Regulation rethought
Proposals for reform

October 2016

professional standards authority

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 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. 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. Introduction

This paper sets out our proposals for a transformation of the regulation of health and care professionals. We suggest how we could put into practice the ideas set out in our paper *Rethinking regulation* (2015)[1]. It should therefore be read in the context of that earlier publication. We have not repeated here the arguments or the evidence we set out there, but all of the proposals we put forward in this paper have been formed with the intention of offering solutions to those problems.

The public often find the regulatory system baffling and hard to navigate, particularly when they have a concern or complaint and want to report it in the right way; the role of the regulator is easily misunderstood. Employers have to engage with multiple regulators in order to check their workers' registration, report concerns and support revalidation and continuing professional development. People in multi-disciplinary teams work to different standards and may be subject to different decisions by different regulators for the same or similar events for which they have individual and shared responsibility. They may be subject to different sanctions which patients, employers and registrants find hard to reconcile. Educators too are affected by multiple regulators with different standards and quality assurance mechanisms. This may inhibit their ability to train practitioners who are centred on patients' needs, with shared values, and who can work across professional boundaries within health and care. Team roles and functions may change as population needs, technological innovations or service requirements alter.

Those striving to re-design service delivery, integrate care, or introduce new working practices may be frustrated and delayed by the difficulties inherent in flexing scopes of practice or creating new roles, because of protected titles and boundary protection by particular professions. Those seeking to bring about change are also seeking independent assurance about the standards and competencies of those who are not subject to statutory professional regulation. Regulation is often cited as a barrier to innovation, although that is not always so, whereas its position should be one of enabling both change to practice and flexible roles in the workforce.

There is a real need for legislative reform; without legislation, the changes proposed in this paper cannot be fully realised

Our proposals are intended to support the achievement of the ambitions of the *Five Year Forward View*[2], and other plans for workforce and service change across the UK. In particular the flexibilities we propose may be of value in the discussions currently taking place about new roles in the NHS, such as physician associates and nursing associates and about the role of regulation in the devolved Greater Manchester Health and Social Care Strategic Partnership.

Fitness to practise processes are lengthy and costly in both financial and personal terms. The confrontational nature of proceedings and the stress that hearings engender can affect the health and wellbeing of all concerned. The approach inherent in our existing fitness to practise arrangements runs counter to our growing understanding of the situations where things go wrong, and the inter-connections between workplace, leadership, culture, systems, human factors

1 Professional Standards Authority (2015) *Rethinking regulation*. Available at: www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/rethinking-regulation-2015.pdf

2 NHS England (2014) *Five Year Forward View*

and human behaviour. Regulators would prefer to shift their focus and expenditure, as a number are now trying to do, towards the prevention of harm and the maintenance of standards, building on these insights to achieve greater effectiveness, efficiency, and a reduction in harm to patients.

In this paper, we recognise the intentions of the government announced by the former Parliamentary Under-Secretary of State, Ben Gummer MP[3], in December 2015 when he set out the government's objectives for regulatory reform saying, 'Our priorities for reform in this area are better regulation, autonomy and cost-effectiveness while maintaining and improving our focus on public protection. We intend to consult on how these priorities can be taken forward, taking account of the Law Commissions' work on simplification and consistency and building on the Professional Standards Authority for Health and Social Care's paper *Rethinking regulation* published in August 2015. We will present proposals that give the regulators the flexibility they need to respond to new challenges in the future without the need for further primary legislation'[4].

In *Rethinking regulation* we argued that the whole regulatory system needed reform, including system regulators such as the Care Quality Commission, if regulation is going to be effective for patients and professionals alike. That is still our view. However, we have focused here on professional regulation alone.

There is a real need for legislative reform; without legislation, the changes proposed in this paper cannot be fully realised. We have also discussed in this paper improvements of approach, which might be achieved through collaboration, innovation, imagination and determination, rather than through legislative and structural change to the institutions of regulation. Those qualities will not, we are sure, be lacking in the regulators. However, real progress is necessary and while some change can be achieved within the legal framework we have this does not remove the need for new legislation.

The objectives we set out in *Rethinking regulation* align to a considerable extent with the government's intentions. They are:

- 'A shared 'theory of regulation' based on right-touch thinking
- Shared objectives for system and professional regulators and greater clarity of roles
- Transparent benchmarking to set standards
- A rebuilding of trust between professionals, the public and regulators
- A reduced scope of regulation so it focuses on what works
- A proper risk assessed model of who and what should be regulated put into practice through a continuum of assurance
- Breaking down boundaries between statutory professions and accredited occupations
- Making it easier to create new roles and occupations within a continuum of assurance
- A drive for efficiency and reduced cost which may lead to functional mergers and deregulation
- Placing real responsibility where it lies; with the people who manage and deliver care.

A shared 'theory of regulation' would encompass a common purpose, common objectives, and a shared understanding of the differences between regulation, inspection and quality improvement.

At the conclusion of *Rethinking regulation* we wrote 'some of this needs merely a change in thinking, a new attitude, a willingness to do less

3 Ben Gummer MP was appointed Minister for the Cabinet Office and Paymaster General on 14 July 2016

4 Regulation of Health and Social Care Professionals: Written statement - HCWS417, 17 December 2015

regulating and to take more responsibility for the quality of our own work, our team's performance, our organisation's delivery. Other changes will need legislation and a willingness to deregulate, and to sharpen regulatory tools where necessary'.

When in 2011 the Law Commissions set out on the task of revising the legal framework for professional regulation, they were charged with simplifying the law and improving public protection.

In this paper we propose a series of improvements to professional regulation. Our proposals are primarily focused on public protection and professional responsibility. They are intended to create clarity for patients, and allow greater flexibility of approach for regulators, employers, policy makers and others shaping the workforce. They will encourage a wide variety of regulatory interventions and responses to the regulatory challenges arising across different professions. We have sought to embody the idea of agility as one of the principles of good regulation, an idea we first put forward in 2008 when we wrote that 'regulators must be consistently in a state of readiness to respond to changes and developments in healthcare professional practice and circumstances'[5].

We have adopted three principles against which to test our proposals for change. They are that the health professional regulatory system should be:

- Proportionate to the harm it seeks to prevent
- Simple to understand and operate
- Efficient and cost-effective.

Those proposals which would require legislation might result in the removal of statutory regulation from some of the groups that are currently subject to it and in a reduction in the scope of statutory regulation. At the same time our proposal for a single register for health and care professions and occupations will potentially extend registration (though not statutory regulation) to a much larger group of health and care workers. It will also provide broader assurance to the public and employers about more of those working in health and care services, whether regulated or not.

Our proposals apply right-touch regulation principles, which advocate an efficient, risk-based approach to regulation, focused on the prevention and reduction of harm. In our publication *Right-touch regulation*[6] we also identify the different agents, such as employers, professional bodies, individual professionals, and service users, responsible for mitigating the potential risks presented by health and social care professionals. These same people will all have a role to play in honing, supporting, and implementing the changes suggested in this paper, particularly if the scope of regulation becomes more clearly focused.

We recognise that regulation at the national level can be a blunt instrument for mitigating risks of harm, as regulators are distant from the actual risks that they seek to manage. With the four UK health and care systems continuing to diverge, the improvements we propose would strike a balance between consistency and flexibility across and within the four countries of the UK to allow for the development of both local and national approaches where desirable. Our proposals would allow regulators to

5 Council for Healthcare Regulatory Excellence (2008) *Advice to the Department of Health and the Pharmacy Regulation and Leadership Oversight Group on aspects of the establishment of the General Pharmaceutical Council*. Available at www.professionalstandards.org.uk/docs/default-source/publications/policy-advice/establishing-the-general-pharmaceutical-council-advice.pdf

6 Professional Standards Authority (2015) *Right-touch regulation*. Available at www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/right-touch-regulation-2015.pdf

apply different approaches flexibly and creatively, striking the right balance between regulators and local management, and appropriate to the risks arising from the practice of their registrants. This would enable regulators to maximise their impact and influence to protect patients from harm.

In developing our proposals for regulatory reform we have drawn on our understanding of the current regulatory framework, including accredited registers, and on conversations with colleagues in the regulators and registers, with government officials and with health professionals, patients and service users in the UK. We have also made use of our understanding and experience of professional regulation in other jurisdictions around the world, particularly Canada and Australia. We have drawn on the many academic studies which are building an evidence base and we acknowledge the influence on our thinking of Professor Malcolm Sparrow of Harvard University[7].

We have adopted three principles against which to test our proposals for change. They are that the health professional regulatory system should be:

- Proportionate to the harm it seeks to prevent
- Simple to understand and operate
- Efficient and cost-effective

In a separate but complementary paper, *Right-touch assurance: a methodology for assessing and assuring occupational risk of harm* (2016)[8], we propose a methodology by which decisions about the risk of harm posed by occupations and professions could be profiled and how decisions could be made as to the proportionate level of assurance that is needed for each. We have summarised the methodology in Section 9 of this paper.

2. A shared purpose for regulators

We propose that in future, all parts of the regulatory system should have a shared purpose:

- Protecting patients and reducing harms
- Promoting professional standards
- Securing public trust in professionals;

and that all regulatory functions and activities should be directed towards and only towards those purposes.

This will ensure clarity of purpose and alignment of effort towards common goals, supported by shared professional standards. It will enable regulators and others to operate more effectively as a safety system, rather than working in silos with separate objectives and diluted impact.

In pursuit of our objective of simplicity and better understanding of regulation by the public we consider that a change of language is needed. The technical language of regulation is obscure and alienating for service users and registrants alike. The government itself has made a start in changing the language that relates to our appeal powers from 'unduly lenient' to 'insufficient to protect the public'. We propose that terms like 'fitness to practise', 'impairment' and 'revalidation' are avoided, and replaced with plain English. Further work will need to be undertaken to explore ways of describing regulation that are more readily accessible to everyone. We believe that the arrangements for licensing that we propose at Section 5 will be an important step towards public understanding.

7 Malcolm Sparrow (2008) *The Character of Harms and other works*

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

3. A renewed focus on core functions

We propose that the set of core functions carried out by regulators should be:

- To maintain a shared, public register of appropriately qualified health and care practitioners
- To award and renew licences to practise in specific occupations
- To set common standards that all registrants must meet
- To investigate allegations that registrants do not meet the standards and take action.

Implicit within these core functions are such roles as assuring that once registered, practitioners remain appropriately qualified and that they continue to meet professional standards.

In the absence of legislation, we are aware that some regulators are looking for a closer alignment of regulatory operations, and considering opportunities to work together to deliver functions on a shared basis. This should be particularly the case across occupations in similar working environments. This would apply for example to those working from 'High Street' commercial premises such as many registrants of the General Dental Council, General Optical Council, General Pharmaceutical Council, Pharmaceutical Society of Northern Ireland[9], General Osteopathic Council and the General Chiropractic Council.

In relation to the regulators of those professionals working in the 'High Street' we think that there would be merit in exploring the possibility of their assuming regulatory responsibility for the environments in which registrants work, as part of an improved strategic alignment of regulatory responsibilities. Under current arrangements, the CQC inspects dentists' and GPs' premises but not pharmacies or the premises of opticians, osteopaths or chiropractors. Merging the regulation of people and premises has advantages for patient safety as pharmacy regulation has shown. We propose that the regulation of premises of those working in 'High Street' practice is brought within the scope of the professional regulators.

In the longer term there would be merit in merging regulators to simplify access, improve efficiency and reduce costs. We discuss this further in Section 4, see page 6. Some regulators may wish to explore that option voluntarily in relation to alignment of their functions where this is possible within existing legislation.

We propose nevertheless a move to a shared and public-facing register for all people working in health and care, with a range of registration and licensing arrangements depending on the level of assurance needed. We believe that a single register, together with our proposal for common standards that apply to all, will support multi-disciplinary working, individual and collective accountability and team-based regulation. The register could be established as a shared portal and ultimately as a single entity.

We make specific proposals about reform of the approach to concerns about professionals' conduct or competence including replacing the language of fitness to practise with the concept of giving and taking away licences to practise certain occupations. This is discussed in Section 5. We encourage discussion of a new approach to quality assurance of higher education at Section 8.

9 We note that the PSNI is the only regulator in the UK which combines professional representation with regulation and that the Department of Health, Northern Ireland has recently consulted on its future.

We propose that the functions carried out by regulators should be:

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- To set common standards that all registrants must meet
- To investigate allegations that registrants do not meet the standards and take action

4. Effectiveness and efficiency

In pursuit of their objectives, regulatory bodies should direct their resources solely to those functions and activities that support their purpose. They should avoid activities which are better delivered through other organisations: employers, professional associations, unions, Royal Colleges, patient organisations and others.

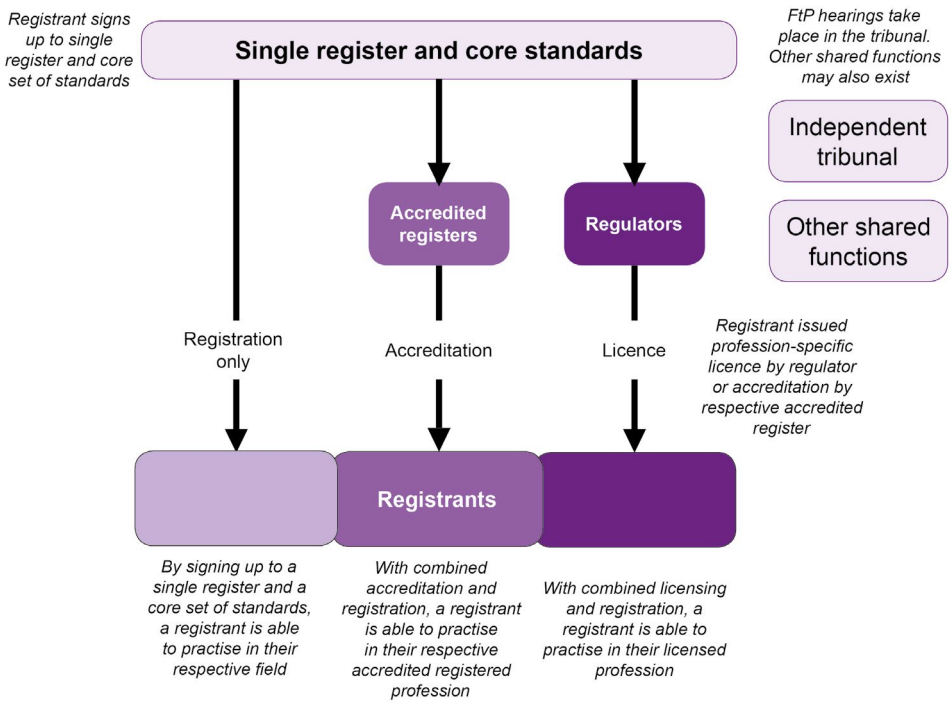
Regulators should continue to pursue cost-effective working. We propose that regulators in future should be held accountable for using their income for those purposes necessary to fulfil their functions as regulators, focused on ensuring that the required standards are being met. This should be a discipline within which all regulatory expenditure is framed. We propose therefore that regulators report annually on their cost-effectiveness, to support analysis, benchmarking and learning.

As there are several forms which mergers could take we have not explored in any detail here the cost benefits that might flow from merging regulators. However, our previous work on cost-effectiveness indicates there are significant savings to be made. Regulators should actively consider opportunities to reduce their number and share functions if savings can be realised by doing so. The Health and Care Professions Council, and the Australian Health Practitioner Regulation Agency demonstrate that multi-professional regulators can be both efficient and cost-effective. Several accredited registers, not constrained by statute, have already merged or are considering doing so.

When the opportunity exists for new legislation, we propose the creation of a single assurance entity for all health and care occupations. We describe this proposal in the Figure below. It would be responsible for a range of functions for all registered groups, including registration and licensing, the publication of a single register, maintaining a common set of standards for all registrants, and the receipt, investigation and prosecution of concerns about breaches of standards. It would contain regulatory bodies responsible for issuing licences, setting standards, quality assuring specialist education and training, and providing expertise where needed for the operation of the common functions. An independent tribunal service would perform the adjudication function across all professional groups for whom this type of quasi-judicial approach was deemed appropriate.

This proposed structure draws to some extent on the Health and Care Professions Council's multi-profession model and the Australian Health Practitioner Regulation Agency, both of which demonstrate the effectiveness of shared regulatory functions with no diminution of professional expertise. It would offer benefits to the public, employers and others in terms of the accessibility and transparency of regulation, providing a single destination to check registered practitioners and to raise concerns. While we acknowledge that there would be significant transition costs, it would

Figure: a single assurance body



also offer the potential to realise substantial efficiency and economies of scale in its operating costs once established and over the long term, and thus for reduction in registration fees. Some elements of this proposal are realisable within existing legislation, in particular a shared register, which we discuss below.

5. A shared, public register and a system of licensing

We propose that the regulators collaborate to establish a shared, public register for statutorily regulated professions, which in due course is extended to encompass accredited registers and other currently unregistered occupations, subject to proper risk profiling. This will make it easier for the public and employers to access and to understand, and together with shared professional standards, should support multi-disciplinary working, individual and collective accountability and team-based regulation. A single register, or initially a single portal, will provide a simple means for the public, employers, commissioners and others to find every registered practitioner, and check that they are licensed.

We propose that under this arrangement becoming registered would involve signing up to a *statement of professional practice*, a shared set of core standards that would apply to all health and care practitioners on the single register. The statement of professional practice would define the standards of conduct, behaviour and ethics required of all registrants, irrespective of their profession or occupation. Profession or occupation-specific standards would of course also be required, tailored to the clinical practice of each. We propose that higher risk occupations would then be

issued with a licence by their regulator allowing them to practise and appear on the register in that capacity. Others – namely those currently under the remit of accredited registers but also those in future covered by credentialing[10] – would be registered and accredited but not licensed, and therefore subject to proportionate registration and renewal requirements. Among the licensed groups, a range of requirements could apply for awarding and renewing of the licence, depending on the levels of assurance required, including restricting scopes of practice where necessary.

A wider part of the workforce such as care assistants could be registered, signing up to the statement of professional practice in a similar way to the employers' code of conduct for such groups used in Scotland. Registration and deregistration could be linked to the Disclosure and Barring Service.

The creation of a shared public-facing register and a licensing system would provide a simple means for the public, employers, commissioners and others to find registered practitioners, and check they are licensed. It would also help better public understanding of the purpose of regulation, since the concept of licensing is well understood by the public, in particular of course in relation to driving licences and the Driver and Vehicle Licensing Agency (DVLA). We do not claim that driver licensing is as complex as regulating health professionals, but we do believe that the language of registration and licensing would provide a frame through which the purpose and functions of regulation can be made clearer and more accessible to everyone.

10 'Credentialing' in this context refers to the NHS project developing a method of ensuring safety of patients and staff for unregulated occupations, ahead of encouraging the formation of an accredited register. 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.

For this model to be consistent and risk based we need a rational and consistent approach to which occupations are or are not registered or regulated. To support this we have developed a methodology for determining the appropriate level and type of assurance needed to protect the public from the risk of harm, which we set out in our complementary paper *Right-touch assurance: a methodology for assessing and assuring occupational risk of harm* (2016) and summarise below in Section 9.

6. Working in partnership to prevent harm and promote professionalism

Research and studies of human factors, safety science, behavioural science and organisational psychology, major inquiries and investigations incontrovertibly demonstrate the behavioural links between systems, organisations, places and people. Therefore, preventing and reducing harm, promoting professionalism, improving quality and encouraging compassionate care require a coordinated approach by regulators, employers, educators and professional bodies. Professional and system regulators and educators need to share intelligence and alert each other to heightened risk of harms. They need to use their insights to support employers to recognise the circumstances in which harm occurs, and to support the development of cultures, workplaces and systems that empower registrants to comply with professional regulatory standards. Fitness to practise data in particular can yield insights to help others who are closer to potential problems to take preventative action. Its analysis can assist in the identification of situational factors most prone to be associated with complaints. It provides a starting point for further analysis and research into why such patterns exist and how they might be best addressed.

This requires the continuation of the change of emphasis by regulators from responding to complaints to contributing insight and knowledge to the active prevention and reduction of harms. It also requires a careful approach to ensure that in working in this way, the responsibilities of different organisations remain clear and organisational boundaries are maintained. Regulators will need to continue to work with stakeholders to build the relationships through which they can exert influence and achieve impact, building on the insights that are already emerging through data analysis. The focus of this work should be to support preventative measures being taken by those who are closest to problems.

7. Maintaining standards, preventing harm

Fitness to practise proceedings are protracted and expensive, the number of cases which go through the process resulting in a decision to take no further action is too high, and patients and the public feel disenfranchised from the process even where they may feel that they have paid a high personal price for raising a concern with a regulator. The experience of patients, professionals and employers of the current procedures often fail the trust and confidence tests we set ourselves in thinking about a new way of doing things. Regulators themselves are frustrated by the limitations of the legislation within which their processes operate. Therefore we believe that a significant change of approach is needed.

We propose that the purpose of procedures to assess, investigate, prosecute and adjudicate on competence, conduct and health concerns across the professions should reflect the proposed purpose of the regulatory system as a whole, as set out in the first paragraph of Section 2 (see page 4):

- Protecting patients and reducing harms
- Promoting professional standards
- Securing public trust in professionals.

We propose that regulators' focus should remain on whether a registrant is fit to practise (although described with plainer language). It should not become a complaints process with the focus on redress or other remedies for people who complain. The tests of conduct and competence applied in fitness to practise proceedings are important and need to remain. However, we do believe the regulators should continue to move towards shorter, less costly and more consensual ways to close cases. Regulators also need to identify trends, correlations with organisational and human factors and potential risks of harm that should be brought to the attention of healthcare providers, other regulators and improvement bodies to contribute to reducing harms.

The purpose of fitness to practise procedures:

- Protecting patients and reducing harms
- Promoting professional standards
- Securing public trust in professionals

We do however believe that the language used to describe fitness to practise processes should be more plain English to make them easier for all to understand. The adoption of a licensing system and associated language would, we believe, make the purposes of fitness to practise more accessible and create clearer expectations for people who complain.

Local resolution

The health and care regulators have worked hard over recent years to make the experience of raising a concern, and appearing as a witness at a hearing, less stressful and time-consuming for the public. However, it is their role as a witness to the regulator's proceedings that is often dissatisfying to people who complain; the focus of the process is the registrant not the patient.

We consider that a larger proportion of those cases currently handled by regulators' fitness to practise processes could be resolved locally by employers, registrants and local mediation where available. Many cases which may not require regulatory attention are subject to investigation and processing. If the Responsible Officer role were expanded to all regulated professions it would provide a means of encouraging better complaints handling by registrants, and better use of local processes, ensuring that matters were resolved more quickly and effectively. It would also support the separation of complaints from fitness to practise concerns, and enable appropriate handling of both.

We believe that some of the other changes that we are proposing – in particular the idea of a single shared register and a system of licensing for professionals – will help the public to understand the role of regulation, and the distinction between regulatory proceedings and a complaints procedure. The idea of a licence to undertake particular activities such as driving is well understood as are different driving tests and licences for different vehicles and the idea of points on a licence or removal of a licence for the most serious offences.

Adopting an inquiring instead of a confrontational approach

We believe that under new legislation there should be a change from the current adversarial approach in fitness to practise to one which is more inquisitorial, in other words, based more on inquiring into the circumstances of a case. The process should allow for non-confrontational exploration of the circumstances in which alleged misconduct occurred, with opportunities for resolving a case through discussion and agreement, without the need for a formal hearing.

Of course the committees of regulators currently have the ability to be inquiring but this is not their primary approach. Our proposal would build on that and would provide the basis for a more proportionate, quicker and more cost-effective resolution, with less reliance on a final hearing. In order to achieve this it will be necessary to add to the various methods of resolving complaints or concerns about registrants which are currently available (short of a full panel hearing) in order to make registrants more likely to accept these alternatives. There might also have to be a strengthening of powers or abilities to deal with registrants restrictively who do not engage or co-operate. Clearly this would require new legislation.

There needs to be a greater emphasis on addressing cross-professional or organisational questions which are difficult for the current model to deal with. New processes could allow an adjudicator to suggest to a registrant that, on the basis of the untested evidence, there was a real question about their fitness to practise. This could then be addressed by remedial activity, or in cases of wider public interest agreement to an appropriate sanction.

The key advantage would be for the case to be looked at as a whole, identifying the risk to the public posed by the behaviour concerned. If a professional is given an indication of how seriously his or her regulator views their conduct at an early stage, this could result in resolution without recourse to a full hearing. The employer might have input to, and oversight of, any remedial activity and ensure that learning is utilised, at a local level.

For those cases that did require a public hearing (and criteria would need to be developed to describe this category of case), the file of evidence obtained by the regulator should be considered by an adjudicator to identify the questions which need to be addressed by the regulator and the registrant.

Achieving efficiency and consistency through shared delivery of investigation, prosecution and adjudication

There is scope for considerable benefits in terms of consistency and efficiency to be achieved by regulators collaborating to deliver their investigation, prosecution and adjudication functions in a shared way.

There would be particular benefits from shared adjudication across all professions, by a separate tribunal service, building on the model developed by the Medical Practitioners Tribunal Service. This would reduce variability and would potentially generate cost savings from economies of scale. There would be other benefits such as more straightforward monitoring of performance and statistics, and the opportunity to develop greater expertise of hearing panellists. A number of the regulators are already exploring with the GMC the possibility of a shared tribunal service.

Similarly, we also believe that there would be merit in exploring how regulators could collaborate to establish shared investigations and prosecutorial arms, whether in-house or by managing legal services provided by panel firms. This would help to increase consistency both in the conduct of investigations and in the way that cases are presented to panels, thereby removing or at least alleviating in particular the under-prosecution that the Authority continues to identify in a number of cases.

8. Exploring a new approach to education and training regulation

There is currently a wide range of practices and approaches across the regulators in relation to the way in which they quality assure higher education courses. These are to some extent determined by different legislative requirements. We recognise that these also reflect the fact that different occupations require different types and levels of education and that education has changed over time. Regulators have adapted their approaches to the various models of assessment, examination, education and training that exist for the different professions. Individual regulators assure the quality of assessment, education and training against different sets of standards, and there are various methods used to determine how and when on-site inspections and desk-based assessments are undertaken. Some regulators are making particular efforts to ensure that the courses they quality assure are preparing students for the roles of the future, for example, the General Optical Council has recently commenced a review of the standards of competence that students must meet and how they are assessed in view of future effects of technological change and enhanced services. Others are seeking to

simplify and rationalise the standards they apply – for example, the General Medical Council from January 2016 has introduced a single set of standards covering its span of both undergraduate and postgraduate medical education. The responsibilities of the GMC for postgraduate and specialty training are significantly different from those of other regulators.

We consider however that the current arrangements for the regulation of undergraduate and other pre-registration training tend to duplication of regulatory responsibilities between professional regulators and other regulators in education, and this may be resulting in unnecessary expense and regulatory burden on higher education and training institutions.

We recommend that the health professional regulators should ensure that their focus is upon setting and assessing the learning outcomes required for registration, since it is through examination and assessment that a student or trainee actually demonstrates competence in the relevant profession and therefore that they are suitably qualified for registration. This would leave other regulators and quality assurance mechanisms to deal with broader questions of course management. Regulators would continue to work in partnership with higher education institutes (HEIs) and other training providers to understand the impact of future population and workforce needs.

We believe that such a change of approach would offer the potential for cost-savings and efficiency in the way that registrants prove their suitability for registration, as well as reducing the regulatory burden on HEIs. The introduction of a common statement of professional practice discussed in Section 5, see page 9 would provide a focus for ensuring consistency in the values that underpin training courses across professions.

For these reasons we propose a review of regulatory approach and responsibilities in this area, working together with other bodies involved in the regulation of universities and other training institutions, and with the bodies delivering training themselves. The objectives of the review would be to ensure that regulators have a clear focus, are sharing intelligence appropriately, and are not duplicating each other's responsibilities. A review would also seek to ensure that there is a clear rationale for differences of practice and approach, and that such differences are proportionate and risk-based.

9. Right-touch assurance: a methodology for assessing and assuring occupational risk

In parallel with our proposals for regulatory practice improvement we have proposed a methodology for assessing occupational risk, with which to determine which occupations should be statutorily regulated, which risks are effectively controlled within an accredited register, and which can be well managed by employers. This approach should help the Department of Health and others make more objective and transparent decisions in relation to roles such as physician associate and nursing associate. This aspect of the reforms we propose is not dependent on legislative change and aligns closely with the principles of right-touch regulation. The proposed methodology is set out in detail in our paper *Right-touch assurance: a methodology for assessing and assuring occupational risk of harm* (2016).

In the short term, we anticipate that our developing approach will be employed to assess new occupations to determine what type of oversight would be appropriate to manage risk of harm. In the long term, the methodology could have a broader function of determining the appropriate level of assurance for those occupations already on

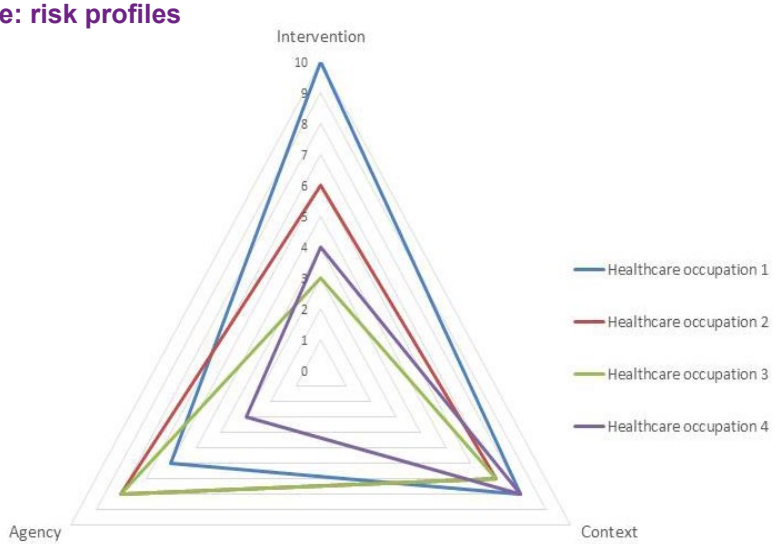
either the statutory or accredited registers, recommending the appropriate point on the continuum of assurance (see below) at which any given occupation should sit. The methodology may also be used or adapted by the regulators to aid decisions on whether or not specialties should be regulated, if there should be other types of annotation on the register, as well as reviewing provisional and student registration. Our intention is that the methodology should be used to support decisions about the type and degree of assurance needed to manage the risk of potential harm. This approach supports the single register and licensing model set out above.

Our proposed methodology for right-touch assurance is a two-stage process. Whilst we employ scoring, the decision to be made by government is a matter of judgement based on information, not a matter of science or of ideology.

The first stage is to create a risk profile of an occupation taking into account the intrinsic risks of harm arising from clinical care or practice, the context of the practice and the agency of the patient and service user. Hazards associated with the practice of an occupation are grouped into three broad categories as outlined in *Right-touch regulation*. These are intervention (the complexity and inherent dangers of the activity), context (the environment in which the intervention takes place) and agency (service user vulnerability or autonomy). For existing professional groups, an important source of evidence will be fitness to practise data, to establish actual harm that has been caused, its severity and its prevalence. Based on an assessment of the evidence related to the hazard, a risk score is allocated to each category and then to the occupation overall. By plotting the score on a radar chart, a risk profile can be created for each occupation. This is illustrated below.

Once the hazards are understood and the risk of harm described through an occupation's risk profile and volume, in a second stage the occupation or profession will be considered against the assurance assessment criteria. This assessment will inform where the profession or

Figure: risk profiles



occupation sits on the continuum of assurance and allow the formulation of advice to government. The criteria identify extrinsic factors that may mitigate the risk of harm occurring or, conversely, increase it thereby altering the risk volume. This allows the use of a right-touch approach and ensures that any action is proportionate.

10. Conclusion

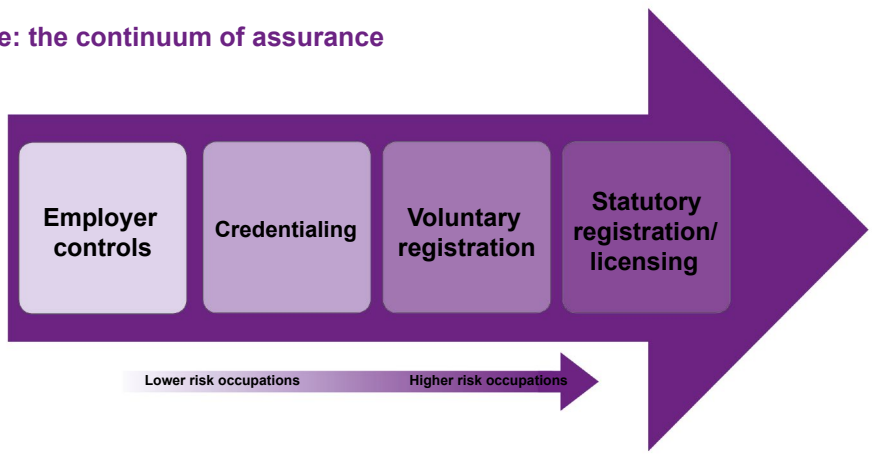
In Section 1 of this paper we set out three principles against which to test our proposals. We believe that a health professional regulatory system reformed in the way that we propose would be:

- Proportionate to the harm it seeks to prevent: because it would be risk based, because decisions on regulatory arrangements would be determined through the continuum of assurance, and because it would have a clear and shared purpose and set of core functions
- Simple to understand and operate: because of the greater simplicity of a single register and other merged functions, because of the adoption of a well-understood licensing regime, and through reforms to the language with which regulatory processes are described
- Effective and efficient: because it would seek to benefit from available economies of scale through mergers and other alignments of regulatory responsibility, it would use its intelligence towards prevention of harm away from costly fitness to practise processes, and because it would focus its use of resources on its core functions.

The Authority is committed to working with partners and stakeholders to take forward reform in our sector. There is already considerable momentum and energy for future change, to make regulation yet more focused on the interests of the public and to ensure more efficient spending on regulatory functions. We believe that the proposals we have set out in this paper will build on this and help achieve these aims. Detailed work will be needed to develop plans for implementing these proposals, and further, to prepare for future opportunities for legislative change.

With cooperation, imagination, innovation and determination much may be achieved, but it is only with new legislation that the radical reform we propose in this paper can be fully realised.

Figure: the continuum of assurance



Annex A: Table of proposed changes

	Practice changes proposed	Legislative change required?
Shared purpose	Agreement on common purpose across the sector: explore common interpretation and explore scope to harmonise and agree common outcomes. Adopt plain English in public-facing communications.	Change to statutory objectives required to achieve outcome.
Single register	Establishment of a single assurance body holding a shared public-facing register of all health and care professions and occupations.	Required to establish a single assurance body.
Common standards	Agreement on statement of professional practice, i.e. common professional standards agreed by consensus between regulators and accredited register holders to apply to all registrants whether licensed or not. Develop profession/occupation specific standards as necessary.	If required to codify a common set of standards applicable to all registrants.
Licensing	Establishment of a licensing regime. Adopt language change to align with a licensing process, similar to DVLA. Explore scope for issuing licences within existing legislation and proportionate approaches to different professions.	Required to establish formal power to issue licences.

Fitness to practise	Adoption of shared approach to key elements of fitness to practise: investigation, prosecution, and adjudication (building on MPTS); explore scope to further harmonise sanctions; explore scope for achieving a more inquisitorial approach within existing legislation. Use of clearer, more public-focused language. Further co-operation with employers to achieve local resolution at an earlier stage where possible.	To enable adoption of an inquisitorial approach and to enable harmonisation of sanctions.
Co-operation with others	Further implementation of co-operative working in particular to use regulatory data and insight in partnership with others to reduce harm.	Legal duty of co-operation only if required to achieve change.
Education	Review arrangements for quality assurance of education in view of current and future needs. Explore new approach to align with licensing regime, based on assessment of applicant.	As required to enable change of focus.
Cost-effectiveness	Introduce accountability for cost-effective working with regular formal assessments of regulators' cost-effectiveness and efficiency.	New legislation required if decision taken to pursue merger of regulators.
Right-touch assurance	Implement methodology set out in *Right-touch assurance: a methodology for assessing and assuring occupational risk of harm.*	Legislation not required.

Annex B: Table 1 Statutorily regulated professions, accredited registers of occupations, and other occupations

Type of regulation	Regulator	Occupation/*other*
Statutory	General Chiropractic Council	• Chiropractors
	General Dental Council	• Dentists • Dental hygienists • Dental therapists • Clinical dental technicians • Orthodontic therapists • Dental nurses • Dental technicians
	General Medical Council	• Doctors
	General Optical Council	• Dispensing opticians • Optometrists • *Students* • *Optical businesses*
	General Osteopathic Council	• Osteopaths
	General Pharmaceutical Council	• Pharmacists • Pharmacy technicians • *Pharmacy premises*
	Health and Care Professions Council	• Arts therapists • Biomedical scientists • Chiropodists/Podiatrists • Clinical scientists • Dietitians • Hearing aid dispensers • Occupational therapists • Operating department practitioners • Orthoptists • Paramedics • Physiotherapists • Practitioner psychologists • Prosthetists/Orthotists • Radiographers • Social workers in England • Speech and language therapists
	Nursing and Midwifery Council	• Nurses • Midwives
	Pharmaceutical Society of Northern Ireland	• Pharmacists • *Pharmacy premises*

Professional Standards Authority Accredited Registers programme[12,13] NOTE – all of these registers are voluntary to join, meaning that it is not a requirement so some of the workforce in these occupations may choose not to join and therefore be unregulated. In addition there are a number of other voluntary registers that have either not yet gained or have not sought accreditation, however these have not been included for this purpose	Academy for Healthcare Science	Healthcare science practitioners working in a wide variety of disciplines, *including*: • Physiological sciences • Microbiology • Nuclear medicine • Life sciences • Health informatics • Physical sciences • Healthcare science • Haematology • Biomedical science • Biomechanical engineering • Bioinformatics • Audiology • Anatomical pathology technologists • Genetic technologists • Ophthalmic science practitioners • Tissue bankers
	Alliance of Private Sector Practitioners	*Including*: • Foot health practitioners
	Association of Child Psychotherapists	*Including*: • Psychoanalytic child psychotherapists • Adolescent psychotherapists
	Association of Christian Counsellors	*Including*: • Psychotherapists • Counsellors
	British Acupuncture Council	*Including*: • Acupuncturists
	British Association for Counselling and Psychotherapy	*Including*: • Psychotherapists • Counsellors
	British Association of Play Therapists	*Including*: • Play therapists
	British Association of Sport Rehabilitators and Trainers	*Including*: • Graduate sport rehabilitators

12 Please note that the occupations listed in this section of the table are not exhaustive for each accredited register, given the large number of modalities and disciplines in some areas.
13 Please note that two of the accredited registers (Save Face and Treatments you can Trust) register people who are only statutorily regulated.

	British Psychoanalytic Council	*Including*: • Psychotherapists • Counsellors
	Complementary and Natural Healthcare Council	Complementary therapists working in a range of modalities *including*: • Sports therapists • Nutritional therapists • Reflexologists • Naturopaths • Massage therapists • Hypnotherapists • Acupuncturists • Craniosacral therapists • Bowen therapists • Alexander Technique practitioners
	COSCA (Counselling & Psychotherapy in Scotland)	*Including*: • Counsellors • Psychotherapists
	Federation of Holistic Therapists	Complementary healthcare therapists working in a range of modalities *including:* • Yoga therapists • Sports therapists • Shiatsu practitioners • Reiki healers • Reflexologists • Nutritional therapists • Massage therapists • Naturopaths • Kinesiologists • Hypnotherapists • Homeopaths • Craniosacral therapists • Aromatherapists • Bowen therapists • Acupuncturists • Alexander Technique practitioners
	Genetic Counsellor Registration Board	*Including*: • Genetic counsellors
	Human Givens Institute	*Including*: • Psychotherapists • Counsellors

	National Counselling Society	*Including*: • Psychotherapists • Counsellors
	National Hypnotherapy Society	*Including*: • Hypnotherapists
	Play Therapy UK	*Including*: • Play therapists
	Register of Clinical Technologists	Clinical technologists working in a variety of disciplines, *including*: • Renal technology • Radiation physics • Rehabilitation engineering • Radiotherapy physics • Radiation engineering • Medical engineering • Clinical technology • Nuclear medicine • Healthcare science • Clinical science
	Save Face	*Including*: • Doctors • Nurses • Dentists Covering non-surgical cosmetic injectables
	Society of Homeopaths	*Including*: • Homeopaths
	Treatments You Can Trust	*Including*: • Doctors • Nurses • Dentists Covering non-surgical cosmetic injectables
	UK Council for Psychotherapy	*Including*: • Counsellors • Psychotherapists
	UK Public Health Register	*Including*: • Public health practitioners • Public health specialists • Specialist registrars

Table 2: Unregulated occupations

	Category	Roles
Currently unregulated occupations NOTE – this is intended to be indicative only and not a comprehensive list as the status of different occupations is subject to change	Physical health	*Including*: • Physician associates • Health care assistants • Nursing associates (new role to be created) • Alternative therapists practitioners not covered by relevant accredited registers
	Health promotion and protection	*Including*: • Health records and patient information • Clinical management
	Mental health and wellbeing	*Including*: • Psychological therapy practitioners and counsellors not covered by relevant accredited registers
	Social work and care	Including: • Care workers/care assistants • Home care workers • Personal assistants

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