

## Recommendations to improve antenatal and neonatal detection of congenital heart disease (CHD)

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## 1. Abstract

The new Congenital Heart Disease (CHD) Review's sixth objective is to improve antenatal and neonatal detection rates of CHD. Problems with detection were highlighted in discussions with stakeholders early in the review's process and the issue was also raised to the Independent Reconfiguration Panel (IRP) who recommended that NHS England should ensure that a clear programme of action was implemented to improve antenatal detection rates to the highest possible standard across England.

A project group was established to investigate the issues, challenges and opportunities associated with the antenatal detection rates for CHD. The findings and recommendations developed by the project group now need to be considered as part of the overall review process, particularly as it moves into the commissioning phase.

The Programme Board is asked to consider the recommendations outlined in this report and to endorse the work required to ensure robust adoption and sustainability of the recommendations going forward.

In summary the key recommendations relate to:

- Inclusion and continuation of congenital heart anomalies in the agreed National Congenital Anomaly and Rare Disease Registration Service (NCARDRS).
- Sonography education and workforce review
- Commissioning assurance and quality improvement

## 2. Introduction

Delivering improvements in antenatal or neonatal diagnosis of CHD would support the Review's aims of securing the best outcomes for all patients and tackling variations in services. The Review has also set standards for fetal diagnosis including counselling for patients which will also support the review's aim of improving patient experience.

Routine screening for CHD occurs at two stages: during pregnancy and soon after birth. All pregnant women are offered a fetal anomaly scan in the second trimester and new parents are also offered the new born and infant physical examination (NIPE) which includes screening for heart defects. Most cardiac anomalies will occur in pregnancies where the risk of CHD has not previously been recognised.

Detection of CHD in early pregnancy carries a range of benefits:

- It allows parental choice and time to prepare the parents for the likely course of events after delivery.
- It allows referral for further investigation, diagnosis and counselling as soon as possible.
- With appropriate management and treatment, prenatal diagnosis can improve outcomes for babies with congenital heart disease and may help to prevent some of the devastating consequences of early circulatory collapse, such as brain damage.
- Early detection supports the logistical management of care, facilitating planned delivery in the most appropriate hospital, with necessary neonatal facilities.

- For parents at high risk of having a child with congenital heart disease, examining the fetal heart during pregnancy can also be of great benefit, when normality is confirmed, because of the reassurance this provides.

The primary outcome for newborn screening for CHD is a reduction in pre-diagnosis collapse and deaths from critical CHDs. The benefit of timely diagnosis is that it allows for supportive medical and intensive care treatment and earlier timing of surgery, in order to reduce mortality and morbidity.

The current target that 50% of detectable cardiac anomalies should be detected has been set by FASP. This is based on historical data and would need to be refreshed in light of the current work. The rate of detection is referred to later in this paper suffice to say there is variation across the country.

The project group reported to the Programme Board in September 2014 on the contributing factors of poor detection as summarised below:

- The rate of diagnosis of congenital heart disease in the antenatal period varies between 20% and 50% across the different areas of England.
- Stakeholders have told us that there are long standing issues with the sonographer workforce and training and that the 2010 FASP standards have not been fully implemented across England.
- The commissioning process is complex although it has been identified as the mechanism to deliver the improvements.
- In addition stakeholders informed us of an additional investigation that could be made to the NIPE programme which could potentially identify more babies with CHD.

### 3. Methodology

A project group was formed including fetal, neonatal and obstetric clinicians, representatives from Public Health England (PHE), NHS England specialised commissioners and the National Clinical Director (NCD) for Maternity and Women's Health, NCD for Children, Young People and the Transition to Adulthood, and the NCD for Diagnostics and Imaging. Additional stakeholder expertise has also been sought from partners such as; Health Education England (HEE), and professional bodies. The scope of the project was agreed by the group to include initial screening for CHD at the anomaly scan in mid pregnancy.

The role of the group was to map the current patient pathway, identify key issues and opportunities for improvement by engaging with the key partners of the service.

### 4. Findings

#### 4.1 Data capture

There are two datasets with information about antenatal detection of congenital heart disease in the UK: National Institute for Cardiovascular Outcomes Research (NICOR) and British Isles Network of Congenital Anomaly Register (BINOCAR). Both datasets have partial information and therefore no complete national dataset for congenital heart disease exists, which includes robust information about antenatal diagnosis.

### 4.1.1 NICOR database

NICOR is responsible for managing six national clinical cardiac audits including the national congenital heart disease audit (NCHDA), commissioned by HQIP on behalf of NHS England. NICOR collects data and produces analyses to enable the monitoring of cardiovascular patient outcomes to measure improvement both within individual centres and nationally.

NICOR collects data on antenatal diagnosis of those children who have surgery or a procedure in their first year of life. This data therefore does not include any antenatally diagnosed anomalies where there has been a death during pregnancy, termination of pregnancy, perinatal death or death in infancy in those infants with congenital heart malformations who did not have a procedure. NICOR is seeking to increase antenatal detection data on their National Congenital Heart Disease Audit (NCHDA) to include all diagnosed CHD as part of their plan to have a robust national database for all of congenital heart disease.

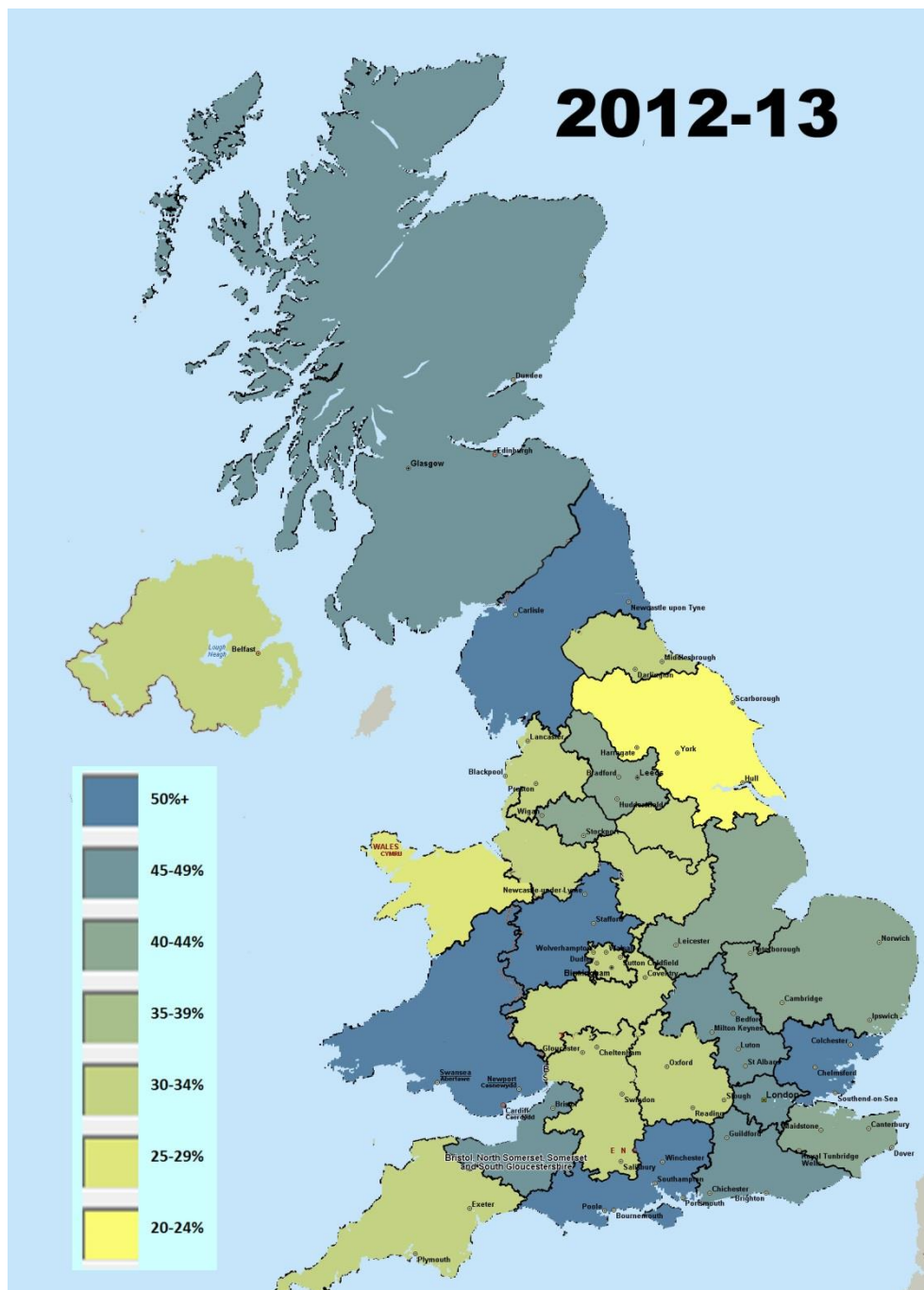
Figure 1 demonstrates a steady improvement since 2009-10 in England.

#### **Figure 1. National detection rates**

<b>Country</b>	<b>2010-11</b>	<b>2011-12</b>	<b>2012-13</b>	<b>2013-14</b>
England	38.1%	40.0%	42.5%	46.9%
Ireland	21.8%	37.0%	32.6%	38.1%
N Ireland	31.6%	36.0%	33.8%	38.6%
Scotland	29.7%	37.3%	46.6%	37.6%
Wales	47.3%	60.9%	56.1%	54.7%
<b>GB and Ireland</b>	<b>36.1%</b>	<b>40.3%</b>	<b>42.2%</b>	<b>45.7%</b>

Figure 2 shows the variation in antenatal diagnosis rates in regions across the UK.

Figure 2. Regional differences in percentage of infants who required treatment and were antenatally diagnosed.



Data source: National Congenital Heart Disease Report 2009-2013

#### 4.1.2 BINOCAR

BINOCAR comprises regional and disease-specific registers across the United Kingdom and the Republic of Ireland and aims to provide continuous epidemiological monitoring of the frequency, nature and outcomes of congenital anomalies for the population of the British Isles.

Data are collected on all suspected and confirmed congenital anomalies identified in utero, at birth or in childhood. In addition to live births and stillbirths affected by congenital anomalies, information about terminations of pregnancy with fetal anomaly following prenatal diagnosis (TOPFA) and late miscarriages (20-23 weeks gestation) where an anomaly is present, are also collected. BINOCAR collects data for 49% of England as seen below.

**Figure 3: Map of England and Wales showing geographical coverage of the congenital anomaly registers**



#### 4.3.1 National Database

As part of the work required by the Chief Medical Officer and for the DH 2020 Rare Disease Strategy, Public Health England (PHE) is currently leading the development of a National Congenital Anomaly and Rare Disease Registration Service (NCARDRS).

The aim of the new service will be to collect information on everyone with rare diseases in England and will include cases identified through antenatal screening and detection of fetal anomalies.

PHE is using established regional registers and will develop new registers in those areas in England not currently covered. BINOCAR are working closely with PHE to help facilitate this process and to ensure that high quality congenital anomaly data is both maintained for established regions and developed for new regional registers.

Timelines for implementation of NCARDRS:

- **April 2015:** New regional teams established, migrate existing registration staff, new data management system in place. National CAR operational
- **December 2015:** Rare disease data sharing arrangements in place
- **December 2016:** Patient portal in place

The information on the database will:

- provide continuous epidemiological monitoring of the frequency, nature, cause and outcomes of congenital anomalies and rare diseases for the population of England
- provide a resource for clinicians to support and monitor their clinical practice including establishing systems to collect self-reported information from patients,
- empower patients and their carers, through the provision of personalised information relevant to their disease,
- support research into rare diseases and genomic medicine including basic science, diagnostics and therapeutics and public health,
- monitor, evaluate and audit health and social care services, including the efficacy and outcomes of screening programmes, and
- inform the planning and commissioning of health and social care provision for pregnancies and infants affected by congenital anomalies and patients affected by rare diseases.

PHE has agreed, in conjunction with NICOR, the British Congenital Cardiac Association (BCCA), and the Congenital Heart Services Clinical Reference Group (CRG) to conduct an audit in the first year to understand the actual diagnosis rates for the four major cardiac anomalies. For this pilot, it has been agreed that the initial part of the national congenital anomaly register data collection should focus on four major cardiac abnormalities that can readily be detected by screening at the time of the fetal anomaly scan.

## 4.2 Commissioning assurance and quality improvement

The commissioning and assurance process for antenatal screening is complex given that PHE are responsible for antenatal and newborn screening through a section7A agreement, whereas the funding for screening is included in the maternity tariff for which Clinical Commissioning Groups (CCG's) are the responsible commissioner. PHE is the responsible commissioner for the quality assurance process of the screening element of the maternity pathway. NHS England public health commissioners oversee the quality assurance process of the screening elements of the pathway.

The PHE national service specification incorporates the standards set by FASP 2010 (updated in 2013/14) but there are no specific measures or KPIs for the CHD element of the

programme. Commissioners told the project group that information available about individual provider performance is limited and there are opportunities to drive improvement.

It was beyond the scope of the project to examine the referral pathway when a cardiac lesion is suspected at the 18+0 to 20+6 week scan. However improvements in scanning would see a proportional increased demand for those services required following referral. These services would include but are not limited to specialty fetal medicine and fetal cardiology, counselling and psychological support. Commissioners would be required to monitor the effect of this in order to plan for future service provision.

### 4.3 Sonography

The 18+0 to 20+6 week scan is undertaken by obstetric sonographers who come from various backgrounds including radiology, midwifery and medicine.

Anecdotally we have heard from a number of stakeholders that there is a shortage of sonographers in NHS posts. A number of issues are contributing to difficulties in recruitment and retention of the number of sonographers needed to deliver the service. There are education issues interrelated with workforce issues.

Although it is not possible at this stage to quantify the size of the problem the issues are well recognised and agreed amongst stakeholders. The issues are summarised below.

#### 4.3.1 Insufficient workforce

Stakeholders agree that the workforce numbers are insufficient to meet current demand for sonography. Sonography is recognised as a shortage specialty by the UK Government Migration Advisory Committee (MAC). The Society and College of Radiographers conducted their own workforce survey in 2014. 212 ultrasound departments were included and 60 (28%) responded. The results were:

- Vacancy rates across responding departments is 18.1%
- Recruitment is difficult and 30% departments employ agency or locum sonographers on a regular basis
- 32 responding departments had absences of 9% with a recognised high level risk of work-related musculo-skeletal injury
- 65% of their workforce are part time workers
- 33% of their workforce is over 50 years old

#### 4.3.2 Sonography is not a regulated profession.

The titles 'sonographer' and 'ultrasonographer' are not protected. There is no legal requirement for sonographers to be registered with a statutory regulatory body although registration is available as a radiographer or a nurse / midwife. Some employers insist on statutory registration (which will also have the effect of limiting the pool of candidates available to those employers) but in the survey reported above, 25% of responding departments have sonographers not registered with a statutory body.



There are up to 20 occupational routes to becoming a sonographer because there are no rules in relation background, training or registration so that it is not possible to assure consistent educational standards. Universities are not required to seek accreditation from the Consortium for the Accreditation of Sonographic Education (CASE). There is no requirement for post graduate courses to be approved by statutory regulator.

Stakeholders have shared many other issues that are affecting the sonography workforce as a whole which could also be improved by considering the recommendations contained within this paper.

#### **4.3.3 Feedback to sonographers**

Providers and sonographers do not receive any feedback on their performance. The project team heard from sonographers and PHE quality assurance leads that there is no formal or consistent two way communication between the scan unit & the referral centres so outcomes of referrals are not consistently tracked.

#### **4.3.5 Training**

There are three elements of training for sonographers that were reviewed: basic and specialised training, training when screening requirements change and bespoke local training.

##### **Basic and specialised training**

Medical sonography is taught at post graduate level in the UK with many sonographers having come from a healthcare background such as radiography and midwifery. Post graduate training is accredited by the Consortium for the Accreditation of Sonographic Education (CASE) and delivered at either certificate or diploma level. This training is funded through Local Education and Training Boards (LETB's). As it is not a commissioned programme, courses are run in response to local provider requests with different numbers trained across the country.

##### **Training for screening standards**

FASP are responsible for setting standards for fetal anomaly screening and have responsibility for training sonographers to those standards. In 2010 the first standards were produced. FASP provided funding to regions to deliver training. There was no oversight or regulation of the training delivered resulting in variation in how regions delivered the training. Stakeholders have told us that the 2010 FASP standards have still not been fully implemented across England.

The standards have been further updated in 2013 introducing two further cardiac views to improve screening for CHD. FASP is currently developing a training package for sonographers and their timetable for implementation is from April 2015 to end of December 2017. Their methodology is based on training champions and cascading that training which includes a new interactive e-learning to support face to face training.

##### **Other training**

Bespoke training is carried out in response to local demand. A charity, Tiny Tickers, commissions training, and fetal specialists run training programmes in local areas and

regions. These courses are unregulated but are felt to complement post graduate training by offering updates and refreshers.

#### **4.3.6 Work already in progress**

HEE recognises that there are significant issues with sonography and has established a Working Group including NHS England, NHS Employers and professional bodies, to identify the challenges trusts are facing with the sonography workforce and put in place an action plan to address issues in this area. This will include looking at whole workforce supply and demand factors, implications for education and training and whether any improvements to how services are managed and configured could better utilise the existing workforce. This work will take account of the recommendations of this review, focussing on the improvement in ante natal and neonatal detection of CHD.

The Sonography Working Group will make recommendations to the HEE Directors of Education and Quality through to the HEE Executive in relation to the workforce implications arising out of the Working Group.

#### **4.4 Neonatal detection**

CHD screening after birth is part of the newborn and infant physical examination (NIPE) which consists of general observation of the baby's colour and respiration, palpation and auscultation of the heart and chest area. Many trusts in England have added pulse oximetry readings to the NIPE as further screening for CHD.

At the start of the new Congenital Heart Disease review the National Screening Committee (NSC) – part of PHE - carried out a public consultation about including pulse oximetry as part of the NIPE. In response to that consultation the NSC will carry out a pilot in several areas across England of pulse oximetry reading in conjunction with the NIPE. Whilst it is agreed that pulse oximetry is a good screening tool, the NSC will evaluate the wider impact of implementing newborn pulse oximetry screening on the NHS.

PHE will assess how pulse oximetry can be implemented nationally and offered in all care settings: large and small units, tertiary units and district generals and midwifery led units. The screening pathway will be tested and referral pathways assured including:

- availability of responsive paediatric services for screen positives,
- availability of echocardiograms, and
- transport issues.

14 trusts have been recruited – seven which already use pulse oximetry and seven that don't. The trial is divided into two phases – baseline assessment and data collection and trial roll out of a standard pathway to all trusts. A report and decision about national rollout is expected in March 2016.

The Programme Board is asked to note progress on this piece of work.

## **5. Discussion**

## 5.1 Data capture

Robust data collected by the National Congenital Anomaly and Rare Disease Registration Service (NCARDRS) will enable PHE to inform NHS England commissioners of future demand to support future commissioning, training and workforce. The register will be able to provide information about the number of cases of CHD detected antenatally.

The anomaly register is needed to:

- Compile a database of all CHD from diagnosis
- Track outcomes by diagnosis not just by procedure
- Allow clinical services to follow the patient through their lifetime: mapping transition of patients from fetal to child, child to adolescent, adolescent to adult to facilitate continuity of care and thereby helping to avoid lost to follow up
- Inform PHE and NHS England diagnosis rates at a regional level: once a comprehensive register is established, for example after a year's data was available, it will be possible to review whether the current 50% target is sufficiently challenging.

Once the data collection is in place there will be more local understanding of the detection rates. NHS England would then work with partners to develop a targeted approach to improvement e.g., the CRG could work with FASP to analyse data as it becomes available and develop an action plan to improve rates of early detection in parts of the country where it is low.

PHE and NICOR are committed to working together to assure data quality by sharing their data which is drawn from separate sources. In addition discussions will need to be held to identify the best way for NCARDRS and NICOR to work together.

The project group has assured that the governance arrangements and reporting are appropriate for the circumstances, the methodology and engagement is sound and feel assured of delivery in the timescales. NHS England should continue to monitor implementation of the NCARDRS to ensure delivery according to the timetables that have been set and once in place that it meets its needs.

## 5.2 Commissioning assurance and quality improvement

There is no information for commissioners to let them know whether antenatal screening for CHD is of the standard required though several different measures have been identified that could help. The NCARDRS will let commissioners know the percentage of detection at regional level, although at this stage it is not clear whether this would be available at provider level. Commissioners could also gain assurance of the quality of service through measurement of the number of scans successfully completing the five cardiac views. No methodology is currently in place to capture this information in real time but NHS England could add a requirement to the proposed standards for CHD services that networks complete an annual audit of antenatal screening that includes assessment of the completion of the five views.

The project team has begun working with PHE to identify other suitable measures such as time from scan to submission of data to the national anomaly register. Other approaches to

assuring quality include external review of scans and retrospective quality assurance review. These would require storage of scans.

### 5.3 Sonography

The current arrangement for sonography workforce and training means that there is no assurance of consistency in the training or skills of the current workforce. HEE has therefore started a review of the sonography workforce which will also consider implications for education and training. Basic and specialist training should be standardised to ensure that all sonographers have a clear picture about what training is expected, commissioned and how they would access it. It is in NHS England's interest to support standardised training that delivers sonographers with the skills that the service requires. There is also a lack of clarity about the demonstration of ongoing competency and recommendations on these from the HEE led working group would also be useful.

Given the complexity and interdependency of the issues we would suggest that NHS England consider engaging with partners in a review of sonography similar to that carried out for healthcare scientists. Some of the issues to be explored could be direct entry training which could help with planning the workforce nationally, and enable discussions to commence about statutory registration.

As a priority the current workforce needs to be upskilled to deliver the 2013/14 FASP standards. The proposed timeline to develop and implement training for the new standards will delay improvement in antenatal detection rates of CHD. While sonographer training is being explored by HEE and partners, there is an opportunity for FASP and HEE to explore the possibility of joint working to develop training for the new standards.

NHS England public health commissioners should work with providers to develop measures of the quality of CHD imaging.

There is an opportunity to develop formal feedback to sonographers. Development of consistent communication between the scan unit & the referral centres would help to track the outcomes of referrals for referrers. In addition regular audit would help sonographers know how they are doing. With the proposed networks there is the possibility to develop that type of relationship where sonographers are congratulated for identifying a problem & get constructive feedback so they can improve.

### 5.4 Oversight and project management

Work is already underway to improve fetal detection of CHD. However, work is at different stages of implementation and led by a variety of organisations and would benefit from co-ordination and project management support. The organisations involved should discuss and agree the provision of project support to this group to maximise its effectiveness. This is likely to be required at least until March 2016.

A shared implementation plan should be developed which should include:

- Oversight of creation of a national anomaly register
- Development of commissioning KPI's and potential incentives and penalties
- Workforce and training review for obstetric sonographers with implications for training and education

In addition to this partnership approach, NHS England should identify an individual or group with lead responsibility on its behalf, ideally with links to the relevant CRGs.

## 6. Recommendations

### 6.1 Data capture

A national anomaly register will provide detailed information about the number of CHD cases detected in the antenatal period and will inform NHS England commissioners where improvements are required. It is recommended that:

- NHS England should ensure continued reporting on the implementation of the national congenital anomaly and rare disease registration service by PHE, to ensure that this remains on schedule, and once introduced that it meets its needs.
- PHE should update the service specification / NHS Standard Contract to include the requirement for data submission to NCARDRS.
- Once the register is fully operational and contains at least one year's data NHS England should work with partners to develop plans to improve fetal detection rates in those parts of the country with the lowest detection rates.

### 6.2 Commissioning assurance and quality improvement

At the moment there is no measure of quality of the antenatal screening for CHD. Given the variation in performance commissioning would ensure that appropriate quality assurance is in place. NHS England Commissioners need more information to understand the quality of the service they commission. Once this information is available commissioners are able to utilise levers to improve individual provider performance.

It is recommended that:

- PHE should add a requirement to its contract with providers that the percentage of scans in which the five cardiac views are successfully captured is measured and monitored.
- A requirement for an annual audit of scanning by congenital heart disease networks should be added to the proposed CHD service standards
- Commissioners, including PHE, CCGs and NHS England, should develop commissioning levers such a CQUIN or a requirement for a service development improve plan (SDIP) to support improvement.

### 6.3 Sonography education and workforce review

The current arrangement for sonography workforce and training means that is it not clear to either providers or commissioners what standard of scanning or training has been delivered. It is recommended that:

- NHS England should support the work of HEE in completing the planned sonographer workforce analysis and review of education and training requirements. This review should ensure that:
  - Basic and specialist training are standardised
  - Clear requirements are established for sonographer CPD.
- FASP should ensure that training for sonographers to support the implementation of the 2013 standards is developed and implemented as quickly as possible.
- In future new standards should not be released until firm timely plans for supporting their implementation including infrastructure and training requirements have been developed.

## 6.4 Oversight and project management

Work already underway should be subject to shared oversight and project managements. It is recommended that:

- An implementation and oversight group be established by the key partners involved including NHS England, Health Education England, Public Health England and provider representatives.
- The organisations involved should provide project support to this group to maximise its effectiveness at least until March 2016.
- A shared implementation plan should be developed.
- NHS England should identify an individual or group with lead responsibility on its behalf, ideally with links to the relevant CRGs.

## 7. Conclusion

Early detection of CHD is important to ensure improved outcomes and to improve patient experience. At present there is considerable variation in detection across the country, no consistent approach to sonographer training (whether basic or CPD) and little active management of the quality of scanning by commissioners. Many partners are involved in this area adding to the complexity of solutions. Completion of the recommendations made in this report would address these issues and can be expected to lead to significant improvements. NHS England has a role to play in each of these areas but needs to work in partnership with other NHS organisations for effective implementation to be achieved.