Interim report on oversight of Nursing Associates

November 2016

1. The Professional Standards Authority

1.1 The Professional Standards Authority 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. As part of our work we:

- Oversee nine health and care professional regulators and report annually to Parliament on their performance
- Conduct research and advise the four UK governments on improvements in regulation
- Promote right-touch regulation and publish papers on regulatory policy and practice
- Accredit organisations that register health and social care practitioners who are not regulated by law.

2. Scope of the work

2.1 In August 2016, the Department of Health asked the Professional Standards Authority for Health and Social Care (the Authority) to provide advice on what would be the appropriate level of oversight for the emerging role of the Nursing Associate. 'Oversight' refers to a number of mechanisms, including – but not limited to - statutory regulation. In order to reach a recommendation, the Authority was asked to pilot its new methodology '*Right-touch assurance'*. This is an evidence-based process for assessing the risks of harm in an occupation or profession, and the appropriate level of assurance needed to mitigate them. It was, therefore, also an opportunity to test out the new model with a view to further developing and refining the *Right-touch assurance* approach. Use of this model is in line with the principles of Better Regulation[1] and will help to ensure that the form of oversight chosen is likely to be commensurate with the risk of harm to patients and avoid any undue regulatory burden on health and care services.

2.2 The bulk of the information, evidence and data for the assessment was to be provided by Health Education England (HEE). The Department of Health also convened weekly teleconferences with the Authority, representatives from the Governments of Scotland, Wales and Northern Ireland, HEE and the Nursing and Midwifery Council.

[1] Better Regulation Task Force, *Principles of Good Regulation*. [Online]. Available at: http://webarchive.nationalarchives.gov.uk/20100407162704/http:/archive.cabinetoffice.gov.uk/brc/upload/assets/www.brc.gov.uk/principlesleaflet.pdf [Accessed: 01/11/2016]

2.3 It was not within the scope of this work to assess the need for, or shape, the emerging role of Nursing Associate nor to carry out formal impact assessments on any recommendations made.

2.4 It emerged from the evidence that there is not yet clarity about the scope, clinical practice and working environments envisaged for Nursing Associates as the role or roles is/are still in development. We are therefore unable to provide a definitive recommendation to government at this stage. Given the short timetable available to do this work we have agreed with the Department that we will submit this interim report. This summarises work undertaken to date, the additional evidence that would be required to finalise our assessment, some of the methods of assurance that could be considered for the role when its scope is further defined and tested. In our conclusion we also suggest an interim position on oversight of the role.

3. Right-touch assurance

3.1 As health and care needs change, discussion continues about how safety and quality are 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.

3.2 Whilst statutory regulation plays an important role in certain circumstances, there is now, as a result of recent legislation, 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 in place in NHS Scotland for Healthcare Support Workers)[2]
- An accredited register.[3] This could be held by a regulator, such as the NMC or HCPC, by an existing accredited register or by a new body.[4,5] A requirement for providers to use only registered Nursing Associates could apply in NHS settings, and form part of commissioning contracts for providers across publicly-funded health and care.
- A statutory code of practice; breaches of the Code could lead to disciplinary action and dismissal.

[2] NHS Education for Scotland, *HCSW Standards and Codes.* [Online]. Available at: http://www.hcswtoolkit.nes.scot.nhs.uk/resources/hcsw-standards-and-codes/ [Accessed: 01/11/2016]

[3] The Professional Standards Authority accredits registers of health and care occupations who are not statutorily regulated and has now accredited 23 registers. Professional Standards Authority, *Find an accredited register*. [Online]. Available at: http://www.professionalstandards.org.uk/what-we-do/accredited-registers/find-a-register [Accessed: 01/11/2016]

[4] Statutory regulators have the power to set up voluntary registers under section 25D of the National Health Service Reform and Health Care Professions Act 2002. *National Health Service Reform and Health Care Professions Act 2002, Section 25D.* [Online]. Available at: http://www.legislation.gov.uk/ukpga/2012/7/section/228/prospective [Accessed: 01/11/2016]

[5] There is a precedent for Government setting up a body for the purposes of holding a voluntary register of unregulated practitioners: the Complementary and Natural Healthcare Council was set up with Government support to register complementary therapists. Complementary and Natural Healthcare Council, *UK voluntary regulator for complementary therapists.* [Online]. Available at: http://www.cnhc.org.uk/ [Accessed: 01/11/2016]. In addition, the register, the Academy for Healthcare Science was established as a joint initiative of the UK Health Departments and the professional bodies. Academy for Healthcare Science. [Online]. Available at: https://www.ahcs.ac.uk/about-us/about-the-academy-for-healthcare-science/ [Accessed: 01/11/2016]. The register, COSCA (Counselling & Psychotherapy in Scotland) receives financial support from the Scottish Government. COSCA. [Online]. Available at: http://www.cosca.org.uk/about.php [Accessed: 01/11/2016].

3.3 The Authority's *Right-touch assurance*[6] model is designed to provide government and others with objective and transparent advice on whether roles in the health and care sector should be regulated or what alternative action ought to be taken to manage possible risks and to protect patients and the public.

3.4 The model (Annex A of this paper) comprises two parts which make an integrated whole. In the first stage, we create a risk profile for the relevant role; this takes into account the intrinsic risks of harm arising from the practice of a particular occupation or profession. It requires an assessment of risk in three areas: intervention (the complexity and inherent hazards of the activity); context (the environments in which the intervention takes place); agency (service user vulnerability or autonomy).

3.5 In the second stage, we consider a number of extrinsic factors, to assess the type of oversight needed to manage the risk of harm. Extrinsic factors include the various types of oversight available, risk perception and need for assurance for stakeholders and the public, as well as possible unintended consequences of any action proposed to be taken. This second stage is essential because it gives us a recommendation based on the principles of *Right-touch regulation*[7]*,* which take account of other means of securing public safety.

3.6 The *Right-touch assurance* model allows for a broad interpretation of the term 'risk of harm'. Risks could arise, for example, from the failure of a healthcare professional to recognise and act upon signs of deterioration in a patient who is being cared for at home, as well as from a doctor carrying out complex surgery.

3.7 We have been conscious throughout the pilot that we were primarily reliant out of necessity on just one source for our information and evidence. This has been less than ideal – a satisfactory assessment would require assessment of information and evidence from a range of sources to ensure it was robust, and to balance any possible predetermination or bias in the views or information put forward. We would ordinarily wish to carry out our own targeted consultation and/or research on scope of practice, risks, and options for assurance.[8] We would also have convened an informed, independent panel to assess evidence and make recommendations. These elements are central to the robustness of the process, and therefore to the value of the recommendations we make.

4. Background to the Nursing Associate role

4.1 We thank Health Education England (HEE) for having worked closely with us to aid our understanding of the Nursing Associate role.

4.2 The development of the role of Nursing Associate has its roots in the Shape of Caring Review published in March 2015. Since then, HEE has engaged with a wide range of stakeholders to explore the need for and shape of a role to 'act as a bridge between

[6] Professional Standards Authority (2016) *Right-touch assurance: a methodology for assessing and assuring occupational risk of harm.* [Online]. Available at: http://www.professionalstandards.org.uk/publications/detail/right-touch-assurance-a-methodology-for-assessing-and-assuring-occupational-risk-of-harm [Accessed: 01/11/2016]

[7] Professional Standards Authority (2015) *Right-touch regulation (revised).* [Online]. Available at: http://www.professionalstandards.org.uk/what-we-do/improving-regulation/right-touch-regulation [Accessed: 01/11/2016]

[8] The HEE workshops in the summer looked at some of these issues, but we would wish in our consultation to explore the issues in considerably more depth.

the unregulated care assistant workforce and the registered [regulated] nursing workforce'[9].

4.3 The Nursing Associate role is being developed for England only and is described as working at a level between healthcare assistant and registered nurse. (However, it should be noted that broadly similar roles are utilised in Scotland, Northern Ireland and Wales who have developed their own arrangements out-with statutory regulation. We return to this below). At the time of writing, we understand that the Nursing Associate will have a broad initial training in the way that a nurse does.[10] However the training curriculum for Nursing Associates has not yet been finalised. During their working life, Nursing Associates may choose to practise and, therefore, develop their knowledge and skills in a particular area of practice or working environment. The Nursing Associate would form part of a care workforce comprising, among others, healthcare assistants, senior healthcare assistants, assistant practitioners and registered nurses. The precise difference in roles and responsibilities between the four occupations remains undefined.

5. Right-touch assurance – Stage 1: evaluating intrinsic risks of harm for Nursing Associates

5.1 In the first stage of our Right-touch assurance process, we consider the intrinsic risks of harm associated with the practice of an occupation or profession. The potential hazards that may lead to risks of harm are grouped into three broad categories as follows: intervention (the hazards inherent in activities undertaken by practitioners in the role); context (the environments in which the activities take place); agency (including service user autonomy or vulnerability).

5.2 We have identified a range of evidence which needs to be used to assess the level of risk posed by a role and consider the most appropriate form of assurance. This is captured in the attached evidence template (Annex B) which we used to request information for this assessment. This is not a prescriptive list but indicates the kinds of information required for this exercise and covers information needed for stages 1 and 2 of the process.

5.3 In order to develop a risk profile for the Nursing Associate role (stage 1), it is necessary to have an understanding of its scope of practice. This would then inform the 'complexity', and to an extent the 'context' and 'agency' elements of the risk profiling. Our intention is not to restrict the occupation to a list of tasks, but to gain an understanding of the core types of task a typical Nursing Associate would be qualified to do or expected to undertake in their day-to-day practice. Our work to date has brought to light that there is likely to be divergence across work settings (community, primary care or hospital) in the types of task undertaken. It may therefore be that the role could be better described and assessed by looking at different scopes for different settings depending on the outcomes of further piloting and development.

5.4 HEE submitted a substantial amount of evidence to us at a time when they were engaged in activities to gain consensus on the role. We also received information from the Scottish Government as well as a submission from the Northern Ireland Government. Broadly speaking, the evidence – submitted in accordance with our guidance – fell into three key areas: the scope of the role; risks intrinsic to practising

[9] Health Education England, *'Raising the Bar: Shape of Caring': Health Education England's response.* [Online]. Pg. 22. Available at: https://www.hee.nhs.uk/sites/default/files/documents/Raising%20the%20Bar%20-%20Shape%20of%20Caring%20-%20HEE%27s%20response.pdf [Accessed: 01/11/2016]

[10] We understand from discussions with HEE that the initial training programme for Nursing Associates will last two years and – on a weekly basis –would typically comprise: one day on release in education; three days in the trainee's workplace (for example, a care home); one day in another healthcare setting (for example, a hospital).

within the scope of the role; extrinsic factors. They have drawn our attention to the potential risks associated with the increasingly complicated health and care needs of patients, and to the fact that risks arise not only from defined clinical interventions such as wound management, or medicines administration – they also arise from a practitioner's ability, say, to identify a patient's deteriorating condition or to assist them to self-care.

5.5 The scope of practice for the Nursing Associate role that we considered – based on two extensive consultation exercises run by HEE – was still in draft form. At the time of writing, the core competencies and curriculum document for training were still being developed. [11] HEE have been cautious about setting out prescriptive lists of tasks, or types of task that they feel might be seen to limit the scope of the role, or understate the complexity or level of autonomy that would be required of the Nursing Associate. We understand that the administration of medicines would form part of every Nursing Associate's role, but it has not been possible to identify a broader set of core clinical tasks, responsibilities, or competencies at this stage.

5.6 The *Right-touch assurance* methodology also involves the analysis of data relating to the types of settings an occupation would be working in and the types of patient or service user they would be caring for. HEE have supplied us with helpful information, both verbally and on paper, describing some of the settings that Nursing Associates would be practising in. Our understanding is that they would be deployed in a wide range of settings, including nursing homes, domiciliary care, general practice, acute care, and mental health. It has not been possible though, at this early stage, to obtain any data about the likely spread of the workforce across these different care environments.

5.7 The level of responsibility and autonomy afforded to a Nursing Associate is also key to developing a risk profile. HEE have produced a number of specific case scenarios demonstrating the differences in responsibility and autonomy between the healthcare assistant, the Nursing Associate and the registered nurse. However, there is not yet available a document that gives, in general terms, agreed descriptors distinguishing between healthcare assistants, Nursing Associates, advanced practitioners and registered nurses.

5.8 If this had been an existing occupation, we would have analysed a sample of job descriptions, and carried out an audit of scopes of practice in the workplace. We would have been able to use data about existing practice settings and levels of supervision to develop an understanding of the risk factors relating to context and patient vulnerability. With a new role, if the training pilot were already underway, we could have carried out an analysis of the scopes emerging from the different training sites; we would have had a better idea of where Nursing Associates would be employed and how they would be supervised.[12]

5.9 However, as this is a new role in its early stages of development, we have been reliant on projections in a number of different forms about what the role might entail, and where and how it would be deployed, which at this stage appear inevitably to be speculative. We have recognised the specific circumstances relating to the status of the role's development and have sought to adapt to this by making use of different kinds of information including scenarios demonstrating how the role might operate. However, this has not proved to be a direct substitute for what is required. As a result,

[11] The first two-year trainee Nursing Associate programmes are scheduled to start in January 2017 at a number of test sites.

[12] We understand that the training test sites taking part in the pilot will be given considerable scope for developing their own curriculum, provided that it meets the broad outcomes set out by HEE in its overarching curriculum.

we have not been able to extract from the information provided by HEE the detailed data about complexity of activity, practice context, and patient agency that we needed to conduct an objective risk analysis. We therefore conclude that the information required to pilot stage 1 of our *Right-touch assurance* process is not available at this time.

6. Mechanisms for oversight

6.1 From discussions with HEE and review of the summary of responses to the HEE consultation carried out on the role, there were a number of outcomes which some stakeholders viewed as important for the role. These included:

- Clearly defined national standards of education and training
- Reassurance for employers that Nursing Associates will be accountable and traceable to avoid individuals moving on to a new role following misconduct
- Reassurance for Registered Nurses working in partnership with the new Nursing Associates on skill level and accountability to enable them to delegate tasks with confidence and to avoid implications for their own registration status in the case of misconduct
- Protection for Nursing Associates to ensure they are not pressured to work beyond their competencies or scope of practice
- Enhanced professional status for the role to encourage professionalism and highlight differentiation with other roles as part of a defined career path.

6.2 We understand from the stakeholder engagement carried out by HEE that statutory regulation was seen by many as a way of delivering some of the above outcomes and as a way of mitigating the risks that might be presented by Nursing Associates, however it is not always clear on what basis these views were formed. Education and training, and robust employment practices were also put forward as possible mitigations.[13] The Authority has long argued that although enhanced professional status may be a consequence of statutory regulation it is not its purpose or a reason for regulating any particular occupation.[14]

7. Conclusion

7.1 At the time of writing, the scope of the role of Nursing Associate has not been defined to the level that is needed to assess the risks of harm, and data about the spread of the workforce across different settings were not available. A curriculum for training has not yet been finalised. We therefore cannot currently offer objective advice on the type of oversight or assurance that will ultimately be needed for this new workforce. This is not a criticism of HEE, who have been helpful throughout, it is simply a matter of timing.

7.2 We note that *Enabling Excellence* sets out Government policy as follows:

'In a limited number of cases […], statutory regulation may be the only way of effectively mitigating against risks to people using services, although it would need first

[13] This is outlined in a draft HEE report seen by the Authority, of workshops about the role that took place in the summer of 2016.

[14] Professional Standards Authority (2015), *Rethinking regulation*. [Online]. p.9. Available at: http://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/rethinking-regulation-2015.pdf?sfvrsn=6 [Accessed: 01/11/2016]

to be clear that assured voluntary registration would be insufficient to help guide choices by commissioners and patients.' [15]

7.3 The government has to date resisted calls from other occupations for statutory regulation citing this policy. We also note that Scotland and Northern Ireland have expressed significant concerns about the role and its oversight. Whilst an occupational role might be intended to support the workforce requirements of England, should there be a move to formally regulate the role, the UK-wide remit of the regulatory bodies automatically brings about considerations for all four of the UK countries.

7.4 We recognise the importance and value of new roles in meeting the challenges that the health and care service is facing. We also recognise that roles will increasingly not be task based and will need to be flexible to demands and may need to be developed and refined following testing. Flexibility is indeed one important reason why statutory regulation (which tends towards inflexibility) may not be the best approach to patient safety. In our view it could do a disservice to the potential value of Nursing Associates to make a premature recommendation and could lead to undesirable preparation and investment in an inappropriate form of assurance. It is probable that more of the information needed to carry out a robust assessment may be available following the trialling of the role which we understand is due to commence in early 2017.

7.5 We would therefore suggest that an interim position be adopted, in line with *Enabling Excellence*, whereby the role is registered, but not yet regulated. This would allow HEE to complete its work in defining the role, employers to have confidence in adopting and testing it, nurses to have confidence in working alongside new colleagues. We could then collect the necessary evidence and provide robust advice to government on the appropriate oversight. A regulator such as the NMC could establish a voluntary register under its existing legislation, which would facilitate an easy transition to regulation, should that later prove to be the right solution.

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Annex A

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

October 2016

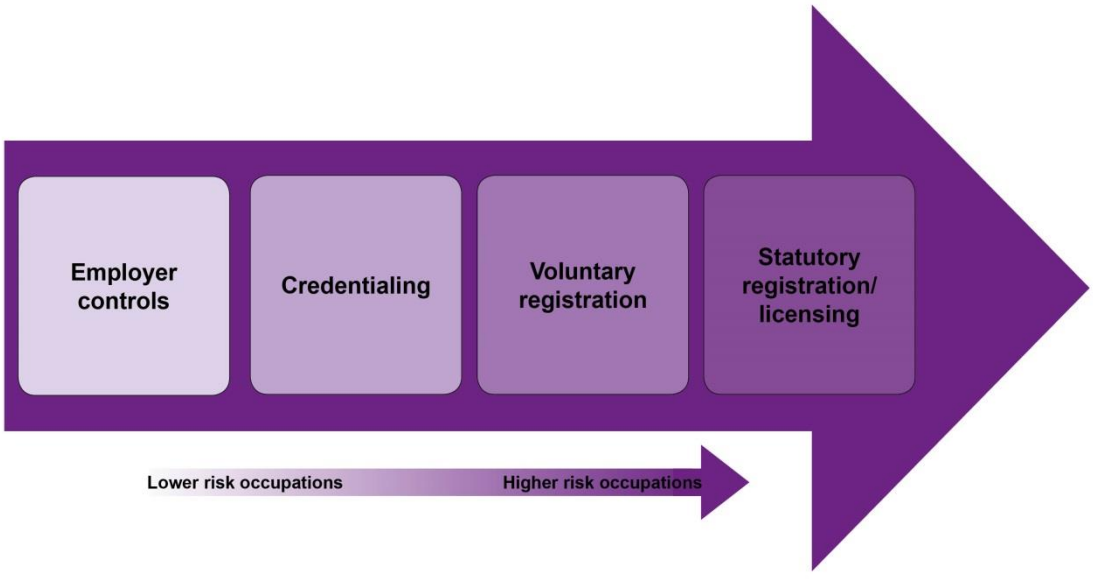
1. Rationale for a methodology for assessing and assuring occupational risk

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

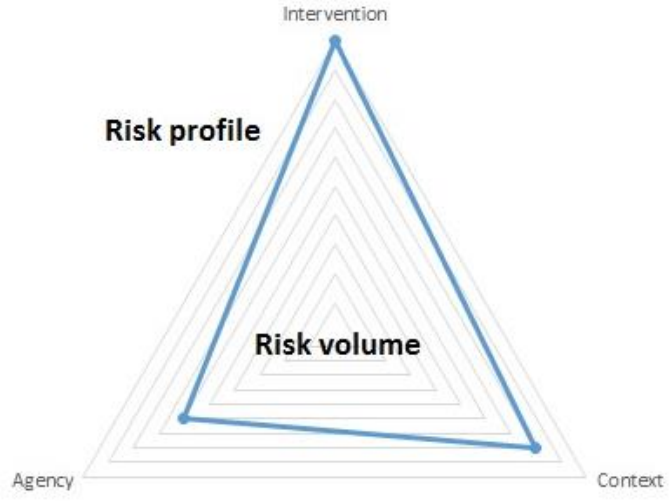
2.4 In the first stage of the process, which is both qualitative and quantitative, hazards associated with the practice of an occupation are grouped into the three broad categories outlined in *Right-touch regulation* (2015): intervention (the complexity and inherent hazards of the activity); context (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.

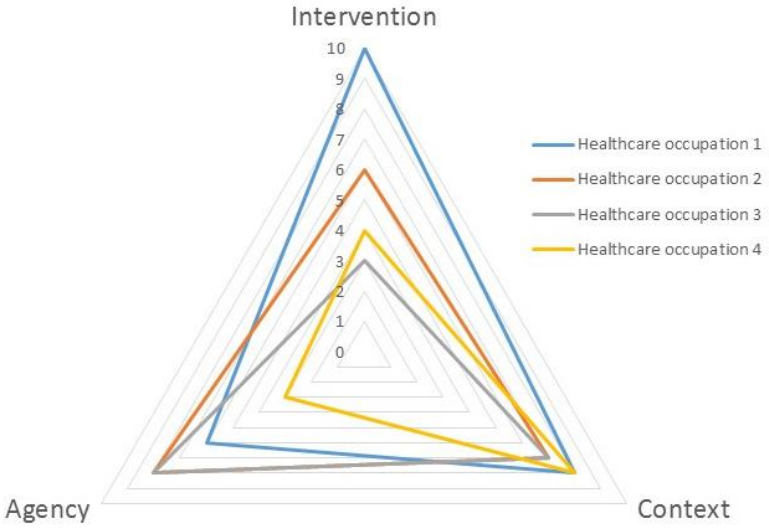
2.5 Based on an assessment of the evidence related to the hazards and a judgement on the likelihood and severity of harms resulting, a risk score will be allocated to each category and then to the occupation overall. The three scores are represented visually on a radar chart, see examples below for illustrative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

Figure 2 – Risk profile and volume



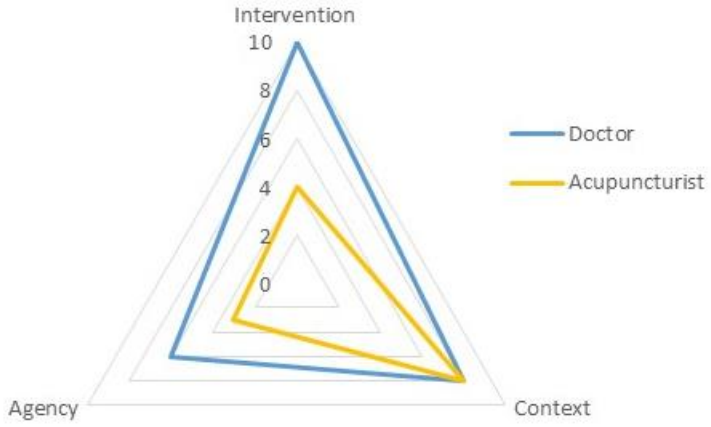
2.6 This approach allows us to create a risk profile for each occupation and gain a clear picture of where the risks occur as well as indicate a risk volume from the area of the triangle. This will help to demonstrate the difference in both the level and type of risk in different occupations.

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: • 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.
3. Sector impact: • Market • Workforce • Quality	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.

• Cost • Innovation	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.
4. Risk perception: • Need for public confidence in the occupation • Need for assurance for employers or other stakeholders	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.
5. Unintended consequences	This criterion requires that any identifiable unintended consequences of the proposed forms of assurance are considered so that any implications can be addressed.

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.

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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*

Annex B

professional standards authority

Right-touch Assurance: assessing the level of oversight required for health and care occupations

Submission of evidence template

Name of body submitting evidence	***Health Education England***		
Title of occupation	***Nursing Associate***		
For which UK countries is the occupation applicable?	***England***		
Evidence area	**Explanation**	**Examples of evidence**	**List the evidence supplied and add comments if needed**
1. Description of role	In order to create a risk profile based on the occupation, we will need an understanding of the breadth and depth of the role. Each submission will refer to a single role with a common set	• Scope of practice document(s) • Standards document(s) • Learning outcomes for training and education	[Type here, boxes will expand]

	of standards applicable across one or more UK countries.	• A common framework for education and training curricula • A generic role profile (as distinct from a job description for a post in the NHS).	
2. Complexity of intervention	Indicative examples of intervention include: surgical, medical, other physical and psychological interventions; role in diagnosis and treatment planning and referral; diagnostic and therapeutic techniques; oversight of patient care; prescribing rights. Ideally, evidence of the risk of harm should relate to the risks posed by practitioners in the particular occupation being considered undertaking the intervention. Where this is not possible, evidence may be sourced either from similar roles outside of the UK or from different roles within the UK where similar tasks are undertaken.	• Evidence listed under **1 Description of role** above • Evidence of risk of harm in relation to interventions, which may include: Data collected on clinical outcomes for patients and patient safety and incident data in general Academic research Expert opinion Grey literature Fitness to practise data Complaints data.	
3. Context in which the practitioner is working	Health and social care takes place in a variety of settings with different levels of oversight and supervision, opportunities for professional development	• Data on the environments in which practitioners are / will be / are projected to be working	

	and support from other colleagues and practitioners.	• Evidence of current mechanisms for overseeing, supervising and supporting practitioners in their role, which may include clinical governance arrangements and opportunities for learning • Evidence of pressures associated with the context in which the practitioners are working.	
4. Vulnerability of the patient or service user	Certain groups of patient or service user may be considered more vulnerable than others (whilst accepting that all patients and service users are – to some extent – vulnerable). Vulnerability refers to the ability of the patient or service user to make decisions on their care and exercise control over their care.	• Information on type of patient or service user for whom practitioners will be caring, including proportion of time spent on each of these groups • Evidence of level of vulnerability of identified groups of patient and service user.	
5. Scale of risk Size of actual / potential practitioner group Size of actual / potential patient	The intrinsic risks of an occupation might be high but the likelihood of harm is affected by the size of the workforce and population treated. Conversely, the intrinsic risks of an occupation might be low, but	• Data on size of practitioner group and number of patients or service users. This may include projections for future growth based on evidence.	

or service user group	workforce numbers and population treated high.		
6. Means of assurance	This section enables assessment of the various options that could become available to manage the risks of harm. These might include - among others - supervision by a regulated professional or employment controls, clinical governance processes and mechanisms for learning.	• Information on systems already in place which could be strengthened to manage risk • Information on systems that might be put in place to manage risk.	
7. Sector impact	In this criterion we will consider the possible impact on the sector. This might include the effect on: prices; trading conditions; labour supply; flexibility in roles; possibility for innovation; quality of care and service; availability of education and training.	• Data may cover demographics of the workforce, average salaries, market structure and flexibility of the workforce, labour supply issues • Data and reports on projected impact on the sector following any changes in the framework for assurance and oversight.	
8. Risk perception: Impact on public confidence in the occupation Impact on employers' and other	This criterion considers the level of reassurance that stakeholders may need in order to be confident that any occupational risks are being managed.	• Survey data • Other published views including grey literature.	

stakeholders' confidence in the occupation	It will assess the public's view, as well as the needs of other stakeholders in terms of assurance of safety.		
9. Unintended consequences	This criterion ensures that we consider any unintended consequences of the recommended form of assurance.	• Additional evidence which may demonstrate new risks created by, or unintended consequences of, statutory regulation or other mechanisms for oversight and assurance.	

A note on evidence:

Evidence, particularly in relation to harm, may come from a variety of sources, including:

- Indemnity organisations
- Employers
- Professional Associations
- Regulators of other occupations, as well as premises and businesses
- Primary research undertaken by the applicant
- The media
- Charities and voluntary organisations (particularly those concerned with patient safety)

There are also different types of evidence, which may be available:

- Empirical evidence from randomised control trials and other trials
- Analytic studies such as cohort or case control studies
- Time series analyses
- Before and after studies
- Outcomes of consultation exercises
- Surveys
- Structured qualitative research
- Academic research

- Expert opinion
- Grey literature
- Fitness to practise data
- Complaints data
- Data collected on clinical outcomes for patients and patient safety and incident data
- Curriculum documents
- Scope of practice and standards documents

The panel will assess and weight the different types of evidence submitted before making a recommendation.

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