General Medical Council

Executive Board meeting

PUBLISHED
16 July 2018

Working with doctors Working for patients

General Medical Council

Agenda item:	**8**
Report title:	**The Harms Reduction Programme: progress update**
Report by:	**Thomas Jones**, Head of Regulation Policy, Strategy and Policy thomas.jones@gmc-uk.org, 020 7189 5370
Action:	**To note**

Executive summary

Within our Corporate Strategy, we set a commitment to identify, understand and address (through regulatory intervention) problems which present a risk of harm to both patients and doctors. As part of a more upstream approach to regulation, our intention is to identify opportunities to intervene before harm occurs.

We have conceptualised 'harm' as any significant problem that is likely to impede the delivery of safe and ethical practice (and by extension, create the potential for harm to occur). Such problems may occur at the registrant, system or regulatory level. Although our focus is on identifying opportunities for preventing such problems from reoccurring, a key aim of the programme will be to support and embed wider learning about how and why (where possible) such things occur.

We then present a practical example of how we are tackling communications failure, culminating in a stakeholder workshop, to be held at the end of 2019, to test our findings and explore potential next steps.

Recommendation

The Executive Board are invited to note the progress update for the harms reduction programme.

What is the harms reduction programme?

1 As a regulator, our core priority is public protection. We believe that the best way in which we can protect patients is by supporting doctors to maintain Good Medical Practice (GMP).

2 We therefore have a legitimate interest in identifying, understanding and addressing problems that might impede the delivery of this and by extension, present a risk of harm to patients or doctors. And this is the central premise behind our harms reduction programme.

3 In line with our narrative on 'upstream regulation' (Annex A), the types of problem that we are interested in are typically knotty, perennial issues that occur at one or more of the following levels:

- **a** At the registrant level - specific examples of failures to practise safely and ethically. Such issues may relate to clinical competence (e.g. prescribing), skills (e.g. communication) or behaviours (crossing boundaries), each of which may compromise an individual's ability to comply with GMP.

- **b** At the systems level – specific issues that limit the ability of the system to support safe and ethical practice (and may create the conditions in which harmful or substandard care is more likely – culminating in 'cultures of short cuts' and 'selective empathy'). Such issues might include inadequate training, rota gaps, limited supervision or more broadly 'toxic environments'.

- **c** At a regulatory / national body level – specific issues that impact upon our ability to regulate, and thereby facilitate, safe and ethical practice. These may be real or supposed unintended consequences arising from our regulatory processes (for example the practice of defensive medicine arising from doctors' perceptions about the level of risk of a GMC investigation). Equally, they may relate to specific regulatory gaps that limit the detection of potentially harmful or unethical care.

4 Within the Corporate Strategy, we make a specific commitment to have scoped, developed and put in place a process that helps us identify and better understand how, when and why patients or doctors come to harm. Furthermore, we commit to having piloted regulatory intervention on three themes of identified harm by 2020.

Potential limitations and points for consideration

5 Although our goal is to 'prevent bad things happening' we have to recognise that some problems are highly resistant to change, and whereas we may be effective in

learning and understanding more about their occurrence, using this knowledge to deliver meaningful change, irrespective of whether that is attributable to our action, remains a significant challenge.

6 This may be due to practical considerations. Firstly, our data may not be collected or structured in such a way to accurately identify contributory factors, given the primary aim of our fitness to practise work is to determine whether an individual's fitness to practise is impaired, rather than to contribute insight to a broader preventive approach. However, as part of our programme of work on data improvement, DRIH are considering how we might improve the capture of contextual information encountered in FtP processes to facilitate future analysis. This extends to information captured during both investigations and MPTS hearings.

7 At the recent July away day, Council members expressed support for us accelerating the development of an approach to capturing - and sharing with the healthcare sector – insights about contextual factors and learning about the environment/systems in which doctors practise that emerge from MPTS cases. We will need to consider how we can give greater priority to what is currently an embryonic piece of work.

8 Secondly, we may not have the right tools to lever change or we may not be sufficiently well placed to effect it. Collaboration will therefore be critical to the success of this programme, as will work to identify and review new, pioneering regulatory tools that are employed in other settings and jurisdictions, tools which may lever the type of change that we are looking to deliver.

9 Equally, it may be that the healthcare system is simply too complex to think in such primitive bimodal terms of cause and effect. It has been claimed by some, for this reason, that the 'Swiss cheese model' of investigation is an inaccurate way of conceptualising the occurrence of patent safety incidents and related failings.

10 And lastly, one individual's view of a 'harmful behaviour' may, when viewed through another's eyes, represent a 'workaround' or 'adaptation' to practising within a system under significant pressure, and essential in delivering a minimum standard of care. It is only when, through misfortune, that these adaptations align at a particular point to create an adverse outcome that such behaviours result in a referral to the GMC. And on this point, we have recently commissioned research (Adapting, coping, compromising – exploring the tactics and decisions doctors are applying in a system under pressure) to further explore how doctors are adapting their individual practice in the face of such pressures.

11 Therefore, while our focus will be on considering potential intervention, we will not overlook the value of 'softer' actions such as the development of learning summaries

and associated resources to share our findings, akin to similar products produced by NHS Improvement, the MHRA and NHS Resolution.

Piloting the approach – exploring communication failure

12 The first 'harms project' we have selected is focused on poor communication. This is one example of a complex multi-dimensional harm, and is often cited as a key factor in patient complaints, with the potential to cause both psychological harm (by failing to keep a patient adequately informed or failing to treat an individual with dignity or respect) and physical harm (for example, failing to take an adequate medicines history from a patient and subsequently prescribing a contra-indicated drug).

13 This is a collaborative multi-stage project undertaken in collaboration with the Scottish Government (our partner is Jason Birch, Head of Regulatory Unit, part of the Chief Nursing Officer's Directorate).

14 We are nearing the completion of stage one – where our focus has been to map out the different types of communication failing that occur between healthcare professionals, and between the medical profession and the public. This has been informed by a jointly commissioned literature review and small-scale internal engagement work with stakeholders in Scotland including the Scottish Patient Safety Ombudsman, NHS National Services Scotland, Medical and Dental Defence Union of Scotland, and representatives of the patient advice and support services.

15 Stage one has identified the following types of high level communication failure as most likely to result in moderate to severe harm (based on the number of published studies identified by the review):

- **a** Failure to listen to the patient
- **b** Failure to work in partnership or collaboratively with patient / family or carers
- **c** Failure to keep colleagues informed / share appropriate levels of information
- **d** Failure to provide the patient with appropriate an timely information

16 Drawing on these, and two additional themes identified through our engagement work (incomplete medical records and failure to meet communication needs), stage two will comprise an in-depth review of fitness to practise complaints (prioritising particular documents within our qualitative complaints bundles) to identify key themes and potential contributory factors. To deliver this, we have appointed a qualitative researcher on a 12 month contract, based within the Data, Research and Insight Hub.

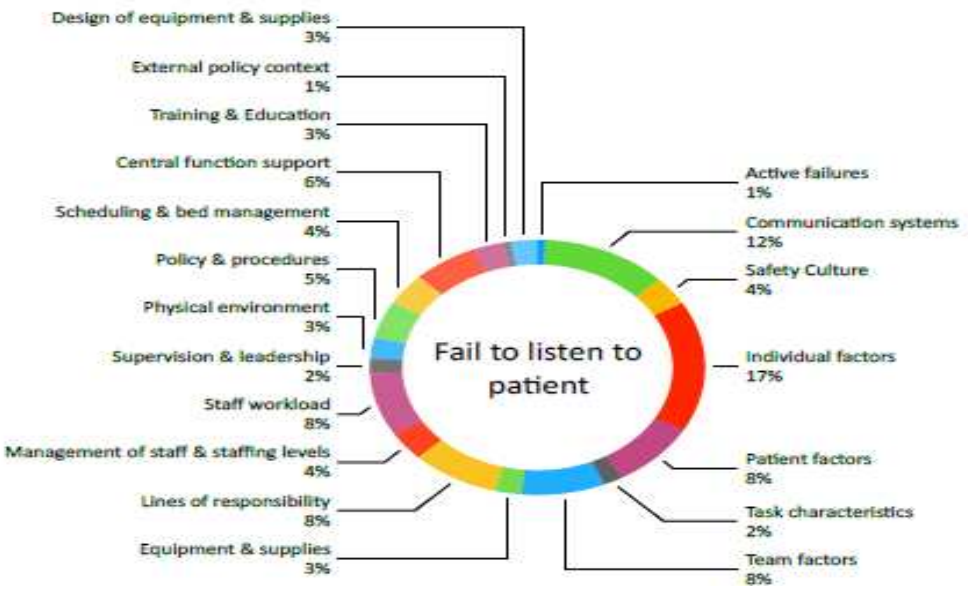
17 For stage three, in partnership with the Scottish Government, we will convene a workshop at the end of this year with interested parties to share our findings. This will explore how our findings resonate with those closer to the front line, but more importantly, will consider what, if any, action may be taken to improve communication in these areas (recognising that any action might be collaborative or delivered by another organisation better placed to act). Depending on the nature of the conversation, this could have implications for our 2019 Business plan, so we may wish to consider retaining some capacity to address any identified actions.

18 The Scottish Public Services Ombudsman, who have recently undertaken a separate mapping exercise of communication training, tools and frameworks (within healthcare), have also expressed an interest in collaborating on our proposed workshop and we are working to identify a joint list of potential stakeholders to invite (working closely with the GMC Scotland Office to do so).

19 Separately, we are aware that NHS Improvement are undertaking a similar project to explore the link between verbal communication failures and patient safety incidents, focused on understanding the nature of such issues and how they may be prevented in future. We have made contact with the project lead to discuss potential synergies (and to offer an invitation to attend our workshop).

20 The illustration below is taken from the draft literature review and represents an assessment of the various contributory factors that are associated with a 'failure to listen'. Without dwelling on the detail, the number of groups neatly illustrates the multi-faceted nature of these issues and perhaps suggests why anyone body cannot tackle this in isolation.

Figure 7. Individual contributory factors identified as contributing to a communication failure to listen to patients



21 Therefore, we are keen to ensure that our workshop involves representation from a broad range of groups, including communication experts and individuals from other industries and sectors where appropriate (adopting a similar approach to that taken by the Health Foundation for their problem-solving focused 'Q labs').

Future harms projects

22 Our second harms project – sponsored by our Standards (Mary Agnew) and Fitness to Practise teams (Anna Rowland) and provisionally scheduled for November 2018 to June 2019 - will take a broader focus, seeking to understand how and why doctors struggle to comply with certain aspects of GMP (for which we receive high volumes of complaints).

23 Our interest is in understanding whether there are common contributory factors but, more importantly, whether we are consistently issuing similar types of warning or types of advice, and / or agreeing similar forms of undertaking. Patterns of this nature may suggest that a more strategic response is required rather than continuing to respond on a more piecemeal basis to individual concerns.

24 Future harms projects are still to be agreed and will largely depend on the successful completion of the first two projects. To inform future choices, we are continuing to compile a GMC 'harms register' (Annex B), informed by internal consultation and supplemented with commissioned research on avoidable harm.

25 A number of these harms are broad, well known issues and our ability to effect change will be limited - however, in certain cases, there may still be potential opportunities to offer new perspectives and insights, recognising the value of the unique and comprehensive datasets that we have access to.

26 However, our commissioned research identified medication-related harm as the most commonly occurring type of avoidable harm (with 4% of patients experiencing this and with most errors occurring at the prescription stage of the medicines pathway) so we may wish to focus on this (building on earlier research on research we commissioned into prescribing errors in primary and secondary care in 2008 and 2009 and exploring how far the recommendations were subsequently addressed).

Governance for the harms programme

27 We have assembled a cross-directorate group to provide challenge and expert input to the programme on an ongoing basis, with the first meeting held in June. Key decision points – in terms of decisions to tackle new harms and / or agree regulatory responses to existing harms will be brought to the relevant decision making body (informed by our governance guidance for the policy framework).

General Medical Council

8 – Annex A

Upstream narrative

1 Our approach to upstream regulation is described below:

Upstream regulation means pro-active, early and specific interventions in order to either decrease the likelihood of an undesirable outcome (e.g. ftp) or to increase the likelihood of a more favourable outcome. In cases, this involves identifying, understanding and addressing potential problems which present potential barriers to our desired outcome. As such, it can also be described as a 'problem-solving' approach to regulation.

How we intervene will depend upon the nature of the problem we seek to prevent or the opportunity we hope to exploit. It may involve doing things differently, with a greater focus on 'influencing' rather than 'enforcement'. It may also involve working more collaboratively with partners closer to the point of care, should they be better place to deliver the required action.

But underpinning this is the premise that it is more efficient, effective and less harmful (to both doctors and patients) to apply regulatory effort at an earlier point, rather than take more costly, remedial action after an event has occurred.

'Upstream regulation' does not apply to any business as usual action we take to keep patients safe and / or promote high standards in the delivery of medicine (for example, Good Medical Practice, Revalidation, QA of education providers). Rather, upstream regulation is focused on the delivery of discrete projects aimed at addressing the following:

- Improving the safety and effectiveness of medical practice delivered by our registrants (for example, Welcome to UK Practice and our work on tackling mental health issues and communication related harm).
- Improving the ability of the healthcare system to support safe and effective medical practice at an individual registrant level (for example, our work to understand toxic environments and work to respond to emerging concerns from the training environment).
- Improving our ability to regulate and thereby facilitate safe and effective medical practice (for example, our work on local first, provisional enquiries, differential attainment and primary source verification).

General Medical Council

8 – The Harms Reduction Programme: progress update

8 - Annex B

Draft harms register

1 The table below sets out a long list of harms for potential future consideration.

Harm	Detail
1. Problems that are harmful to the delivery of safe and ethical practice (Individual level harms)	
Direct patient harms	
Poor care coordination – ownership	Increasing complexity of clinical management – more tests involving different specialties and more complex drug / intervention treatment. Multiple parties involved but lack of patient overview / ownership, therefore increasing risk of error / substandard care.
Poor care coordination – continuity (handover)	Inadequate / absent handover. In some cases, anecdotal feedback suggests this can be focused more on symptoms / acute scores as opposed to the holistic needs of patients.
Care of psychiatric in-patients	Particularly in Scotland.

Failure to diagnose / missed diagnosis	Particularly cancer (exacerbated by pressures on GPs).
Inadequate pain relief	Failure to prescribe or administer pain medication.
Failure to follow up	In particular, failure to follow up on monitoring such as blood tests and failure to act on test results (also a common issue from CQC primary care CQC inspections)
Poor communication	Between patients and carers / families and between professional colleagues. Particular issue in plastic surgery (e.g. mis- selling, fail to gain proper informed consent etc).
'Low level unprofessionalism'	Can lead to unsafe care. Issue of doctors failing to understand / grasp importance of softer skills - e.g. taking steps to avoid confrontation with patients and therefore not passing on accurate information.
Prescribing errors	Inappropriate due to failure to take a complete medication history and therefore fully account for other co-morbidities (exacerbated by increasing levels of patient complexity – in terms of chronic conditions and multiple morbidities).
Inappropriate / excessive prescribing	Increasing risk of antimicrobial resistance. Preventing healthcare acquired infections is cited as a key area for improvement within the NHS Five Year Forward View.
Failure to act / respond	Failure to identify deteriorating patient and prevent avoidable deterioration.
Inadequate assessment	Doctors failing to undertake a holistic assessment and focusing instead on the symptoms / condition.
Poor maternity care	Given prominence in recent inquiries and reviews (particularly in light of the Kirkup inquiry into Baby Elizabeth Dixon) are there general themes in the maternity cases that we've received over the past 5 years? In keeping with the NHS Five Year Forward View – which highlights maternity safety as a key

	area for improvement.
Never events	e.g. wrong site surgery.
Inappropriate use of Mental Health Act to section Doctors	Survey of psychiatric trainees undertaken by the Royal College of Psychiatrists revealed that a third of respondents claimed that "a colleague had used the Act to detain a patient knowing it would make provision of care more likely" while "24 per cent reported that bed managers had told them that unless a patient had been sectioned they would not get a bed".
Treating with dignity and respect	Potential psychological harm for patients – what are they key characteristics here – are there common case studies relating to this area? Are there themes in the advice / warnings we offer?
Indirect patient harms	
Raising concerns (and receiving feedback)	Poor compliance with raising concerns due to culture and limited knowledge of local practices. Datix seen as the only channel for raising concerns but also seen as failing and not very effective. Poor use of datix and raising concerns systems. Key issues: time to complete, logic flow impedes completion, culture (no feedback, no change). Raising and acting on concerns raised as an issue in every major inquiry / investigation over past 15 years.
Failure to learn / improve	Due to ineffective approach to quality improvement at systems level – not one for us despite being a supporting information requirement?
Dishonesty	Can we identify relevant ftp cases and explore key themes. Could look at dishonesty in job applications (potential overlap with CQC and Fit and proper persons test?).
Conflicts of interest	With a particular focus on referrals to units that the referrer has a vested interest in. Again, can we identify relevant case material to look at – and is this now an 'old' issue following the CMA report?

Student FtP	Behaviour most likely to lead to student fitness to practise and their impact on future professional practice.
Harm to doctors	
Health concerns	Given increasing risk and reality of burn out within general practitioners, are there patterns of health concerns by specialty (in terms of type and prevalence). Are some specialities at greater risk of issues like burn-out and addiction than others?
Bullying and undermining	What characterises this, what can we learn – is there anything to add beyond the NTS report undertaken in 2016?
2. Problems that are harmful to the ability of the system to support doctors to practise safely and ethically (System level harms)	
Team working and collaboration	
Poor care coordination – continuity (between teams)	Transfer of care for elderly patients who end up seeing a large number of doctors and therefore the continuity of care is being compromised. Same issue can apply to patients in primary care – whereby patients see 6/7 doctors before a diagnosis made (and each consultation tends to focus on symptoms / issues, less so on previous consultations so real continuity of care here contributing to missed / delayed diagnosis).
Poor care coordination – continuity (multi-agency involvement)	We have seen an increase in complaints with multi-agency involvement – where no one organisation has taken the lead, therefore patients haven't been receiving the appropriate care / treatment.
Poor care coordination – continuity (across care interfaces)	Poor transfer of information across the care interface (referrals, tests, results etc). Relationships between primary and secondary care have broken down in a number of cases.

Poor care coordination (loss of data)	Loss of / failure to handover / compile relevant data leading to key delays in treatment (e.g. St George's University Hospitals NHS Trust admitted 2 patients had come to severe harm because of this, and 10 patients with low harm – ongoing review to identify if this is a wider problem).
Ineffective multi-disciplinary team working	Involving lack of collegiality, hierarchies and dysfunctional teams.
Management support and leadership	
Quality of leadership and continuity	In part reflecting conflicting priorities – balancing political priorities with quality leadership. More generally, what characterises good and poor leadership in the face of current pressures?
Foundation Trust Application	To what extent does this lead to a deterioration in training quality in the run up to an application?
No management support for appraisal and CPD	Medical leaders are being pressured to focus on rotas, bed management and delivery a service which may lead them to de-prioritise the management of low level concerns and other professional relation activities such as appraisal and CPD.
Quality of governance	Doctors not engaging with appraisal or not part of a well governed process may present a particular risk – may be one to add to the intelligence model product?
Governance	Quality of governance arrangements (primarily for locum agencies but may wish to look also at failing trusts) – are there inadequate safeguards concerning employment checks, induction arrangements etc. But is this feasible? How would we get at this information?
Poor quality induction	In terms of content and relevance.

Process failure / non-compliance	
Non / poor compliance with clinical guidelines	For example, failure to complete WHO checklists in surgery, failure to adhere to infection control guidelines (similar issue arose about a separate clinical guideline in care provided by Ian Paterson).
Inappropriate discharge	Individuals being discharged prior to the results of investigations – particularly in A&E.
Safeguarding concerns	Deficiencies in basic care in wards and nursing homes.
Wider resource pressures	
Poor referral practices	Some doctors being paid not to refer.
Delays in Surgery	Due to access to diagnostic tools.
Lack of patient contact time	Patients poorly fed, not fed or eating due to lack of assistance (but more of a nursing issue?).
Lack of time for reflection and CPD	
Education and training	
Rota gaps / working rotas in breach of WTR	Focusing on the notion that poorly designed rotas present a risk to patient safety (and a sub-optimal training experience). Exacerbated by growing tensions between service delivery and education (approx.. 40% service delivery currently provided by trainees?) with trainees in some cases working beyond areas of competence. Is there any correlation between NTS scores relating to rota design and education outcomes and / or measures of care quality?

Lack of effective supervision & support for trainees / lack of consultant cover	Frequently cited as an issue, and referred to in investigations into Bristol Royal Infirmary (2001), Northwick Park Hospital (2006), Maidstone and Tunbridge Wells (2007), Morecambe Bay (2015) and Vale of Leven (2015).
Quality of leadership / supervision for doctors in training	Supervisors poorly prepared with, in some cases, poor interpersonal and communication skills (providing feedback). Anecdotal evidence suggests some supervisors are forced to undertake this role rather than because they want to. No additional financial reward / time for the role.
Trainees feeling isolated	Lack of social support – due to frequency of movement. No peer support or family support present.
3. Problems that are harmful to our ability to regulate, and facilitate, the delivery of safe and ethical practice (Regulator / national level harms)	
General	
Defensive medicine	Over investigation and treatment due to fear of litigation / fitness to practise.
Transient doctors	Can we build on previous work in the Intelligence model to understand more about the risks these groups present – particularly peripatetic locums, but also other doctors moving frequently through the system (in terms of use of zero hour contracts and short term contracts). Creates difficulties for information to be shared about doctors – and also means that doctors are never in one place long enough to be considered to be working within a 'governed system'.
Increasing ethical complexities of care	Legal consent issues, end of life care issues and concerns over capacity.
Lack of knowledge / Limited awareness of	Core GMC guidance not taught / limited awareness – also referred to in investigations into Vale of Leven (2015) and Northwick Park (2006).

core guidance (GMC)	
Poor regulatory management of low level & behavioural concerns	Healthcare providers have fed back that GMC manages clinical concerns but is not consistent or supportive in the management of behavioural issues, persistent low level clinical concerns and medical management concerns (How would we evidence this? Could this be audited somehow as a research project?).
Declaration of health concerns	Anecdotal evidence suggests that some doctors may withhold details of health concerns on registration (avoiding need for complex casework). But how do we know - how can we separate out longstanding health conditions from those identified post registration.
System pressures	The massive pressure that the NHS is experiencing at the moment and the knock on effect to the wider independent sector. It's not just about funding, it's about capacity, unprecedented numbers of patients arriving at A&E, lack of beds, lack of doctors, poor social care arrangements etc. Many of these issues are totally outside of individual doctors' control and outside the GMC's control but patient safety issues may arise from them. Leading to doctors being asked to work in environments that are likely to increase the risk of breaches of GMP.
Warnings	May want to focus on warnings for clinical / conduct issues and explore whether there are common themes - are we issuing similar types of warnings etc. Which areas of GMP (which warnings are linked to) tend to receive highest numbers of warnings – and what are these focusing on? Can we do anything proactive to mitigate these – case studies etc?
Education	
Characteristics of a poor training environment	What are the key factors, if any, that link organisations within Enhanced Monitoring (for a prolonged period of time) or organisations that have triple / quadruple red outliers for the NTS.

Revalidation	
Differential attainment	Are certain groups experiencing disproportional barriers / problems / issues revalidating? (where a prescribed connection exists).
Registration	
Complex casework	What happens to doctors treated through complex casework in terms of future ftp referral / quality of practice? (But may not be able to identify these doctors through Siebel – should we start capturing this?).
Registration status	To what extent do our registration decisions correlate with future fitness to practise decisions, and do certain registration routes present particular challenges and concerns at a later point (for example, to what extent do temporary registered doctors present particular challenges?).
Equivalence ruling / RPQ	To what extent are EU qualifications equivalent – do some lead to high levels of concern compared to others (may be able to explore further as part of the Intelligence Model once quality assured).
Erased / unlicensed doctors	Anecdotal evidence suggests that some doctors that were refused registration or were erased go onto practise privately – to what extent are we able to further explore this issue? Unlikely to be feasible – are these cases ever brought to our attention?