



Right-touch assurance for sonographers
based on risk of harm arising from practice

Report to Health Education England



February 2019

About the Professional Standards Authority

The Professional Standards Authority for Health and Social Care promotes the health, safety and wellbeing of patients, service users and the public by raising standards of regulation and voluntary registration of people working in health and care. We are an independent body, accountable to the UK Parliament.

We oversee the work of nine statutory bodies that regulate health professionals in the UK and social workers in England. We review the regulators' performance and audit and scrutinise their decisions about whether people on their registers are fit to practise.

We also set standards for organisations holding voluntary registers for people in unregulated health and care occupations and accredit those organisations that meet our standards.

To encourage improvement we share good practice and knowledge, conduct research and introduce new ideas including our concept of right-touch regulation.¹ We monitor policy developments in the UK and internationally and provide advice to governments and others on matters relating to people working in health and care. We also undertake some international commissions to extend our understanding of regulation and to promote safety in the mobility of the health and care workforce.

We are committed to being independent, impartial, fair, accessible and consistent. More information about our work and the approach we take is available at www.professionalstandards.org.uk.

¹ The Professional Standards Authority (2015). [Right-touch regulation – revised](#).

Sonographers

Key facts about what they do and where they work

WHAT ARE SONOGRAPHERS?

Sonographers, also known as ultrasound practitioners in the UK are health practitioners who use ultrasound imaging or sonography/ultrasonography to carry out examinations either for diagnostic, screening or interventional purposes.

WHAT DO THEY DO?

As part of their role sonographers will:

- ▶ assess referrals for ultrasound imaging
- ▶ undertake the most appropriate examination to aid the diagnosis
- ▶ record images appropriate to the diagnosis
- ▶ report on the results of diagnostic, screening or interventional ultrasound examinations.

HOW MANY ARE THERE?

There are around 3,000 ultrasound practitioners working in the UK. Exact numbers are difficult to establish due to lack of uniformity around job title and the unregulated status of the role.

RISK

The role of a sonographer requires a high degree of skill and clinical knowledge across a range of areas and for individuals to practise with significant autonomy. There are a number of inherent risks arising from sonographers' practice including from misdiagnosis and misuse of ultrasound equipment and the risks associated with carrying out what may be intimate examinations.

WHERE DO THEY WORK?

Sonographers in England work primarily for NHS Trusts but across a range of different contexts including within hospital radiology departments, independent hospitals, community GP settings, independent providers, agencies, in small businesses/partnerships.

WHAT QUALIFICATIONS DO THEY HAVE?

Sonographers will generally hold qualifications equivalent to a post-graduate certificate or diploma in medical ultrasound. Training is delivered by universities and accredited by the Consortium for the Accreditation of Sonographic Education (CASE). Currently the majority of sonographers are either qualified nurses or radiographers and are therefore statutorily registered by the Nursing and Midwifery Council or the Health and Care Professions Council. However, a new under-graduate programme has recently been developed by Birmingham City University, creating the potential for direct entry into the role. There are also two direct entry post-graduate courses currently available at the Universities of Derby and Cumbria.



The data gathered by the Centre for Workforce Intelligence indicates that diagnostic radiographer is the most common job role of those within the sonography workforce.



Sonographers in the UK generally have a higher level of responsibility in the diagnostic process compared to similar roles in Canada and the United States where interpretation of images and diagnosis is primarily carried out by medical professionals.

60%

Just under 60% of sonography workforce is made up of diagnostic radiographers

Diagnostic radiographer is followed by consultant (15.8%) and healthcare scientist (12.7%).



Sonographers also practise across a range of departments including:

- ▶ Obstetrics/gynaecology
- ▶ Vascular
- ▶ Cardiac
- ▶ Early pregnancy assessment units
- ▶ Musculo-skeletal ultrasound.

An ultrasound scan, sometimes called a sonogram, is a procedure that uses high-frequency sound waves to create an image of part of the inside of the body.

49%

Of the staff identified were registered with the HCPC

The majority (49%) were registered as a radiographer with the HCPC, 4.5% were registered with a voluntary register, around 3.5% had no registration. (*Centre for Workforce Intelligence, 2015*)



How the British Medical Ultrasound Society and the Society and College of Radiographers defines a sonographer:

A healthcare professional who undertakes and reports diagnostic, screening or interventional ultrasound examinations. They will hold qualifications equivalent to a post-graduate certificate or post-graduate diploma in medical ultrasound that has been accredited by the Consortium for the Accreditation of Sonographic Education (CASE). They are either not medically qualified or hold medical qualifications but are not statutorily registered as a doctor in the UK.

41.3m

Imaging tests reported in England from January-December 2017



The test with the highest proportion of GP referral was ultrasounds that may have been used to diagnose ovarian cancer (44% of which were requested by GPs). (*NHS England, 2017*)

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1. Executive summary

- 1.1 This report sets out our advice to Health Education England (HEE) on the means of assurance to manage risk of harm to the public from sonographers. Although we have tried to take account where possible of four-country workforce implications, this report has focused on sonographers in England.
- 1.2 Sonographers in the UK use ultrasound, high-frequency sound waves, to produce images from within the body and report and interpret results to recommend further treatment or diagnosis. Ultrasound is used by a range of professions. It can be used as a diagnostic and therapeutic tool in areas ranging from obstetrics and gynaecology to radiology/diagnostics, vascular, cardiac and musculo-skeletal.
- 1.3 The role of a sonographer requires a high degree of skill and clinical knowledge across a range of areas and for individuals to practise with significant autonomy. There are a number of inherent risks arising from sonographers' practices, including from misdiagnosis and misuse of ultrasound equipment and the risks associated with carrying out what may be intimate examinations.
- 1.4 There are around 3,000 sonographers practising across the UK and although sonographers are not regulated as a distinct group, the majority are registered with an existing statutory regulator, generally as a radiographer, nurse or midwife. Most sonographers currently work within the NHS although private provision is increasing, particularly in maternity care. Diagnostic and imaging services in England within the NHS and private sector are both regulated by the Care Quality Commission (CQC). Sonographers generally complete a post-graduate qualification to practise sonography.
- 1.5 There is a long-term shortage of qualified sonographers in the UK along with increasing demand for ultrasound and radiography services; in part due to their increasing importance in cancer diagnosis. Currently, unregistered sonographers are unable to train as supplementary prescribers, administer medicines under Patient Group Directives or refer patients for clinical imaging involving ionising radiation.
- 1.6 Whilst we have seen evidence of instances of harm occurring, there is insufficient data suggesting widespread prevalence of harm, although this may be partly due to limitations with the data available. It has not been possible due to data limitations to compare the incidence of harm arising from the practice of regulated and unregulated practitioners. We have suggested that further consideration may be needed of how to improve data visibility for ultrasound.
- 1.7 Having considered the evidence available, we have concluded that there is currently not a clear case for immediate statutory regulation of sonographers as a separate profession in England. Statutory regulation is already mitigating risks due to the fact that the majority of those practising as sonographers are already regulated in other professional roles. Additionally, all diagnostic and screening services are required to be registered with the CQC in England.

- 1.8 Remaining risks could be managed more effectively by strengthening clinical governance and encouraging the relatively low number of unregulated practitioners to join the Public Voluntary Register of Sonographers, although public protection would be strengthened if the register applied for accreditation or transferred practitioners to an existing Accredited Register.
- 1.9 However, we consider that statutory regulation would need to be considered in future, if the changes to routes entry to the profession and to the practice of sonography identified in our report materialise. This includes any significant increase in the number entering the role through the under-graduate route and increased vulnerability and complexity of patients undergoing ultrasound procedures.
- 1.10 Key issues to take into account if the Government were to consider statutory regulation are:
- workforce, health and care needs and specific risks across the four countries of the UK
 - the importance of maintaining workforce flexibility for ultrasound to continue to be utilised as a tool where appropriate and both sonographers and other professionals to move into and out of the profession when required.

2. Introduction

Project overview

- 2.1 The Authority was commissioned by HEE to assess the risk of harm arising from the practice of sonographers, using the Authority's right-touch assurance model to analyse evidence and provide advice to HEE on the options for regulatory assurance when considering future development of the role.
- 2.2 The purpose of the project is to analyse the evidence available under the criteria outlined in *Right-touch assurance: a methodology for assessing and assuring occupational risk of harm* and consider the most appropriate method to manage the risks identified.
- 2.3 HEE's statutory remit is to ensure that there is an effective education and training system in place to supply a qualified workforce for the English NHS. While there may be UK-wide implications arising from this assessment, HEE has only requested the Authority to assess the role in the context of practice within the English NHS, as this is HEE's remit. Whilst we have sought to engage as widely as possible with stakeholders, the focus of the assessment has therefore primarily been England. We touch further on some of the other limitations of the review later in the report. However, we advise that recommendations arising from this report would require further testing with stakeholders and full consideration of the four-country implications of any changes to the regulatory regime for the occupation.
- 2.4 Any decisions on statutory regulation of new roles will be made by Government. There is currently a commitment to a consistent approach to regulation of health professionals across the UK, although regulation of the social care workforce is devolved. We examined this issue as part of a recent commission for the Scottish Government, looking at regulating an occupation in fewer than all four UK countries and potential implications for policy-makers the public and practitioners.² Overall, the report recommended that UK-wide regulation should remain the norm, but that there might be circumstances where risk assessment justifies a different approach. These included where:
 - different approaches between UK countries are justified by the outcome of an objective and robust assessment of occupational risk, and
 - the impact of taking different approaches has been assessed as having a minimal impact on workforce supply across the UK, or
 - measures can be taken that mitigate the impact on supply by facilitating the movement of workers around the UK.
- 2.5 Previously the Health and Care Professions Council (HCPC) were given the role to advise Government on which occupations should be statutorily regulated.³ In

² Professional Standards Authority (2018). *Regulating an occupation in fewer than all four UK countries: implications for policy-makers, the public and practitioners*. Available at: www.professionalstandards.org.uk/news-and-blog/latest-news/detail/2018/06/28/the-authority-publishes-report-on-regulating-an-occupation-in-fewer-than-all-four-uk-countries

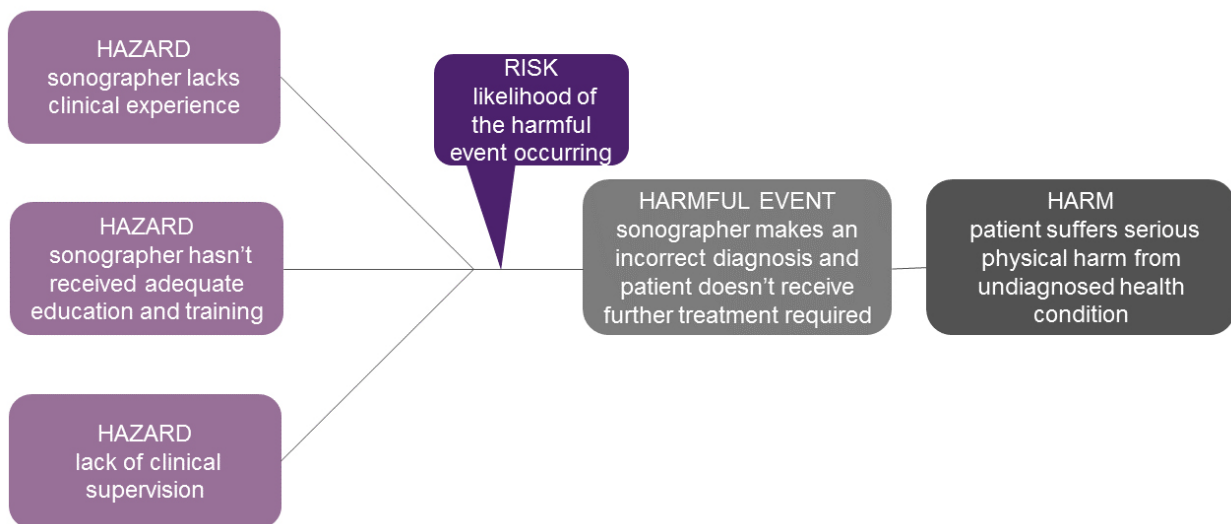
³ Health and Care Professions Council. *How the government decides which professions should be regulated*. Available at: www.hcpc-uk.org/about-us/who-we-regulate/regulation-of-further-professions/

the consultation on reform of the framework for professional regulation, *Promoting professionalism, reforming regulation* which closed in January 2018, Government also consulted on giving the Authority a formal role advising on the appropriate level of assurance for different occupations.⁴ At the time of writing, the Government response to this consultation had not yet been published.

Right-touch assurance

- 2.6 The Professional Standards Authority published *Right-touch assurance: a methodology for assessing and assuring occupational risk of harm (2016)*.⁵ It outlines a methodology for assessing the risk of harm arising from the practice of an occupation and considering other relevant factors to make recommendations on the most appropriate form of assurance.
- 2.7 One of the key drivers behind the development of this model was to ensure that decisions about regulatory action were based on a clear understanding of the likelihood and severity of harm occurring rather than theoretical risks based on the existence of hazards, which may already be adequately managed. The diagram below outlines the distinction between hazards, risk and harms:

Figure 1: Hazards, risk and harms



- 2.8 The model outlined proposals for scoring and weighting the risks of harm identified in the three different areas to allow creation of a quantifiable risk profile for an occupation. The three areas are:
- intervention/complexity
 - context
 - vulnerability/agency of patient group.

⁴ Department of Health (2017) *Promoting professionalism, reforming regulation*. Available at: <https://consultations.dh.gov.uk/professional-regulation/regulatory-reform/>

⁵ Professional Standards Authority (2016) *Right-touch assurance: a methodology for assessing and assuring occupational risk of harm*

- 2.9 The Authority intends to commission a piece of work to develop this element of the model, and therefore we have not sought to carry out this element of the process for sonographers.
- 2.10 We have carried out a qualitative assessment of the evidence available in each area in order to describe the likelihood and severity of risks arising. We have also reviewed further evidence and information to help shape our recommendations on any further assurance required to manage the risks. Further information on the methodology for this assessment is outlined in the next section.

Models of assurance

- 2.11 As health and care needs change, discussion continues about how risk of harm can be most appropriately and cost-effectively assured. The purpose of health and care professional regulation is to protect the public by upholding standards of practice and taking action against individuals who fall below the standards expected of them.
- 2.12 Whilst statutory regulation plays an important role in certain circumstances, there are a range of different methods of assurance which can provide proportionate oversight for occupations, depending on the level of risk arising from their practice. These might include:
- An employer-led code of practice and minimum training standards (similar to the model currently in place in NHS Scotland for Healthcare Support Workers)⁶
 - Credentialing. A consistent method of validating the identity and legitimacy of employees with occasional or frequent access to healthcare settings. (This is distinct from the General Medical Council (GMC) use of the term credentialing for specific areas of medical practice for doctors who are already on a register). This may be combined with other forms of assurance, see below reference to the life sciences credentialing register.
 - A voluntary register. Practitioners would be required to meet the requirements as laid out by the register. Membership of the register is non-mandatory.
 - An Accredited Register.⁷ Based on the standards that registers accredited under the programme are required to meet, practitioners must achieve a set standard of education and training, meet ongoing training requirements and could be sanctioned or removed from the register for misconduct or lack of competence. Membership of an Accredited Register is non-mandatory. However, providers can commit to use only registered practitioners in NHS settings, which in turn could form part of commissioning contracts for providers across publicly-funded health and care. A recent example is the life

⁶ NHS Education for Scotland, *HCSW Standards and Codes*. Available at: www.hcswtoolkit.nes.scot.nhs.uk/resources/hcsw-standards-and-codes/

⁷ The Professional Standards Authority accredits registers of health and care occupations who are not statutorily regulated and has now accredited 26 registers. Professional Standards Authority, *Find an accredited register*. Available at: www.professionalstandards.org.uk/what-we-do/accredited-registers/find-a-register

sciences credentialing register, which covers all life sciences practitioners working within the NHS.⁸

- Occupational licensing. This is currently not widely used in healthcare in the UK. However, some occupations or tasks in the UK do require that those carrying them out obtain a licence, from either the Government or a local authority. This was also an option explored by the Department of Health's Extending Professional Regulation working group in 2009.⁹ For example, a licence is currently required to possess or prescribe controlled drugs for the treatment of addiction (GPs are required to apply for a licence of this nature).¹⁰ In certain contexts, such as the previous example, when combined with statutory professional regulation this approach can provide a higher level of assurance.
- A statutory code of practice and registration. Registrants are legally required to gain an approved qualification to be allowed on to the professional register and must agree to comply by the professional Code, pay a registration fee and meet ongoing training requirements. Breaches of the Code can lead to fitness to practise proceedings and potentially suspension or removal from the register, preventing an individual from continuing to practise in that profession. This may be combined with protection of title which prevents anyone who is not on the professional register from using one or more protected professional titles.

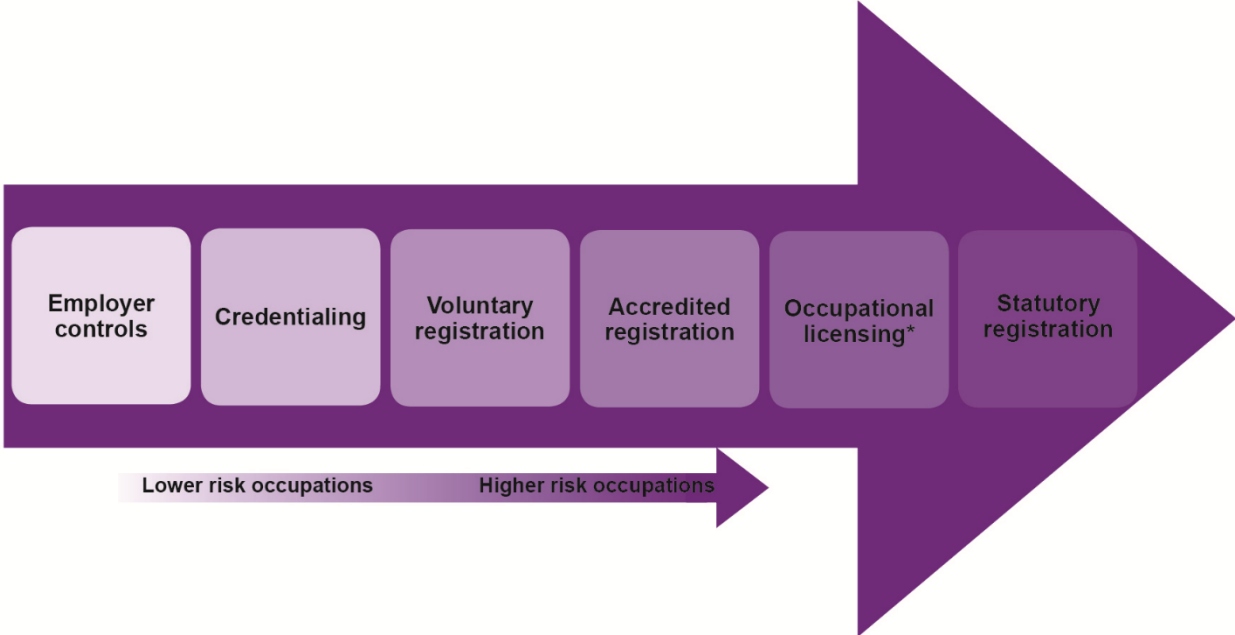
2.13 It is also important to consider the role of system regulation and the regulation of products and devices alongside any mechanisms used to regulate individuals. The diagram below highlights the need for an approach to assurance based on the risk of harm identified:

⁸ Professional Standards Authority, *Life sciences credentialing register receives accreditation: a step forward for patient safety*. Available at: www.professionalstandards.org.uk/docs/default-source/press-releases/29032018-psa-press-release---ahcs-life-sciences-register.pdf?sfvrsn=e3c37220_0

⁹ Extending Professional and Occupational Regulation, The Report of the Working Group on Extending Professional Regulation 2009. Available at: https://webarchive.nationalarchives.gov.uk/20130103005749/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_102824

¹⁰ Licences and licence applications. Available at: www.gov.uk/browse/business/licences

Figure 2: Continuum of assurance



* Occupational licensing can also provide a higher level of assurance if combined with statutory registration.

2.14 The full *Right-touch assurance* paper is attached as Appendix A to this report. We describe the methodology that we have used for this assessment in more detail in the next section.

3. Methodology and evidence base

- 3.1 As outlined, the framework we have used for this assessment is the right-touch assurance methodology and criteria although as noted, we have not sought to score or weight the risks as part of this exercise. We have carried out a qualitative assessment of the evidence to identify risks, the prevalence of harm arising as a result, and to develop recommendations on any additional means of assurance needed to manage the risks and reduce harm.
- 3.2 HEE gathered a significant amount of evidence and information to inform the assessment of risk exercise, which they provided to the Authority. The Authority has sought additional evidence and information where required and issued a call for evidence from relevant stakeholders, which ran between 5-30 November 2018. A full list of those who responded to that call is included at Annex 4.
- 3.3 Following the review of evidence, the Authority held a meeting with an Independent Review Panel to discuss our assessment and summary of the evidence, the risks of harm identified, and options for assurance. The purpose of the meeting was to check and challenge the Authority's assessment of the evidence and emerging thinking. The terms of reference and membership of the Panel are available at Annexes 5 and 6.
- 3.4 Following the meeting with the Panel, the Authority sought some additional information before drafting the final report and recommendations for HEE.
- 3.5 In general, the evidence and information relied upon for this assessment fell into the following categories:
 - Opinion/expert views - including media articles, briefing papers, outcomes of consultation exercises
 - Reports and guidance - including workforce reports, reports from sector organisations, guidance and standards
 - Academic research - including surveys, structured qualitative research, literature reviews
 - Data - including fitness to practise data, data on clinical outcomes for patients, workforce data.

Limitations - data

- 3.6 When developing the right-touch assurance model we indicated a number of potential sources of data that might be of use in establishing harm arising from the practice of a particular occupation. These included complaints data, data collected on clinical outcomes for patients, patient safety and incident data, and data from indemnity organisations and in relation to clinical negligence claims. We sought data from the NHS Independent Healthcare Providers Network and NHS Resolution in relation to claims data, however this data was either unavailable or could not be provided in the form we needed for this exercise.
- 3.7 Much of the evidence we reviewed for sonography fell into the first two categories at 3.5 above. Whilst there was anecdotal information about harm occurring, there was little patient safety or serious incident data available to demonstrate

prevalence of harm. We received information on incidents of harm associated with ultrasound errors after we had completed our primary phase of research from a survey carried out by the Society and College of Radiographers (SCoR) and the British Medical Ultrasound Society (BMUS) of their registered expert witnesses and members of SCoR. This information is useful in terms of demonstrating the type of incidents that occur and their impact but does not allow us to accurately gauge prevalence or scale at the national level. It is also not possible from the data to compare risks between regulated and unregulated practitioners or between different professions.

- 3.8 We acknowledge that gaps in the evidence we have reviewed do not necessarily indicate an absence of harm occurring. These gaps may be due to limitations in our methodology and timescales for conducting this assessment or to the inaccessibility of relevant information. They may also be due to challenges in the way that relevant data is collected, coded and made available for analysis, including the fact that sonography is currently an unregulated occupation. This report therefore represents an assessment of the risks of harm arising from the evidence that has been available to us at this time.

The contribution of the Independent Review Panel

- 3.9 The conclusions and recommendations in this report are the Authority's, however we note the valuable role fulfilled by the Independent Review Panel, the membership of which is outlined at Annex 5. As outlined in the Terms of Reference available at Annex 6, the role of the Independent Review Panel was to advise the Authority on its interpretation of the evidence and proposed recommendations for managing the risk of harm arising from the practice of sonographers.
- 3.10 Ahead of the meeting of the Panel in January 2019, Panel members were provided with a summary of the Authority's assessment of the evidence and a table summarising risks identified, the existing mitigations in place, any gaps in assurance identified and further options identified to manage these risks. A version of this is reproduced at Annexes 1 and 2.¹¹ At the meeting, the Panel discussed the merits of the different options for assurance and concluded that, based on the assessment of evidence, other forms of assurance were likely to be insufficient to manage the developing risk profile for sonographers and that ultimately statutory regulation was required.
- 3.11 We acknowledge the important contribution of the Panel to our thinking and also the useful suggestions provided by the Panel for further areas of research ahead of finalising our conclusions and recommendations. We have highlighted areas where we were able to gather further information or evidence in the summary of our assessment of the evidence at Annex 1.

¹¹ To note – the summary of evidence assessed and table of options for assurance included as annexes have been updated following the Panel meeting with any further evidence and information that we subsequently gathered.

4. Background - sonographers

Scope of practice

- 4.1 Sonographers, also known in the UK as ultra-sonographers or ultrasound practitioners, are health practitioners who use ultrasound imaging or sonography/ultrasonography to carry out examinations either for diagnostic, screening or interventional purposes. The British Medical Ultrasound Society (BMUS) and the Society and College of Radiographers (SCoR) defines a sonographer as: 'A healthcare professional who undertakes and reports diagnostic, screening or interventional ultrasound examinations. They will hold qualifications equivalent to a post-graduate certificate or post-graduate diploma in medical ultrasound that has been accredited by the Consortium for the Accreditation of Sonographic Education (CASE). They are either not medically qualified or hold medical qualifications but are not statutorily registered as a doctor in the UK.'¹²
- 4.2 As part of their role sonographers will:
- assess referrals for ultrasound imaging
 - undertake the most appropriate examination to aid the diagnosis
 - record images appropriate to the diagnosis
 - report on the results of diagnostic, screening or interventional ultrasound examinations.
- 4.3 An ultrasound scan, sometimes called a sonogram, is a procedure that uses high-frequency sound waves to create an image of part of the inside of the body. A small device called an ultrasound probe is used. A lubricating gel is placed on the skin to allow the ultrasound probe to move smoothly and to ensure there is continuous contact between the probe and the skin. In some cases, patients may be given a sedative to help them relax or may be given an injection of a substance called a contrast agent before the scan, which can help to make the images clearer. The ultrasound probe emits high-frequency sound waves as it is passed over the area under examination. These bounce off different parts of the body and create 'echoes' which are picked up by the probe and turned into a moving image. This image is displayed on a monitor while the scan is carried out and is then interpreted by the ultrasound practitioner.¹³
- 4.4 Sonographers in the UK generally have a higher level of responsibility in the diagnostic process compared to similar roles in Canada and the United States where interpretation of images and diagnosis is primarily carried out by medical professionals.

The sonographer workforce

- 4.5 Workforce data on sonographers is difficult to establish due to a lack of uniformity of job title and the number of other professionals and practitioners either

¹² Society and College of Radiographers and British Medical Ultrasound Society (2016). *Guidelines for Professional Ultrasound Practice*.

¹³ NHS England, *Ultrasound scan*: www.nhs.uk/conditions/ultrasound-scan/

practising as a sonographer or using ultrasound imaging as a tool. However, there are currently thought to be around 3,000 ultrasound practitioners in the UK. According to the Centre for Workforce Intelligence (CWI), sonographers in England are employed primarily by NHS Trusts but work across a range of different contexts including within hospital radiology departments, independent hospitals, community GP settings, independent providers, agencies (employed or self-employed basis), and in self-employed or small businesses/partnerships.¹⁴

- 4.6 Sonographers also practise across a range of departments including:
- Radiology/diagnostic imaging
 - Obstetrics/gynaecology
 - Vascular
 - Cardiac
 - Early pregnancy assessment units
 - Musculo-skeletal ultrasound.
- 4.7 The data gathered by the CWI indicates that diagnostic radiographer is the most common job role of those within the sonography workforce (just under 60 per cent) followed by consultant (15.8 per cent) and healthcare scientist (12.7 per cent). Of the staff identified, the majority (49 per cent) were registered as a radiographer with the HCPC, 4.5 per cent were registered with a voluntary register and around 3.5 per cent had no registration. Across departments, most worked in radiology and diagnostic imaging, followed by obstetrics and gynaecology and then cardiology.¹⁵

Education and training routes

- 4.8 Most current sonographer training is delivered as a post-graduate Diploma or Certificate in Medical Ultrasound. Training is delivered by universities and accredited by the Consortium for the Accreditation of Sonography Education (CASE).¹⁶ However, a new undergraduate programme has recently been developed by Birmingham City University, creating the potential for direct entry into the role.¹⁷ There are also two direct entry post-graduate courses currently available at the Universities of Derby and Cumbria.¹⁸

Regulation of sonographers

- 4.9 Sonographers are not statutorily regulated as a profession in their own right. However, many individuals practising ultrasound train as radiographers and

¹⁴ Centre for Workforce Intelligence (2017). *Securing the future workforce supply - Sonography workforce review*.

¹⁵ The workforce review identified around 2,300 staff working in sonography roles across England. The survey was completed by just under half of eligible NHS Trusts in England, so figures will be different for the whole of the UK. The estimate of 3,000 sonographers across the UK comes from a HEE briefing on the sonographer workforce.

¹⁶ The Consortium for the Accreditation of Sonography Education: www.case-uk.org/

¹⁷ Birmingham City University, *Medical Ultrasound - BSc (Hons)*: www.bcu.ac.uk/courses/medical-ultrasound-bsc-hons-2019-20

¹⁸ The Society and College of Radiographers. *How to become a sonographer*. www.sor.org/news/how-become-sonographer

register with the HCPC in that capacity, before carrying out post-graduate training to allow them to work as a sonographer. The HCPC has previously recommended regulation of sonographers, in 2009, following consideration of the application for regulation by the Society and College of Radiographers.¹⁹ The recommendation, made to the then Secretary of State, highlighted the potential for the licensing of scanning equipment by the CQC and the potential for consideration of occupational licensing for the role, building on the conclusions of the Department of Health's Extending Professional Regulation Working Group.²⁰ There are also professionals registered as nurses or midwives who either practise as a sonographer or use ultrasound within their practice.

Developments in ultrasound

- 4.10 Ultrasound examinations have traditionally been carried out in a fixed location within radiology departments. However, the use of ultrasound imaging in the health service has developed considerably in recent years both in relation to the different uses it is being put to and the method of carrying out examinations with an increase in the use of portable ultrasound scanners which can be used at patients' bedsides.²¹
- 4.11 Some of the literature also notes an expanding role for sonographers in sonographer-led interventional practice, which includes both diagnostic and therapeutic procedures across different areas such as ultrasound guided breast biopsy and for an increasing range of different purposes such as musculoskeletal ultrasound examinations, evaluations of deep vein thrombosis, and carotid artery investigations. High intensity ultrasound is also used for procedures such as kidney stone fragmentation and cancer treatment, however, this is generally carried out in specific units by those with specialist training.
- 4.12 This expansion in the use of ultrasound has coincided with a shortage of qualified sonographers to fill available roles. The CWI report found that vacancy rates for sonographers of around 10 per cent and higher (up to 18 per cent).²² The draft health and care workforce strategy for England identified sonography as a workforce gap, and the role of sonographer (within the group medical radiographers),²³ has been on the Migration Advisory Committee's shortage occupations list for the UK since 2005.²⁴ In addition, the Cancer Strategy published by the Independent Cancer Taskforce highlights the importance of radiography and ultrasound in cancer diagnosis.²⁵

¹⁹ Health and Care Professions Council 2009, *Recommendation to Secretary of State for Health about the regulation of sonographers*.

²⁰ Department of Health (2009), *Extending Professional and Occupational Regulation - The Report of the Working Group on Extending Professional Regulation*.

²¹ Society and College of Radiographers and Royal College of Radiologists (2014). *Standards for provision of an ultrasound service*.

²² Centre for Workforce Intelligence (2017). *Securing the future workforce supply - Sonography workforce review*.

²³ *Facing the Facts, Shaping the Future - A draft health and care workforce strategy for England to 2027*.

²⁴ Migration Advisory Committee (2015) *Review of Tier 2: Balancing migrant selectivity, investment in skills and impacts on UK productivity and competitiveness*.

²⁵ Cancer Research UK, Report of the Independent Cancer Taskforce. *Achieving world-class cancer outcomes – A strategy for England 2015-2020*.

4.13 Further information and evidence about the practice of sonographers is included in the evidence assessment available at Annex 1.

5. Conclusions and recommendations

Current situation

- 5.1 From the evidence we have reviewed for this assessment,²⁶ we conclude that there are risks arising from the intervention/complexity of the practice of sonographers, the context they are working in, and the vulnerability of the patient group. The role of a sonographer is highly skilled and requires individuals to exercise a significant degree of autonomy. The main risks arise from the requirement to be able to interpret and report accurately from ultrasound images, and from the need to be able to use ultrasound equipment safely and effectively. Additional areas of risk arising across the three areas within the right-touch assurance model include:
- faulty or poorly maintained equipment
 - cross infection associated with poor hygiene around equipment
 - the potential for sexual misconduct due to the need for intimate examinations
 - the potential for misconduct by ultrasound practitioners
 - the physical effects of ultrasound scanning
 - practitioners lone working or in isolated practice
 - an absence of effective clinical governance
 - a lack of access to supervision
 - the misleading marketing of services
 - difficulties for employers or patients in checking the conduct or competence of a practitioner
 - inability to prevent poor practitioners from practising.
- 5.2 We have seen evidence demonstrating that there are instances of harm occurring because of errors made by sonographers and those using ultrasound and that the consequences of this can be severe. Harms range from psychological distress caused to patients who have received incorrect information or diagnosis, through to serious physical harm or death either of the individual or in the case of obstetrics, the foetus. Evidence we have reviewed includes fitness to practise data from the HCPC and NMC, coroners' reports, reports on NHS Resolution maternity claims and informal survey information outlining the experiences and observations from the British Medical Ultrasound Society (BMUS) and the Society and College of Radiographers (SCoR) members over the last three years.
- 5.3 We have not had access to patient safety data indicating significant prevalence of harm arising in these areas. As we noted in our assessment of the evidence, the lack of availability of patient incident data may not be indicative of low prevalence of harm but may be more related to the challenges of capturing data about an unregulated occupation; or the fact that there are existing mechanisms in place

²⁶ See full summary of evidence assessment in Annex 1.

for controlling risk. For example, most sonographers are already regulated in another professional role such as nurse, or radiographer. Most sonographers still work within the NHS within its clinical governance systems and with access to advice. In addition, all diagnostic and screening services in England are required to be registered with the CQC.

- 5.4 The evidence we have received from stakeholders, particularly the survey of BMUS and SCoR members, suggests that there may be an increased risk of harm within parts of the independent sector, and in relation to maternity services. However, we do not have sufficient data to state this conclusively. Whilst this appears to be known by the profession, it is apparently not visible through current data collection systems, or we have been unable to access the relevant data. One of the reasons for this appears to be that incidents occurring outside of the NHS are not recorded in NHS incident data, even if patients subsequently report to NHS services for a second opinion or further treatment/diagnosis. The NHS, regulators and the profession may wish to address this data gap to ensure that that incidents of harm are being accurately recorded and appropriate action is taken to protect patients.
- 5.5 It has been difficult to establish from the evidence we have reviewed whether there is a significantly greater risk of harm arising from unregulated sonographers or whether risks differ substantially between the currently regulated professions – more detailed research would be required to establish this conclusively. However, if unregulated sonographers are required to perform the same range of tasks as regulated practitioners, without other clinical supervision, it is reasonable to deduce that the risk of harm is at least comparable.
- 5.6 Separately from the specific risk of harm identified, unregulated sonographers face some specific limitations to their scope of practice. They are unable to administer medicines under Patient Group Directives, including using contrast agents, which may be used to enhance ultrasound images, and which are considered best practice in some areas of ultrasound.²⁷ Unregulated sonographers are also unable to train as supplementary prescribers or refer patients for clinical imaging involving ionising radiation under the IM(RE) regulations.²⁸

Future changes to risk profile

- 5.7 In addition to the findings outlined above, the evidence that we have reviewed suggests a strong likelihood that the risk profile for sonography will change significantly in the near future. This view is based on planned changes to the routes of entry to the profession, allowing direct entry. There are currently two post-graduate direct entry courses for sonographers at, Cumbria and Derby which have been running for around three years and which are already contributing to the sonographer workforce. Further to these changes is the increase in private sector provision of ultrasound services and changes to the

²⁷ National Institute for Health and Clinical Excellence, Diagnostics Assessment Programme - SonoVue (sulphur hexafluoride microbubbles) -contrast agent for contrast enhanced ultrasound in liver imaging. [Online] Available at: www.nice.org.uk/guidance/dg5/documents/sonovue-sulphur-hexafluoride-microbubbles-scope2

²⁸ The Ionising Radiation (Medical Exposure) Regulations 2017: www.legislation.gov.uk/uksi/2017/1322/contents/made

composition of the patient group with a potential increase in the number of children undergoing ultrasound procedures.

- 5.8 Whilst numbers currently enrolled on the undergraduate programme provided by Birmingham City University are low (around 14 in total), we understand from HEE that there is support for growth of this method of entry to the profession along with the introduction of the apprenticeship route into sonography, in conjunction with the new career framework for sonographers. This is in line with the workforce strategy for England, which identifies the need for significantly more capacity in diagnostic and imaging services and increasing use of ultrasound as a diagnostic tool for cancer.
- 5.9 We also understand that graduates entering the profession after a three-year undergraduate degree will be practising independently after a short preceptorship, and exercising similar levels of responsibility to an experienced sonographer. In addition, pressures on clinical supervision may mean that sonographers will not always have access to advice and support when required. We have also heard evidence from stakeholders that an increase in the complexity of health conditions, and the physical nature of ultrasound scanning, particularly in maternity services, is increasing the challenges associated with accurate interpretation and diagnosis from ultrasound images.
- 5.10 Whilst it has been difficult to establish definitively the growth in private sector provision of ultrasound services, there is evidence that many patients choose to have alternate or supplementary ultrasound scans outside of the services that are provided through the NHS. Furthermore, the ready availability and lack of limitations on the purchase and use of ultrasound equipment makes private provision of ultrasound services viable.
- 5.11 In relation to changes to the profile of the patient group, we have referenced the recent changes to the law in the United States that allow use of contrast agents in children and the potential for Europe and the UK to adopt this change. This change links to the *Image Gently* campaign.²⁹ This is a global initiative to improve safe and effective imaging care of children worldwide, partly through reducing children's exposure to radioactive scans through increase of non-harmful alternatives such as ultrasound. However, if adopted this change would increase the vulnerability of the patients that sonographers see.

Recommendations

- 5.12 Following our assessment and in line with the conclusions above, we have considered each of the possible methods of assurance and make the following recommendations.

Current workforce

- 5.13 The potential for harm arising from the practice of sonographers is high, but it appears currently to be mitigated by existing controls. These include that most practitioners are already regulated professionals (nurses, midwives, radiographers, biomedical scientists). They practice within controlled work environments that are regulated by CQC. They take a post-graduate qualification.

²⁹ The Image Gently Campaign: www.imagegently.org/

Many are members of the Society and College of Radiographers, which is a well-established professional body that holds a voluntary register which is open to unregulated practitioners. The evidence available does not present a clear case for immediate statutory regulation of sonographers as a distinct profession, although we consider that position is likely to change if there is a substantial increase in direct entry to the profession at under-graduate entry.

- 5.14 We acknowledge concerns about workplace pressures impacting factors such as clinical supervision. However, in line with right-touch principles and the continuum of assurance, regulation should not be used as a substitute for effective employment practice, safe working systems and sound clinical governance. We also acknowledge that some sonographers report finding it difficult to maintain registration within their statutorily regulated profession because they are working solely as a sonographer and therefore find it hard to demonstrate continuing fitness to practise as a radiographer.
- 5.15 Sonographers are currently a relatively small group of practitioners, compared for example to the c.30,000 registered radiographers on the HCPC register.³⁰ Although sonography is not statutorily regulated as a profession in its own right, most sonographers appear to be regulated either by the GMC, HCPC or the NMC in other professional roles. This is already providing a level of public protection, as professionals must adhere to their professional codes and are responsible for ensuring that they are competent to perform a procedure. This requirement extends therefore to use of ultrasound. Those found not to be fit to practise can be removed from the register, and there is evidence that regulators have taken action in relation to those practising as sonographers. There is also the Public Voluntary Register of Sonographers (PVRS) operated by the SCoR and potential for the establishment of an accredited register for any unregulated practitioners. Most current sonographer training is delivered as a post-graduate Diploma or Certificate in Medical Ultrasound and most courses are accredited by the Consortium for the Accreditation of Sonography Education (CASE). All diagnostic and screening services in England (NHS and independent) are required to register with the CQC and undergo inspections to ensure compliance with its quality and safety standards.³¹
- 5.16 There is a paucity of clinical incident data. The survey data from BMUS and SCoR members, while illustrative of the types of harm, is not sufficiently detailed to rely upon for calculating prevalence and many of the cases cited involve regulated practitioners. The number of incidents we have seen are relatively low given the high volume of procedures carried out each year. We acknowledge that there may be further cases not visible through current data collection systems, for example where harm occurs in the independent sector but is only identified as a result of subsequent treatment or diagnosis within the NHS.

³⁰ The number of radiographers may also include some registrants who are currently practising as sonographers. As noted in our assessment of the evidence, it is estimated that there are 3,000 sonographers practising in the UK. The Public Voluntary Register of Sonographers has 585 sonographers on its register, of which 186 are not also statutorily regulated (figures as of December 2018).

³¹ Care Quality Commission, Review of compliance, CS Partners Medical Ltd - The Baby Scan Studio Colchester: www.cqc.org.uk/sites/default/files/old_reports/1-125892769_CS_Partners_Medical_Limited_1-156959169_CS_Partners_Medical_Ltd_-_The_Baby_Scan_Studio_Colchester_20120420.pdf

- 5.17 We suggest that risk of harm by unregulated practitioners could be further mitigated by more unregulated sonographers joining the PVRs. A modest increase in the number of unregulated workers currently being trained on undergraduate courses could also be managed through the voluntary register. We would however, recommend that the PVRs seek accreditation or consider finding a home for the register of sonographers under the umbrella of an existing Accredited Register such as the Academy for Healthcare Science (AHCS), to strengthen public protection if there are constraints to seeking accreditation in its own right. We suggest the AHCS as an option for exploration. In addition to regulating various health scientists it also hosts a credentialing register for life sciences.
- 5.18 On the continuum of assurance Accredited Registration provides a higher level of public protection than other forms of voluntary registration, as it requires registers to be independently assessed against standards and awarded a quality mark. These ensure that registers set appropriate standards for practitioners on the register and for levels of education and training. They must also have an effective complaints management system, effective governance, and ongoing monitoring and management of risks. The need for independent assurance of voluntary registers was set out in the Government Command paper *Enabling Excellence*, which stated that ‘there are a range of voluntary registers, but no system which allows the public, employers or professionals to gauge whether they operate effectively and to high, or common, standards’.³²
- 5.19 As a minimum we would suggest that the PVRs be independently benchmarked against the Authority’s standards. Although we understand there is no commitment to maintain the voluntary register beyond 2021, in the absence of profession specific statutory regulation for sonographers, it is important that employers and members of the public have the choice to select an ultrasound practitioner from a register who meets minimum standards, even when membership of such a register is not mandatory. Where members of the public do have concerns there should also be a clear and transparent route for these to be raised, and where necessary for a practitioner to be removed from the register or sanctioned. Furthermore, although membership of any voluntary register is by its nature not mandatory it can be encouraged, for example through employer recruitment preferences.
- 5.20 With regard to sonographers who are already statutorily regulated in other professional roles, the evidence suggests that this is mitigating the risks arising from practice. We would, therefore, not suggest any change to the regulatory status of these individuals.
- 5.21 We suggest however that the HCPC, GMC, NMC and CQC may wish to consider the concerns raised by the informal survey data supplied to us by the BMUS and SCoR to see if any regulatory or other action is warranted to ensure standards are being met and the public is protected. If BMUS and SCoR are concerned that sonographers are experiencing difficulties with regulators’ CPD requirements,

³² *Enabling Excellence - Autonomy and Accountability for Healthcare Workers, Social Workers and Social Care Workers*(2011). Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/216580/dh_124374.pdf

they may wish to discuss that with them. Our understanding, as we set out in our 2010 advice *Managing Extended Practice*, is that professional regulators' existing arrangements usually accommodate professionals' expanded scopes of practice.³³

Future workforce

- 5.22 With regard to England, if a commitment is made to significantly increase the number of sonographers joining the workforce via the direct entry under-graduate route, then we believe the inherent risks of the occupation are significant enough that the option of statutory regulation should be considered. We recognise that decisions on regulation are for Government and could only be carried out following further stakeholder engagement on the issues across the four countries of the UK; further collection of incident data if possible and formal consideration of the costs and benefits to such an approach.
- 5.23 We considered whether other forms of assurance, including occupational licensing, as recommended by the HCPC as an option in 2009, or accredited registration, would provide sufficient assurance. Occupational licensing, whilst providing a potentially lighter touch alternative to statutory professional regulation, is not widely used for health and care purposes in the UK and tends to be focused primarily on specific dangerous or restricted acts, such as possession or sale of certain chemicals. It therefore may not adequately manage the primary risks associated with misdiagnosis and misuse of equipment by sonographers, and there would be no requirements for ensuring ongoing competence through maintaining CPD.
- 5.24 Accredited registration incorporates the key elements of statutory regulation, including requirements for a basic level of qualification and adherence to standards of conduct and competence. It also requires a mechanism for ensuring complaints about practitioners are fairly and transparently dealt with and allows practitioners to be removed from the register where necessary. However, it is not mandatory and therefore practitioners can choose not to be a member of the register whilst practising. Although many of the registers within the programme have gained broad support from employers, who increasingly choose practitioners from a register where available, this is reliant on employer buy-in, which may be more difficult to achieve from independent ultrasound services. Ultimately, we are of the view that the inherent risks arising from the practice of sonography are significant enough that, if there were a significant expansion in under-graduate entry to the profession, Accredited Registration is likely to be insufficient to adequately manage the risk of harm arising. This was a view shared by the Independent Review Panel following their consideration of our assessment of the evidence and options for further assurance.
- 5.25 If statutory regulation were to be considered by Government, we recommend the following factors be kept in mind:
- We have already touched on the need to consider the range of issues across the UK and ensure a consistent approach to decisions about regulation where

³³ Professional Standards Authority (2010) *Managing extended practice - Is there a place for 'distributed regulation'?* Available at: www.professionalstandards.org.uk/docs/default-source/publications/advice-to-ministers/managing-extended-practice-2010.pdf?sfvrsn=88c77f20_8

possible. We suggest that work be carried out with HEE's equivalent bodies in Scotland, Wales and Northern Ireland, and with other stakeholders across the four countries, to test these findings in line with specific workforce needs and evidence of risk of harm arising in different parts of the UK. This would help to ensure that any changes to the regulatory framework take into account any differences there may be with the situation in England.

- The strength of our current health professional regulatory system is its flexibility, in that it allows health professionals to broaden their scopes of practice and engage in specific tasks provided they can demonstrate the competency to do so. Ultrasound is already used as an extension of practice by many health professionals, and technological developments may in future make this even easier. A key consideration therefore must be to avoid restricting health professionals' ability to adopt ultrasound as a tool within in their scope of practice.
- Similarly, sonography is currently associated with four main professions: radiography, midwifery, nursing and clinical science. The NHS Long Term Plan makes clear that it foresees greater workforce flexibility in future, with inter-profession credentialing. Given the need for an agile workforce able to adapt to future needs, it would be sensible to retain the flexibility for different professions to move in and out of sonography as required. Equally, it will be important for sonographers who have both depth and breadth of diagnostic knowledge to be able to adapt to make use of existing and future technologies as they are developed.

6. Annex 1 – Assessment of evidence

Intrinsic risk of harm

Type of intervention/complexity of practice

- 6.1 The evidence we reviewed suggests that an ultrasound in itself poses little of risk of harm. It is generally considered a relatively safe procedure unlike radiography, for example where the material presents a direct risk of harm. Based on the scope of practice for the role, outlined in the *Guidelines for Professional Ultrasound Practice* however, the practice of sonography has a number of inherent risks. Sonographers are required to operate ultrasound imaging equipment primarily as a diagnostic tool and interpret the images in order to make recommendations for further treatment or referral for further diagnosis. Skills required include technical knowledge, understanding of health conditions and clinical information, ability to accurately observe, analyse and interpret, ability to communicate with and advise the patient and to take appropriate action.³⁴
- 6.2 As highlighted by the literature review carried out by the Health Professions Regulatory Advisory Council (HPRAC) in Ontario, sonographers in the UK have significantly more autonomy and responsibility with regard to interpretation of images and diagnosis compared to their counterparts in Canada and the United States, where doctors carry out the majority of analysis and make recommendations arising from ultrasound imaging.³⁵
- 6.3 They key risks reported to us in this area are:
- risk of harm to patients arising from misdiagnosis
 - risks of harm to patients arising from mis-use of equipment
 - risk of harm to patients arising from faulty or poorly maintained equipment
 - risk of cross-infection arising from poor hygiene procedures associated with use of ultrasound
 - risk of sexual assault or breach of sexual boundaries due to intimate nature of examinations
 - risk of harm to patients arising from misconduct by ultrasound practitioners
 - risk of harm associated with physical effects of ultrasound scanning.
- 6.4 Based on the evidence considered, the risks associated with misdiagnosis, either due to mis-interpretation of imaging or lack of knowledge of correct onward referral routes, appear to be the most significant and the most frequently referenced. Misdiagnosis broadly falls into two main categories - false positives, when a patient is incorrectly diagnosed with a condition which may require potentially harmful further diagnostic intervention or treatment, or false negatives, when a potentially harmful health condition or concern is missed, or its

³⁴ Society and College of Radiographers and British Medical Ultrasound Society Revised (2017) *Guidelines For Professional Ultrasound Practice*.

³⁵ Health Professions Regulatory Advisory Council (2013). *Diagnostic Sonographers: A Literature Review*.

seriousness underestimated, and the patient is not referred for further diagnosis or treatment required.

- 6.5 Causes of misdiagnosis include inadequate education and training, leading to a lack of competence in operating equipment, producing and interpreting images and diagnosing and making further recommendations for treatment or referral; outdated or poorly maintained equipment and/or the absence of clinical audit of performance and poor communication between staff.
- 6.6 Evidence we reviewed demonstrated the potentially severe implications of errors made by individuals practising sonography. This included the risks in obstetric ultrasound when misdiagnosis may lead to an incorrect recommendation to terminate a pregnancy.³⁶ There was also evidence from a coroner's report where death of a patient occurred due to missed diagnosis of thoraco-abdominal aneurism³⁷ and failure to refer for further investigation and treatment.³⁸ Fitness to practise cases involving radiographers practising as sonographers also serve to demonstrate the harm that may occur when errors are made.³⁹ We therefore conclude that the impact of the harm that may result is high, with potentially severe implications for patients concerned.
- 6.7 With regard to the prevalence of harm occurring as a result of misdiagnosis, the evidence that we had access to was more limited and was inconclusive on whether there was significantly greater risk of harm posed by unregulated practitioners compared to those who are currently on a statutory register.
- 6.8 A review of fitness to practise cases from the HCPC identified six cases out of 68 final decisions about radiographers which related to radiographers practising as sonographers. Issues identified were primarily about lack of competence but also referenced conduct issues including alcohol consumption at work.⁴⁰ A review of NMC cases on the Authority's database identified three decisions involving midwives between 2013-2018 where the registrant's use of ultrasound was relevant to the charges brought.⁴¹
- 6.9 Further anecdotal evidence of harm occurring was provided to us after discussion with the Independent Review Panel from an informal survey carried out of Society and College of Radiographers' (SCoR) registered expert witnesses and members of SCoR and the British Medical Ultrasound Society (BMUS). This information included details of a number of cases, either observed or communicated to individuals working within ultrasound services of errors made resulting in harms ranging from delayed diagnosis and psychological distress, through to serious physical harm and death. We have treated such information

³⁶ W. Hatley, J. Case, Professor S. Campbell. *Establishing the death of an embryo by ultrasound: report of a public inquiry with recommendations.*

³⁷ 'Cardiff and Vale University Health Board's. *Report to Prevent Future Deaths*

³⁸ Senior Coroner for Berkshire's *Report to Prevent Future Deaths*

³⁹ Final hearing, Dr Emmanuel I O Ehiwe: www.hcpts-uk.org/hearings/hearings/2018/february/dr-emmanuel-i-o-ehiwe/

⁴⁰ Health and Care Professions Council, Radiographer Final Hearings: www.hcpts-uk.org/hearings/search/search/?page=3

⁴¹ Figures as of 3 January 2019. These were identified by searching NMC decisions on the Authority's Section 29 database for references to ultrasound or sonography. Other decisions reviewed referenced ultrasound tangentially and not where the registrant was responsible for carrying out ultrasound procedures.

with caution as it is not independently collected or verified, and we do not have sufficient information to assess whether harms identified are always a direct or associated result of errors made. It also suggests that errors are being made by both regulated and unregulated practitioners. However, this does provide further evidence that existing mechanisms are not fully preventing instances of harm occurring.

- 6.10 There are a number of studies looking at accuracy of diagnosis in different areas of ultrasound practice that indicate a good level of accuracy of sonographers at varying levels of experience. For example, one study looked at the results of a study comparing expert and novice sonographers in lung ultrasound diagnosing patients with acute heart failure syndrome and found that clinicians with only 30 minutes training could obtain adequate images 95 per cent of the time and interpret results with a similar sensitivity and specificity compared to experts. The study was conducted in a single hospital and notes a number of limitations. It also notes that these results may not be generalisable to other fields of sonography and other settings, or to the UK, as the study was carried out in the United States. It also has limited relevance in considering the accuracy of non-clinician sonographers.⁴²
- 6.11 Another study looked at the difference in sonographer and radiologist findings in 400 cases and found that although radiologists were deemed correct slightly more frequently, the difference was not statistically significant. The study indicates a broad level of similarity between findings, however as it also relates to a discrete area it may be difficult to generalise to other areas.⁴³
- 6.12 A further study on the accuracy of endoscopic ultrasound indicated that the results may be operator dependent and highlighted an overall lower level of accuracy from the non-expert endo-sonographers in diagnosing spread of cancer within the body both in relation to underestimating and overestimating severity. However, the study was carried out in Korea and based on American definitions of competence which highlights that physicians only should carry out endo-sonography. It may therefore have limited application to the UK where the context is different.⁴⁴
- 6.13 The literature review carried out by the Health Professions Regulatory Advisory Council (HPRAC) in Ontario references three studies which suggest a high level of alignment in accuracy of diagnosis between those practising as sonographers and radiologists. In some of these studies those practising as sonographers are registered as radiographers but have a post-graduate qualification in sonography.⁴⁵

⁴² Alan T. Chiem MD, MPH, Connie H. Chan MD, Douglas S. Ander MD, Andrew N. Kobylivker MD William C. Manson MD. (May 2015) *Comparison of Expert and Novice Sonographers' Performance in Focused Lung Ultrasonography in Dyspnea (FLUID) to Diagnose Patients with Acute Heart Failure Syndrome.*

⁴³ Dawkins A, George N, Ganesh H, Ayoob A, Lee J, Nair R, Kiper C, Duncan K, Stevens S. (December 2017). *Radiologist and Sonographer Interpretation Discrepancies for Biliary Sonographic Findings: Our Experience.*

⁴⁴ Lee W. C. (September 2015). *Staging accuracy of endoscopic ultrasound performed by nonexpert endosonographers in patients with resectable esophageal squamous cell carcinoma: is it possible?*

⁴⁵ Health Professions Regulatory Advisory (2013). *Diagnostic Sonographers: A Literature Review.*

- 6.14 With regard to further evidence of prevalence of harm we looked at reports from NHS Resolution covering litigation in relation to maternity services. A report from 2012 covering claims from 2000-2010 identified 92 cases relating specifically to investigations of errors in diagnosis/interpretation made in ultrasound scanning.⁴⁶ However, a more recent report, more narrowly focused on the issue of cerebral palsy claims between 2012 and 2016, identified no missed foetal abnormalities on ultrasound that could have resulted in or increased the risk of brain injury. It notes this is a promising sign, as previous reports have highlighted that missed foetal abnormalities during antenatal ultrasound scanning, although rare, were a high source of compensation.⁴⁷ We requested recent data from NHS Litigation regarding claims made involving errors made in ultrasound procedures across different areas, however they were unable to provide this due to the way that claims are categorised.
- 6.15 As we have already acknowledged, the lack of evidence does not necessarily mean that unregulated practitioners do not pose a risk and limitations to the evidence base are partly due to difficulties in gathering data about an unregulated workforce and the limited numbers of unregulated sonographers who are currently practising. We also note that a number of the studies reviewing accuracy of results are based on the practice of registered radiographers and which may indicate that registration as a radiographer is providing a level of public protection in itself.
- 6.16 We saw limited evidence demonstrating risk of harm arising from misuse of equipment and poorly maintained equipment. However, this was a concern referenced by a number of stakeholders and appeared in some of the fitness to practise cases examined. This may reflect the fact that the majority of evidence reviewed related to the practise of sonography within the NHS, and there may be information that we were unable to access from the independent sector. We did request any information available on patient safety incidents related to ultrasound occurring within the independent sector, from the NHS Confederation Partners Network⁴⁸ (a body representing certain organisations within the independent sector). However, this information was unavailable in the form required.
- 6.17 We did not see any specific evidence of prevalence of sexual assault or breach of boundaries by sonographers carrying out intrusive procedures, however, this may be more related to a lack of available data. Similarly, there was limited information on instances of misconduct. Although this was evident from the HCPC fitness to practise cases we looked at, the numbers involving those practising as sonographers were small.
- 6.18 There was limited evidence of physical harm arising from thermal or mechanical effects of ultrasound imaging. A number of documents reviewed referred to this as a potential risk, however, there was a lack of evidence of prevalence of harm arising; although the HPRAC literature review notes that the main studies relied upon were based on older ultrasound equipment with lower frequencies. It also noted that risks may relate more to a lack of knowledge on how to interpret

⁴⁶ NHS Resolution (2012). Ten Years of Maternity Claims: An analysis of NHS Litigation Authority data.

⁴⁷ NHS Resolution (2017). Five years of cerebral palsy claims.

⁴⁸ NHS Confederation, Independent Healthcare Providers Network:
www.nhsconfed.org/networks/independent-healthcare-providers-network

equipment readings or operate equipment. The literature review also referenced studies suggesting there are low levels of knowledge in this area amongst ultrasound users, including sonographers.⁴⁹

- 6.19 Government advice from the Health Protection Agency (now Public Health England) states that although there is little direct evidence on the safety of modern techniques, no ill effects have been reported. It further recommends that people should not hesitate to continue using ultrasound for diagnostic and other medical purposes.⁵⁰
- 6.20 Ultrasound use for kidney stone fragmentation or cancer treatment is undertaken at significantly higher energy levels than for diagnostic purposes, however evidence from stakeholders suggests that this is primarily carried out by specialists in specialist units and is therefore outside of the scope of the majority of practising sonographers.

Context of practice

- 6.21 As noted, sonographers in England work primarily for NHS Trusts but across a range of different contexts including within hospital radiology departments, independent hospitals, community GP settings, independent providers, agencies (employed or self-employed basis), and self-employed or small businesses/partnerships as well as in different departments, including radiology, obstetrics, vascular, cardiac and musculoskeletal.
- 6.22 There is also a growing market in provision of so-called 'lifestyle scanning' services such as 3D and 4D baby scanning, gender scans or full body health scans. The College and Society for Radiographers (SCoR) in the supplementary evidence submitted to the HCPC in support of its 2008 application for regulation of sonographers highlighted concerns about misleading advertising of such services, and of the increased patient safety risk arising from inadequate levels of training for practitioners and a lack of clinical governance.
- 6.23 Workforce data is limited due to the challenges of gathering data about an unregulated workforce where there is variation in job titles, and sometimes a lack of clarity in whether practitioners are using ultrasound as a tool or practising as a sonographer.
- 6.24 The main risks of harm reported to us in relation to the context in which sonographers are working are outlined below:
- risk of harm arising from lone working or isolated practice
 - risk of harm arising from absence of clinical governance
 - risk of harm arising from level of lack of access to supervision
 - Risk of harm arising from misleading marketing of services.
- 6.25 The majority of sonographers practise within the NHS but across a variety of different departments. The 2015 workforce survey carried out by the Centre for

⁴⁹ Health Professions Regulatory Advisory (2013). *Diagnostic Sonographers: A Literature Review*.

⁵⁰ Public Health England, *Ultrasound: what it is, how it works and impact of exposure*: www.gov.uk/government/publications/ultrasound-what-it-is-how-it-works-and-the-impact-of-exposure/ultrasound-what-it-is-how-it-works-and-impact-of-exposure

Workforce Intelligence (CWI) appears to be the most comprehensive set of data about the sonography workforce. The workforce review identified around 2,300 staff working in sonography roles across England. However, the survey was completed by just under half of eligible NHS Trusts in England, so figures will be different for the whole of the UK. However, they do provide a useful indication of the makeup of the sonography workforce. According to the most recent information from the SCoR, there are currently 585 individuals listed on the Public Voluntary Register of Sonographers (PVRS), with 186 of that number not on any statutory professional register.

- 6.26 As noted in the introduction, the CWI report highlighted that the diagnostic radiographer was the most common job role of those within the sonography workforce (just under 60 per cent) followed by consultant (15.8 per cent) and healthcare scientist (12.7 per cent). Of the staff identified, the majority (49 per cent) were registered as a radiographer with the HCPC, 4.5 per cent were registered with a voluntary register and around 3.5 per cent had no registration.⁵¹ Across departments, most worked in radiology and diagnostic imaging followed by obstetrics and gynaecology and then cardiology.
- 6.27 Whilst the data does not provide a clear picture of the specific contexts that the majority of sonographers are working in, it suggests that for the majority of staff working within the NHS there is likely to be a higher level of oversight and support available for those practising sonography as there is a higher likelihood they are working alongside others in larger departments. However, evidence submitted by stakeholders suggests that, due to a shortage of radiologists in England, there is a shortage of medical supervision for sonographers. This may mean that less experienced sonographers will not always have access to a second opinion from a more experienced clinician when required.
- 6.28 There are a range of references in the evidence reviewed about the increase in privately provided lifestyle scanning services where there may be greater chance of those using ultrasound practising in isolation without access to senior level expertise where required. The information which we had access to did not identify the number of practitioners employed in such settings or the scale of demand from patients using such services. However, non-obstetric ultrasound formed the majority of the diagnostic tests carried out by independent sector organisations in 2018.⁵²
- 6.29 A number of documents reviewed highlight the importance of effective clinical governance for sonography. Diagnostic and imaging services must be registered with the CQC and comply with relevant requirements. The CQC now recognise the voluntary Imaging Services Accreditation Scheme (ISAS) developed by the SoR and the Royal College of Radiologists (RCR), as part of their inspections.

⁵¹ Centre for Workforce Intelligence (2017). *Securing the future workforce supply - Sonography workforce review*.

⁵² NHS Confederation, NHS Partners Network (October 2018). *Independent sector providers caring for NHS patients - Comparative performance indicators*. Available at: www.ihpn.org.uk/wp-content/uploads/2018/08/NHSPN-headline-indicator-summary-Oct-2018-with-data-up-to-Aug-2018.pdf

⁵² Imaging Services Accreditation Scheme (ISAS): www.isas-uk.org/default.shtml

The scheme includes standards on leadership, clinical practice, facilities resources and workforce, patient experience and safety.⁵³

- 6.30 In relation to concerns expressed about the risks arising from misleading claims in advertising from private lifestyle scanning services, the Advertising Standards Authority (ASA) have investigated and upheld six complaints of this nature, under their codes of conduct for broadcast and non-broadcast advertising.⁵⁴ The SCoR in the supplementary evidence to its 2008 application to the HCPC, provided a number of examples of advertisements from such services, and a number of documents note this as an issue. Based on the evidence that we have seen it appears that this remains an issue of concern with potential risks attached. However, it is difficult to assess the overall prevalence or severity of harms arising from such practices, as the ASA will only investigate complaints that fall under their code, and it may be difficult to establish the scale of other forms of promotion and advertising, direct mailing in particular.

Vulnerability of patient/service user group

- 6.31 Due to the nature of the role, sonographers are likely to come into contact with patients with different levels of vulnerability or agency. However, this will vary depending on the area they are working in and the particular nature of the procedures carried out.
- 6.32 According to the sonography workforce review by the CWI the highest users of diagnostic ultrasonography are those between 25-34 and those aged 65 and older.⁵⁵
- 6.33 The *Guidelines for Professional Ultrasound practice* jointly published by the SCoR and the BMUS highlights the risks to patients with particular vulnerabilities for example high BMI or those that have been subject to female genital mutilation (FGM).⁵⁶ It is of note that registered healthcare professionals have an obligation to report instances of FGM, however this does not extend to unregistered practitioners.
- 6.34 In certain instances, the nature of a procedure may be particularly invasive or personal, which may convey additional vulnerability on the patient or service user who is the subject of the diagnostic procedure, for example trans-vaginal ultrasound.⁵⁷
- 6.35 According to the sonography workforce review, the second highest number of sonographers identified in the survey practise in obstetrics and gynaecology (just under 20 per cent). However, there is potential for contact with vulnerable patients in all areas of practice, as there are a number of serious medical conditions which may require referral to ultrasound services.

⁵³ Imaging Services Accreditation Scheme (ISAS)

⁵⁴ Figures taken from a search of relevant adjudications on the Advertising Standards Authority website: www.asa.org.uk/search.html?q=ultrasound

⁵⁵ Centre for Workforce Intelligence (2017). *Securing the future workforce supply – sonography workforce review*.

⁵⁶ Society and College of Radiographers and the British Medical Ultrasound Society (2018). *Guidelines for Professional Ultrasound Practice*.

⁵⁷ Health Education England (2018). *Sonographer's scope of practice and the potential risk associated with each activity/competence*.

- 6.36 Stakeholders also highlighted that there is a drive to reduce children's exposure to ionising radiation during imaging investigations highlighted by the *Image gently* campaign for paediatric patients.⁵⁸ The FDA in America have recently licensed the use of ultrasound contrast agents in children for liver lesions, a practice which may be also be carried out in Europe in the future. This may increase the use of non-ionising radiation investigations such as ultrasound for children in place of Computerised Axial Tomography (CT) and Magnetic Resonance Imaging (MRI).
- 6.37 Stakeholders with knowledge of maternity ultrasound services also offered views about the increasing complexity of the work of ultrasound practitioners in this area, in part due to increasing levels of obesity amongst service users. This can make accurate imaging and interpretation more difficult and may increase the vulnerability of those subject to ultrasound procedures.
- 6.38 Ultimately all patients have an inherent level of vulnerability, as they are dependent on the practitioner to provide expertise for their particular health condition. They are also dependent on the practitioner's employer to ensure that they are sufficiently competent to undertake the tasks associated with the role they are in.
- 6.39 The primary risks reported to us in this area are therefore:
- risk of harm arising from patients or employers being unable to check conduct or competence of a practitioners through a register
 - risk of harm arising from an inability to prevent poor practitioners from practising.

Extrinsic risk of harm

Scale of risk

- 6.40 As noted, data on the sonographer workforce has been difficult to accurately record, due to the fact of practitioners having varying job titles, there being no statutory register of professionals and other practitioners using ultrasound as a tool. There is currently estimated to be around 3,000 ultrasound practitioners in the UK. Of these, the majority are registered in another professional role, for example as a radiographer or nurse. There is also a wider group of practitioners who use ultrasound techniques as a tool to supplement practice, this includes nurses, midwives and physiotherapists. Of the estimated 3,000 ultrasound practitioners, the Society for Radiographers has 585 on the PVRs it runs, of which 186 are unregulated (as of December 2018).
- 6.41 As previously outlined, there is growing demand for ultrasound services due in part to a severe shortage of qualified radiographers and the widening use of ultrasound for diagnostic purposes. There were 41.3 million imaging tests reported in England in the 12 months from January 2017 to December 2017. The second most common imaging test was Diagnostic Ultrasonography (0.7 million), more than CT scan at 0.41 million and Magnetic Resonance Imaging at 0.27 million. The test with the highest proportion of GP referral was ultrasounds used to diagnose ovarian cancer (44 per cent of which were requested by GPs). In total 1.344 million ultrasound tests for abdomen and/or pelvis, suitable for

⁵⁸ The Image Gently Alliance: www.imagegently.org/education

diagnosing cancer, were placed during these 12 months.⁵⁹ The 2017 CWI report states that there has been a 75.8 per cent increase in the number of non-obstetric ultrasound procedures carried out in England between 2007-08 and 2014-15, a compound annual growth rate of 8.4 per cent.⁶⁰

- 6.42 Whilst the numbers of ultrasound practitioners in the health service remains relatively small, the increased demand on services is clear; along with the pressures on related workforces of radiographers and radiologists. This suggests that the number of ultrasound procedures being carried out will continue to grow.

Risk perception

- 6.43 HEE has carried out a certain amount of stakeholder engagement as part of their work considering the expansion and development of the role. Several of the documents we examined as part of the assessment included views of the stakeholders on the regulation of sonographers. We also sought additional views and information as required, to ensure we were able to gain a balanced view of the perception of risks arising from the practice of sonographers, and of the best way to manage these risks. We also carried out a targeted call for information with relevant stakeholders.
- 6.44 Evidence from NHS Trusts in England highlighted a reluctance by employers to take on unregulated sonographers, due to concerns about insurance, ensuring adequate level of training and data protection, CQC registration, and the need for CPD. A report from the University of Cumbria, on findings from interviews with 20 ultrasound departments in North West England, found that participants agreed that the standard of training was more important for employability than whether a candidate was HCPC-registered or not. HR stipulations were viewed as the biggest obstacle to employing non-HCPC registered practitioners, however this was not a national study and therefore may not be indicative of views nationwide.⁶¹ NHS Employers also advise members not to exclude well-qualified sonographers by requiring registration as a condition of employment.⁶²
- 6.45 Sonographers are regulated in Canada, Australia, New Zealand and in some US states. Some European ultrasound experts believe that ultrasound can only be safely performed by medical practitioners, a view held by some in the UK.⁶³
- 6.46 We received nine responses to the call for evidence, in addition to the evidence and submissions provided by HEE – a full list of those who responded to the call for information is available as an Annex. Six organisations signed the single response from the SCoR.⁶⁴ The call was open between 5-30 November 2018.

⁵⁹ NHS England, *Diagnostic Imaging Dataset Statistical Release*: www.england.nhs.uk/statistics/wp-content/uploads/sites/2/2018/04/Provisional-Monthly-Diagnostic-Imaging-Dataset-Statistics-2018-04-19.pdf

⁶⁰ Centre for Workforce Intelligence (2017). *Securing the future workforce supply – sonography workforce review*.

⁶¹ The University of Cumbria (June 2015). *The Future of Sonographic Education*.

⁶² NHS Employers, *Medical radiography and ultrasound workforce*

⁶³ K. Seitz (2017)., *European Journal of Ultrasound. Who's Doing Your Scan? The German Perspective on Ultrasound Services: Ultrasound is More Than a Technique, it's a Medical Art* www.thieme-connect.com/products/ejournals/pdf/10.1055/s-0043-122440.pdf

⁶⁴ British Medical Ultrasound Society, Chartered Society of Physiotherapy, The College of Podiatry, Institute of Physics and Engineering in Medicine, The Society and College of Radiographers, The Society for Vascular Technology of Great Britain and Ireland.

Overall, the responses were strongly supportive of statutory regulation of the role of sonographer. The only notes of caution were that regulation should not restrict those who can practise diagnostic ultrasound and that there are challenges in establishing the entry criteria to any register for those without recognised qualifications. Generally, the responses constituted informed opinion on why the role should be regulated rather than providing additional data or research on the inherent risk of harm arising from practice. There were no responses from representatives of patients, service-users or the public although this may be more related to the limited scope of our call for information rather than any indication of absence of views on this issue. We subsequently followed up with specific charities with experience of working with patients in areas where ultrasound services are of specific relevance, including cancer and pre and post-natal care for mothers and babies, to explore any further views or issues of concern arising. We also carried out some research on online forums where there were discussion threads about patients' experience of ultrasound service.

- 6.47 The relevant information we received through the call for information has largely been covered elsewhere in the report, since the responses generally summarised the conclusions from the body of evidence received separately from HEE. That being the case, here we just mention a selection of key areas that were drawn out, particularly in relation to the complexity of the work undertaken by sonographers. It is recommended, for example, that diagnoses be made during the ultrasound examination, rather than from static images afterwards. This means that the sonographer generally has full responsibility for the report. Sonographers may perform interventional ultrasound procedures such as biopsies, intra and extra cavity drainages, fine needle aspirations and amniocentesis. The intimate nature of some of the examinations combined with the need to be sensitive in communicating findings to patients are also significant aspects of this form of imaging technique. Attention was also drawn to the need for more autonomous working by sonographers, including through lack of ready access to radiologists (a group affected by a workforce shortage in this specialty) and by undertaking scans at the point of care. It was also suggested that as obstetric ultrasound is primarily routine screening this does not need to be carried out by experienced band 7 sonographers whose skills could be better deployed elsewhere.
- 6.48 Another theme from the stakeholder evidence was the need to standardise education and training across sonography programmes, something that could be enabled through statutory regulation. A regulator could also stipulate English language requirements, as good verbal communication is necessary for discussing potentially distressing findings with patients.
- 6.49 One response outlined how the perceived benefits of statutory regulation may apply to sonography, including having a transparent register available to the public and robust fitness to practise processes. It was also noted that the PVRS currently has no plans to be accredited by the Authority and its continued existence is reviewed on a biennial basis – as such, it could not be guaranteed to fulfil the role of an effective professional register.
- 6.50 We have already highlighted that the scope of this assessment has meant that we have been unable to fully explore the views and evidence from Scotland,

Wales or Northern Ireland and the information we have looked at has been primarily focused on the issues as they relate to England where the workforce pressures within diagnostic services are particularly acute. We recognise that the four countries remain committed to UK-wide regulation of health professionals, however the decision has recently been taken to proceed with regulation of nursing associates in England only.

- 6.51 We have recently completed work for the Scottish Government looking at the regulation of a role in fewer than the four UK countries. This report recommends that UK-wide regulation should remain the norm, but that there might be circumstances where risk assessment justifies a different approach provided the impact on workforce supply and mobility of workers can be minimised.⁶⁵ Fuller engagement with stakeholders across the four countries would therefore be required ahead of any decision on changes to the regulatory regime for sonographers to ensure that all issues and unintended consequences are taken into account.

Means of assurance

- 6.52 A range of different mechanisms are already in place to manage some of the risks arising from the practice of sonography. These broadly fall into three main areas and are outline below. They are also covered in more detail, in relation to the specific risks being managed in the table in the Annex.

Assuring competence

- 6.53 There is a range of different standards which are relevant to some or all of those practising as a sonographer. Those who are statutorily registered as a radiographer or nurse will be subject to the standards and fitness to practise mechanisms of the relevant regulator, usually either the HCPC or the NMC.
- 6.54 Those who are part of the PVRS run by the Society and College of Radiographers will be subject to the standards set by the register, although membership of the register is optional.⁶⁶ The SCoR believe that the register meets around 60 per cent of the standards of the Accredited Registers programme. However, they believe that voluntary registration will never be sufficient as it is not mandatory, cannot ensure a standardised level of education and training for all and may be unable to hold practitioners to account for poor practice.
- 6.55 The SCoR report that there have not been any direct complaints to them about non-statutorily registered sonographers on the PVRS. Sanctions taken by the statutory regulators would be applied to anyone also on the PVRS. The SCoR monitors the Health and Care Professions Tribunal Service (HCPCTS) website and has prevented a registrant under a HCPC interim suspension from being admitted to the PVRS. In some cases, radiographer-sonographers under investigation by the HCPCTS have also chosen to not renew their voluntary registration. Voluntary registrants may choose to remove themselves from the PVRS in the event of a complaint before action is taken.

⁶⁵ Professional Standards Authority (2018). *Regulating an occupation in fewer than all four UK countries: implications for policy-makers, the public and practitioners.*

⁶⁶ Public Voluntary Register of Sonographers: www.sor.org/practice/ultrasound/register-sonographers

- 6.56 There are also standards set for ultrasound education and training through the Consortium for the Accreditation of Sonographic Education (CASE) which has support from the British Medical Ultrasound Society, the Chartered Society of Physiotherapy, the College of Podiatry, the Institute of Physics and Engineering in Medicine and the Society and College of Radiographers. According to the 2017 CWI report, the majority of post-graduate courses are CASE-accredited, however some universities have chosen not to seek this assurance.⁶⁷ CASE has also worked with HEE on draft standards for the BSc (Hons) Medical Ultrasound programme being run by the Birmingham City University and the apprenticeship standard has been developed for Medical Ultrasound.
- 6.57 The Royal College of Radiologists (RCR) has also published ultrasound training recommendations for medical and surgical specialties⁶⁸ and there is ongoing work through HEE's Sonography Workforce Sub-Group on Sonography career and progression framework.

Assuring service provision

- 6.58 There is also a number of sets of standards and guidance relating to provision of a safe and high-quality ultrasound service. As noted, all diagnostic and scanning services are required to register with the CQC and comply with relevant requirements. This includes both NHS and independent providers of services.⁶⁹ The CQC now recognise compliance with the voluntary standards developed by the SCoR and the RCR through the Imaging Accreditation Scheme (IAS), developed through UKAS.⁷⁰ All NHS Trusts will be required to meet any additional CQC requirements.
- 6.59 The British Medical Ultrasound Society has published guidance on clinical governance⁷¹ and the RCR and SCoR have published joint standards for the provision of an ultrasound service.⁷²

Assuring safety of equipment

- 6.60 Medical devices are regulated by the Medical Devices Regulations through the Medicines and Healthcare Products Regulatory Agency (MHRA) in England. This is based on requirements set at European level. The MHRA is the responsible authority for the UK and has the power to investigate adverse incidents which could then result in safety warnings and the issuing of guidance.⁷³ The MHRA ensures that manufacturers meet UK legislation and investigates incidents in England and Wales relating to the operation and maintenance of medical

⁶⁷ Centre for Workforce Intelligence (2017). *Securing the future workforce supply - Sonography workforce review*.

⁶⁸ Royal College of Radiologists (2017). *Ultrasound training recommendations for medical and surgical specialties*.

⁶⁹ Care Quality Commission, *The Scope of Registration*.

⁷⁰ Imaging Services Accreditation Scheme (ISAS).

⁷¹ British Medical Ultrasound Society (October 2008). *Ultrasound Clinical Governance*.

⁷² The Royal College of Radiologists and the Society and College of Radiographers (2014). *Standards for the provision of an ultrasound service*.

⁷³ Medicines and Healthcare Products Regulatory Agency (2014). *Reusable transoesophageal echocardiography, transvaginal and transrectal ultrasound probes (transducers) – failure to appropriately decontaminate*.

equipment.⁷⁴ However, in Northern Ireland and Scotland the responsibility for enforcement lies with the relevant bodies within the devolved nations.

- 6.61 The standards for the provision of an ultrasound service published by the RCR and the SCoR notes that the Food and Drug Administration (FDA), Centre for Devices and Radiological Health in the USA impose an upper limit on acoustic output of diagnostic scanners under the 510(k). These are legal limits in the USA, however the majority of manufacturers comply with these for all their markets and they are expected to be used in the UK. The document notes that there are limits on surface temperatures. It also notes the potential risk of cross contamination and signposts to MHRA guidance on the cleaning and disinfection of endoprobes.⁷⁵
- 6.62 The BMUS highlights the importance of regular equipment maintenance and effective quality assurance in its guidance.⁷⁶ It notes that best practice would require a three-level quality assurance programme that can be carried out by the sonographer on a daily, weekly and monthly basis. These include thorough cleaning of the scanner and the probes as part of the infection control policies, visual checks for damage, and testing of the scanner and transducers. This should form part of the wider equipment maintenance plan which may be carried out by the Medical Physics Department (if available on the site). Reference was also made to guidelines produced by the Institute of Physics and Engineering Medicine (IPEM) which is affiliated to the Register of Clinical Technologists (RCT) an Accredited Register that registers people practising medical physics.
- 6.63 The regulatory framework and guidance in this area primarily relates to the overall safety of equipment rather than regulating who is able to access and operate equipment. It is also unclear exactly how the regulatory framework applies to technological innovations in this area, such as portable scanners for use at the patient's bedside. Some of the views considered as part of this assessment suggested that there was potential for the regulatory framework for ultrasound equipment to be tightened, with a focus on limiting the purchase and operation of ultrasound equipment. This was also a suggestion from the HCPC as part of their recommendation to the Secretary of State in 2009, for the CQC to license the use of scanning equipment.⁷⁷

Sector impact

- 6.64 As noted there is a UK-wide shortage of sonographers along with radiographers and radiologists at the same time as demand is increasing for diagnostic and imaging services with 41.3 million imaging tests reported in England in the 12 months from January 2017 to December 2017. Ultrasound is now one of the three key tests used to diagnose cancer. The role of sonographer has been on the recognised occupation shortage list of the Migration Advisory Committee since 2005.

⁷⁴ Medicines and Healthcare products Regulatory Agency (April 2015). *Managing Medical Devices*.

⁷⁵ The Royal College of Radiologists and the Society and College of Radiographers (2014). *Standards for the provision of an ultrasound service*.

⁷⁶ British Medical Ultrasound Society (2009). *Guidelines for the safe use of diagnostic ultrasound equipment*.

⁷⁷ Health and Care Professions Council (2009). *Recommendation to Secretary of State for Health about the regulation of sonographers*.

- 6.65 The evidence suggests that there is a reluctance by employers to recruit unregulated sonographers, however this appears to be mainly related to the inability to ensure a sufficient standard of education and training. It is also contradicted by NHS Employers advice to members highlighting that by insisting on statutory registration, employers could be further limiting their pool of candidates and missing out on otherwise well qualified individuals. A 2014 SCoR survey of ultrasound departments also found a general difficulty in recruiting to ultrasound positions and identified that 90 per cent of those surveyed reported that their organisation require that sonographers hold statutory registration.⁷⁸
- 6.66 There are currently specific limitations to the scope of unregulated sonographers who are unable to administer medicines under Patient Group Directives, which includes using contrast agents that may be used to enhance ultrasound images. Whilst contrast agents are not always used, there is evidence from stakeholders that this considered best practice, and guidance from NICE and other international bodies recommending the use of contrast agents in particular treatment areas, for example liver imaging.⁷⁹ Unregulated sonographers are also unable to train as a supplementary prescriber or refer patients for clinical imaging involving ionising radiation under the IM(RE) regulations.⁸⁰
- 6.67 The BMUS has published a report which highlights a number of options for increasing the capacity of ultrasound services, including standardised education and training to improve the numbers and quality of the workforce, and changes to ultrasound services to increase capacity (including the removal of low priority services, and increased capacity for providers).⁸¹
- 6.68 In its workforce strategy for England, HEE highlight the current gap in workforce provision of sonographers in maternity care and propose to work with professional regulators and others to make credentialing available to registered health professionals, so they can extend their practice to ultrasonography. They also make the case for regulation of an under-graduate pathway in sonography.

Unintended consequences

- 6.69 Unintended consequences will vary depending on what, if any, changes Government chooses to make to the level of assurance for the role. However, potential issues arising from a change to the regulatory oversight for ultrasound include:
- Implications of dual registration - depending on the form that any changes to regulatory requirements took, this may have implications for those professionals who currently use ultrasound as an extension of their practice, for example some nurses and midwives.
 - Impacts on use of technology - any changes to the regulatory regime for sonographers or ultrasound equipment may have an impact on the

⁷⁸ Society and College of Radiographers. *Sonographer Workforce Survey Analysis*.

⁷⁹ National Institute for Health and Clinical Excellence, Diagnostics Assessment Programme - SonoVue (sulphur hexafluoride microbubbles) - contrast agent for contrast enhanced ultrasound in liver imaging.

⁸⁰ The Ionising Radiation (Medical Exposure) Regulations 2017

⁸¹ British Medical Ultrasound Society (September 2003). *Extending the provision of ultrasound services in the UK*.

development and increasingly flexible use of ultrasound equipment in different contexts.

- Barriers to entry - although it is unclear from the evidence currently available, changes to the regulatory regime could increase costs or barriers to entry of the occupation.
- Workforce mobility across the UK - as this assessment has focused primarily on evidence relating to England, it is possible that any changes to the regulatory framework for the role may have an impact on workforce mobility across the four countries of the UK.

7. Annex 2 – Risks and options for assurance

7.1 The table below summarises the risks identified, the existing mitigations in place, any gaps in assurance identified and further options identified to manage these risks:

Risks of harm arising	Existing mitigations in place	Gaps in assurance	Potential additional means of assurance
<p><i>Risk of harm to patients arising from misdiagnosis</i></p>	<ol style="list-style-type: none"> 1. Employer requirements – through HR recruitment requirements or contractual obligations. 2. Standards for education and training: <ul style="list-style-type: none"> • Consortium for the Accreditation of Sonographic Education (CASE) standards for ultrasound education and training 	<p>Employers may require a specific level of education and training to ensure that those employed as sonographers are competent to carry out a specific role. However, this would be employer specific and not based on any mandatory external standard.</p> <p>The majority of sonographer post-graduate training courses are accredited by CASE, but a few choose not to be. CASE have also worked with HEE to develop standards for the first under-graduate</p>	<p>Standardised requirements for education and training. This could be addressed through:</p> <ol style="list-style-type: none"> 1. Enhanced employer requirement for attainment of a minimum level of qualification from a CASE accredited course.

	<ul style="list-style-type: none"> The Royal College of Radiologists Ultrasound training recommendations for medical and surgical specialties. <p>3. Standards on clinical governance and service provision:</p> <ul style="list-style-type: none"> British Medical Ultrasound Society guidance on clinical governance Royal College of Radiologists and Society and College of 	<p>degree now in use and for the sonographer apprenticeship. There are also sonographer training recommendations for medical and surgical specialties, but these are not mandatory.</p> <p>There are guidance and standards produced by the British Medical Ultrasound Society, the College of Radiographers and the Royal College of Radiologists, covering service provision and clinical governance. However, these are not mandatory.</p> <p>There are thought to be around 3,000 sonographers practising in the UK. Not all sonographers are on a</p>	<p>2. Employer requirement for membership of an accredited or voluntary register with a required level of qualification.</p> <p>3. Statutory regulation for sonographers and protection of title which would ensure that only those with minimum qualification could use the title sonographer and/or ultra-sonographer.</p>
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	<p>Radiologists standards for provision of an ultrasound service.</p> <ol style="list-style-type: none"> 4. Standards for the Public Voluntary Register of Sonographers 5. Academy for Healthcare Science (part of the Accredited Registers programme) standards for those registered as clinical scientists. 6. Health and Care Professions Council or Nursing and Midwifery Council standards for those registered as radiographers, biomedical scientists, nurses or midwives. 7. Care Quality Commission (CQC) registration of diagnostic and screening services – England only. 8. The UKAS Imaging Services Accreditation Scheme (ISAS), also recognised by the CQC in their inspections of registered services. 	<p>statutory professional register. 585 are on the Public Voluntary Register of Sonographers (PVRS), administered by the Society and College of Radiographers and of these 186 are not statutorily regulated. Sonographers on this register must meet certain standards of education and training, however membership of the register is not mandatory.</p> <p>The ISAS standards of imaging services cover appropriate training of staff. Although accreditation is not mandatory it is recognised by the CQC in their inspection of diagnostic and screening services in England. All diagnostic and imaging services are required to register with the CQC (England only).</p>	<ol style="list-style-type: none"> 4. Licensing requirement for those operating ultrasound equipment (licences could be issued by Government, local authorities or potentially the CQC).
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<p><i>Risks of harm to patients arising from misuse of equipment</i></p>	<p>See all above for existing mitigations.</p>	<p>As above – the same gaps apply as staff who are not on the PVRS are not required to have undertaken specific education and training. However, employers may have their own requirements in place and the majority of ultrasound training is accredited by CASE.</p> <p>Additionally, there is a large amount of guidance and standards produced by the different bodies in the sector intended help to ensure that practitioners are competent. However, the amount of differing materials available may lead to overload or confusion about which guidance to follow.⁸²</p> <p>There are currently no limitations on who can purchase and use ultrasound equipment, however all diagnostic and screening services are required to be registered with the CQC (England only).</p>	<p>See above.</p>

⁸² See reference to cognitive confusion in *Asymmetry of Influence*:
www.health.org.uk/sites/default/files/AsymmetryOfInfluenceTheRoleOfRegulatorsInPatientSafety.pdf

<p><i>Risk of harm to patients arising from faulty or poorly maintained equipment</i></p>	<ol style="list-style-type: none"> 1. Medicines and Healthcare Products Regulatory Agency (MHRA) enforcement of the Medical Devices Regulations in England and Wales (enforcement devolved in NI and Scotland). 2. Royal College of Radiologists Standards for the provision of an ultrasound service. 3. British Medical Ultrasound Society Guidelines for the safe use of diagnostic ultrasound equipment. 4. CQC registration of diagnostic and imaging services. 5. UKAS Imaging Services Accreditation Scheme (ISAS) also recognised by the CQC in their inspections of registered services. 	<p>Medical devices including ultrasound equipment are covered by the safety and performance requirements of the Medical Device Regulations (underpinned by the European Medical Devices Directive). The MHRA acts as the competent authority for the UK and enforces the regulations in England. It covers:</p> <ul style="list-style-type: none"> - inappropriate management procedures - inadequate servicing or maintenance - inappropriate use (including incompatible devices) - inadequate decontamination <p>The MHRA cooperates closely with the Northern Ireland Adverse Incident Centre (NIAIC) and Health Facilities Scotland – Incident Reporting & Investigation Centre (HFS -IRIC) who have the responsibility to investigate in Northern Ireland and Scotland.</p> <p>The ISAS standards cover protocols for ensuring that equipment is safe, and this is now recognised by the CQC in its inspection of diagnostic and screening services.</p>	<p>Already covered by existing regulation.</p> <p>Enhanced awareness of publications covering good practice in equipment maintenance and safety procedures.</p> <p>Training in equipment maintenance and safety could be encouraged or enforced through any of the above methods depending on the level of assurance required.</p>
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<p><i>Risk of cross-infection arising from poor hygiene procedures associated with use of ultrasound</i></p>	<ol style="list-style-type: none"> 1. Local/employer infection control policies and protocols. 2. CQC registration of diagnostic and imaging services. CQC hygiene code for service providers. 3. Medicines and Healthcare Products Regulatory Agency (MHRA) regulation through the Medical Devices Regulations in England and Wales 4. MHRA guidance on the on the cleaning and disinfection of endoprobes. 5. Royal College of Radiologists Standards for the provision of an ultrasound service 6. UKAS Imaging Services Accreditation Scheme (ISAS) also recognised by the CQC in their inspections of registered services. 	<p>See above. The MHRA can investigate incidents associated with poor hygiene procedures and have produced guidance for cleaning of ultrasound endoprobes. This is also covered by the ISAS standards which are recognised by the CQC who consider hygiene as part of their inspections of registered services.</p> <p>This is also covered by the RCR in their guidance, and within guidance produced by BMUS however use of this guidance is not mandatory.</p>	<p>Already covered by existing regulation.</p> <p>Better awareness of publications covering good practice in hygiene procedures.</p> <p>Training in this area could be encouraged or enforced through the mechanisms outlined in the first section, depending on the level of assurance required.</p>
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	7. British Medical Ultrasound Society Guidelines for the safe use of diagnostic ultrasound equipment		
<i>Risk of sexual assault or breach of sexual boundaries due to intimate nature of examinations</i>	<ol style="list-style-type: none"> 1. Criminal law. 2. Employer requirements. 3. Disclosure and Barring scheme – criminal records background and ‘barred’ list for those not allowed to work in a regulated activity (including healthcare). 4. Standards for the Public Voluntary Register of Sonographers. 5. Health and Care Professions Council or Nursing and Midwifery Council standards. 6. Council for Healthcare and Regulatory Excellence guidance on clear sexual boundaries between health professionals and patients. 	Staff who are on a voluntary or statutory register will have standards covering maintenance of sexual boundaries between patients. This will not be in place for those who are not covered by either, although employers should take action in such circumstances. This would not prevent practitioners moving elsewhere unless they have a conviction or are on the DBS ‘barred’ list.	<p>This could be covered by enhanced employer requirements to be on an accredited or voluntary register which would require certain standards of registrants. However, this would be dependent on uptake by employers.</p> <p>This could also be addressed through statutory regulation and protection of title which would ensure that only sonographers who comply with the relevant professional standards are able to practise.</p>

<i>Risk of harm to patients arising from misconduct by ultrasound practitioners</i>	See above.	See above.	See above.
<i>Risk of harm associated with physical effects of ultrasound scanning</i>	<ol style="list-style-type: none"> 1. Existing education and training. 2. Food and Drug Administration (FDA), Centre for Devices and Radiological Health in the USA - upper limit on acoustic output of diagnostic scanners. 3. Medical Device Regulations. 4. Royal College of Radiologists and Society and College of 	<p>The Food and Drug Administration sets legal limits for ultrasound equipment in America, however the majority of manufacturers comply with this for all their markets and it is expected to be used in the UK.</p> <p>MHRA enforce the Medical Device Regulations in England and Wales (in collaboration with equivalent bodies in NI and Scotland) and will investigate safety incidents and issue bulletins and guidance as appropriate.</p>	<ol style="list-style-type: none"> 1. Greater awareness of publications highlighting good practice in minimising acoustic output and effective clinical governance. <hr/> <ol style="list-style-type: none"> 2. Training in this area could be standardised through the mechanisms previously highlighted depending on the level of assurance required.

	<p>Radiographers standards for provision of an ultrasound service.</p> <p>5. UKAS Imaging Services Accreditation Standards (ISAS).</p>	<p>The ISAS standards, which are recognised by the CQC, cover the importance of minimising acoustic output and exposure times in ultrasound.</p> <p>This is also covered in RCR and SCoR standards for provision of an ultrasound service, however these are not mandatory.</p>	<p>3. UK specific legal limits on acoustic output of ultrasound equipment.</p>
<p><i>Risk of harm arising from lone working or isolated practice</i></p>	<p>1. Employer requirements.</p> <p>2. CQC requirements for registered diagnostic and scanning services.</p>	<p>Employers may have mechanism in place to mitigate risk from lone working or isolated practise, which may leave practitioners without access to advice or support when required. This is less likely to be a risk within the NHS where practitioners are more likely to be working within teams but may be more of a gap in the independent sector, where services are more likely to be operated by fewer practitioners.</p> <p>The CQC require registered services to mitigate the risks associated with lone working.</p>	<p>Captured under CQC requirements.</p> <p>Enhanced employer mechanisms and clinical governance mechanisms to ensure that there is sufficient support available, particularly for those who have recently qualified.</p> <p>This could also be supported through a clearer career framework outlining levels of responsibility and oversight requirement at different levels of qualification and experience (HEE are currently developing this through their sonography advisory group).</p>

<i>Risk of harm arising from absence of clinical governance</i>	<ol style="list-style-type: none"> 1. Employer requirements. 2. UKAS Imaging Services Accreditation Scheme (ISAS). 3. British Medical Ultrasound Society, October 2008. <i>Ultrasound Clinical Governance</i>. 4. CQC requirements. 	<p>This is covered by the CQC in their requirements for registered services.</p> <p>The importance of effective clinical governance is also captured within the ISAS standards. Whilst not all services will be ISAS accredited, these are also recognised by the CQC in their inspection methodology.</p>	Greater awareness of good practice in clinical governance through dissemination of relevant publications.
			Greater awareness of the ISAS standards which are now used by the CQC in their inspections.
<i>Risk of harm arising from lack of access to supervision</i>	<ol style="list-style-type: none"> 1. Employer requirements. 	<p>Anecdotal evidence from stakeholders suggests that this is a growing problem due to the increasing pressures on radiologists, senior radiographers and sonographers in the NHS and staff shortages. This may also be a gap in the independent sector where access to supervision is likely to be more limited.</p> <p>The new career framework being developed by HEE supports senior staff providing second opinions, however these staff may not themselves be regulated.</p>	This could be addressed through a clearer career framework outlining levels of responsibility and oversight requirement at different levels of qualification and experience.

<i>Risk of harm arising from misleading marketing of services</i>	1. Advertising Standards Authority (ASA) co-regulation of broadcast and non-broadcast advertising.	The ASA are limited to investigating complaints that are raised under their Codes of practice for broadcast and non-broadcast advertising but may not be aware of all direct marketing activities or have the capacity to address any issues arising from.	1. This is covered by ASA co-regulation.
			2. A requirement for responsible marketing could be covered in any kind of enhanced occupational or business licensing for use of ultrasound equipment.
<i>Risk of harm arising from patients or employers being unable to check conduct or competence of a</i>	1. Employer controls – access to DBS criminal records checks. 2. Public Voluntary Register of Sonographers.	It is not currently mandatory to be on a register as a sonographer. Employers and patients will be unable to check on the conduct of competence of a practitioner who is not on a voluntary or statutory register and who does not have a criminal record/is not on the DBS barred list.	This could be covered by: 1. Enhanced employer requirement that all sonographers must be on an accredited, voluntary or statutory register.

<i>professional through a register</i>	3. Health and Care Professions Council or Nursing and Midwifery Council register.	The SCoR have not committed to maintain the PVRs beyond 2021 and the register has limited mechanisms for dealing with complaints made against members of the register.	2. Statutory regulation and protection of title for sonographers.
<i>Risk of harm arising from an inability to prevent poor practitioners from practising</i>	1. Employer controls – access to DBS and criminal records check. 2. Health and Care Professions Council or Nursing and Midwifery Council registers – those who are removed from the register may not continue practising.	It is not possible to prevent a sonographer from practising entirely, even if they are removed from a statutory register or the Public Voluntary Register of Sonographers, as sonographer is not a protected title and there are no limitations on who can purchase and use ultrasound equipment.	1. Enhanced employer requirement that all sonographers must be on an accredited, voluntary or statutory register. 2. Statutory regulation and protection of title for sonographers. 3. Licensing the use of ultrasound equipment.

8. Annex 3 – List of documents and evidence reviewed

Year	Author/ Source	Description	Location (where publicly available)
1995	W. Hately, J. Case, Professor S. Campbell	<i>Establishing the death of an embryo by ultrasound: report of a public inquiry with recommendations.</i>	www.ncbi.nlm.nih.gov/pubmed/7614144
2003	The British Medical Ultrasound Society	<i>Extending the provision of ultrasound services in the UK -</i>	www.bmus.org/static/uploads/resources/EXTENDING_THE_PROVISION_OF_ULTRASOUND_SERVICES_IN_THE_UK.pdf
2004	S. Barnett	<i>QA and the accreditation of ultrasound practitioners: is it really necessary? Advanced metrology for ultrasound in medicine lecture</i>	http://iopscience.iop.org/article/10.1088/1742-6596/1/1/004/pdf
2004	H. Finberg	<i>Whither (wither?) the ultrasound specialist?</i>	https://onlinelibrary.wiley.com/doi/full/10.7863/jum.2004.23.12.1543
2004	B. Benacerraf	<i>The future of ultrasound: viewing the dark side of the moon?</i>	https://obgyn.onlinelibrary.wiley.com/doi/epdf/10.1002/uog.993
2006	A. Bodenham. British Journal of Anaesthesia. 2006; 96(4), 414-417	<i>Ultrasound imaging by anaesthetists: training and accreditation issues.</i>	https://bjanaesthesia.org/article/S0007-0912(17)35145-0/fulltext
2007	The Department of Health	<i>Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century</i>	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/228847/7013.pdf
2008	The Society of Radiographers	<i>Application for statutory regulation to the Healthcare and Professions Council</i>	www.hcpc-uk.org/globalassets/meetings-attachments3/council-meeting/2009/september/20090910-council---enc-08---sonographers-application/
2008	The Society of Radiographers	<i>Further evidence in support of 2008 application for statutory</i>	www.hcpc-uk.org/globalassets/meetings-attachments3/council-

		<i>regulation to the Healthcare and Professions Council</i>	meeting/2008/december/28-new-professions---sonography/
2008	The Society and College of Radiographers	<i>The Scope of Practice of Assistant Practitioners in Ultrasound</i>	www.sor.org/learning/document-library/scope-practice-assistant-practitioners
2008	National Ultrasound Steering Group	<i>Ultrasound Clinical Governance</i>	www.bmus.org/static/uploads/resources/ClinicalGovernanceInUltrasound-061108.pdf
2009	The Society and College of Radiographers	<i>Developing and Growing the Sonographer workforce: Education and Training needs</i>	www.sor.org/learning/document-library/developing-and-growing-sonographer-workforce-education-and-training-needs
2009	The Health and Care Professions Council	<i>Recommendation to Secretary of State for Health about the regulation of sonographers</i>	www.hcpc-uk.org/globalassets/meetings-attachments3/council-meeting/2009/october/20091007-council---enc-7---sonographers/
2009	British Medical Ultrasound Society	<i>Guidelines for the safe use of diagnostic ultrasound equipment</i>	www.bmus.org/static/uploads/resources/BMUS-Safety-Guidelines-2009-revision-DETAILED.pdf
2011	Department of Health	<i>Enabling Excellence: Autonomy and Accountability for Health and Social Care Staff</i>	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/216580/dh_124374.pdf
2011	National Institute for Health and Clinical Excellence	<i>Diagnostics Assessment Programme - SonoVue (sulphur hexafluoride microbubbles) -contrast agent for contrast enhanced ultrasound in liver imaging</i>	www.nice.org.uk/guidance/dg5/documents/sonovue-sulphur-hexafluoride-microbubbles-scope2
2012	Medical Radiation Practice Board of Australia	<i>When it is necessary to be registered as a Medical Radiation Practitioner? Information for Sonographers and Practitioners undertaking Ultrasound</i>	www.medicalradiationpracticeboard.gov.au/documents/default.aspx?record=WD12%2f8321&dbid=AP&checksum=GM7vlpJseBfHwn%2fInKRXtw%3d%3d
2012	NHS Resolution	<i>Ten Years of Maternity Claims</i>	https://resolution.nhs.uk/wp-content/uploads/2018/11/Ten-years-of-Maternity-Claims-Final-Report-final-2.pdf
2013	Migration Advisory Committee	<i>Recommended shortage occupation lists for the UK and Scotland</i>	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/257241/mac-report.pdf

2013	Health Professions Regulatory Advisory Council	<i>Diagnostic Sonographers: A Literature Review</i>	www.hprac.org/en/projects/resources/DiagnosticSonographyLiteratureReview_EN_Final_28062013_Secured.pdf
2013	Vivien Gibbs, Faculty of Health & Life Sciences, University of the West of England	<i>The long and winding road to achieving professional registration for sonographers</i>	www.radiographyonline.com/article/S1078-8174(12)00100-9/fulltext
2014	Royal College of Radiologists & the Society and College of Radiographers	<i>Standards for the provision of an ultrasound service</i>	www.rcr.ac.uk/publication/standards-provision-ultrasound-service
2014	Nigel Thomson and Audrey Paterson	<i>Sonographer registration in the United Kingdom – a review of the current situation</i>	www.ncbi.nlm.nih.gov/pmc/articles/PMC4760522/
2014	The Society and College of Radiographers	<i>Sonographer workforce survey analysis</i>	www.sor.org/learning/document-library/sonographer-workforce-survey-analysis
2014	NHS Employers	<i>Modernising Scientific Careers - Explaining the Facts</i>	www.nhsemployers.org/~media/Employers/Documents/Plan/ExplainingTheFacts_Br0935_6a%20as280114.pdf
2014	Medicines and Healthcare Products Regulatory Agency	<i>Reusable transoesophageal echocardiography, transvaginal and transrectal ultrasound probes (transducers) – failure to appropriately decontaminate.</i>	www.gov.uk/drug-device-alerts/medical-device-alert-reusable-transoesophageal-echocardiography-transvaginal-and-transrectal-ultrasound-probes-transducers-failure-to-appropriately-decontaminate
2015	The Society and College of Radiographers and British Medical Ultrasound Society	<i>Guidelines for professional ultrasound practice</i>	www.bmus.org/policies-statements-guidelines/professional-guidance/guidelines-for-professional-ultrasound-practice/
2015	University of Cumbria	<i>The Future of Sonographic Education</i>	http://insight.cumbria.ac.uk/id/eprint/2949/1/Waring,%20Miller%20&%20Sloane%20(2015)%20-%20Ultrasound%20Futures.pdf
2015	Australasian Sonographers' Association	<i>Submission for Consultation Regulation Impact Statement</i>	www.health.gov.au/internet/main/publishing.nsf/Content/55F0A2C5D9396592CA257E4500175

			FC4/\$File/05%20%20Austasn%20Sonographers%20Assoc.pdf
2015	The Care Quality Commission	<i>Registration under the Health and Social Care Act 2008 - The scope of registration</i>	www.cqc.org.uk/sites/default/files/20151230_100001_Scope_of_registration_guidance_updated_March_2015_01.pdf
2015	Migration Advisory Committee	<i>Balancing migrant selectivity, investment in skills and impacts on UK productivity and competitiveness. Review of Tier 2</i>	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/493039/Tier_2_Report_Review_Version_for_Publishing_FINAL.pdf
2015	Independent Cancer Taskforce	<i>Achieving world class cancer outcomes - A strategy for England 2015-2020</i>	www.cancerresearchuk.org/sites/default/files/achieving_world-class_cancer_outcomes_-_a_strategy_for_england_2015-2020.pdf
2015	NHS Employers	<i>Medical radiography and ultrasound workforce</i>	www.nhsemployers.org/your-workforce/retain-and-improve/standards-and-assurance/professional-regulation/role-of-the-employer/medical-radiography-and-ultrasound-workforce
2015	Sonography Canada	<i>National Sonographer Competency profiles</i>	www.sonographycanada.ca/Apps/Sites-Management/FileDownload/DataDownload/43493/NCP%205.0%20Final%20Feb2016/pdf/1/1033
2015	The British Medical Ultrasound Society	<i>Educating the future sonographic workforce: membership survey report</i>	http://openaccess.city.ac.uk/12592/1/Educating%20the%20Future%20Sonographic%20Workforce%20-%20FINAL.pdf
2015	Pamela Parker	<i>Undergraduate education for sonography: a statement from BMUS</i>	www.ncbi.nlm.nih.gov/pmc/articles/PMC4760599/
2015	Alan T. Chiem MD, MPH, Connie H. Chan MD, Douglas S. Ander MD, Andrew N. Kobylivker MD, William C. Manson MD.	<i>Comparison of expert and novice sonographers' performance in focused lung ultrasonography in dyspnea to diagnose patients with acute heart failure syndrome</i>	www.ncbi.nlm.nih.gov/pmc/articles/PMC5225273/

2015	W. C. Lee	<i>Staging accuracy of endoscopic ultrasound performed by nonexpert endosonographers in patients with resectable esophageal squamous cell carcinoma: is it possible?</i>	https://academic.oup.com/dote/article/28/6/574/2328720
2015	Medicines and Healthcare Products Regulatory Agency	<i>Managing Medical Devices</i>	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/421028/Managing_medical_devices_-_Apr_2015.pdf
2016	The Whitehouse Consultancy	<i>The futile mission of voluntary registers</i>	https://journals.sagepub.com/doi/full/10.1177/1356262216646895
2016	Health Education England	<i>Facing the Facts, Shaping the Future - A draft health and care workforce strategy for England to 2027</i>	www.hee.nhs.uk/sites/default/files/documents/Facing%20the%20Facts,%20Shaping%20the%20Future%20-%20e2%80%93%20a%20draft%20health%20and%20care%20workforce%20strategy%20for%20England%20to%202027.pdf
2017	Public Voluntary Register of Sonographers	<i>The Standards of Conduct, Performance and Ethics</i>	www.sor.org/system/files/article/201702/2017.1.1_pvrs_standards_of_conduct_performance_and_ethics_0.pdf
2017	Centre for Workforce Intelligence	<i>Securing the Future Workforce supply - Sonography Workforce review</i>	www.gov.uk/government/publications/review-of-the-sonography-workforce-supply
2017	Health Education England	<i>Sonography Options Appraisal</i>	
2017	Health Education England	<i>HEE's Sonography Workforce Sub-Group's Sonography Career and Progression Framework</i>	
2017	The Society and College of Radiographers	<i>Report on Voluntary Registers with regard to Sonographers</i>	
2017	Cardiff and Vale University Health Board	<i>Report to Prevent Future Deaths</i>	
2017	Senior Coroner for Berkshire	<i>Report to Prevent Future Deaths</i>	
2017	Health Education England	<i>Analysis of top three risks of harm from the scope of practice for the sonographers (from stakeholder table</i>	

		<i>feedback at HEE event November 2017)</i>	
2017	Health Education England	<i>Draft standard for Integrated Degree Apprenticeship for Sonographer</i>	
2017	The Society and College of Radiographers	<i>The Public Voluntary Register of Sonographers - Information for employers, voluntary registrants and members of the public, Policy and processes</i>	www.sor.org/system/files/article/201702/2017.1.1_pvrs_policies_and_processes.pdf
2017	The Royal College of Radiologists	<i>Ultrasound training recommendations for medical and surgical specialties</i>	www.rcr.ac.uk/system/files/publication/field_publication_files/bfcr173_ultrasound_training_med_surg.pdf
2017	Health and Care Professions Council	<i>Radiographer struck off on grounds of misconduct</i>	www.hcpts-uk.org/hearings/mediareleases/radiographer-struck-off-on-grounds-of-misconduct2/
2017	Health and Care Professions Council	<i>Radiographer suspended for lack of competence</i>	
2017	Public Health England	<i>NHS Abdominal Aortic Aneurysm (AAA) Screening Programme</i>	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/598365/AAA_Screening_Standard_Operating_Procedures_March_2017.pdf
2017	NHS Resolution	<i>Five years of cerebral palsy claims</i>	resolution.nhs.uk/resources/five-years-of-cerebral-palsy-claims/
2017	The Society and College of Radiographers	<i>Why sonographers should maintain registration</i>	www.sor.org/news/why-sonographers-should-maintain-registration
2017	Sheffield Hallam University	<i>The benefits and challenges of employing new sonography graduates: Key stakeholder views</i>	http://shura.shu.ac.uk/16596/
2017	A. Dawkins, N. George, H. Ganesh, A. Ayoob, J. Lee, R. Nair, C. Kiper, K. Duncan, S. Stevens. <i>Ultrasound Quarterly</i> 2017;33(4)	<i>Radiologist and Sonographer Interpretation Discrepancies for Biliary Sonographic Findings: Our Experience.</i>	https://journals.lww.com/ultrasound-quarterly/Abstract/2017/12000/Radiologist_and_Sonographer_Intpretation.2.aspx

2017	Fabrizio D'Abate and Angelo La Leggia	<i>The role of sonographers: future professionals across Europe?</i>	https://healthcare-in-europe.com/en/news/the-role-of-sonographers-future-professionals-across-europe.html
2017	K. Seitz	<i>European Journal of Ultrasound. Who's Doing Your Scan? The German Perspective on Ultrasound Services: Ultrasound is More Than a Technique, it's a Medical Art</i>	www.thieme-connect.com/products/ejournals/pdf/10.1055/s-0043-122440.pdf
2017		<i>The Ionising Radiation (Medical Exposure) Regulations 2017</i>	www.legislation.gov.uk/uksi/2017/1322/contents/made
2018	Health Education England	<i>Draft Sonography Workforce Proposals</i>	
2018	Health Education England	<i>Overview table - Sonographers in the UK</i>	
2018	Royal College of Radiologists	<i>Standards for Interpretation and reporting of imaging investigations</i>	www.rcr.ac.uk/system/files/publication/field_publication_files/bfcr181_standards_for_interpretation_reporting.pdf
2018	Health Education England	<i>Sonographer's scope of practice and the potential risk associated with each activity/competency.</i>	
2018	Health Service Journal	<i>Professions call for more regulation following patient death</i>	www.hsj.co.uk/workforce/professions-call-for-more-regulation-following-patient-death/7021735.article
2018	Health Education England	<i>The Future for NHS Ultrasound Service Provision</i>	
2018	Health and Care Professions Council	<i>HCPC Catalogue of Final Hearings of Radiographers</i>	www.hcpts-uk.org/hearings/about/finalhearings/
2018	Health Education England	<i>HEE's report on Statutory regulation – Sonographers/ Ultrasonographer</i>	
2018	NHS England	<i>Diagnostic Imaging Dataset Statistical Release</i>	www.england.nhs.uk/statistics/wp-content/uploads/sites/2/2018/04/Provisional-Monthly-Diagnostic-Imaging-Dataset-Statistics-2018-04-19.pdf

2018	Health and Care Professions Council	<i>Dr Emmanuel I O Ehiwe - final panel decision</i>	www.hcpts-uk.org/hearings/hearings/2018/february/dr-emmanuel-i-o-ehiwe/
2018	NHS Employers	<i>Voluntary registers</i>	www.nhsemployers.org/your-workforce/retain-and-improve/standards-and-assurance/professional-regulation/voluntary-registers
2018	Health Education England	<i>Sonography briefing</i>	
2018	Professional Standards Authority	<i>Regulating an occupation in fewer than all four UK countries: implications for policy-makers, the public and practitioners.</i>	www.professionalstandards.org.uk/news-and-blog/latest-news/detail/2018/06/28/the-authority-publishes-report-on-regulating-an-occupation-in-fewer-than-all-four-uk-countries
	Health and Care Professions Council	<i>HCPC Tribunal Service cases - reference to ultrasound practice</i>	www.hcpts-uk.org/
	Birmingham City University	<i>Medical Ultrasound - BSc (Hons)</i>	www.bcu.ac.uk/courses/medical-ultrasound-bsc-hons-2019-20
	Health and Care Professions Council	<i>International - process for international applicants</i>	www.hcpc-uk.co.uk/apply/international/

9. Annex 4 – List of stakeholder responses

9.1 Below is the list of organisations and individuals who submitted responses to the call for information carried out between 5th – 30th November 2018.

Status of response/role	Organisation
Organisation	The Society and College for Radiographers
Organisation	The Royal College of Radiologists
Organisation	The General Osteopathic Council
Organisation	The Health and Care Professions Council
Individual - Consultant Radiologist	University Hospitals Plymouth NHS Trust
Individual - ULHT Consultant Sonographer	United Lincolnshire Hospitals NHS Trust
Individual - Ultrasound Services Manager	Imperial College Healthcare NHS Trust
Individual - Superintendent Sonographer	Morrison Hospital, Swansea
Organisations	Joint response received from: <ul style="list-style-type: none"> • The British Medical Ultrasound Society • The Chartered Society of Physiotherapy • The College of Podiatry • The Institute of Physics and Engineering in Medicine • The Society for Vascular Technology of Great Britain and Northern Ireland • The Society and College for Radiographers

9.2 As part of our work on the project we also spoke to the Scottish Government, the Welsh Government, NHS Employers, the Care Quality Commission, BLISS (the premature and sick baby charity), the Twin and Multiple Births Association (TAMBA) and Prostate Cancer UK.

10. Annex 5 – Independent Review Panel members

10.1 We are grateful to the members of our Independent Review Panel for their help in considering our assessment of the evidence and the options for managing risks arising. The members of the Panel are listed below:

- Suzanne Rastrick - Chief Allied Health Professions Officer, NHS England
- Robert Jago - Senior Lecturer, School of Law, Royal Holloway University of London
- Pamela Parker - Consultant Sonographer, Hull & East Yorkshire Hospitals
- Simon Denegri - Director of Patient and Public Involvement, National Institute for Health Research.

Annex 6 - Terms of Reference

Independent Review Panel for Right-touch Assurance assessment of sonographers

1. Context

- 1.1 The Professional Standards Authority ('the Authority') has been commissioned by Health Education England (HEE) to carry out an assessment of the risks arising from the practice of sonographers using its Right-touch assurance © model, and to provide recommendations on the most appropriate level of assurance for the role.
- 1.2 The Authority will be assessing evidence to establish risk of harm and developing recommendations on how these risks can best be managed. We will be seeking input from an Independent Review Panel with a range of expertise.

2. Purpose/role of panel

- 2.1 The Independent Review Panel is an advisory group. It will advise the Authority on interpretation of the evidence and proposed recommendations for managing the risk of harm arising from the practice of sonographers. The group will help the Authority to identify factors that should be taken into account, including any unintended consequences.
- 2.2 The panel will test the Authority's thinking ahead of the drafting of the Authority's final report and recommendations. The Authority will consider carefully any suggestions or comments made by the Panel as part of the assessment but reserves full control over the content of the final report and recommendations.
- 2.3 The group will be convened on a short-term basis for the purpose of providing advice on the development of recommendations.

3. Membership

- 3.1 The Panel will be comprised of four members, who between them will cover the following key attributes and competencies:
 - Senior clinical expertise and experience in sonography
 - Experience of analysing and quality assuring evidence at a senior level
 - Involvement in developing patient focussed policy
 - Experience of deploying sonographers in the workforce
 - Ability to maintain an open mind in considering the range of regulatory levers available to manage risks arising and the potential impact of any change to the regulatory regime for this occupation.

4. Meetings

- 4.1 The Panel will be sent the summary of the evidence on risk of harm and the draft recommendations in advance of a meeting and can request or suggest any further information required. It will then meet once, along with the Authority to discuss the proposals and provide expertise and challenge on the interpretation of the evidence and proposed recommendations.

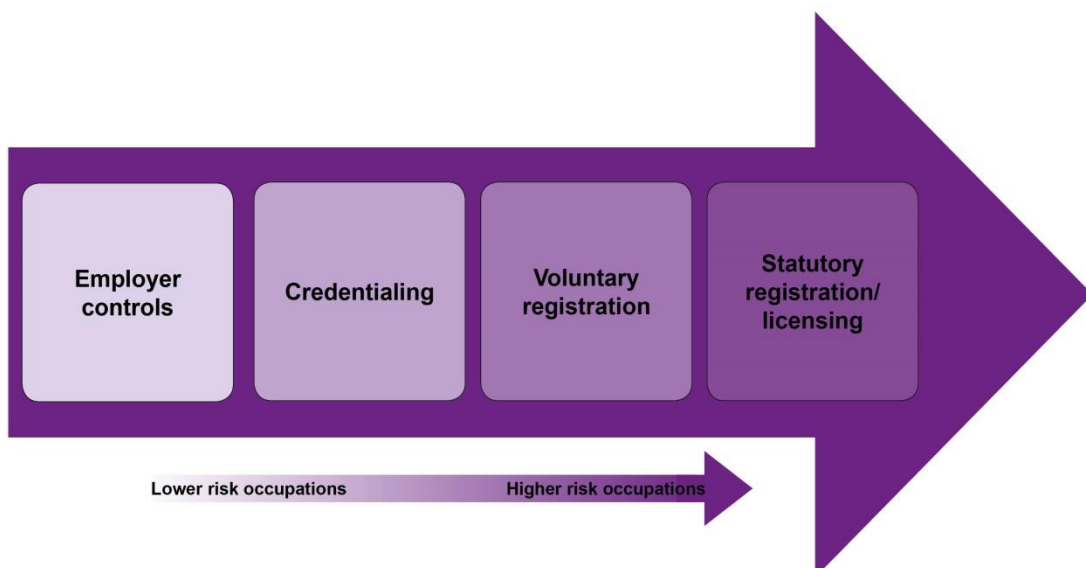
Right-touch assurance: a methodology for assessing and assuring occupational risk of harm

October 2016

1. Rationale for a methodology for assessing and assuring occupational risk

- 1.1 The Professional Standards Authority (the Authority) has developed a new tool for assessing the risk of harm presented by different health and care occupations. The methodology will indicate what form of assurance is needed to manage the risk of harm to patients and service users arising from the practice of an occupation. This paper sets out how the model will operate.
- 1.2 As health and care needs drive the development of new roles within the health service, discussion remains about how safety and quality are most appropriately and cost-effectively assured. This approach will assist government in making objective and transparent decisions on whether new roles should be regulated or what alternative action should be taken. It will also ensure that any action taken is clearly focused on managing potential for harm to patients and service users.
- 1.3 This approach has been developed for the purpose of assessing new and unregulated occupations to determine what type of oversight would be appropriate to manage risk of harm. In the long term, the methodology could be used or adapted to aid decisions on whether or not specialties should be regulated, if there should be other types of annotations on the register, as well as reviewing provisional and student registration, however this is outside the scope of this piece of work.

Figure 1 – Continuum of assurance



1.4 Figure 1 shows the continuum of assurance, as described in *Rethinking regulation* (2015), which demonstrates that as the level of risk increases, the regulatory force required to manage that risk also increases. The following definitions apply to the terms used in the diagram:

- Employer controls - refers to any requirements that employers might put in place to provide assurance of minimum standards of practitioners such as training, qualifications, codes of conduct, supervision and appraisal
- Credentialing - refers to developing a consistent method of validating the identity and legitimacy of external employees with access to healthcare settings. (This is distinct from the GMC use of the term credentialing for specific areas of medical practice for doctors who are already on a register)
- Voluntary registration - refers to the Accredited Registers programme operated by the Professional Standards Authority. The Authority accredits organisations that hold voluntary registers of health and social care practitioners who are not regulated by law, against 11 standards
- Statutory registration and licensing - refers to the legal requirement for registration of health and care professionals who are currently covered by the nine statutory regulators.

2. A two-stage process

2.1 Our methodology for right-touch assurance is a two-stage process. The first stage is to create a risk profile of an occupation taking into account the intrinsic risks of harm arising from practice. The second stage is to apply extrinsic factors in assessing the level of assurance needed to manage the potential risk of harm.

2.2 Evidence of intrinsic risk of harm is gathered, assessed and scored to profile the risk. Evidence relating to the extrinsic factors is also gathered and is analysed. An independent panel considers the risk profile and then assesses the occupation against the extrinsic factors. The result of the assessment and their recommendations is presented to government to aid policy decisions.

2.3 Below we set out in more detail how the approach will work and illustrate it with examples.

Stage 1 – Profiling the intrinsic risk of harm

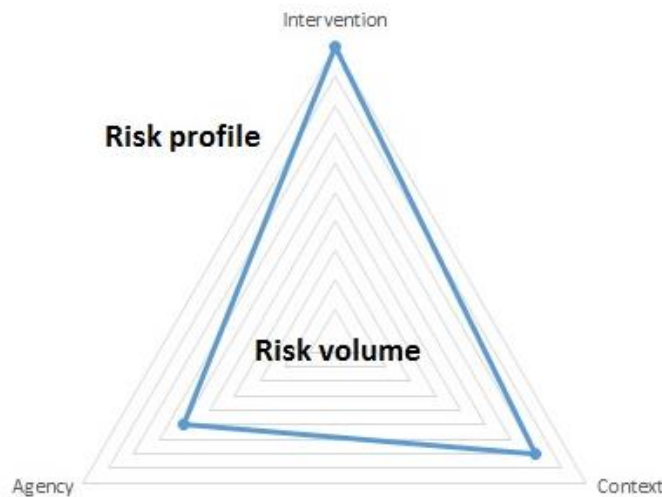
2.4 In the first stage of the process, which is both qualitative and quantitative, hazards associated with the practice of an occupation are grouped into the three broad categories outlined in *Right-touch regulation* (2015): intervention (the complexity and inherent hazards of the activity); context (the environments in which the intervention takes place); agency (service user vulnerability or autonomy). The advantage of this approach is that it disciplines us to probe on hazards beyond those related to the complexity of an occupation. Below we have given some examples of hazards that fit under each of the three categories:

- Intervention/complexity: potential for harm caused by features of practice from prescribing, surgical and psychological interventions to other kinds of physical therapies such as massage or invasive diagnostic techniques
- Context: including environments with varying levels of oversight (hospitals, community pharmacies and hospices amongst others), as well as patients' and service users' homes or high street premises

- Agency/vulnerability: contact with patients and service users who may have less or more ability to exercise control over their care and circumstances, potentially including children, people with disabilities, those with literacy and communication problems or competent adults purchasing services.

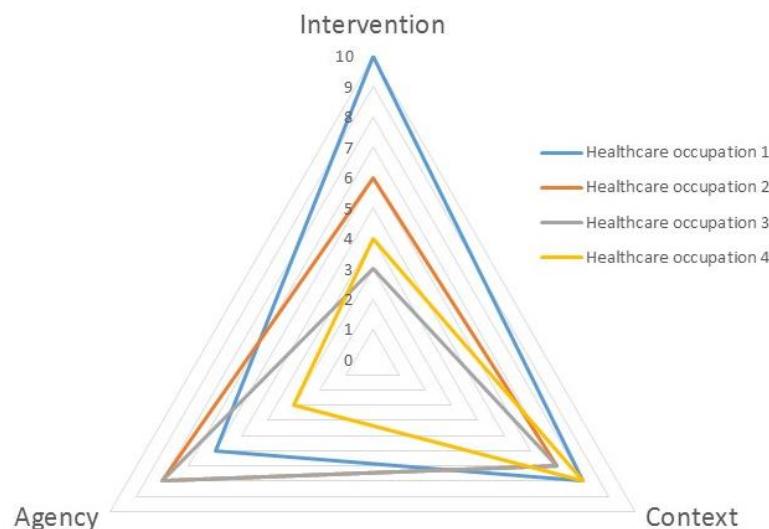
2.5 Based on an assessment of the evidence related to the hazards and a judgement on the likelihood and severity of harms resulting, a risk score will be allocated to each category and then to the occupation overall. The three scores are represented visually on a radar chart, see examples below for illustrative purposes:

Figure 2 – Risk profile and volume



2.6 This approach allows us to create a risk profile for each occupation and gain a clear picture of where the risks occur as well as indicate a risk volume from the area of the triangle. This will help to demonstrate the difference in both the level and type of risk in different occupations.

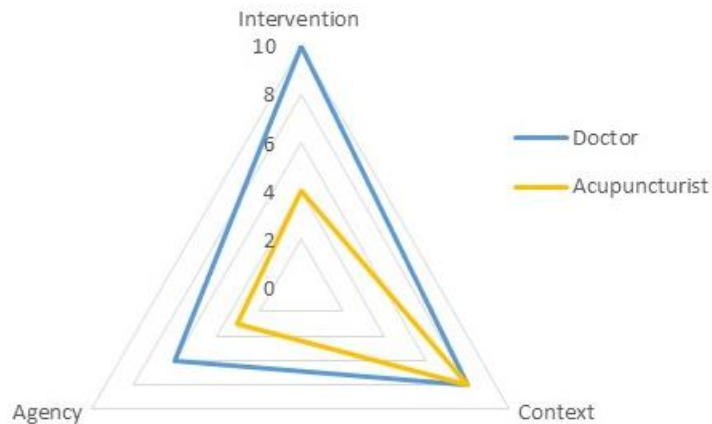
Figure 3 – Examples of risk profiles



2.7 For example, a health care assistant would have a lower level of risk than a doctor due to the nature of tasks they are carrying out and being highly supervised but may score higher on vulnerability based risk due to them having day-to-day care

for vulnerable people. The example below shows how the risk profiles for a doctor and an acupuncturist could be presented to reflect the different volume of intrinsic risk (diagram for illustrative purposes only).

Figure 4 – Example of risk profile and volume comparison



Stage 2 – Assessing the extrinsic risk factors

- 2.8 Once the hazards are understood and the intrinsic risk of harm has been described through an occupation's risk profile and volume, in stage 2 the occupation or profession is considered against the extrinsic risk factors. This assessment will inform where the profession or occupation sits on the continuum of assurance and allow the formulation of advice to government. This stage allows the panel to consider extrinsic factors that may mitigate the risk of harm occurring or, conversely, increase it. This will shape the recommendation on what level of assurance is appropriate. This allows the use of a right-touch approach and ensures that any action taken is proportionate.
- 2.9 The assessment criteria are:

Criterion	Rationale
1. Scale of risk: <ul style="list-style-type: none"> • Size of actual/potential practitioner group • Size of actual/potential patient or service user group 	This criterion helps to ascertain the dimensions of harm. Some occupations present a level of risk of harm but a regulatory response would not be proportionate due to the size of the workforce. An example is genetic counsellors, who number fewer than 200. Equally, if the group of service users or patients who are treated by the occupation is small, then this may suggest an alternative method of assurance would be appropriate. Conversely, support workers might achieve a small risk volume in terms of complexity, but number approximately a million. These factors need to be taken into account.
2. Means of assurance	This criterion enables examination of the various options that are available to manage the level and type of risk of harm, for example use of technology, supervision by a regulated professional or employment controls.

<p>3. Sector impact:</p> <ul style="list-style-type: none"> • Market • Workforce • Quality • Cost • Innovation 	<p>This criterion takes into account the impact of assurance mechanisms on the cost and supply of the occupation. Market impact might include market size, prices, trading conditions, labour supply, employer needs. Regulation of low paid occupations has been shown to increase cost and reduce supply. Regulation may restrict innovation. In this risk model we assess the impact of assurance on the availability of healthcare and therefore on patient care and safety.</p>
<p>4. Risk perception:</p> <ul style="list-style-type: none"> • Need for public confidence in the occupation • Need for assurance for employers or other stakeholders 	<p>This criterion enables consideration of probable effects on public confidence in the occupation or needs of employers or other agencies using the services of the occupational group.</p>
<p>5. Unintended consequences</p>	<p>This criterion requires that any identifiable unintended consequences of the proposed forms of assurance are considered so that any implications can be addressed.</p>

- 2.10 The assessment criteria do not cover ‘readiness to be regulated’. ‘Readiness’ indicates that an occupational group is organised and has agreed standards so could be brought into statutory regulation but it is not relevant to this model when deciding where an occupation should fall on the continuum of assurance. If a recommendation to regulate has been made, on the basis of the risk assessment, then readiness should be taken into account only when establishing a timeframe for this to happen.
- 2.11 Having considered the factors, and established whether and how risks can be managed or mitigated, the regulatory force required and thus the appropriate level and form of oversight can be determined. This follows the principles of right-touch regulation and ensures that the minimum regulatory force is applied to achieve the desired effect.
- 2.12 Consideration of these extrinsic factors is necessary to develop a full picture of the actual risk of harm from the occupation to the public and to assess what the most appropriate form of assurance is. This stage is not intended to act as a regulatory impact assessment which would be carried out at a later stage when government is making a policy decision.

3. In summary

This paper outlines a two-stage process to assess the risk of harm to patients and service users posed by different occupations. This is intended as a method of providing evidence-based recommendations to government on the most appropriate means of assurance for an occupation to assist with policy decisions.

Sources reviewed

To inform the development of the risk assessment methodology we have reviewed literature, research and a range of different approaches to quantifying and qualifying risk. We have developed our previous thinking in *Right-touch regulation* where we outlined the different categories of hazards in relation to the complexity of the intervention, the context it takes place in and the vulnerability of the patients and service users that the practitioner comes into contact with. Alongside this, key sources which particularly influenced our thinking in developing the model include:

- The work of the Health Professions Advisory Council in Ontario which carries out an assessment of the risks involved in the practice of health and care occupations and provides advice to government on whether they should be regulated or not
- The 2007 White Paper *Trust, Assurance and Safety* which looked at criteria to establish which new and unregulated occupations should be considered for statutory regulation
- The work carried out by the Health and Care Professions Council to inform their process for annotating the register to indicate post-qualifications of registrants
- The work being carried out by the General Medical Council to develop medical credentialing
- The process undertaken by the Accredited Registers programme, operated by the Professional Standards Authority to require registers applying for accreditation to carry out an assessment of the risk involved in the occupation and how they intend to manage this
- The Care Quality Commission's regulated activities, highlighting areas with a higher potential risk of harm
- Work carried out assessing the issue of patient and clinician vulnerability in healthcare by Dr Joanne Travaglia and Hamish Robertson at the University of New South Wales

Other sources

There is a non-exhaustive list of other publications and sources we have reviewed below.

UK regulators

Denham L. Phipps, Peter R. Noyce, Kieran Walshe, Dianne Parker, Darren M. Ashcroft
December (2010) *Risk Assessment in Pharmacy*

Europe Economics (2010) *Risks in the Optical Profession - a report for the General Optical Council*

Europe Economics (2010) *Counterfactual for Revalidation - Report to the General Chiropractic Council*

Europe Economics (2014) *Risk in Dentistry - Report for the General Dental Council - October 2014*

Risk assessment - general

Health and Safety Executive *Use of Risk Assessment within Government Departments*

Risk assessment in the health and care sector

Mutual Recognition of Professional Qualifications Directive *Review of Professional Qualifications: United Kingdom National Action Plan*

Department of Health (2009) *Extending professional and occupational regulation: the report of the Working Group on Extending Professional Regulation*

NHS National Patient Safety Agency (2008) *A risk matrix for risk managers*

Kieran Walshe and Denham Phipps (2013) *Developing a strategic framework to guide the Care Quality Commission's programme of evaluation*

(2013) *The Cavendish Review: An Independent Review into Healthcare Assistants and Support Workers in the NHS and social care settings*

Professional Standards Authority (2013) *Response to the Cavendish Review*

Professional Standards Authority (2013) *Advice to the Secretary of State following recommendation 14 of the Cavendish Review*

Department of Health (2013) *Review of the Regulation of Cosmetic Interventions, Final Report, Prepared by the Review Committee*

Professor David R. Walker (2015) *Report on the Regulation of Herbal Medicines and Practitioners*

Griffiths, A., Beaussier, A-L., Demeritt, D. and Rothstein, H. (2016) *Intelligent Monitoring? Assessing the Ability of the Care Quality Commission's Statistical Surveillance Tool to Predict Quality and Prioritise NHS Hospital Inspections' British Medical Journal Quality and Safety*

Risk assessment in other sectors and abroad

The Health and Safety Executive (1992) *The tolerability of risk from nuclear power stations*

Financial Conduct Authority (2016) *Risk Management (website article)*

Solicitors Regulation Authority (2014) *Risk Framework*

Engineering Council (2011) *Guidance on risk*

New Zealand Government (2016) *Regulating a new profession (website article)*

Scopes of practice and professional standards

General Medical Council (2013) *Good Medical Practice*

Nursing and Midwifery Council (2015) *The Code - Professional standards of practice and behaviour for nurses and midwives*

Royal College of General Practitioners General Practice Foundation (2014) *Healthcare Assistants (General Practice) Competency Framework*

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