ward 32 put forward. In December 2012, it was clarified that the responsibility for commissioning such proposals lay with the NHS Commissioning Board (the predecessor of NHS England), rather than the CCGs. In March 2013, UHB received the agreement of the South of England SCG and the NHS Commissioning Board at the meeting of the 2013/14 Contract Negotiation to establish dedicated cardiac HDU care in Ward 32 of the Children's Hospital.
- 5.12 As the Trust had started recruitment in the autumn of 2012, the cardiac HDU began functioning from April 2013 with 2 beds. It was fully staffed and functioning by August 2013, flexing between 4 and 6 beds subject to demand.
- 5.13 The establishment of a medical HDU was also supported by commissioners in March 2013 and established in April 2013 by the Trust.
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6 Conclusions

- 6.1 We note that the Review was not able to access the entire archive on specialised commissioning from NHS England. This has limited the Review's ability to compile a comprehensive record of the discussions and actions regarding specialised commissioning involvement. We repeat a point which we fear is made all too often: that reorganisations will lead to a significant loss of 'organisational memory' unless comprehensive steps are taken to retain and organise archives.
- 6.2 From the perspective of commissioners (both within the PCTs and the Specialised Commissioning Group), there were widespread gaps in the provision of high

⁹⁹ Or their successors, the Clinical Commissioning Groups from April 2013 onwards.

dependency care in the South West region from 2010 – 2012. Steps were taken to identify those gaps, through the Review which reported in July 2011.

- 6.3 The relevant hospital services failed to seek explicit assurances that the gaps had been identified and risks were being properly managed.
- 6.4 The Review of High Dependency Care in the South West, completed in July 2011, did feed into a more thorough consideration of the proposal for a medical HDU which was put forward by the Trust in early 2012. Although that bid was not immediately agreed, it was not wholly dismissed and further work on the proposal continued.
- 6.5 The Trust faced a dilemma common to other Trusts: whilst it wanted to secure funding for its bids, it would not wish to do so by suggesting that there were real or unmanaged risks to safety. There is no answer to this dilemma except honesty. Here, the manner in which the bid was presented by the Trust was consistent with its internal assessment of the risk, which we have discussed in preceding chapters.
- 6.6 The commissioners' perspective up to this point in time was that, '... the issue was seen more that it was about the children were being cared for in the wrong place rather than that they were at risk. I don't think that the Trust were to saying to us [that] we regard there's a safety issue here.' Assurance was also derived from the fact that the Children's Hospital had a greater number of registered sick children's nurses than, say, a District General Hospital, such that it was felt that the skills-mix overall meant that children in the Hospital would be safely cared for.
- 6.7 The commissioner's perspective is open to challenge: the detail of the Trust's self-assessment for the SW's Review of HD care, if carefully scrutinised, showed wider issues than children being cared for for too long on PICU, and set out concerns about the nursing care available on the wards.
- 6.8 But viewed overall, we accept that until later in 2012, there was an absence of information to indicate to commissioners a pressing need to prioritise the development of HD facilities at the Bristol Children's Hospital. In particular, and in relation to paediatric cardiac services specifically, the serious incidents that were reported, NICOR's data on the outcomes and the manner in which the Trust itself presented its own bids for funding, did not suggest that immediate intervention was needed. We have made reference to a number of serious incidents and their subsequent investigations, in our review of the pathway of care. They were appropriately reported to the local lead commissioner, the Bristol Primary Care Trust and latterly the Bristol Clinical Commissioning Group, by the Trust. But, in 2010 – early 2012, those serious incidents did not relate to any failings on Ward 32 of a nature that might have led to questions about the need for high dependency care.

- 6.9 Neither the unsatisfactory debate over who was responsible for funding HD care, nor uncertainties caused by the reorganisation of the NHS taking place at the time, were reasons why no funding was agreed before commissioners had to respond urgently to the results of the CQC's inspection of September 2012. Equally, it would be wrong to criticise (or second-guess with the benefit of hindsight) the judgments on the priorities for funding that were made by those who assessed the bids for funding of HD care made prior to the CQC's inspection.
- 6.10 Nonetheless, having been notified about the problems which the Trust was having in adhering to the SW's standards on HD care, commissioners should have been clear about the need for all Trusts in that situation to show that they had effective plans to manage the consequent risk.

7 Recommendations

- 7.1 In light of the above, we make the following **recommendation**:

<p>(25) That when structural changes to the NHS are made, adequate resources are devoted to organising and archiving records in a way that will enable them to be retrieved and studied at a later date.</p>
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CHAPTER SIXTEEN: INVESTIGATING CONCERNS OF FAMILIES

1 Investigations and Handling Complaints

- 1.1 We noted in our review of parents' concerns that they might be potentially involved in a number of processes. They might choose to make a complaint. The Trust itself might consider that a serious incident had occurred and might initiate its own investigation, conducting a root cause analysis (RCA). If their child had died, a child death review (CDR) was required by law. The involvement of the Coroner's office and a Coroner's post-mortem might add a further layer of investigation and consequent complexity. These overlapping processes were established by law or national frameworks, rather than by the Trust.
- 1.2 The Report on the Bristol Public Inquiry contained a recommendation that 'there should be a clear system, in the form of a 'one-stop shop' in every trust for addressing the concerns of a patient about the care provided by, or the conduct of, a healthcare professional.'¹⁰⁰
- 1.3 We were told that the Trust operates a system merging complaints and 'PALS' (Patient Advice and Liaison Service) under the banner of the 'Patient Support and Complaints Team' (PSCT). The PSCT deals with enquiries, questions, concerns and complaints raised by patients.
- 1.4 The complexity noted above at paragraph 1.1 means that families raising a number of often complex concerns did not experience a 'one-stop shop', but rather a series of overlapping processes with an uncertain relationship to each other.
- 1.5 We saw that clinicians sought to manage some of this complexity by ensuring that a CDR followed once a RCA, or other investigation, was completed, whilst the PSCT provided an overall point of contact for families.
- 1.6 However, the relationship between the PSCT and clinicians was unclear. On one occasion, we saw that the views of the lead clinician determined the conduct of a meeting. Insufficient weight was given to the approach being taken by the PSCT's member who had been in contact with a family about their wishes as to whether the meeting would deal both with a complaint and with feedback about a CDR. Although we recognise that this was an attempt made, in good faith, to streamline parallel processes, it seemed to us contrary to spirit of the Trust's policy on dealing with complaints. Prior to July 2013, the policy did not explicitly address the issue of overlap between response to complaints and CDRs. But, referring to overlap between patients' complaints and investigations into safety, it stated that the Patient Support &

¹⁰⁰ We do not believe that this recommendation is inconsistent with the recommendation in the Francis Report that there should be 'multiple gateways' for people to make complaints. There should be many ways of accessing the complaints process, but a co-ordinated response to that process once accessed.

Complaints Team and Patient Safety Team would liaise and agree a way forward, ‘in conjunction with the complainant’.¹⁰¹

- 1.7 We saw examples of poor or inconsistent communication in responses to families about the processes involved.
- 1.8 In another case that we reviewed, the parents were not informed that a RCA was being conducted until after the meeting of clinicians had taken place. Although an apology for this omission was offered promptly by the Chief Executive and a meeting with the chair of the RCA then took place, the failure contributed to suspicions about the integrity of the investigation. Taken together with other instances which we have described in earlier Chapters, in which a family was not kept informed about the progress of investigations, the Review felt that in these cases both clinicians and the Trust’s leadership had struggled to take consistent and effective account of families’ perspectives in the investigation of serious incidents. We have no doubt that this had a detrimental effect not just on communication with the families involved, but on their trust in the integrity of the process and of the Trust’s general approach.
- 1.9 We recognise that we looked at complex cases, but it was apparent that there was a need for standard pathways, clearer communication and better support for families.
- 1.10 The review of risk management commissioned by the Trust in 2014¹⁰² stated that: ‘Risk management is taken very seriously within the Children’s Hospital but there is a concern that it could be described in some instances as over analysis with insufficient action i.e. a number of different reviews/meetings including the Child Death Overview Panel, Clinical Governance meetings and Clinical Audit reviews are potentially looking at the same things.’ It recommended that ‘The Division should review the processes for the Child Death Review Process in conjunction with any internal investigation to clarify boundaries of each enquiry and the role undertaken by Trust staff.’ There needed to be ‘clarity over the communication and involvement of parents and family’.¹⁰³
- 1.11 The Review was assured by the Chief Executive and senior clinicians that these challenges had been recognised. The Chief Executive told the Review that he considered that there had to be one response to the family, with all other activities subordinated to that requirement. The challenge was to find a process that met the needs of families within the requirements of statutory processes or frameworks, including those for complaints and child death reviews.
- 1.12 The Review noted that the Medical Directorate of NHS England (in its ‘Children and Young People Policy’) was aware of the need to work towards standardisation of the response to the death of a child, given the range of processes currently involved and

¹⁰¹ Paragraph 5.19 (e) of the Complaints and Concern Policy July 2012

¹⁰² Bristol Royal Hospital for Children, Review Of Risk Management System – April- May 2014, Ms A. Utley

¹⁰³ Page 9, Page 11.

was in the early stages of carrying out this work. It has received some initial information from provider Trusts as to the processes that they follow at the moment, and intends to undertake an analysis to understand the full range of processes and the interaction between them that exist currently. Although the work was in its infancy, the hope was to take this work forward in collaboration with other national organisations such as NHS Improvement, and expert clinicians. An important overall aim would be to improve the experience of parents and families, given that currently, some parents will have to navigate several different processes at an extremely difficult point in their lives.

2 Resources for dealing with the complaints process, and for RCAs and CDRs

- 2.1 Weaknesses in handling complaints and co-ordinating investigations are likely to have been linked to the limited resources available to the relevant teams. We noted documentation recording, in early 2014¹⁰⁴, that the resources for PALS/complaints were small compared to benchmarked peers. The judgment reached by CQC's inspectors in December 2014 was that the work on improving the handling of complaints was 'work in progress'. We agree that further work was required to improve the experience of those who complained to the Trust about paediatric cardiac services.
- 2.2 Clinicians, too, require adequate support. There is evidence in minutes of concern that RCAs took too long. In the course of the Review, we saw examples of the enormous efforts made by families to set their account of events before Trust staff, seeking to ensure that their perspectives were fully reflected in the reports produced and challenging inaccuracies or statements that they disagreed with. Clinical and family expectations about the level of detail needed were frequently at odds. This process led to multiple drafts of documents such as CDRs and RCAs being exchanged between families and Trust staff, with no clear mechanism for resolving disputes or calling an end to the re-drafting process. The involvement of chairs from outside the Trust added a further layer of complexity. The Review heard this had been difficult and at times stressful for clinicians, too, to manage. Email correspondence and letters indicated that clinicians, rather than the Patient Safety Team or the PSCT, were required to deal with communications from the parents, not least as complex issues relating to treatment were in issue. We felt that clinicians struggled to manage these responsibilities and also required additional support.

3 Independent voices in investigations

- 3.1 The Bristol Public Inquiry Report recommended that in dealing with complaints: 'There should be a strong independent element, not part of the trust's management or board, in any body considering serious complaints which require formal investigation.'

¹⁰⁴ We were told that a further 3 new posts were created in the corporate Patient Support and Complaints team in 2014, following recognition of the team's comparatively small size.

- 3.2 These recommendations were echoed by the Francis report, which spoke of the need for an ‘arms-length’ investigation if a complaint amounted to a serious incident.¹⁰⁵
- 3.3 The Trust told us that UHB ‘receives approximately 1600 complaints each year, roughly half of which are addressed through formal resolution. This means that the complaint is investigated by a senior officer who is independent of the circumstances of the complaint, but who is nonetheless an employee of the Trust. This is standard practice in the NHS.’ The Trust regards the PSCT as ‘positioned appropriately at ‘arms-length’ from clinical services’. It noted that an independent investigation happened only occasionally, usually relying on the good will of another Trust. There were no established criteria for when this route was chosen, whether locally or as a result of national requirements or guidance.
- 3.4 It appeared to the Review that the Trust, perhaps in common with other NHS organisations, could not meet the criterion of ‘independent element’ in an investigative process (whether of a complaint, an incident or the review by the Trust’s staff of a child’s death), save by making exceptional arrangements¹⁰⁶. Our review of files relating to the handling of complaints did not give us confidence that PSCT’s members had the authority or capacity to carry out effective ‘arms-length’ investigations. They tended to function by asking staff to give a written response to those aspects of a complaint which touched on their particular work. The answers were then incorporated into a draft letter of response, for approval by the Trust’s executives. Not least because as individual members of staff would comment in isolation and not see the composite response, the Review felt that there were occasions when the tone or sensitivity of the response suffered as a consequence, as did the ability to identify and focus upon key areas of concern.
- 3.5 Some families’ unhappiness about the lack of an independent element in investigations led them to request that RCAs or CDRs should have external chairs. The Review noted that in a small number of complex investigations considered by the Review, clinicians from other Trusts had been involved in chairing either the RCA or the CDR. Meetings involving such independent chairs took place in 2012 and 2014.
- 3.6 However, as the Trust acknowledged, this was on an ad-hoc basis, without established criteria. There was also room for confusion and disappointment arising from the involvement after an independent figure: e.g., concerning the extent to which an independent chair of a meeting would be involved in any follow-up, or have responsibility for the overall authorship of a report.
- 3.7 Moreover, there were some difficulties in securing the services of colleagues to act as chair, not least as other children’s cardiac services did not, we were told, run the CDRs

¹⁰⁵ The Clwyd-Hart report also recommended that an independent (external) investigation should be offered in such circumstances

¹⁰⁶ See the Trust’s Serious Incident Policy (V7, 2013), which did not appear to have been updated to make any changes in relation to allowing for independent elements in an investigation, following the Clwyd-Hart report.

in the same way. The Review heard from clinicians that, for these reasons, there was some hesitation in taking forward requests for independent chairs. This was interpreted, unfortunately, by some families as a reluctance to comply with their request and indicative of a lack of openness to scrutiny.

- 3.8 We were satisfied that the difficulties with regard to securing independent chairs were due to the lack of an established process for doing so. Weaknesses in this regard in the management of two complex complaints in 2012 persisted into 2014. They do not appear to have been resolved, judging from the policies on complaints and investigations policies, which have not been further developed. The Expert Panel, however, noted that it is unusual to involve external experts in RCAs; the lack of an established process to allow this was not uncommon amongst other hospital trusts.
- 3.9 We heard that some clinicians entertained a degree of scepticism about the benefits of calling on someone from outside the Trust to chair investigations. They felt that the best people to contribute to investigations were those who had been directly involved in the child's care, and queried the 'added value' of an independent element. However, the Review felt that there was a considerable benefit gained from the reassurance provided from such an element of independence, at least in cases involving serious incidents and, particularly, when the trust between clinicians and parents or patients was either threatened or had broken down.
- 3.10 We note the proposal for the establishment of the Healthcare Safety Investigation Branch (HSIB)¹⁰⁷, from April 2016. This Branch's service is intended to offer support and guidance to NHS organisations (both those involved in investigation and in commissioning) on investigation incidents concerning the safety of patients, as well as carrying out a certain number of investigations itself. When operational, it may provide a source of guidance and support in the management of investigations into deaths such as the ones that we reviewed.

4 Involving Families in Improving Services

- 4.1 The PHSO's thematic report of August 2013, 'Designing Good Together' was a national review aimed at all organisations in the NHS which dealt with complaints. It noted that patients commented that: 'It is frequently unclear what action is being taken as a result of the complaint. Complainants often felt uncertain that their complaint had led to tangible change that would prevent a similar thing happening again.'
- 4.2 One of the PHSO's recommendations was that patients 'Where applicable, [should] be involved in the changes that arise from their complaint. For example, seeing drafts of new leaflets; being involved in the design of new training courses, and so on.'
- 4.3 We took the view that the Trust's mechanisms for involving parents or complainants in the changes that took place as a result of their complaint or of an investigation were

¹⁰⁷ Formerly described as the Independent Patient Safety Investigation Service (IPSiS).

weak. We should be clear that we did see an example of the effective involvement of a family in action by way of follow-up after a complaint, as well as constructive meetings with clinicians with families, to discuss and resolve complaints. But we have also noted how the offer to another family in 2012, of involvement in the follow-up and actions outlined in the RCA relating to their child was not followed through. Whilst the Review does not underestimate the challenges of so involving parents in situations where relationships are strained, this is not an adequate reason for not trying, particularly when an offer has previously been made.

- 4.4 In a review of its handling of complaints in early 2014¹⁰⁸ the Trust noted ‘We do not routinely ask complainants whether they want to be kept informed about any action being taken as a result of their complaint. This needs to be introduced.’
- 4.5 The current version of the Complaints and Concerns Policy dates from August 2014 and states that if the complainant ‘has accepted the Trust’s offer for a copy of the action plan as part of the resolution to their complaint, the Patient Support & Complaints Team will send this with the final response letter and will ensure the complainant is kept up to date with progress of the action plan, if required by the complainant.’¹⁰⁹
- 4.6 Whilst this certainly represented progress, we felt that there was still a significant gap between the policy set out and the recommendation from the PHSO, which related not only to sending information about actions taken, but involvement in their design if the parent so wishes.

5 Child Death Reviews and the Child Death Overview Panel

- 5.1 A particular feature of the investigations following a child’s death in the Children’s Hospital was its system for conducting Child Death Reviews.
- 5.2 Since 1st April 2008 the Local Safeguarding Children Boards (LSCB) in England have had a statutory responsibility for a process of what are called child death reviews (CDR). This responsibility is contained in the Children Act 2004 and applies to all young children under the age of 18 years within the area of each Board.¹¹⁰ LSCBs must set up sub-committees, the CDOPs, to review the deaths of children in order to inform planning of how ‘best to safeguard and promote the welfare of the children in their area.’¹¹¹
- 5.3 In Bristol, the West of England CDOP worked in collaboration with the four Local Safeguarding Children Boards of Bristol, North Somerset, South Gloucestershire and Bath and North East Somerset. The membership of the Panel involved leading

¹⁰⁸ Board Paper- UHB Response to Clwyd-Hart.

¹⁰⁹ Paragraph 5.23

¹¹⁰ See ‘Working Together to Safeguard Children (2013): Chapter 5 Child Death Review Processes’, together with the earlier edition of ‘Working Together’ published in 2006. The reviews covered the deaths of all children resident within the area and the deaths of non-resident children under the care of a specialist paediatric medical or surgical team in Bristol.

¹¹¹ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/246567/DFE-RB303.pdf

professionals from a range of multiple agencies and representation from each LSCB. It included clinicians from the Trust:¹¹²

- 5.4 If a child dies, the national framework requires:
- meetings of professionals by way of a rapid response, if the death is ‘unexpected’;
 - an overview of all deaths of those under 18, in the area of the local CDOP, to be carried out by the CDOP.
- 5.5 Each death will be reviewed by the CDOP after information has been sent to it by the professionals involved in the child’s case. There are standard forms drawn up nationally for collecting and submitting information. The information on each child is anonymised before review by the Panel. The Panel considers any factors contributing to the death and any lessons to be learnt from it or from patterns of similar deaths in the area, completing a ‘Form C’ for this purpose. Using that form, a standard national dataset is gathered and ‘modifiable factors’ examined in a consistent fashion. ‘Modifiable factors’ are defined as ‘one or more factors which may have contributed to the death of the child and which, by means of national or locally achievable interventions, could be modified to reduce the risk of future child deaths’. An annual report is produced, a public document providing an important source of information about services for children and young people.
- 5.6 We were told that, as the Designated Lead for the West of England CDOP until January 2013, Dr Fraser was instrumental in developing the CDOP’s process to review specific areas of care, for example of congenital heart disease, on a ‘thematic’ basis. Three ‘themed’ meetings of West of England CDOP were convened during the period 2010-2015¹¹³ to consider the deaths of children under the care of the children’s cardiac service. We heard that the meeting in 2010 was the first of this nature to be held in England. The cases selected for review were suggested by all of the regional CDOPs in the area covered by the specialised service (i.e., from the whole of the South West and Wales), as well as by Dr Fraser, as Designated Lead, in order to reflect a spectrum of conditions and the most complex cases. The Panel was supported in its analysis of the cases by a paediatric cardiologist, surgeon and pathologist, from centres in other parts of the country.
- 5.7 We noted the discussion of and lessons learned from selected complex cases. In relation to the meeting in July 2012, we noted that the deaths of the children discussed whose care had been complex had occurred in 2011. The matters which we have noted as having been raised by CDRs in spring 2012 were not, therefore, amongst those presented for discussion. Although failings in aspects of one child’s care on Ward 32 were noted, the discussion did not identify systemic issues.

¹¹² Dr James Fraser was the Designated Doctor for Child Deaths until January 2013, in particular. Dr Margrid Schindler was a designated Acute Paediatrician from February 2013.

¹¹³ In July 2010, July 2012 and July 2015.

- 5.8 Some families were concerned by the fact that Dr Fraser had a prominent role, both as a senior clinician within the UHB and as the Designated Doctor in CDOP (until early 2013). They felt that the involvement in a CDR of a person who would then play a role on the CDOP was inappropriate. It seemed to the Review that the answer did not lie in excluding clinicians from the UHB from involvement in either CDRs, or CDOP. Rather, it lay in ensuring that there was appropriate peer review by specialists of complex cases, such as those related to congenital heart defects, whereby the CDOP's expertise could usefully be supplemented. This type of peer review was occurring, within the West of England CDOP.
- 5.9 The Review noted that at a national level, there are questions about the design and effectiveness of the CDOP as a process, including the consistency of approach from area to area and the mechanisms at a national level for capturing lessons that arise from CDOP activities. We noted the existence of a project, the 'Child Death Review Database Development Project', which is currently investigating the feasibility of developing a 'national' database for England and Scotland to collect information from CDRs. The ultimate goal is to reduce the number of deaths of children in England and Scotland, and it is stated that this 'short-term development project is the first step on the way to developing a national information resource needed to support this goal.'¹¹⁴

6 The Trust's Process for Child Death Reviews

- 6.1 We heard from staff in the Trust that the Trust has been, and continues to be, fully committed to the process of Child Death Review. We noted that in the documents provided, 'rapid response' meetings of professionals did take place after those deaths which were regarded as unexpected. In addition, in relation to all deaths of children, clinicians did not merely fill in the information required by the 'Form B'. Rather, they held a full meeting of the professionals concerned in the child's care (including community-based paediatricians or staff based at other hospitals) and filled in the fuller analysis required in the 'Form C'. The possibility of this fuller discussion was suggested by the guidance 'Working Together'¹¹⁵, to allow a fuller engagement of professionals in the CDR; but it was not mandatory.
- 6.2 A member of the Review's Expert Panel reviewed all CDRs held by the Children's Hospital CDOP's office for the period 2010 to 2014. We did not identify any concerns beyond those identified through the Review's Expert Case Reviews.
- 6.3 The Review observed that the process for CDRs followed by the Bristol Children's Hospital was unusually thorough compared to other Trusts (indeed, some at the Trust questioned whether the reviews had become wider than their statutory purpose). The Expert Panel took the view that Bristol was putting significant resources into this process and that it was an exceptionally comprehensive approach to considering the issues arising and learning any lessons from any child's death. The reviews served a valuable purpose, particularly in the absence of other investigations (such as RCAs).

¹¹⁴ <https://www.npeu.ox.ac.uk/cdr>

¹¹⁵ Paragraph 7.94.

- 6.4 That said, there were challenges. The CDR, and the actions agreed as a result, stood somewhat outside of the Trust's normal processes of governance. The staff in the CDR's office, although based in the Children's Hospital, were not funded by the Trust and were engaged to work for the West of England's CDOP. The expectation was that findings of CDRs would be fed back into governance groups, but more clarity was required to ensure that CDR findings and actions were noted and fitted into the Trust's governance framework. At the PCG in February 2014 this need was noted:

'The committee agreed that the log is an extremely useful mechanism for identifying actions arising from child death review meetings and acknowledged the importance of completing the actions with departmental / speciality governance teams assuring the committee of completion of actions. The log will link with Root Cause Analysis (RCA) reports held on the RCA log.'

- 6.5 Further recommendations to link all actions together, however initiated, were made in the review of Risk Management in early 2014. The Trust's Chief Executive told the Review that he considered the information from CDRs had not been embedded in the process of reporting and learning in the Trust in the way that in retrospect he felt they should be. He told the Review that he insisted that the CDR office be brought into the structure of, and effectively hosted by, the divisional management.

7 Concerns Expressed by Families about the Trust's process of Child Death Review

- 7.1 We heard from some families with experience of these processes that they felt that they should be more open to families who should be invited to attend meetings. They also felt that the process was not independent, as the professionals involved in the discussions and input into information sent to CDOP were those who had been involved in their children's care.
- 7.2 The issues about independence mirrors those discussed at paragraphs 3.5 – 3.10 above.
- 7.3 The Review noted that, in line with practice elsewhere, family members were not invited to attend the CDR's meetings of the relevant clinicians. However, as part of the processes which followed a child's death, they were generally given an opportunity to raise, in writing or by prior meetings, matters or questions which were then taken for discussion at the meeting of the professionals'. In addition, a meeting would be arranged between parents and the clinician with leading responsibility for the CDR after the professionals' meeting had taken place, to feed back to parents what had been discussed or the conclusions of the CDR. We also saw clinicians engaging with families after a draft CDR had been produced, seeking to respond to further queries or challenges to the accuracy that the contents of the Form C generated. We noted that, perhaps inevitably, such a process did not always work perfectly; for example, there were occasions when parents felt that their concerns had not been fully explored at the professionals' meeting. But we felt that there was evidence that the professionals

concerned sought genuinely to respond to the questions that had been raised, and to make appropriate changes to the draft CDR to reflect parents' perspectives.

- 7.4 The Review felt that the process adopted struck an appropriate balance. The Expert Panel noted that the opportunities for families to contribute and comment were more extensive than, from their experience, was common practice at other centres. We further noted that the discussions in the professionals' meetings were frequently very technical in nature. We felt that a subsequent meeting and discussion with family members, after that meeting, recognised this reality.
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8 Conclusions

- 8.1 We examined difficult and complex situations, perhaps unrepresentative of the general range of complaints seen within the Trust. We saw examples of good handling of complaints and at least one case where good support was offered to a family to explore their questions.
- 8.2 But in the difficult and complex situations which lay at the heart of the Review, investigations and handling of complaints had not succeeded in resolving concerns. At times, the approach taken had, on the contrary, deepened suspicions and rifts. We felt that there was a need for alternative approaches to resolving conflicts, including approaches such as medical mediation.¹¹⁶

9 Recommendations

- 9.1 In light of the above, we make the following **recommendations**:

(26) That the Trust should explore urgently the development of an integrated process for the management of complaints and all related investigations following either a death of a child or a serious incident, taking account of the work of the NHS England's Medical Directorate on this matter. Clear guidance should be given to patients or parents about the function and purpose of each element of an investigation, how they may contribute if they so choose, and how their contributions will be reflected in reports. Such guidance should also draw attention to any sources of support which they may draw upon.

(27) That the design of the processes that we refer to should take account also of the need for guidance and training for clinical staff as regards liaising with families and enabling effective dialogue.

¹¹⁶ See for example "Mediation; an approach to intractable disputes between parents and paediatricians" Mellor and Barclay, *Arch Dis Child* 2011 96: 619 – 621 (2011).

(28) That guidance be drawn up which identifies when, and if so, how, an 'independent element' can be introduced into the handling of those complaints or investigations which require it.

(29) That as part of the process of exploring the options for more effective handling of complaints, including the introduction of an independent element, serious consideration be given to offering, as early as possible, alternative forms of dispute resolution, such as medical mediation.

(30) That the Trust should review its procedures to ensure that patients or families are offered not only information about any changes in practice introduced as a result of a complaint or incident involving them or their families and seek feedback on its effectiveness, but also the opportunity to be involved in designing those changes and overseeing their implementation.

(31) That the Trust should review the history of recent events and the contents of this report, with a view to acknowledging publically the role which parents have played in bringing about significant changes in practice and in improving the provision of care.

CHAPTER SEVENTEEN: CONCLUDING REMARKS AND RECOMMENDATIONS

1. We have set out an account of the information we received, and the views we formed, about the journey of patients and their families through the pathway of care, in the delivery of treatment for congenital heart disease at the BRHC.
2. The conclusions which we reached in respect of each stage, and the recommendations we have made, are set out both in the concluding section of each Chapter and the Executive Summary. We have listed all the recommendations below, for ease of reference, but do not repeat the detail of those conclusions.
3. We have reached the firm conclusion that there was no evidence to suggest that there were failures in care and treatment of the nature that were identified in the Bristol Public Inquiry of 1998-2001. The outcomes of care at the Children's Hospital were broadly comparable with those of other centres caring for children with congenital heart disease. There was evidence that children and families were well-looked after and were satisfied with the care their children received. There was, however, also evidence that, on a number of occasions, the care was less good and that parents were let down. The principal focus of the Review was on Ward 32 where cardiac children were cared for. It was clear that, particularly prior to the CQC's inspection in 2012, the nursing staff were regularly under pressure, both in terms of the numbers available and the range of skills needed. This led on occasions to less than good care for children and poor communication with parents and families.
4. We have noted what we consider to have been weaknesses in the response to evidence of risks on Ward 32, prior to the CQC inspection of September 2012, as well as strains on the capacity of outpatient clinics and the PICU.
5. Detailed review of individual families' concerns suggested that there were some flaws in the management of investigations, such as RCAs and CDRs, but viewed overall, we accept that these processes were reasonably thorough, and candid. We did not see evidence of attempts to mislead or to avoid confronting areas of weakness. The investigations formed the basis of much of the work set out in the action plan which followed the CQC inspection. In the Review's judgment, there had been substantial learning, within cardiac services, from the criticisms which had been voiced and the findings of the Trust's own reviews and investigations.
6. The process of investigating a number of complex complaints or concerns did not succeed in maintaining, or rebuilding, trust between a number of families and the UHB and its staff. We have made recommendations which we hope would help to reduce the risk of such an outcome, in the future.

7. We have noted the references, in Trust policy and papers, to the concept of ‘patient safety’. We refer back to the Bristol Public Inquiry, which referred throughout to ‘the safety of patients’. This central value is poorly served by references to the term ‘patient safety’. It is widely used, but this shorthand term suggests an abstract or administrative concept. We have included a final recommendation which is designed to put the safety of patients at the cultural heart of the organisation.
8. We express the hope any response to this Report will strengthen not only paediatric cardiac services, but the partnership between families and staff which is the basis of delivering safe and effective care of a high quality.
9. We repeat our thanks to all those who took part and have contributed to it.
10. We would like to thank those within the Review’s own team. The members of the Expert Panel were unfailing generous with their time and expertise. All the members of the Review’s own staff have made substantial contributions and we are grateful to them all. Special thanks must go to the Review’s Secretary and Deputy Secretary, both of whom have worked tirelessly, well beyond the call of their normal duties, to see this Review complete its work.

Eleanor Grey QC
Professor Sir Ian Kennedy
June 2016

RECOMMENDATIONS

- (1) That any review of the Department of Health's Outlier policy (the policy followed by the NCHDA when its audits trigger alerts or alarms) should give specific attention to the need for publication of the responses to outlier alerts, and of any actions taken as a result.
- (2) That the Trust should review the adequacy of staffing to support NCHDA's audit and collection of data.
- (3) That the Trust should review the information given to families at the point of diagnosis (whether antenatal or post-natal), to ensure that it covers not only diagnosis but also the proposed pathway of care. Attention should be paid to the means by which such information is conveyed, and the use of internet and electronic resources to supplement leaflets and letters.
- (4) That the Commissioners and providers of fetal cardiology services in Wales should review the availability of support for women, including for any transition to Bristol or other specialist tertiary centres. For example, women whose fetus is diagnosed with a cardiac anomaly and are delivering their baby in Wales should be offered the opportunity, and be supported to visit the centre in Bristol, if there is an expectation that their baby will be transferred to Bristol at some point following the birth.
- (5) The South West and Wales Network should regard it as a priority in its development to achieve better co-ordination between the paediatric cardiology service in Wales and the paediatric cardiac services in Bristol.
- (6) There should be explicit recognition at a national level that children are 'lost to follow up' at points in time other than transition and transfer to other centres, which are the points explicitly reflected in the NCHD's current standard. The standard should be broadened, to recognise the matters of safeguarding which can arise for vulnerable children.
- (7) The paediatric cardiac service in Bristol should carry out periodic audit of follow-up care to ensure that the care is in line with the intended treatment plan, including with regards to the timing of follow-up appointments.
- (8) The Trust should monitor the experience of children and families to ensure that improvements in the organisation of outpatient clinics have been effective.
- (9) In the light of concerns about the continuing pressure on cardiologists and the facilities and resources available, the Children's Hospital should benchmark itself against comparable centres and make the necessary changes which such an exercise demonstrates as being necessary.

- (10) NHS England should gather and/or publish, to the extent possible, the data necessary to assess the implementation of the NCHD standard, that tertiary centres should employ one consultant cardiologist per half million people served, working flexibly across the Network.
- (11) That the paediatric cardiac service benchmarks its current arrangements against other comparable centres, to ensure that its ability, as a tertiary 'Level 1' centre under the NCHD Standards, to communicate with a 'Level 2' centre, are adequate and sufficiently resourced. Benchmarking would require a study both of the technical resources underpinning good communication, and the physical capacity of clinicians to attend planning meetings such as the JCC.
- (12) That clinicians encourage an open and transparent dialogue with patients and families upon the option of recording conversations when a diagnosis, course of treatment, or prognosis is being discussed.
- (13) That the Trust review its Consent Policy and the training of staff, to ensure that any questions regarding the capacity of parents or carers to give consent to treatment on behalf of their children are identified and appropriate advice sought.
- (14) That the Trust reviews its Consent Policy to take account of recent developments in the law in this area, emphasising the rights of patients to be treated as partners by doctors, and to be properly informed about material risks.
- (15) That a national protocol be agreed explaining the role of individuals and teams in paediatric cardiac surgery and cardiac catheterisations. Such a protocol should be shared at an early stage of the pathway of care, to ensure that all families are clear about how teams work and the involvement, under supervision of junior members of staff.
- (16) As an interim measure pending any national guidance, that the paediatric cardiac service in the Trust reviews its practice to ensure that there is consistency of approach in the information provided to parents about the involvement of other operators or team members.
- (17) That the Trust carry out a review or audit of (i) its policy concerning obtaining consent to anaesthesia, and its implementation; and (ii) the implementation of the changes to its processes and procedures relating to consent.
- (18) That steps be taken by the Trust to review the adequacy of the procedures for assessing risk in relation to reviewing cancellations and the timing of re-scheduled procedures within paediatric cardiac services.
- (19) That NHS England should commission a review of Paediatric Intensive Care Services across England. We were conscious of the heavy strains placed on families by the limitations on the capacity of the Bristol PICU, during the period of this Review, and consider that this is likely to be a national issue that requires proper attention.

- (20) That the Trust should set out a timetable for the establishment of appropriate services for end-of-life care and bereavement support.
- (21) Commissioners should give priority to the need to provide adequate funds for the provision of a comprehensive service of psychological support.
- (22) That the Trust review the implementation of the recommendation of the Kennedy Report that a member of the Trust's Executive, sitting on the Board, has responsibility to ensure that the interests of children are preserved and protected, and should routinely report on this matter to the Board.
- (23) That the BRHC confirm, by audit or other suitable means of review, that effective action has been taken to ensure that staff possess a shared understanding of the nature of patient safety incidents and how they should be ranked.
- (24) That urgent attention be given to developing more effective mechanisms for maintaining dialogue in the future in situations such as these, at the level of both the provider and commissioning organisations.
- (25) That when structural changes to the NHS are made, adequate resources are devoted to organising and archiving records in a way that will enable them to be retrieved and studied at a later date.
- (26) That the Trust should explore urgently the development of an integrated process for the management of complaints and all related investigations following either a death of a child or a serious incident, taking account of the work of the NHS England's Medical Directorate on this matter. Clear guidance should be given to patients or parents about the function and purpose of each element of an investigation, how they may contribute if they so choose, and how their contributions will be reflected in reports. Such guidance should also draw attention to any sources of support which they may draw upon.
- (27) That the design of the processes we refer to should take account also of the need for guidance and training for clinical staff as regards liaising with families and enabling effective dialogue.
- (28) That guidance be drawn up which identifies when, and if so, how, an 'independent element' can be introduced into the handling of those complaints or investigations which require it.
- (29) That as part of the process of exploring the options for more effective handling of complaints, including the introduction of an independent element, serious consideration be given to offering as early as possible, alternative forms of dispute resolution, such as medical mediation.

- (30) That the Trust should review its procedures to ensure that patients or families are offered not only information about any changes in practice introduced as a result of a complaint or incident involving them or their families and seek feedback on its effectiveness, but also the opportunity to be involved in designing those changes and overseeing their implementation.
- (31) That the Trust should review the history of recent events and the contents of this report, with a view to acknowledging publically the role which parents have played in bringing about significant changes in practice and in improving the provision of care.
- (32) That the Trust redesignate its activities regarding the safety of patients so as to replace the notion of “patient safety” with the reference to the safety of patients, thereby placing patients at the centre of its concern for safe care.

APPENDICES

Appendix 1: Terms of Reference

The Terms of Reference for the Review were:

1. To gather evidence from a range of families about their experience of using the Bristol children's cardiac service, from the publication of national standards for children's cardiac surgical service in March 2010, to the date of the Review.
2. To gather evidence from present and past members of staff of the Trust, and other relevant witnesses, regarding the provision of the service during the same period, including its quality and safety.
3. To explore the candour and quality of communication, and the explanation and support made available, to families using the service.
4. To assess the degree to which progress has been made in implementing those recommendations relevant to this review contained in the Report of the Bristol Royal Infirmary Public Inquiry published in 2001.
5. To establish an understanding of the service in sufficient depth to:
 - a. Describe both achievements and any shortfalls by reference to published standards and any other relevant recommendations for change or improvement;
 - b. Assess the extent to which any such achievements and shortfalls were made apparent to the Trust Board, and the adequacy and candour of the reports made by the Trust to those with responsibilities to commission the service provided; and to
 - c. Describe the response of commissioners to the information provided.
6. To contribute, by investigation of the matters outlined above, to emerging National Standards for this service.
7. To make recommendations as appropriate.

Building on the Note of the meeting with families on 14th February 2014, four lines of enquiry were established:

- A. The Environment of Care - to cover issues of staffing, skills, record-keeping, communication between staff (especially when handing over responsibility), equipment, the physical setting, the management of pre- and post-operative care, the demands on the service, and the capacity to meet those demands in a manner which was safe and of an appropriate quality. Such enquiries may directed at any venue at

which care was provided, including at Outreach Clinics, admission through the Accident and Emergency Service, or care and treatment in the paediatric intensive care unit and Ward 32.

- B. Communication - to cover the candour, quality, continuity and consistency of communication with families. This will include the quality of explanations of events, uncertainties and risks, including communication over matters such as critical incidents, root cause analyses, and child death reviews.
- C. Care and Compassion - to explore the quality of the care and compassion extended to families at the various stages in the journey of care, with a specific focus on support, immediate and longer term, in cases of bereavement.
- D. The Culture of the Trust - to cover the access of patients to information within the Trust, and the operation of reporting and the use of information within the Trust at, and below, the level of the Board, including the reporting of information to relevant bodies at a regional or national level and the response of commissioning bodies to the information made available to them.

The Review was set up to be independent of the NHS and it was agreed that Eleanor Grey QC would Chair the Review. Ms Grey is an independent barrister who was formerly Counsel to the Bristol Royal Infirmary Public Inquiry. Professor Sir Ian Kennedy agreed to act as a Consultant Advisor, available to advise generally on the gathering of evidence and issues arising, and upon the contents of a draft report and its recommendations. Ms Grey and Sir Ian were assisted by independent experts who advised on clinical matters and other issues arising.

Ms Grey and Sir Ian were tasked with delivering a report which publishes our findings and recommendations. It was then for NHS England, the Chief Inspector of Hospitals for the Care Quality Commission, and other relevant bodies with responsibilities for the delivery and regulation of services to consider these findings and recommendations, through the normal mechanism provided by guidance from the National Quality Board.

Alongside our work, in a process which was independent of this Review, the Chief Inspector of Hospitals of the Care Quality Commission was asked by the Medical Director of NHS England to undertake a clinical case note review, to consider the cases of a number of the children who have received care from the service.

Appendix 2: Establishing the Review

1. The Review established an office in Bristol separate from any of the local NHS organisations. A small secretariat was established to support the work of the Review.
2. The Review was registered with the Information Commissioner's Office to enable the Review to hold the personal and sensitive data that we needed to review. This was to ensure that there could be a safe release and transfer of material from interested organisations, most significantly from the Trust, which was asked to supply individual patients' records.
3. Appropriate protocols were developed regarding the storage, management, retention and return of material submitted to us (or in some cases the destruction of evidence that need not be returned).
4. Material was submitted to the Review in a variety of electronic file formats and hard copy. Every document submitted to the Review was assigned a unique reference number, and a central log of evidence was maintained by the Review's Evidence Team. All evidence was scanned and placed on our evidence database. We used an on-line file storage and document collaboration system to facilitate the secure storage and sharing of information between the secretariat and the Panel.
5. A website was established to provide information about the Review and the progress of its work and tell people how to submit evidence. It was also used to publish key procedures being used such as the Review's Terms of Engagement and the process for expert case reviews. We published regular updates upon progress.
6. Interested organisations and stakeholders were consulted, via the website, on the Review's Terms of Engagement which set amongst other issues how to contribute to the Review, the principles for receiving information that would be operated by the Review, how meetings would be conducted and the use of information provided.

Appendix 3: Abbreviations

AAGBI	Association of Anesthetists of Great Britain and Ireland
ACHD	Adult Congenital Heart Disease
AUKUH	Association of UK University Hospitals
AVSD	Atrioventricular septal defect
BCCA	British Congenital Cardiac Association
BNSSG	Bristol, North Somerset, Somerset and South Gloucestershire
BRHC	Bristol Royal Hospital for Children
BRI	Bristol Royal Infirmary
BPS	British Psychological Society
CCAD	Central Cardiac Audit Database
CCG	Clinical Commissioning Group
CDOP	Child Death Overview Panel
CDR	Child Death Review
CHD	Congenital Heart Disease
CNS	Clinical Nurse Specialists
CORU	Clinical Operational Research Unit
CPAP	Continuous Positive Airway Pressure
CPR	Cardiopulmonary Resuscitation
CQC	Care Quality Commission
CRES	Cash Releasing Efficiency Savings
CSP	Centralisation of Specialist Paediatric Services
CUSUM	Cumulative Sum Control Chart

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DGH	District General Hospital
DH	Department of Health
DMS	Document Management System
DNA	Did Not Attend
DQI	Data Quality Indicator
ECG	Electrocardiography
ECLS	Extracorporeal Life Support
ECMO	Extracorporeal Membrane Oxygenation
FASP	Foetal Anomaly Screening Programme
GA	General Anaesthetic
GMC	General Medical Council
HCA	Healthcare Assistant
HCPC	Health and Care Professionals Council
HD	High Dependency
HDC	High Dependency Care
HDU	High Dependency Unit
HLHS	Hypoplastic Left Heart Syndrome
HOSC	Health Overview and Scrutiny Committee
HQIP	Healthcare Quality Improvement Partnership
HRG	Health Related Groups
ICQPM	Integrated Quality and Performance Management Meeting
ICD	Implantable Cardioverter Defibrillators
ITU	Intensive Therapy Unit
JCC	Joint Cardiac Conference

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JCPCT	Joint Committee of Primary Care Trusts
LSCB	Local Safeguarding Children Boards
M&M	Mortality and Morbidity Meeting
MDT	Multidisciplinary Team
NBT	North Bristol Trust
NCAPOP	National Clinical Audit and Patient Outcomes Programme
NCHD	National Congenital Heart Disease
NCHDA	National Congenital Heart Disease Audit
NCHDR	National Congenital Heart Disease Review
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NICOR	National Institute for Cardiovascular Outcomes Research
NICU	Neonatal Intensive Care Unit
NEC	Necrotising Enterocolitis
NMC	Nursing and Midwifery Council
NQB	National Quality Board
ONS	Office of National Statistics
OPD	Outpatient Department
PANDA	Paediatric Acuity and Nursing Dependency Assessment
PCCMDS	Paediatric Critical Care Minimum Data Set
PCT	Primary Care Trust
PDA	Patent Ductus Arteriosus
PEC	Paediatricians with Expertise in Cardiology
PEWS	Paediatric Early Warning Score

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PICS	Paediatric Intensive Care Society
PHSO	Parliamentary and Health Service Ombudsman
PICANet	Paediatric Intensive Care Audit Network
PICU	Paediatric Intensive Care Unit
PID	Project Initiation Document
PRAiS	Partial Risk Adjustment in Surgery
PSCT	Patient Support and Complaints Team
PSI	Patient Safety Incident
QSG	Quality Surveillance Group
RCA	Root Cause Analysis
RCPCH	Royal College of Paediatrics and Child Health
RCN	Royal College of Nursing
ReACT	Respond to Ailing Children Tool
RN	Registered Nurses
SCG	Specialised Commissioning Group
SCTS	Society for Cardiothoracic Surgery in Great Britain and Ireland
SHA	Strategic Health Authority
SIRP	Serious Incidents Review Panel
SOP	Standard Operating Procedure
SWSCG	South West Specialised Commissioning Group
TME	Trust Management Executive Group
TPN	Total Parenteral Nutrition
UHB	University Hospitals Bristol NHS Foundation Trust
VLAD	Variable Life Adjusted Display

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WHO	World Health Organisation
WHSSC	Welsh Health Specialised Services Committee
WTE	Whole-Time Equivalents