2. Harm prevention: can we reduce the amount of harm?

Chapter summary

2.1 In *Regulation rethought*[14] the Authority recommended that 'protecting patients and reducing harms' should be one part of the shared purpose of the regulatory system. This is a growing area of interest in research and policy development, and the Authority is keen to progress and clarify thinking in the sector about what is the proper place of regulation in this respect.

2.2 In this chapter, we start by identifying some of the kinds of harm that can occur, and how the core regulatory functions are by their nature preventative. We outline in some detail how regulators are taking forward, through their continuing fitness to practise programmes, ways to prevent harm to patients by supporting and encouraging registrants to remain compliant with regulatory standards throughout their careers.

2.3 We discuss the policy questions that arise from thinking about how regulators might try to do more to prevent harm, setting out some relevant theoretical perspectives, and discuss some of the key ideas in the academic literature about how this might be achieved. While much of the focus in this section is on fitness to practise and the data associated with it, it is important to stress that all regulatory functions contribute to harm prevention.

2.4 We have made a number of recommendations for future work, building on that which is already underway by the Authority and regulators. The chapter is intended as a contribution to the ongoing discussion about the role of regulators in preventing harm to patients. It is not a literature review of this subject, but references some recent thinking which we believe is particularly salient and useful for future policy development.

2.5 As we wrote in *Rethinking regulation*,[15] we understand the challenge of harm prevention to mean 'how can regulators, through their interventions and influence, reduce the prevalence of instances of noncompliance with their standards?' Another way to put the question might be, how and to what extent can regulators shrink the amount of harm, both through their own interventions and those which are achieved through collaboration?

[14] Professional Standards Authority, 2016. *Regulation rethought*. Available at https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/regulation-rethought.pdf?sfvrsn=14&sfvrsn=14 [Accessed 1 November 2017].
[15] Professional Standards Authority, 2015. *Rethinking regulation*. Available at https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/rethinking-regulation-2015.pdf [Accessed 1 November 2017].

Background and purpose

2.6 The standards of competence and conduct set by the regulators address a wide range of aspects of professional practice. Conversely, the fitness to practise cases that result when it is alleged to the regulator that these standards have not been met encompass a wide range of unprofessional behaviours. These can result in many different kinds of harm including, but not limited to:

- Harm to the physical and/or mental health of patients and those close to them, their career, financial status and family life, sometimes irrevocable
- Harm to the physical and/or mental health of the registrant, their career, financial status and family life, sometimes irrevocable
- Harm to the reputation of an organisation delivering care – thus damaging the trust of future patients in the safety of care
- Disruption to the ongoing work of teams, and thus potentially to the quality of patient care in the future
- Damage to the relationship between a registrant's colleagues and their regulator, register-holder and/or employer.

2.7 When referring to harm in this chapter, we use the term harm to mean the harmful impact of the kinds described above that can result from a particular situation or set of circumstances. In *Right-touch regulation*[16] we defined harm as 'physical injury or psychological distress experienced by people through interaction with health or social care practitioners'. We use the term risk to mean 'the likelihood of harm occurring'[17] or the probability of a particular situation or set of circumstances resulting in harm. Many of the fitness to practise cases that are reviewed by the Authority include situations where a health or care professional has exposed a patient, colleague or other to increased risk of harm where they would be expected to have acted otherwise, even where the potential harm has not materialised. The approaches we discuss in this section to harm reduction should be taken also to refer to preventing situations occurring where patients and others are exposed to elevated risk in this way.

2.8 The specific types of misconduct or failures of competence which can result in harm are also wide-ranging – by way of demonstration, we list at Appendix I the categories of misconduct that are used on the Authority's database of final fitness to practise hearing determinations. These categories, while not to be confused with the harm they cause, illustrate the different kinds of event and behaviour to which patients and those close to them can be subject, and of which any of the types of harm listed above can be the consequence. We recognise that harm

[16] Professional Standards Authority, 2015. *Right-touch regulation - revised*. Available at https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/right-touch-regulation-2015.pdf [Accessed 1 November 2017].
[17] Professional Standards Authority, 2015. *The role of risk in regulatory policy*. Available at https://www.professionalstandards.org.uk/docs/default-source/publications/research-paper/risk-in-regulatory-policy-2015 [Accessed 1 November 2017].

occurs in ways other than in consequence of those matters which come before regulators' fitness to practise proceedings, which are concerned with the most serious matters, and do not profess that these form a comprehensive account of all harm that is caused to patients.

2.9 Fitness to practise and complaint processes occur after the fact – after the alleged harm has occurred. An emerging area of interest in regulatory policy in recent years however has been the potential of regulators to contribute to harm prevention. This has also been referred to as regulators becoming more upstream of problems before they occur. As we said in *Rethinking regulation*, 'how can regulators, through their interventions and influence, reduce the prevalence of instances of non-compliance with their standards?' Another way to put the question might be, how can regulators reduce the volume of harm, both through their own interventions, and through those which are achieved through collaboration?

2.10 Seeking to answer this question results in a number of interesting regulatory policy challenges. First, as analysis of fitness to practise cases shows, every such case turns on its own unique circumstances, a combination of personal, environmental and other factors. How can learning be drawn from such specific incidents, in such a way as to change the sequence of distant and future events to a different outcome? Regulators (and the Authority) hold a huge body of data on previous fitness to practise cases, but how capable is this data of supporting retrospective analysis, having been collected in fulfilment of a legal process, not a descriptive one? How can regulators best use their data or share their knowledge with other agencies optimally placed to intervene? How can they encourage potential informants to take prompt action when they think that a registrant is increasing the risk of harm to patients, and bring relevant information to the regulator's attention? How can they encourage and support the public in particular to ask questions or raise concerns when they think that something just isn't right?

2.11 These are just some of the issues that arise from trying to elucidate the potential opportunities, but also to define the boundaries, of how regulators might refashion their approaches to be more preventative of harm. Yet, to address and overcome these challenges and translate these insights into regulatory interventions would have many benefits – principally of course improvement to safety through the reduction of harm caused to patients and those close to them.

2.12 An example of an approach to harm, taken by the Australian Health Practitioner Regulation Agency, places it in the context of risk-based regulation, with the aim to 'collect information on harm in a systematic manner, and then identify hotspots of risk that are amenable to a regulatory response'. This approach entails:

- 'A focus on identifying and reducing risks and harms
- Selective action based on identified risks
- Evidence based regulatory action and policy
- Using a wider range of practice to prevent harm

- Reducing unneeded regulatory interventions'.[18]

2.13 It is tempting to draw the conclusion that the successful implementation of further preventative strategies might result in a reduction in the volume and thus costs of fitness to practise cases, and thus the costs of regulating overall, even despite the resources required to do so, through a reduction in harmful incidents. As the saying goes, 'if you think safety is expensive, try an accident'[19]. The ideas that we discuss in this chapter might also have the potential to reduce the number of allegations being made inappropriately to regulators, which it could also be assumed would have a positive impact on costs. However, we recognise that the cost of fitness to practise as a regulatory function has a number of contributory factors; it is not yet possible to offer any kind of cost-benefit analysis to these questions. We hope in time that it will be.

2.14 We are mindful of the challenge that was given to the General Medical Council (GMC), which we believe applies to all regulators, by the *Report of the Morecambe Bay Investigation*[20]: 'the GMC must use its wealth of knowledge, experience and its capacity as a regulator to approach patient safety from a wider, more holistic perspective to ensure that it maintains its focus on protecting the public while continuing to maintain standards within the medical profession', which we believe applies to the ambition of aiming to be more preventative. The challenge is how regulators can use their position within the architecture of care to do more, and to make their interventions more effective and influential. Can they use their insight, data, knowledge and relationship with registrants and with the public to further shrink the amount of harm?

2.15 At the same time we are cautious to strike the right balance between, on one hand the proper pursuit of creative innovation and exploratory thinking, and on the other, the risk of creating unnecessary and unhelpful duplication or ambiguity of responsibility. Regulators are geographically, and probably psychologically, distant from harmful situations; they are only one of a number of influences on practice. They must avoid blurring their responsibilities with those who are closer, and take care to make their contribution complementary to those others guiding practice. As Quick observed, 'if a number of sources of influence all nudge practitioners in the same direction (eg, terms of employment contracts, clinical guidelines, professional regulation, professional leadership, law and financial incentives) regulatory goals stand a better chance of being realised'[21].

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[18] AHPRA working definition of risk-based regulation, and following bullet points, were presented to the International Society for Quality in Healthcare International Conference, London, October 2017, by Martin Fletcher, Chief Executive. Quoted here with permission.

[19] As quoted for example by Sir Stelios Haji-Iannou in *Management Today*, 1 June 2010. Available at https://www.managementtoday.co.uk/mt-interview-sir-stelios-haji-ioannou-easyjet/article/1004499 [Accessed 1 November 2017].

[20] Kirkup, B, 2015. *The Report of the Morecambe Bay Investigation*. The Stationery Office. Available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/408480/47487_MBI_Accessible_v0.1.pdf [Accessed 1 November 2017].

[21] Quick, O, 2011. *A scoping study on the effects of health professional regulation on those regulated. Final report submitted to the Council for Healthcare Regulatory Excellence.* Available at http://www.professionalstandards.org.uk/docs/default-source/publications/research-paper/study-on-the-effects-of-health-professional-regulation-on-those-regulated-2011.pdf [Accessed 1 November 2017].

2.16 Regulators must also be careful to ensure that their primary focus remains on registrants meeting standards, rather than seeking to improve quality across the board. As we have previously observed, 'inspection, regulation and quality improvement are different things. The role of regulation is primarily to control quality and ensure minimum standards rather than to improve quality'[22] although it may have that effect over time. We recognise that many of the interventions described in this chapter and beyond may have a positive impact on quality, but that is not the primary role of the regulator.

[22] Professional Standards Authority, 2017. *Comments on the Welsh Government consultation 'Services fit for the future'.* Available at https://www.professionalstandards.org.uk/docs/default-source/publications/consultation-response/others-consultations/2017/professional-standards-authority-response---welsh-government-services-fit-for-the-future-consultation.pdf [Accessed 1 November 2017].

The contribution to prevention of the core regulatory functions

2.17 All of the existing core regulatory functions can be seen as contributing to the prevention of harm. In fact, they are all inherently preventative. Regulators apply controls to entry to their registers and quality assure higher education courses to ensure that registered professionals hold the correct, and appropriate qualifications and are fit to practise. Regulators' standards set out the professional behaviour to which registrants should adhere, and registrants are aware that they may be subject to regulatory scrutiny through fitness to practise processes if it is alleged to the regulator that these standards have not been met. The standards include that registrants must take action if they believe that a colleague is placing patients at risk of harm, thus in theory establishing a mechanism whereby problems, or potential problems, are intercepted at an early stage. Fitness to practise processes can remove a registrant from practice entirely or temporarily to prevent future harm.

2.18 Yet we know that in some respects, the underlying logic and intention of these interventions does not translate to their fulfilment in the realities of daily practice. For example, we know from the work that we commissioned from Quick in 2011 that there is little evidence of the impacts of regulators' standards on behaviour in practice; few researchers have directly addressed this question, possibly a reflection of the difficulty of establishing a methodology which is able to discern the impact of regulation from the many other behavioural influences that affect professionals. We also know from inquiries into instances of the most serious, concerted and long-lasting harm to patients that there are always people close to the situation who know what is happening, but who do not take action, whether or not they are subject to a professional responsibility to do so.

2.19 One area in which considerable progress has been made has been in the regulators' developing mechanisms to require registrants to demonstrate their continuing fitness to practise. This has increasingly elided with their work to set and promote standards. We discuss this in more detail in the next section of the chapter.

Compliance with standards and continuing fitness to practise

2.20 Seeking to ensure that registrants remain compliant with regulatory standards, and harm prevention, are very closely-aligned objectives. In 2012, in our paper *An approach to assuring continuing fitness to practise based on right-touch regulation principles,*[23] the Authority proposed that:

[23] Council for Healthcare Regulatory Excellence, 2012. *An approach to assuring continuing fitness to practise based on right-touch regulation principles.* Available at https://www.professionalstandards.org.uk/docs/default-source/publications/policy-advice/continuing-fitness-to-practise-based-on-right-touch-regulation-2012.pdf?sfvrsn=6 [Accessed 1 November 2017].

- In developing continuing fitness to practise schemes, the regulator's role should be focused on ensuring that registrants continue to meet the standards of conduct and competence rather than a narrower focus on measurement of inputs such as hours of continuing professional development (CPD) activity
- The task of seeking to ensure continuing fitness to practise (CFtP) is supported by the regulatory functions of education, standard setting, registration and fitness to practise
- Regulators should take a proportionate approach when developing appropriate continuing fitness to practise mechanisms, based on a clear assessment of the level of risk of harm in the practice of the regulated group, where and why the risk occurs and the context in which the regulated group operates
- Continuing fitness to practise measures should be clearly targeted at areas of risk in performance but regulators should also utilise any existing mechanisms which can help to ensure ongoing compliance with the standards
- Regulators should assess the reliability of different levels of assurance provided by different CFtP measures pursued by assessing how accurately it helps them identify those who continue to meet the standards. The level of risk should determine how reliable a response needs to be
- There should be transparency to the public on the level of assurance provided by different mechanisms and on how decisions are made on what level of assurance is needed.

2.21 The arguments were made in the context of the then ongoing overhaul of medical revalidation by the GMC following the recommendations made by the Shipman Inquiry, and following a steer from the Government in *Enabling Excellence*[24] that any revalidation scheme proposed by the other regulators must be proportionate and demonstrate 'significant added value in terms of increased safety or quality of care for users of health care services'.

2.22 Work in this area has developed in different ways but generally there has been a significant shift from purely input-based systems such as hours-based CPD requirements to much broader frameworks of activity based on assessment of registrants' ongoing fitness to practise and consideration of more innovative measures seeking to ensure that registrants understand and continue to comply with the standards throughout their professional life. Our 2012 paper outlined a continuum of different frameworks for ongoing assurance, based on the level of risk to be addressed. However, since then, a wider spectrum of different approaches has emerged. Key differences include how centralised or

[24] Secretary of State for Health, 2011. *Enabling Excellence Autonomy and Accountability for Health care workers, Social Workers and Social Care Workers*. Available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216580/dh_124374.pdf [Accessed 1 November 2017].

decentralised the systems in place are, the evidence needed to demonstrate compliance carried out by the regulator and the frequency/intensity of reporting.

2.23 Examples of the approaches range from the GMC system of revalidation which requires doctors to participate in local systems of appraisal and receive sign-off from a local Responsible Officer who confirms their ongoing participation in revalidation activity to the Health and Care Professions Council (HCPC), which outlines a set of CPD criteria with which registrants should comply and asks that individuals reflect on their own practice. The GMC is ultimately responsible for making decisions on a doctor's revalidation activity based on a recommendation from a Responsible Officer along with any other information available to them. The Nursing and Midwifery Council (NMC) process of revalidation is similar to the GMC's with the regulator responsible for making decisions about registrant renewal. Some of the other regulators require submission of a CPD portfolio centrally, however most will only audit a sample of submissions to check compliance.

2.24 There are a number of common themes across the different arrangements. Peer review and feedback come through as key areas, with almost all of the regulators including this as a continuing fitness to practise requirement. Similarly, the importance of individual reflection on practice comes through in most systems, with requirements for registrants to participate in reflective discussions or complete reflective writing examining how the standards of conduct and competence have been relevant to specific area of their practice. The use of patient and peer feedback is also a common feature, as is a move to base requirements closely around the standards set by the regulator, although some of the regulators including the General Osteopathic Council (GOsC) and the HCPC have specific standards which registrants must meet to demonstrate continuing fitness to practise.

2.25 Several of the regulators are consulting on changes to their CFtP requirements currently or are due to shortly. The General Pharmaceutical Council (GPhC) has published a consultation on a three-stage model looking at a required element of CPD covering issues of particular relevance to pharmacy professionals, a peer discussion element, and a reflective case study cased on an event from practice which has benefited patients or service users. The General Chiropractic Council (GCC) is shortly due to consult on an enhanced CPD scheme covering an objective activity such as case based discussion, CPD based on an area identified as important to the profession as a whole, and a structured discussion with a peer about CPD. The General Dental Council (GDC) in *Shifting the balance,*[25] its discussion paper on reform of its regulatory processes, laid out proposals to work more closely with partners to embed the standards into registrants' practice. This included proposals to work with employers to ensure that the standards for the dental team are reinforced through performance management and appraisal mechanisms and work to strengthen data-sharing

[25] General Dental Council, 2017. *Shifting the balance: a better, fairer system of dental regulation.* Available at https://www.gdc-uk.org/about/what-we-do/regulatory-reform [Accessed 1 November 2017].

with partners including system regulators, to allow more effective use of complaints data to inform a range of interventions to address potential causes of harm at an early stage.

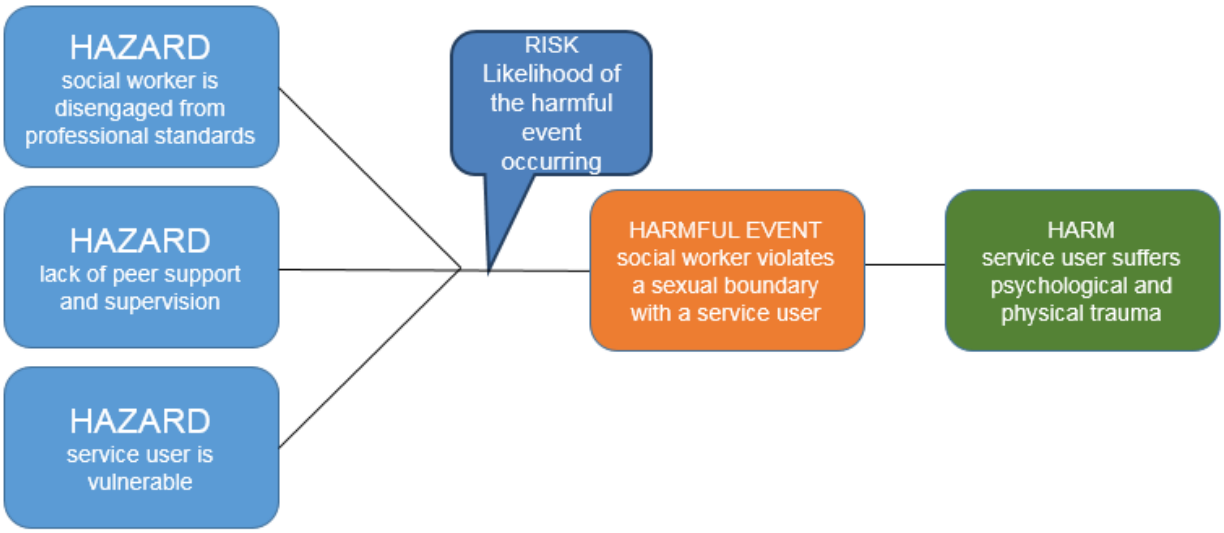
2.26 At Appendix II we set out a summary of current and planned activity across the statutory regulators.

Hazards and harms – thinking on prevention

2.27 The work of Professor Malcolm Sparrow[26] provides one conceptual framework for discussing how regulators might develop further innovative approaches to the deployment of their knowledge and insights towards prevention. It has been influential in developing thinking in the sector in recent years. Sparrow introduced the idea that regulators should place greater focus on actual and specific serious harms and their 'sabotage'. This way of thinking about harm prevention involves an analysis and identification of the 'hazards', the contributory factors that convene and result in harm occurring. In the context of health and care professional regulation these hazards could include those relating to the competence, health, or wellbeing, individuals involved when such harms occur; to the vulnerability of a patient or patient group; to the state of professional relationships within a team; or to features of the working environment or employing organisation, amongst others.

2.28 In *Right-touch regulation* by way of example we applied this model of thinking to a situation where a health professional violates a sexual boundary with a patient. This is illustrated below in Figure 1.

Figure 1: Hazards, risk and harm



2.29 In this example we give three potential hazards, all of which in this example must be present in order for matters to proceed to the harmful event. We separate 'harmful event' from 'harm' to distinguish the event from the effects that it causes. Risk increases as more of the hazards align in time and place.

[26] For example Sparrow, M, 2000. *The Regulatory Craft.* Brookings Institution Press.

Intervention, context, and agency

2.30 In *Right-touch regulation* and *Right-touch assurance*[27], we developed the idea of categories of hazard. This was in the context of putting forward our methodology for assessing the most appropriate form of regulation or assurance for any particular professional group. However, they are also helpful in this context in illustrating the range of different factors which could be considered a hazard:

- **Intervention:** hazards which arise from the complexity and inherent dangers of the activity
- **Context:** hazards which arise from the environment in which care takes place
- **Agency/vulnerability:** hazards which arises from service user vulnerability.

Harm 'sabotage'

2.31 The next stage of analysis, having identified the hazards which combine to result in a particular harm, is to identify ways in which the progress of these factors to the harmful outcome could have been prevented. Could one or some of those hazards have been thwarted to prevent the harmful outcome that was the product of all of them? The process of seeking to intercept particular hazards or factors is what Sparrow refers to as 'sabotaging' harms.

2.32 In (at least) two specific ways efficiency is embedded in this approach to thinking about the regulatory task. In any potentially harmful situation, several hazards might be present together and result in harm occurring. However, it is probably not necessary to thwart all of the hazards individually, but only as many as is necessary to impede the evolution of a situation to a harmful point. The approach is also efficient in that it encourages regulators to focus their resources on the areas of highest priority, those areas where actual harm is known to occur, taking into account their impact and prevalence. To quote *Right-touch regulation,* it is about 'the minimum regulatory force required to achieve the desired result'.

What do we need to know to prevent harms in this way?

2.33 To apply Sparrow's concept successfully, we would first want to know the answer to a series of questions. These questions are to differing degrees already being answered through the research and policy programmes of the Authority and the regulators. They relate to the circumstances in which harm occurs involving health and care professionals, and each relates to the possibility of the risk of harm being elevated in any given situation:

- What are the factors which could negatively influence behaviour, including but not limited to health and wellbeing, or environmental or other factors bearing on individuals' behaviour?

[27] Professional Standards Authority, 2016. *Right-touch assurance: a methodology for assessing and assuring occupational risk of harm* © Available at https://www.professionalstandards.org.uk/docs/default-source/publications/right-touch-assurance---a-methodology-for-assessing-and-assuring-occupational-risk-of-harm-(october-2016).pdf?sfvrsn=0&sfvrsn=0 [Accessed 2 November 2017].

- What are the traits of relationships between professionals which might result in harmful outcomes for patients?
- What are the team dynamics which might result in elevated risk of harm?
- What are the organisational features or factors which might result in elevated risk of harm?
- What are the factors at play when registrants, patients and the public decide whether or not to raise concerns about elevated risk of harm?

Preventing harm – what is the regulator's responsibility?

2.34 Even where it is possible for analysis to demonstrate the salient hazards in any given situation, it is clearly not always or even often the regulator who is best placed to take preventing action in situations that are current and evolving, from which it is distant. The regulator's insights from analysis of fitness to practise data and intelligence derived from the fulfilment of its other functions could for example, indicate ways that standards could be more effectively communicated; identify gaps in higher education curricula; or indicate patient or professional groups that are at higher risk of involvement in harmful situations. However, the regulator will often not be well placed to frustrate an emerging specific harmful situation, since it does not 'own' the hazards in question. These probably more often belong to employers, managers, teams, or individual professionals or patients. A more realistic aspiration for regulators might be seen as the indirect frustration of harm – providing those close to emerging and potentially harmful situations with knowledge to contribute to prevention. There is increasing proactive engagement at the boundary between professional regulators, system regulators and employers, helping to create the conditions in which effective frustration of harm might better be achieved.

2.35 An effective flow of information of course relies on those close to the scene to be willing, able and supported to act when things are going wrong. That they often will not and are not is demonstrated by many cases of serious failings in care, including recently by the recent report into the actions of the surgeon Ian Paterson at Solihull Hospital.[28] The report lists all those close to problems whose intervention might have effectively prevented the harm, or whose contribution might have been acted on to better effect – these include the Senior Management Team, the Board, clinical colleagues of Mr Paterson, the National Cancer Peer Review, and the West Midlands Cancer Intelligence Unit. The report also notes that Mr Paterson's oncology colleague and team members should have reported their concerns to the GMC but did not do so.

[28] Kennedy, 2017. *Review of the response of Heart of England NHS Foundation Trust to Concerns about Mr Ian Paterson's Surgical Practice: Lessons to be Learned; and Recommendations*. Solihull Hospital Kennedy Breast Care Review. Available at http://www.heartofengland.nhs.uk/wp-content/uploads/Kennedy-Report-Final.pdf [Accessed 1 November 2017].

Retrospective analysis of fitness to practise cases

2.36 Retrospective analysis of fitness to practise cases has great potential to generate the insights, knowledge and understanding of patterns which can be used prospectively. Since 2010 the Authority has reviewed 22,548 final hearing decisions by regulators' fitness to practise panels.[29] Records are kept by the regulators and by the Authority in fulfilment of their statutory duties. On the Authority's database, each case has its own record (in the form of the regulator's determination document) which usually includes details of the allegations or charges, and an account of the circumstances in which misconduct has occurred, and of the panel's reasoning in coming to a final decision on sanction. Therefore, a huge body of data about fitness to practise cases has grown; the database currently in use by the Authority which it might be reasonably assumed would help us to address at least some of the questions that arise from seeking to adopt a preventative approach.

2.37 A number of projects have looked retrospectively at fitness to practise cases, including work commissioned by both the regulators and by the Authority. For example, in 2014 the HCPC commissioned Picker Institute Europe to research engagement and disengagement in health and care professionals, which included a review of documentation associated with 27 fitness to practise cases,[30] as well as other methods. More recently, the University of Surrey has published a report on complaints against paramedics and social workers to the HCPC,[31] which, amongst other methods, analysed 284 cases (52 paramedics and 232 social workers). The analysis 'identified a higher number of older, male practitioners in the overall sample relative to their numbers on the registers in both professions', and recommends a range of preventative strategies.

2.38 Gallagher and Jago were commissioned by the Authority to analyse a sample of cases of dishonesty using the Authority's Section 29 database of cases across the professions it oversees. The method included analysis of a sample of 151 cases involving dishonesty. Their report[32] sets out a typology of dishonesty which contributes to our understanding of this particular area of professional misconduct, and which demonstrates common features that apply across all

[29] See Chapter 3, Figure 3.
[30] Health and Care Professions Council, 2015. *Preventing small problems from becoming big problems in health and care.* Available at http://www.hpc-uk.org/assets/documents/10004A7EPreventingsmallproblemsfrombecomingbigproblemsinhealthandcare.pdf [Accessed 1 November 2017].
[31] Van der Gaag, A, et al, 2017. *People like us? Understanding complaints about paramedics and social workers*. University of Surrey. Available at http://www.hcpc-uk.org/assets/documents/10005590Peoplelikeus_Surreyresearchsummary.pdf [Accessed 1 November 2017].
[32] Gallagher, A, and Jago, R, 2017. *A typology of dishonesty illustrations from the Section 29 database.* Professional Standards Authority. Available at https://www.professionalstandards.org.uk/docs/default-source/conferences/presentation/2017-conference/gallagher-and-jago.pdf?sfvrsn=2&sfvrsn=2 [Accessed 1 November 2017].

professions. This will be complemented by the publication of work in the near future by the Authority on how cases are categorised by regulators, and how case categorisation might be more harmonised. Given that care is increasingly delivered by teams, greater harmonisation of the categories that are applied to this dataset should facilitate comparison and analysis on a multi-professional basis.

2.39 A recent report by Searle et al,[33] funded by the Authority, piloted the application of a cluster analysis methodology to 6,714 cases on the Authority's database of final hearing determinations and seeking to identify both typical profiles of the registrants involved and trends in the appearance of different charges together. Three different types emerge from the analysis: the self-serving 'bad apple'; the individual who is corrupted by the falling standards of their workplace; and the depleted perpetrator struggling to cope with the pressures of life. Searle's analysis of these types places our understanding of misconduct within the academic literature on counterproductive work behaviour, and suggests a range of preventative and supportive approaches for each. The GDC has recently published a report on trends within its fitness to practise cases, based on retrospective analysis of fitness to practise data commissioned from the Peninsula School of Medicine and Dentistry.[34]

2.40 The Authority will support and encourage further work to continue to develop our understanding either of traits of perpetrators of misconduct, of patterns of misconduct, or other such analysis which will further our understanding of the circumstances in which misconduct occurs, using both fitness to practise records and any other data, research and insight which can contribute to developing and enriching our understanding of the circumstances where things go wrong. We recognise that there are limitations to this data, not least that it does not capture concerns that have not been raised with the regulator for whatever reason; as we say elsewhere, we do not profess that it captures the sum of all harm. Nevertheless it is a wealth of data with much potential for further exploitation.

2.41 Another concern which has been expressed about using data analysis in this way concerns the potential for unlawful discrimination. The potential for unlawful discrimination has been said to arise where a particular group is identified through analysis to be at higher risk of involvement in patient harm than others; how might any regulatory interventions subsequent to that analysis be conducted without being discriminatory towards those registrants who are part of that group? This demonstrates one of the key weaknesses in the way that fitness to practise data can be analysed. Any particular case will be entered onto a database and will be allocated to a number of predetermined categories including

[33] Searle, R et al, 2017. *Bad apples? Bad barrels? Or bad cellars? Antecedents and processes of professional misconduct in UK Health and Social Care: specific insights into sexual misconduct and dishonesty/theft and qualifications dishonesty.* Available at https://www.professionalstandards.org.uk/latest-news/latest-news/detail/2017/11/03/trust-in-healthcare-undermined-by-bad-apples-ground-breaking-research-reveals [Accessed 3 November 2017].
[34] General Dental Council, November 2017. Available at www.gdc-uk.org/about/what-we-do/research [Accessed 20 November 2017].

those relating to characteristics of the registrant. Analysis which attaches for example personal characteristics to particular categories of misconduct risks generating the appearance of causal links which are in fact only correlations. This may in turn result in the risk of inappropriately discriminatory conclusions being drawn where these are protected characteristics. Further analysis is needed to understand the hazards present, and how they might or might not be associated with any characteristics of the registrant, the context of practice, or any other factor with bearing on the situation. The Authority would support and encourage further research and discussion to explore how this challenge to effective use of data analysis might be overcome. We discuss further below potential improvements to the way that data on fitness to practise is collected and structured.

Improving fitness to practise data

2.42 Despite the obvious potential of fitness to practise data, which we and others are seeking to exploit, there are inherent shortcomings in the data, one of which is summarised in the HCPC's report mentioned in the previous section: 'the documents reviewed included final decision bundles, a summary decision form and the evidence contained in registrant bundles. It is worth noting the context within which the registrants were responding, which has a bearing on the evidence within the registrant bundle. Registrants were defending themselves against an allegation and as such, the evidence presented tended to be set out in order to show themselves in the best possible light'.

2.43 In order to provide the basis for objective analysis therefore the data that accrues in the process of fitness to practise proceedings is at best imperfect. Currently, its purpose is not to furnish the regulator with a comprehensive and unbiased account of what went wrong and why in each case, but is collected in fulfilment of a legal process. The cases are categorised (in the Authority's database) by charges in any given case. Yet not all of the misconduct that features in a case is necessarily included in the charges, making it extremely laborious for researchers to compile or assess a complete picture of what is going on. There are other issues making cross-regulator comparison difficult, such as differences of terminology, and differences of categorisation of allegations. At Appendix I, by way of demonstration of the range of misconduct that occurs within the sector, we reproduced the list of categories that we at the Authority apply to cases when we upload them on our database. However, each of the regulators will also have their own approach to categorisation and data management. As previously mentioned, we have been working in recent months to develop proposals around the use of a shared category set, which we hope will begin a dialogue about how this data can be harmonised and therefore analysed more readily on a cross-professional basis.

2.44 It may be the case that salient hazards which are highly influential in many cases are simply not being captured in the way that the fitness to practise processes are currently operated and documented – resulting in a dataset which is critically flawed for the purpose of recognising those hazards and identifying preventative

strategies relating to particular kinds of harm. The less adversarial approach to fitness to practise that we describe in the following chapter might to some extent address this, since such an approach would involve seeking to establish a more holistic understanding of the circumstances in which alleged misconduct has occurred, which might then result in a fuller dataset capturing a fuller range of hazards more effectively.

2.45 Another issue in using this data, as currently organised, is that it is focused on the registrant, and not those harmed. Just as through Searle's research it has proved possible to describe trends in relation to the perpetration of misconduct, it might also be possible to trace patterns, for example, in the kinds of harm caused in different situations, or in the specific kinds of vulnerability involved. These may be features that are currently out of sight, because they may not currently be recorded or noticed as important in the way that cases are investigated. We recognise that collecting such data in a systematic way will present challenges, and must be in done in such a way as to avoid appearing in any way to blame complainants or victims for what has occurred.

2.46 We would support work to address these limitations. For cases that have occurred in the past, this might involve seeking to engage with registrants and/or patients or other victims of harm, who have been involved in fitness to practise cases and complaints, to explore with them the hazards that were present when things went wrong in an open way, and to seek to uncover hazards that may not have been not visible in the case as investigated and heard. Clearly such a study would require extremely careful design to be successful, not least to avoid a detrimental impact on the individual participating, but we believe that if this could be overcome, it could yield extremely rich insights into hazards and their sabotage.

2.47 To address these limitations as they apply to recording data on cases that occur in future, we recommend that regulators and register holders review how they can better enable future analysis, including for example through agreement on the collection of a common data set, and building on work that has already been done, to better support a preventative approach. Although the emphasis in this discussion has been on fitness to practise data, such review should have regard to other datasets, arising from other regulatory functions, with preventative potential. Further discussions will need to take into account the observation, quoted in our earlier work on the role of risk in regulatory policy, that 'pro-active tailor-made methods of data collection are time-consuming, and costly to the data provider. On the other hand, reactive methods that piggy back on other collections may not provide the data in usable form. Both require a thorough assessment of the quality and reliability of the data, and an understanding of the 'social and organisational processes whereby it enters the database'.[35]

[35] Lloyd-Bostock, SM, and Hutter, BM, quoted in Professional Standards Authority, 2015, *The role of risk in regulatory policy.* Available at https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/regulation-rethought.pdf?sfvrsn=14&sfvrsn=14 [Accessed 1 November 2017].

Encouraging reflective engagement with regulatory standards

2.48 In this section we discuss three specific ideas that have emerged from the academic literature which we believe are particularly useful and helpful as reference points for further discussion on how registrants can be encouraged to engage constructively with regulators' and register holders' standards. A common theme through all of them is that they demonstrate the value for compliance with standards of reflective discussion, involvement, engagement and debate. They recognise the personal and social dynamics that are a feature of professional practice. The authors who have developed and discussed these concepts often refer to each other's work in doing so; they form a coherent and compelling set of ideas which we think should be valuable in future discussions.

Formative spaces

2.49 An element of harm reduction is to seek to encourage registrants to discuss problematic situations openly and at an early stage. One way in which it has been proposed to achieve this is through the creation of 'formative spaces', or regulator-sanctioned confidential discussions between colleagues about problematic areas of practice, even though these discussions may be outside the direct control of regulators. The term[36] appeared in 2012 in work by Fischer in an analysis of organisational turbulence, and the possible result being either a creative 'formative space' or destructive 'perverse space'.[37] In a paper of the same year McGivern and Fischer further advanced the idea of the formative space.[38] This was in the context of a discussion of the potentially counterproductive reactions that might be provoked by regulatory interventions, and the innate tensions between the regulator's desire for transparency and information, and the risks that regulatory interventions might result in registrants either hiding the truth from regulators, or presenting a falsely positive impression. A further result of this might be registrants practising (and representing their practice) defensively at the expense of patient care. To address this risk, the formative space as conceived by McGivern and Fischer provides a regulator-sanctioned but informal context for the early exploration and resolution of potential problems, before risks are elevated, and away from the fear of regulatory scrutiny.

[36] We also recognise earlier ideas that provide a format for open discussion between colleagues, such as Schwartz rounds and Balint groups, which have been supported by regulators.
[37] Fischer, M, 2012. *Organisational turbulence, trouble and trauma: Theorising the collapse of a mental health setting.* Organization Studies, Vol 33, Issue 9. Available at http://journals.sagepub.com/doi/abs/10.1177/0170840612448155 [Accessed 1 November 2017].
[38][38] McGivern, G, and Fischer, M, 2012. *Reactivity and reactions to regulatory transparency in medicine, psychotherapy and counselling.* Social Science and Medicine Vol 74 Issue 3. Available at http://www.sciencedirect.com/science/article/pii/S0277953611006319?via%3Dihub [Accessed 1 November 2017].

2.50 McGivern, Fischer et al in 2015[39] recommended in work for the GOsC that informal discussion of practice with another osteopath be part of the recognised process to assure osteopaths' continuing fitness practise. They found that osteopaths would feel more able to raise 'tough issues' in an informal than in a formal discussion. In other words, the confidentiality of an informal discussion would allow for the open and constructive discussion of more uncomfortable material than a recorded formal discussion. This is potentially an uncomfortable finding for regulators, for whom the pursuit of transparency in professional practice has been an important element of regulatory policy; formative spaces if poorly managed may risk important information not reaching the regulator.

2.51 The Authority recommends further work to explore how the idea of formative spaces could be applied to different professional groups and appropriately supported by regulators, balancing the benefits of the formative space as described with the need for regulators to be alerted to serious concerns, and to avoid unnecessary and confusing duplication with other initiatives by other agencies. There may be further opportunity to develop this idea in order to identify and resolve problematic practice issues at an early stage and before risks to patient safety have arisen. We recognise that the intent of formative spaces is already reflected in a number of regulatory initiatives and approaches, such as the safe space provided by the GMC's employer liaison service for early conversations about potential problems, and the emphasis on reflection in revalidation and other continuing fitness to practise schemes. It has also been adopted as part of the GOsC's continuing fitness to practise arrangements.

Relational regulation

2.52 The concept of relational regulation has becoming of increasing interest to regulators internationally. In 2011 Huising and Silbey[40] defined relational regulation when they identified a gap within the prevailing logic of regulation, between 'law on the books' and 'law in action'. In other words a gap emerges when a regulator aims to set standards which guide registrants on how to act in particular situations 'because the exigencies of practical action exceed the capacity of system prescriptions to anticipate and contain them'. The perceived lack of applicability of regulatory standards to everyday work is inherent in Christmas' and Cribb's[41] recent work for the Authority on professional identity, in which participants reported that they thought of standards as 'what you would expect of yourself anyhow', and said that in times of uncertainty of how to act in a

[39] McGivern, G, et al, 2015. *Exploring and explaining the dynamics of osteopathic regulation, professionalism and compliance with standards in practice*. General Osteopathic Council. Available at http://www.osteopathy.org.uk/news-and-resources/document-library/research-and-surveys/dynamics-of-effective-regulation-final-report/ [Accessed 1 November 2017].

[40] Huising, R and Silbey, SS, 2011. *Governing the gap: Forging safe science through relational regulation*. Regulation and Governance Vol 5 Issue 1. Available at http://onlinelibrary.wiley.com/doi/10.1111/j.1748-5991.2010.01100.x/full [Accessed 1 November 2017].

[41] Christmas, S and Cribb, A, 2017. *How does professional regulation affect the identity of health and care professionals: exploring the views of professionals*. Professional Standards Authority. Available at https://www.professionalstandards.org.uk/docs/default-source/publications/research-paper/regulation-and-professional-identity-july-2017-final.pdf?sfvrsn=4&sfvrsn=4 [Accessed 1 November 2017].

particular situation, they would turn not to the standards but to 'a range of other actors – first and foremost colleagues, but also supervisors/superintendents, managers, helplines provided by employers and training bodies'. These observations are also consistent with the findings of the earlier work that the Authority commissioned from Quick, that found limited evidence of influence of regulators standards on behaviour, and many other influences that were closer to home.

2.53 Relational regulation as defined by Huising and Silbey addresses 'the insufficiency of formalized, prescribed processes to handle the complex, situated demands faced in daily compliance work', and focuses on 'governing rather than erasing the gap between regulation and performance. We call this relational regulation'. They set out four stages which they argue are implicit in governing the gap: narrating the gap, inquiring without constraint, integrating pluralistic accounts, and crafting pragmatic accommodation. They use the example of a University science department and its regulations on disposing of hazardous waste as an example of working meticulously through these stages, resulting in guidance being placed over the sinks on what can and cannot be poured down them, but acknowledging that this guidance 'is not a final answer, but a moment in a continuing process of achieving environmental sustainability, or more narrowly producing compliance'.

2.54 Relational regulation as defined by Huising and Silbey provides an accessible conceptual relationship between regulatory standards, which are relatively fixed in time, with the working world as everyone knows it: a 'complex web of interactions and processes' and 'a set of interdependent yet malleable relationships'. In the process of governing the gap, it is also by necessity bridged – the process requires thoughtful reflection on what the standards mean. Christmas and Cribb's findings as reported above and our other work, reflect on the potential risks that might arise from registrants becoming disengaged from professional standards. For example we wrote in *Asymmetry of Influence* of the danger of the proliferation of different standards for a given situation 'alienating professionals and [causing] them to disengage from the ethical decisions in front of them'. The dynamic process of enquiry, reflection and problem-solving described by Huising and Silbey requires engagement with standards.

2.55 Relational regulation has been adopted by a number of regulators as part of their approach and regulatory philosophy, such as the College of Registered Nurses of British Columbia (CRNBC), which states that:[42]

'Relational regulation means that we believe that it is possible to build genuine relationships with nurses and other stakeholders, while at the same time, regulate effectively in the public interest. Public protection and safety is our utmost concern, and we believe we can best achieve this through collaborative approaches with nurses and the health care community'.

[42] College of Registered Nurses of British Columbia. 2017-18. *Strategic Plan*. Available at https://www.crnbc.ca/crnbc/StrategicPlan/Pages/Default.aspx [Accessed 1 November 2017].

2.56 The CRNBC continue that 'relational regulation implies:

- We build strong relationships with nurses, the public and other stakeholders
- We keep things simple and communicate in easy-to-understand language
- We accept that mistakes happen and believe that open conversations with nurses and the health care community assists us in finding ways to promote safety and reduce risks
- We use the right amount of regulation needed and only use it when necessary
- We use principles, rather than rules, to guide nursing regulation'.

2.57 This is one regulator's interpretation of what relational regulation means for regulatory practice. The Authority recommends that within the sector we continue to consider and discuss relational regulation, its potential for engaging registrants with professional standards and its relationship to right-touch regulation. Further, the Authority recommends that we consider and discuss how the process of bridging the gap described by Huising and Silbey in the context of environmental regulation applies in the context of the exercise of professionalism.

Interpretive vigilance

2.58 Meleyal[43] found perverse behavioural consequences when statutory registration was introduced for social workers in England. This finding was consistent with other work, such as McGivern and Fischer, cited above, on how enforced transparency might result in defensive or secretive practice. In more recent work Meleyal[44] has summarised this and other authors who found that 'the same types of rules governing behavioural expectations fail to achieve the requisite outcomes over and over again', and cites regulatory theorists who show that 'regulation assumes individuals are uniformly interested and capable of modifying their own behaviours in line with imposed rules, and does not take account of those who respond strategically or perversely to regulatory requirements'. The analysis she undertook in her research showed the impact in particular of conduct (ie fitness to practise) cases on other registrants, where 'the publicity about the outcomes of registration conduct cases triggered a negative allegiance to registration with respondents passively avoiding engagement with conduct matters in the workplace'.

2.59 Again, the problem of disengagement from standards is identified, this time with the trigger not of cognitive overload from different standards, nor from a view that the standards fail to add value, but because of anecdotal evidence of how other registrants have fared who have been subject to fitness to practise proceedings.

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[43] Meleyal, LF, 2011. *Reframing conduct: a critical analysis of the statutory requirement for registration of the social work workforce* (doctoral thesis). University of Sussex. Available at http://sro.sussex.ac.uk/7665/ [Accessed 1 November 2017].

[44] Meleyal, LF, 2017. *Nudging workers towards interpretive vigilance: approaches supporting management of conduct in the workplace*. European Journal of Social Work. ISSN: 1369-1457 (print) 1468-2664 (online). Available at http://www.tandfonline.com/doi/abs/10.1080/13691457.2017.1320526 [Accessed 1 November 2017].

It is particularly interesting how disengagement from one area of regulatory activity results from the publicity surrounding another – a point discussed further under trust, as below.

2.60 Meleyal's first study had shown how 'environments that had a positive approach to engaging with regulatory rules and conduct expectations in the workplace were also those that had clear systems and processes in place that encouraged identification of places where risks may occur (eg log books)', and in the second paper she defines this from Macrae's work[45] in the context of aviation as 'interpretive vigilance'. Meleyal shows how the idea of interpretive vigilance speaks to Sparrow's model of harm sabotage in that through such straightforward and practical measures since 'emerging risk can and should be identified by piecing together cues in apparently inconsequential, minor, 'small events', and that interpretive vigilance can protect against 'small mishaps that can combine to create a major catastrophe'.

2.61 Meleyal also shows how a mutually complementary set of ideas is formed with McGivern et al's formative spaces within which 'social workers have the opportunity to actively engage in consideration of regulatory policy, conduct, competence and their values in relation to practice'. Emerging from these different domains of research – harm sabotage, relational regulation, formative spaces, and interpretive vigilance – is a mutually complementary set of ideas spanning both the abstract and the practical, which we recommend are further developed to encourage registrant engagement with regulatory standards in the workplace. We propose further work to explore how, through different ways and through different models, local action at the level of the employer or workplace can assist in clarifying the purposes and meaning of regulatory requirements, and can promote constructive and mature engagement with registrants.

Trust and legitimacy

2.62 In *Regulation rethought*, the Authority called for a 'rebuilding of trust between professionals, the public and regulators'. In so far as this related to the relationship between professionals and regulators, this was in part because of some emerging research evidence that suggested that the relationship between registrants and regulators may not be one firmly underpinned by trust. An example of this is work by Bourne et al[46][47] on the impact on doctors of the GMC's fitness to practise proceedings and other complaints procedures, in which 7,926 doctors submitted responses. The authors found, amongst other things, that 'complaints seriously impact on doctors' psychological wellbeing', and that 'doctors with recent/current complaints have significant risks of moderate/severe

[45] Macrae, C, 2014. *Close Calls – Managing Risk and Resilience in Airline Flight Safety*. Palgrave Macmillan.

[46] Bourne, T, et al. *The impact of complaints procedures on the welfare, health and clinical practice of 7926 doctors in the UK: a cross-sectional survey*. BMJ Open. Vol 5 Issue 1. Available at http://bmjopen.bmj.com/content/5/1/e006687 [Accessed 1 November 2017].

[47] Bourne, T, et al. *Doctors' experiences and their perception of the most stressful aspects of complaints processes in the UK: an analysis of qualitative survey data*. BMJ Open 2016 011711. Available at http://bmjopen.bmj.com/content/6/7/e011711 [Accessed 1 November 2017].

depression'. The research also found an increased incidence of defensive behaviours in those with direct experience or, specifically hedging and avoidance.[48] It is important of course to distinguish these behaviours from careful adherence to standards.

2.63 The authors also found that the behavioural impact was not limited to the doctor who was the subject of the complaint or fitness to practise process, but by extension, to colleagues who were witnessing the experiences of the direct subject. This mirrors McGivern's observation (2012) that certain stories that circulate among professionals have the power to stick, and thus to profoundly influence how the regulator's purpose and interventions are understood. Misunderstanding of the purposes of regulation may threaten registrants' acceptance of its legitimacy. Quick identified in 2011 the importance of acceptance of legitimacy, in that this was more likely to result in compliance with standards. He observed, 'the clear message to emerge from a number of studies is that regulation (however well intentioned) is far more likely to be complied with when accepted as legitimate by practitioners'.

2.64 We are cautious about making any prescriptions that are either too simplistic or too 'heroically rational' (to paraphrase Christmas and Cribb, in their work for us on professional identity) about how misunderstanding or misperception of the role of the regulator might be addressed. However, we recommend that this is taken into account in future policy and communications work, and that the sector continues to seek to understand how the regulator is apprehended by registrants, and to address any misunderstandings while working with the grain of the social dynamics of organisations and social psychology. We think that a greater understanding of the dynamics of these relationships will be vital to the rebuilding of trust that we recommended in *Regulation rethought.*

2.65 Our earlier discussion of the use of fitness to practise data notwithstanding, the ideas of 'stories that stick' could be put to better use by regulators, particularly in relation to key messages about standards and fitness to practise. Greater use could be made of the 'stories' in fitness to practise cases for regulators to explain what it means to stay compliant with standards, to deter registrants from breaching standards, and to explain why it is important for the profession that effective action is taken when standards are breached.

[48] The study defines hedging as 'when doctors are overcautious, leading for example to overprescribing, referring too many patients or over investigation'. Avoidance is defined as including 'not taking on complicated patients and avoiding certain procedures or more difficult cases'.

The role of patients in safe care

2.66 In *Right-touch regulation*, the Authority argued for the importance of people when they use services acting as one of the agents of their own safety. We have also, as mentioned above, called for a rebuilding of trust between professionals, the public and regulators. There are two specific ways in which we propose now that further work is done to respond to these proposals.

2.67 The first relates to what is known about patients involved in fitness to practise cases and has been mentioned above in relation to fitness to practise data. We have discussed both the potential and the inherent problems with using this data for retrospective analysis and future risk management. A further consideration is that because the process is one which assesses the registrant's fitness to practise, the registrant is the protagonist of the story, not the patient who may have been harmed. This of course is at the heart of the frustration experienced by many members of the public who refer problems to regulators. We have also discussed above work which is being taken forward by Searle et al to use fitness to practise data to a number of ends including identifying types or typical circumstances of registrants involved in fitness to practise cases. As we discussed previously, we propose that as part of a review of how data about fitness to practise is gathered and categorised, we also look at how data about trends in harm are captured, and whether there are measures that could be taken by regulators or others to mitigate vulnerabilities in particular situations.

2.68 A second area for further work relates to trust. Trust is an area of growing interest in research in healthcare and in regulatory policy. Recent work by Peters and Bilton[49] has discussed the importance of trust for patients, not least because patients 'have limited information (about their illness or treatments); they delegate responsibility for making decisions about their care to professionals; they rely in turn on professionals' professionalism to ensure the care they receive is appropriate; and in this way their trust addresses the inherent uncertainty underlying medical care'. A loss of trust in either a specific individual, in an organisation or in the arrangements for the delivery of care at a higher level has consequences beyond the individual, such as deterring patients from seeking needed care. Trust transfer can be seen, in that trust in an individual can invoke trust in a wider organisation or system, and vice versa; distrust or loss of trust can also transfer between patients and those close to them because of stories that stick, to use McGivern's phrase.

2.69 Peters and Bilton also describe the dangers of excessive or blind trust, and show how unscrupulous professionals can manipulate perceptions to induce a sense of trust where it is not justified. They describe the importance of patients being actively distrustful – listening to their instincts when they feel that something is not right, asking questions when they feel uncertain, and taking action including reporting or escalating concerns. It is here in particular that we feel patients have

[49] Peters, S, and Bilton, D. *Right-touch trust: thoughts on trust in healthcare* in *Routledge Companion to Trust* (in press). Routledge.

a part to play in helping to mitigate their vulnerability and protecting themselves from harm. In evidence given recently to the Independent Inquiry into Child Sexual Abuse it was described as empowering people on 'what to do and how to speak out if people behave in ways that aren't that which you expect'.[50] We believe that further work should be done to model ways in which patients can be supported and encouraged to be constructively distrustful.

2.70 We recognise that the concept of promoting patients being 'distrustful' may be problematic, and would need to be carefully expressed to avoid in itself provoking a loss of confidence. As a starting point however, the Authority intends to undertake a piece of work to understand better how patients currently contribute to the safety and effectiveness of the care they receive, to develop our understanding of their role in this respect. We propose as a second stage to then develop ideas and proposals around the mutual roles of the patient and of the regulator in this respect, encouraging a conversation which extends beyond the professional regulators and which encompasses a wider range of issues relating to developing innovative ways to support public engagement with regulators.

[50] Christine Braithwaite, Director of Standards and Policy, Professional Standards Authority. Quote from transcript of IICSA seminar 26 September 2017. Available at www.iicsa.org.uk/key-documents/2646/view/26%20September%202017%20IICSA%20Health%20Sector%20seminar%20transcript%20.pdf [Accessed 1 November 2017].

Conclusion

2.71 In conclusion we recommend the following:

- That we continue to develop approaches focused on the avoidance of harms within the sector
- That we continue to seek new ways to use data to support insights into trends and patterns in the circumstances in which misconduct occurs
- That we identify the range of potential targeted regulatory action subsequent to identification of ‘high-risk’ groups, and identify ways in which these could be made non-discriminatory
- That we work to develop a methodology to engage retrospectively with those involved in fitness to practise cases, to discuss the hazards that were present when things went wrong in an open and exploratory way
- That we review of the way in which regulators collect data about fitness to practise, and how within available resources a common data set might be developed
- That we explore how ‘formative spaces’ could add further value for different professional groups
- That there is further work to understand the nature of the relationship between regulators and their registrants and how (it is constructed, and to identify strategies by which misperceptions might effectively be addressed
- That we explore how, through different ways and through different models (formative spaces, relational regulation, interpretive vigilance, or others) local action at the level of the employer or workplace can assist in clarifying the purposes and meaning of regulatory requirements, and can promote constructive and mature engagement with registrants
- That we further explore the role of the patient in the safety of care, and the role of the regulator in supporting patients in this respect.

2.72 The Authority will look to support and encourage this work within the sector, particularly where this is on the basis of collaboration and shared commissioning to address common issues and research questions.