NHS England

Paediatric Cardiac and Adult Congenital Heart Disease Standards Compliance Assessment: Report of the National Panel

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Contents

1 Introduction

NHS England is the direct commissioner of congenital heart disease (CHD) services, as prescribed specialised services. On 23 July 2015, the NHS England Board agreed new standards and service specifications for CHD services, with the expectation that in future all providers would meet the standards, leading to improvements in service quality, patient experience and outcomes. The Board agreed a go-live date of April 2016 to begin implementation of the new standards, embedded in contracts with providers, with a standard-specific timetable giving up to five years to achieve full compliance.

The standards are based on a three tier model of care with clear roles and responsibilities (and standards) for each tier. Networks will help local services to work closely with specialist centres, to ensure that patients receive the care they need in a setting with the right skills and facilities, as close to home as possible. The three tiers are:

> ***Specialist Surgical Centres (level 1)***: These centres will provide the most highly specialised diagnostics and care including all surgery and most interventional cardiology.
>
> ***Specialist Cardiology Centres (level 2)***: These centres provide specialist medical care, but not surgery or interventional cardiology (except for one specific minor procedure at selected centres). Networks will only include level 2 centres where they offer improved local access and additional needed capacity.
>
> ***Local Cardiology Centres (level 3)***: Accredited services in local hospitals run by general paediatricians / cardiologists with a special interest in congenital heart disease. They provide initial diagnosis and ongoing monitoring and care, including joint outpatient clinics with specialists from the Specialist Surgical Centre, allowing more care to be given locally.

The Board agreed proposals for commissioning the service and endorsed initial work with providers to develop proposals for ways of working to ensure the standards would be met. This work with providers commenced in April 2015, culminating in the submission of proposals in October 2015. Seven submissions were received, some from networks based on a single surgical centre, others from new multi-centre networks. The proposals were comprehensively assessed by a commissioner led panel, with clinician and patient/public representation. The panel advised that certain standards were considered particularly important for service quality, safety and sustainability:

- Surgeons should be part of a team of at least four, with an on-call commitment no worse than 1:3 from April 2016 and that each surgeon must undertake at least 125 operations per year. From April 2021 a minimum 1:4 rota will be expected.
- Surgery should be delivered from sites with the required service interdependencies. The standards specify which services should be on the same site, and the level of responsiveness required from these and other services. Some of the requirements for co-location are new, so hospitals have until April 2019 to meet them.

NHS England accepted the panel's assessment that, taken together, the initial provider proposals did not provide a national solution and giving more time was unlikely to yield a different outcome.

It was decided therefore that action should be taken to ensure that the April 2016 standards were met as soon as possible, with immediate action to ensure that appropriate short term mitigations are put in place in the meantime to provide assurance of safety. The process reported in this paper was endorsed by NHS England's Specialised Services Commissioning Committee (SSCC).

2 The assessment process

A further process to assess compliance with the standards was launched in January 2016. It set out 14 requirements organised into five themes:

1. Ensuring that paediatric cardiac / ACHD care is given by appropriate practitioners in appropriate settings
2. Ensuring that those undertaking specialist paediatric cardiac / ACHD procedures undertake sufficient practice to maintain their skills
3. Ensuring that there is 24/7 care and advice
4. Ensuring that there is effective and timely care for co-morbidities
5. Assuring quality and safety through audit

Within the 14 requirements, this assessment covered 24 paediatric standards (and the corresponding adult standards) considered to be most closely and directly linked to measurable outcomes (including the surgical and interdependency standards previously highlighted) and to effective systems for monitoring and improving quality and safety.

Providers of CHD level 1 & 2 services were asked to provide evidence of their compliance with the April 2016 standards. As the standards are being introduced in a phased way to allow hospitals longer to prepare for the more demanding standards, consideration was also given to the ability of providers to reach the later requirements.

Where providers could not demonstrate that standards are met, they were asked to describe their plans to achieve the standards and the mitigating actions they proposed to take to provide assurance of the safety and quality of services until all the standards were met. An acceptable development plan was considered to be one that gave a high degree of assurance (in the view of NHS England) that the standard would be met within 12 months of the standard becoming effective.

This process was closely based on NHS England's usual approach when introducing a new service specification.

Additional information was needed in order to complete the process and this was requested in March 2016. These additional returns were assessed in April 2016.

Each set of returns was initially evaluated at a regional level by the NHS England specialised commissioning team, followed by a national panel review to ensure a consistency of approach. The national panel brought together NHS England staff from its national and regional teams with representatives from the Women and

Children's Programme of Care Board and the Congenital Heart Services Clinical Reference Group to provide wide ranging and senior clinical advice and patient and public perspectives. NHS England then gave each provider organisation the opportunity to comment on the factual accuracy of its assessment, so that the provider's comments could be taken into account before the assessment was finalised.

This report of the national panel's findings represents NHS England's assessment of compliance with the standards and the action it is proposing to take, subject to appropriate public involvement and/or consultation.

3 Specialist Surgical Centres (level 1)

3.1 Overall assessment

The detailed assessment of each centre, based on the evidence submitted is summarised here.

	Green	Green / Amber	Amber	Amber / Red	Red
	Meets all the requirements as of April 2016.	Meets most of the requirements as of April 2016 and has good plans to meet the rest within max. 12 months.	Should be able to meet the April 2016 requirements with further development of their plans.	Does not meet all the April 2016 requirements and is unlikely to be able to do so.	Current arrangements are a risk.
North			Alder Hey Leeds	Newcastle	Central Manchester
Midlands and East		Birmingham Children's	UH Birmingham	Leicester	
London		Great Ormond Street	Barts Guy's and St Thomas'	Royal Brompton	
South			Bristol Southampton		

We found that none of the centres met all the standards tested. This was not unexpected, as the standards were designed to ensure that all services were brought up to the level of the best of existing practice - to be stretching and drive improvement without being unrealistic.

The differences we found between centres, particularly between those rated green/amber and those rated amber/red were starker than the ratings alone may

imply. Those rated green/amber scored 12 out of 14 with only quite small and easily achievable improvements needed to move to a 100% rating. This contrasts strongly with the centre rated red which met only 6 of the 13 areas tested and where the required improvements would be extensive, and considered by the national panel not to be realistically achievable. Indeed it is this - our assessment of whether it is realistic to expect the providers rated amber/red to be able to meet those requirements where they fall short - that separates them from those providers rated amber (rather than a simple assessment of how many of the requirements are met).

The national panel's assessment confirmed that two elements of the April 2016 standards present a particular challenge and this was reflected in the assessments of those centres rated red and amber/red:

3.1.1 Minimum volumes of surgical / interventional activity for individual consultants and the minimum size of a surgical or interventional team.

During the process to develop the standards, surgeons told us that the number of operations they each carried out was the most important factor in achieving good surgical outcomes. Bigger teams are more resilient and better able to support the development of subspecialty practice. The standards require that each surgeon undertakes a minimum of 125 operations per year. This is a minimum threshold rather than a target. They also require that from April 2016 surgeons are part of a team of at least three, and from April 2021 part of a team of at least four. Although some centres significantly exceed the minimum required activity to support the required surgical teams, the national panel found that others (Manchester, Newcastle and Leicester) had not demonstrated that they met the minimum requirement:

- Manchester has fewer than 100 operations annually undertaken by a single surgeon, with interventional cardiology provided on a sessional basis. Appropriate 24/7 surgical or interventional cover is not provided. The national panel considered this to be a risk, and rated the centre red.
- Newcastle reported insufficient activity for three surgeons in 2014-2015. At the time of the national panel's assessment, Newcastle predicted that it would not perform 375 operations annually until 2016 - 2017. The national panel noted that the full standard (effective from 2021) requires a team of four surgeons rather than three, and considered that there was no realistic prospect of this being achieved during this period. Newcastle's response to the fact check indicated that activity in 2015 - 2016 had been higher than expected and had taken its activity to a level sufficient to support a three surgeon team. This is provisional data (as it is not yet validated by NICOR) but if confirmed, and sustained beyond one year, and if the activity was distributed appropriately between three surgeons, would meet the April 2016 requirement.
- Leicester reported insufficient activity for three surgeons in 2014-2015 and 2015-16. Leicester's response to the fact check indicated an expectation that the April 2016 requirement would be met over the three year period 2016-2019 and that it considered it was on target to achieve it in 2016-2017, though no additional data was supplied. Although Leicester described plans to increase activity, the national panel considered that this did not provide sufficient assurance to be confident that the requirements would be met during the next 12 months. The national panel noted that the full standard (effective

from 2021) requires a team of four surgeons rather than three, and considered that there was no realistic prospect of sufficient activity to support this requirement being achieved during this period.

While activity is expected to rise overall across the country, and repatriation of interventional activity from non-specialist centres will provide modest help, this will not resolve the problem that there is not enough activity nationally to support the number of centres now delivering the service.

3.1.2 Availability of advice, care and support from interdependent clinical services

The standards require that a range of other specialists needed by children with CHD must be able to deliver care at the patient's bedside at any time of day, seven days a week and 365 days a year. This is because many children with CHD have multiple medical needs. Co-location of specialised paediatric services is also considered important because it allows much closer working relationships to develop between paediatric cardiology specialists and the wider specialised paediatrics team. For hospitals where all of these services are not provided on the same site, this is more challenging:

- Leicester delivers care for children from a mainly adult hospital and the national panel found that assurance of 24/7 bedside care from a full range of paediatric specialists was lacking. Leicester's response to the fact check indicated an expectation that for a number of these the April 2016 requirement would be met by April 2017. The national panel noted that the full standards (effective from 2019) require co-location of a greater number of paediatric services, not just a 30 minute response time. Leicester does not currently meet these requirements and the national panel considered that it would not realistically be able to do so by 2019.
- Royal Brompton delivers care for children from a mainly adult hospital. While the national panel found that assurance of 24/7 bedside care from a full range of paediatric specialists was lacking, Royal Brompton submitted additional evidence in response to the fact check which provided this assurance. However, the national panel noted that the full standards (effective from 2019) require co-location of a greater number of paediatric services, not just a 30 minute response time. Royal Brompton does not currently meet these requirements and the national panel considered that it would not realistically be able to do so by 2019.
- Newcastle provided evidence to show that it is able to meet the April 2016 requirements. The national panel noted, however, that the full standards (effective from 2019) require co-location of a greater number of paediatric services, not just a 30 minute response time, and that the current arrangements at Newcastle would not meet these requirements.

3.2 Other issues

Care by CHD specialists

The standards require that surgery and interventional practice for CHD patients must only be undertaken by CHD specialists. Some level 1 centres told us in their submissions that this is not always the case, and doctors who are not recognised specialists in the care of CHD are sometimes involved. Some of the centres argue that this represents a legitimate approach because of their specialist skills. This needs to be urgently addressed with those centres and NHS England regional commissioners will follow this up directly with the providers concerned.

Surgical and interventional practice

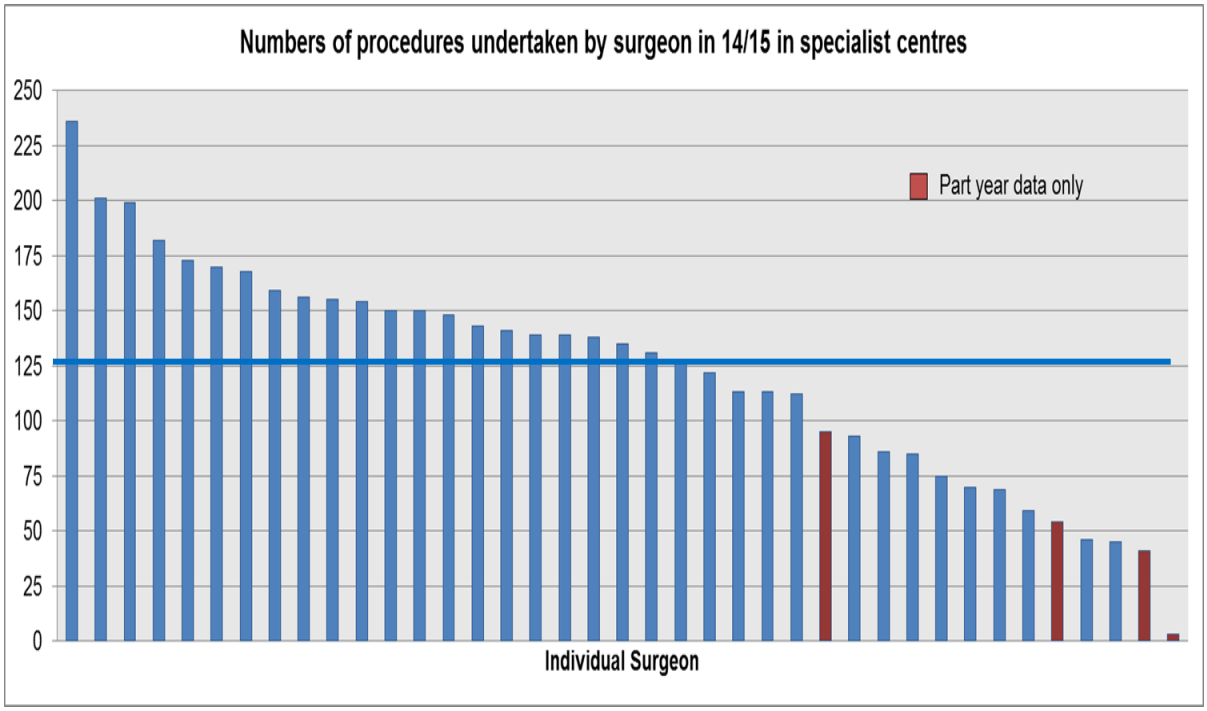
From the data supplied by the level 1 centres (figure 1 below) we can see that there are some surgeons whose activity levels fall below, and in some cases well below stated requirements. This is not just an issue for centres with low activity levels. It also occurs when centres have chosen to have too many practitioners or not to distribute activity in a way that achieves compliance with the standards. This needs to be urgently addressed by those centres and NHS England regional commissioners will follow this up directly with the providers concerned.

Sometimes low activity was seen because of a change of staff, for example a cross-over between a retiring surgeon and their replacement. This is not considered a problem.

Taking the requirements for individual surgeon activity and for team size together, the implication of this is that in order to meet the standards each surgical centre will need a case load of at least 500 operations annually as a minimum. The Clinical Reference Group has previously advised that more than 500 cases would be needed at each centre because it would be operationally challenging to ensure that all surgeons reached the minimum activity required and every patient received their care from an appropriate surgeon if the unit's total activity was exactly 500 or only slightly above.

The evidence supplied shows that it is quite possible for surgeons to undertake 200 or more operations annually, emphasising the point that 125 operations per year is a minimum not a maximum. This is important in considering the efficient use of scarce resources as well as for consistency of outcome.

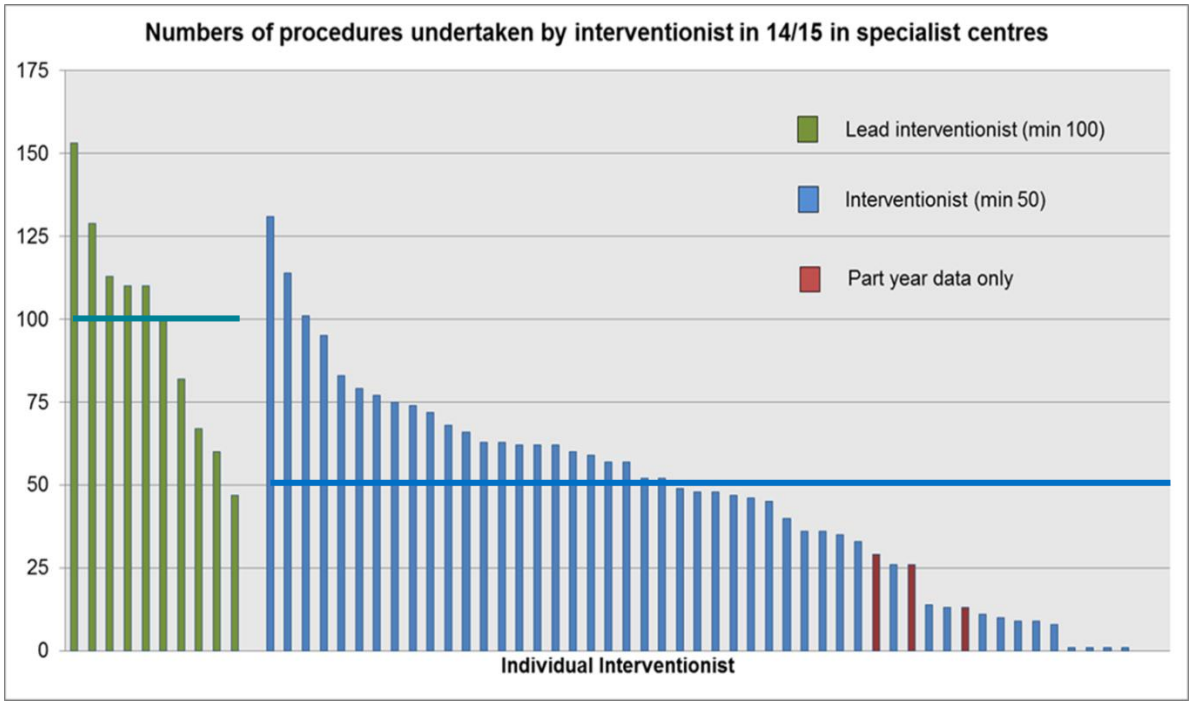
Figure 1: Number of procedures undertaken by individual surgeons in level 1 specialist surgical centres (2014-15)



From the data supplied by the level 1 centres[1] (see figure 2 below) we can see that these challenges are even more pronounced for interventional cardiology practice. There are many interventionists whose activity levels fall below, and in some cases well below, our requirement that lead interventionists undertake at least 100 procedures and other interventionists at least 50 procedures. As with surgery this results from a combination of factors including centres with too little activity, centres with too many practitioners and from poor distribution of activity within a centre. This needs to be urgently addressed by the centres concerned and NHS England regional commissioners will follow this up directly with the providers concerned.

[1] The individual interventionist activity numbers used here are those reported by each centre. Comparison with NICOR data shows that some of these include procedures which cannot be counted towards the volume required by the standards. While it is not possible from the data available to produce an absolutely definitive view of the number of procedures undertaken by each interventionist, whichever data source is used we see that a significant number of interventionists do not meet the minimum activity levels required by the standards. This is addressed in more detail in the individual centre reports.

Figure 2: Number of procedures undertaken by individual interventional cardiologists in level 1 specialist surgical centres (2014-15)



Ensuring there is 24/7 care and advice

The standards include adult care as well as children's services in order to ensure that excellent care is delivered to all age groups. Information from a number of centres showed that 24/7 care – both on-call and seven day working – is less robust for adult patients than for children. This needs to be addressed by those centres and NHS England regional commissioners will follow this up directly with the providers concerned.

The evidence supplied revealed that in a number of centres clinicians are on more than one duty rota at the same time. The national panel considered that while there could be circumstances when it would be acceptable for a clinician to be on more than one rota, this was not always the case. The key test was the likelihood that being on one rota would prevent the clinician from discharging their duties on the other rota. The national panel had particular concerns about out of hours arrangements that would require a member of staff with responsibilities for patient care on one to site to leave that site to attend a CHD patient on a different site. The national panel considered that where these arrangements involved more than one organisation this added to the risk that duty doctors could be faced with conflicting priorities.

While all centres described arrangements to provide advice 24/7 to patients, families and other health professionals, only some described clearly how they made sure staff knew how to handle requests for information and advice. Similarly only some centres had systems in place that ensured those seeking advice (patients, their families and other health professionals) knew how to obtain it.

An age appropriate environment

Around 80% of procedures (surgery and interventional) are undertaken in children so it is important to provide their care in an age appropriate environment where paediatric CHD care is delivered alongside other paediatric services – on the same site and with the ability to meet challenging response times. The evidence supplied showed that this is challenging for providers that deliver paediatric CHD care from specialist hospitals mainly focussed on adult services.

Many centres also found it challenging to articulate how they provided an appropriate care environment for patients with physical and/or learning disability, suggesting that this is an area where sharing best practice could be helpful.

Governance and improvement

The development of formal network governance arrangements and oversight of level 2 centres undertaking interventional cardiology in adults with CHD is a new requirement and progress so far is patchy. There is more to do for providers in establishing these arrangements and for NHS England in establishing which centres will continue to practise at level 2.

Many centres were able to describe clinical governance, audit and improvement activities though evidence of learning and action resulting from this activity was sometimes not available. As networks develop we expect this area to improve as the standards require networks to develop a robust and documented clinical governance framework that includes clinical audit; regular network meetings to discuss patient pathways, guidelines and protocols, mortality, morbidity and adverse incidents.

4 Level 2 centres and occasional practice

The standards do not permit occasional and isolated practice (small volumes of surgery and interventional cardiology being undertaken in institutions that do not offer sufficient specialist expertise in this field). Occasional and isolated practice has been of particular concern to patients and their representatives.

Our analysis showed that surgery and interventional cardiology procedures in CHD patients may have been happening at a number of non-specialist centres. The standards only permit this to continue in very specific circumstances[2]. Most non-specialist centres were not expected to wish to meet these requirements.

We asked all these centres to confirm whether CHD procedures had taken place and if they had, either to cease occasional practice or to take steps to meet the requirements of the standards, including minimum volume requirements. Most providers confirmed that the apparent occasional practice revealed by analysis of HES data was due to coding errors. In other cases, the practice had already stopped or steps were being taken to move this activity to an appropriate level 1 or level 2 centre.

The issue has not yet been resolved at a number of providers, either because no response has been received or because an application to work as a level 2 Adult

[2] Closure of atrial septal defects (ASDs) by interventional cardiology at level 2 ACHD centres can continue providing individual operators meet minimum volume requirements and the centre meets all the level 2 ACHD standards.

CHD centre is unlikely to be agreed. These will be followed up by NHS England regional commissioners to ensure that occasional and isolated practice is eliminated.

Some centres confirmed that they wished to be considered as level 2 (specialist adult CHD medical centres). Centres wishing to work in this way were assessed at the same time as the level 1 centres against the corresponding standards.

The detailed assessment of each centre, based on the evidence submitted, and after the fact check process described above had taken place, is summarised here.

	Green	**Green / Amber**	**Amber**	**Amber / Red**	**Red**
	Meets all the requirements as of April 2016.	Meets most of the requirements as of April 2016 and has good plans to meet the rest within max. 12 months.	Should be able to meet the April 2016 requirements with further development of their plans.	Does not meet all the April 2016 requirements and is unlikely to be able to do so.	Current arrangements are a risk.
North			Liverpool Heart & Chest		Blackpool; South Manchester
Midlands and East	Norwich & Norfolk*			Nottingham	Papworth
London					Imperial
South		Brighton	Oxford		

* Norwich & Norfolk was assessed as a medical only centre – it does not offer interventional ASD closures

NHS England's regional commissioners will discuss the arrangements at those providers assigned an amber/red or red rating with a view to ensuring that in future patients requiring ASD closure receive their care from an appropriate provider.

5 What happens next?

The issues we are grappling with are complex, but as commissioners we intend to see them through with a view to securing the best outcomes for all patients, tackling service variations and improving patient experience. That includes ensuring that all hospitals providing CHD care are able to meet the standards, or get as close as possible to them with satisfactory safeguards in place.

When we launched this assessment process with providers in December 2015 we advised them about how we intended to respond to the findings:

'…the outcome of the assessment may be one of the following:

- *NHS England continues to contract with a provider without conditions;*
- *NHS England will contract with a provider on the basis of a 'derogation' from the service specification (a time-limited agreement that providers can operate outside of the service specification, with an action plan to achieve compliance);*
- *If a provider does not meet the specification and is unlikely to be able to do so, we would need to discuss future service provision.'*

This report was considered by the Specialised Services Commissioning Committee (SSCC), a sub-committee of the NHS England Board, at the end of June. SSCC has recognised that the status quo cannot continue and that we need to ensure that patients, wherever they live in the country, have access to safe, stable, high quality services. SSCC also recognised that achieving this within the current arrangement of services would be problematic.

SSCC has determined that subject to appropriate public involvement and/or consultation, a change in service provision is appropriate and we expect that any such changes will be part of a managed process and that continuity of care for patients will be a high priority.

While the ability to meet the standards is an extremely important consideration as we seek to ensure that all patients benefit from the same high quality of care, it is not the only consideration. The NHS England board recognised this when it agreed the standards in summer 2015, setting out an intention to take into account and balance all the main factors, including: affordability; impact on other services; access; and patient choice; and not to treat the standards as though they existed in isolation.

Heart transplant services were not covered by the CHD standards as they have their own separate service specification. The national panel considered that the potential impact of any changes to CHD services on paediatric heart transplant and bridge to transplant services (which are only delivered by two providers - Newcastle and Great Ormond Street) would need careful consideration. In addition, adult CHD patients with end stage heart failure have limited access to heart transplant. The unit in Newcastle is recognised as delivering more care to this group than other adult heart transplant centres nationally.

For those providers where our assessment has shown that improvements are needed, we expect that agreed development plans and mitigations will become contractually binding by incorporation in provider Service Delivery Improvement Plans (SDIPs). NHS England regional service specialists will set out clearly the evidence required from providers to demonstrate that individual milestones of the agreed action plan have been met, and will meet with providers regularly to monitor progress, at least quarterly.

6 Ongoing approach to assuring standards compliance

We have a comprehensive process for ensuring that providers will meet all of the standards:

- CHD networks will be established with a specific focus on quality and improvement both operational (for example through the network MDT for rare, complex and

innovative procedures) and developmental (through network audit and improvement activities and clinical governance meetings). Patients and families will have an important role in the operation of the new CHD networks.

- Where providers need more support to achieve the standards we will facilitate arrangements to give access to support and advice from other providers. Where appropriate commissioners will provide project support.
- Our work with the CRG on the clinical dashboard and with NICOR on the national audit, and the new patient reported outcome measurement (PREM) tool we have commissioned will make available a much broader range of information about services to guide improvement activities and performance management.
- Regional commissioners will work through STPs and CCOGs to ensure that level 3 services are appropriately commissioned and play a full part in networks.

Meanwhile we are continuing to deliver a very active programme of work to support the implementation of the standards, including a new implementation group. This new group brings together clinicians from across the service with an interest in CHD, service and network managers, patients and their representatives and commissioners to work together on the challenges of meeting the whole span of standards, and to share best practice.