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

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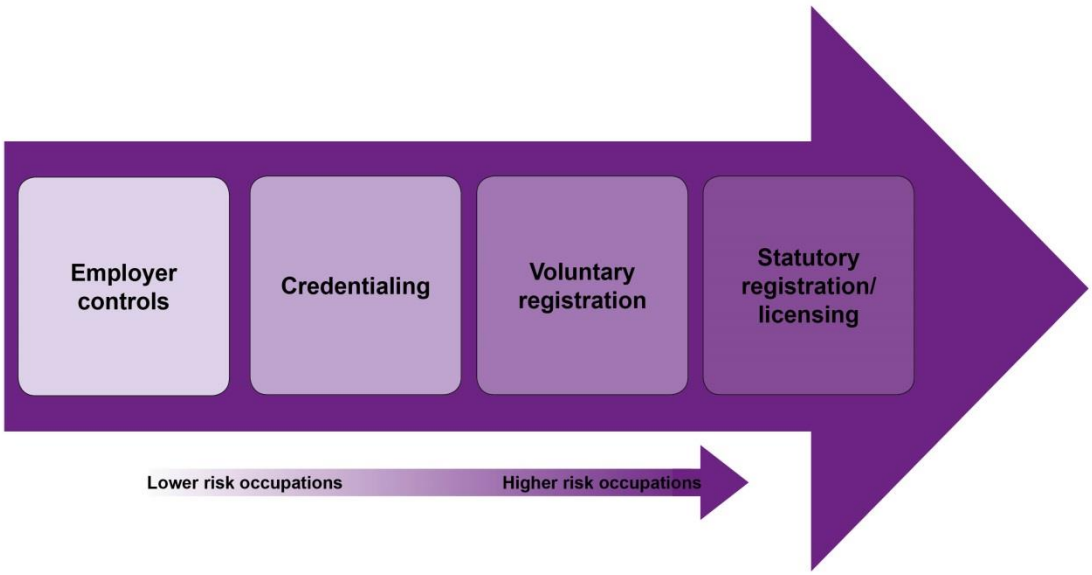
1. Rationale for a methodology for assessing and assuring occupational risk

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

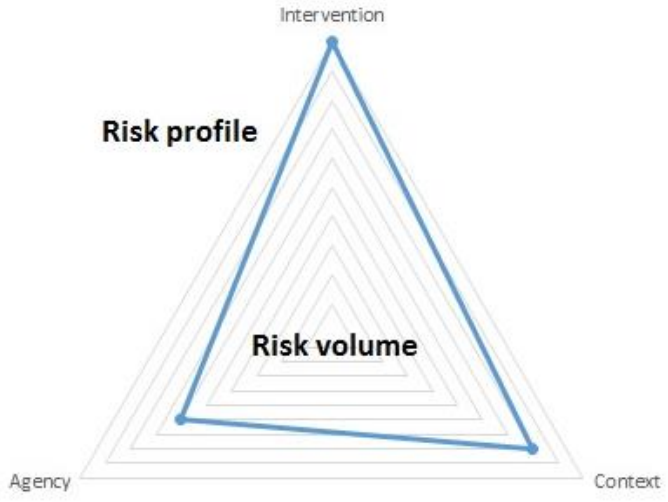
2.4 In the first stage of the process, which is both qualitative and quantitative, hazards associated with the practice of an occupation are grouped into the three broad categories outlined in *Right-touch regulation* (2015): intervention (the complexity and inherent hazards of the activity); context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

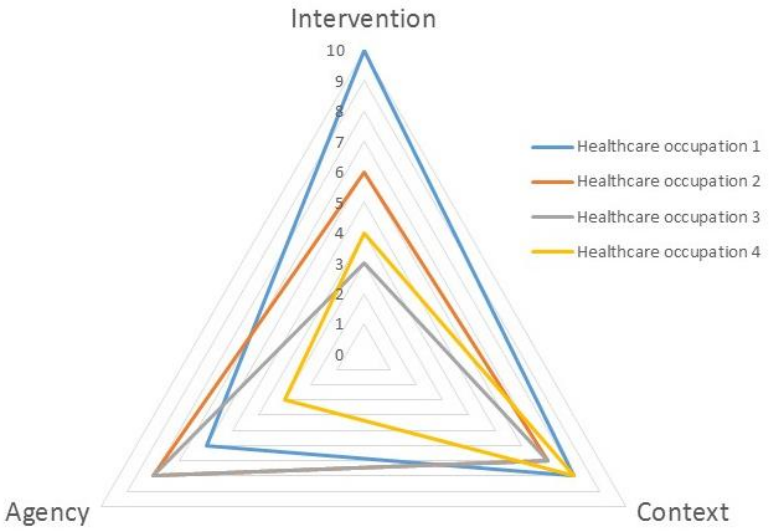
2.5 Based on an assessment of the evidence related to the hazards and a judgement on the likelihood and severity of harms resulting, a risk score will be allocated to each category and then to the occupation overall. The three scores are represented visually on a radar chart, see examples below for illustrative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

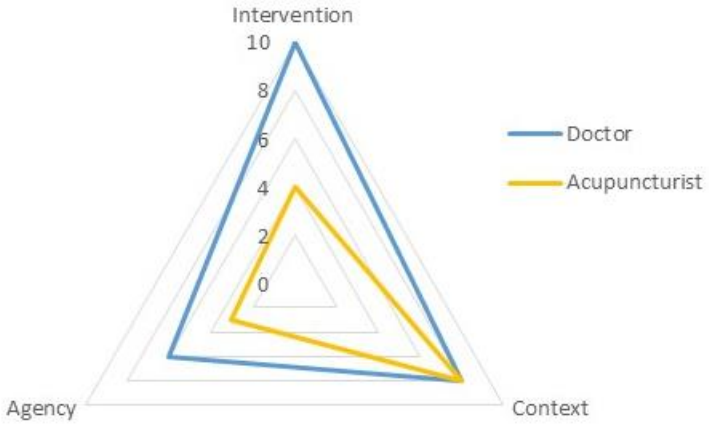
Figure 3 – Examples of risk profiles



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 • Cost • Innovation	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.
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.

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*