General
Medical
Council

GMC response to NHS Improvement's consultation: Developing a patient safety strategy for the NHS

Summary comments

We support the proposals outlined in the consultation. The principles, aims and proposals are sensible, pragmatic and build on a number of existing initiatives that have already been well received.

Notwithstanding this, we believe that the strategy could be improved by placing a greater focus on patient involvement. We therefore suggest that NHSI consider including the additional aim of Involvement: working with patients and those close to them to develop and deliver safety improvements.

We also encourage NHSI to consider how we and other regulatory bodies might collectively work together to support the implementation of the strategy. Critical to the strategy's success will be ensuring adequate provision of support to the organisations and professionals tasked with implementing the new initiatives at a time when both are under considerable pressure. We are committed to doing what we can to facilitate the implementation of the strategy in a way that will not create undue burden on the sector.

We recognise that there are synergies with many of our programmes of work and further opportunities for collaboration. For example, our 'Local First' programme aims to combat some of the issues NHSI identified with local investigations by encouraging learning from complaints and ensuring that patient harms are identified, shared and resolved at local level before being escalated to us.

We welcome the proposal to implement a new patient safety curriculum. The aim that this curriculum will be applied on national scale is a clear benefit; patient safety will be enhanced and systems and processes will be better aligned across healthcare. We recognise that implementation may pose a challenge as professionals may have difficulty in undertaking further training due to existing work pressures and commitments. As detailed in our response below, our Regional Liaison Teams could potentially offer assistance in this area and we welcome the opportunity to discuss with NHSI ways in which this training could be facilitated.

We also support the proposal to develop a Network of Senior Patient Safety Specialists. This initiative will be instrumental in sharing good practice and driving overall system improvement by focusing on those organisations most in need. As it is envisioned that

these roles will be recruited amongst existing staff, we suggest that NHSI consider possible further measures to ensure that those selected are given dedicated time within their job description and working days to undertake these roles effectively.

Finally, we would like to express our support that the consultation is relevant to all types of NHS healthcare, including mental health and primary care. The patient safety agenda is often dominated by acute trusts and there has been insufficient focus on mental healthcare. The focus on mental health patient safety in the initiatives section of the consultation is an important step.

We have provided detailed responses to each of the questions posed by the consultation document below and we are happy to discuss any of the points raised further. We are also happy for our response to this consultation to be published.

Question 1) Do you agree with the consultations aims and principles?

We agree with the principles outlined in the consultation document and believe that they provide a good foundation for an effective patient safety strategy. In terms of the consultation's aims, whilst we are supportive we would like to suggest the inclusion of the additional aim: Involvement. This aim would encompass 'working with patients and those close to them to develop and deliver patient safety improvement'. We are suggesting this additional aim because patient involvement is only briefly referred to in the current patient safety strategy, but evidence from the CQC indicates that patient safety systems are more likely to be effective if patients are actively involved. We believe that ensuring meaningful patient involvement is central to improving patient safety and would be keen to see this underpin the new strategy.

We recognise the challenges described around the capability and capacity of healthcare providers to carry out good quality investigations; the tendency to use investigations for the wrong purposes and the generally poor approach to patient and family involvement. Issues surrounding local investigations are of deep concern to the GMC and we understand that this may prevent the creation a just culture. We have published our Good Investigation Principles, which can be found here. Based on our expertise and experience we have set out the principles that should underpin investigations into concerns about fitness to practise and questions that organisations could ask themselves about how their processes incorporate these principles.

We would welcome the opportunity to work with NHSI to overcome the challenges to achieving good quality investigations which are also relevant to our fitness to practise function. In our corporate strategy for 2018-2020, we committed to developing a "Local First" approach to investigations with the aim that all complaints and concerns about doctors should be dealt with at the right level. We believe that where possible, concerns should be addressed locally, only involving the GMC where this is necessary. This is likely to be most relevant where concerns relate to clinical matters or patient harm where systems and processes have been a key contributory factor. In order to address this, we will need to work closely with NHS organisations to understand the quality and consistency

of local investigations which would provide us with the assurance that a doctor does not pose a serious risk to patients through misconduct, ill-health or significant performance concerns.

Question 2) What do you think is inhibiting the development of a just culture?

We believe that a just culture is vital in ensuring that all healthcare professionals feel confident in raising concerns so that lessons can be learned at both an individual and organisational level. Nevertheless, we are aware of a number of issues that may inhibit the development of this.

We are aware that there remains an unhealthy fear of retribution if something has gone wrong and that this can drive and perpetuate certain behaviours that undermine the development of a just culture. We would like to point out that we agree with the assertion that there should not be an entirely blame free approach; we believe that sanctions should still be taken against health professionals if they are deliberately malicious or wilfully negligent. We agree that, in the absence of wilful negligence or malicious behaviour, blaming individuals for error where there is no question about that person's fitness to practise does not improve patient safety.

However, we understand that doctors and other healthcare professionals are afraid of raising concerns due to fear of personal or professional retribution and being personally blamed. We are also aware from interactions with doctors and whistle-blowers that 'incident' reporting can be used as a tool to facilitate bullying and harassment thus preventing professionals from raising awareness and inhibiting any form of system change. This will prevail as long as it is considered "wrong" to be involved in a Datix incident. NHSI should focus on introducing initiatives that incentivise Datix reporting, for example, providing rewards for staff that can evidence practice change following an incident.

'Toxic' workplace sub-cultures is another significant issue that inhibits the development of a just culture. In the coming months we will be publishing a report by Dr Suzanne Shale exploring the challenges doctors in leadership positions face in creating and sustaining compassionate care cultures in the workplace. We hope that this work will help identify possible solutions to the problem.

Question 3) Are you aware of NHSI's 'Just Culture Guide'

Yes, the GMC is aware of NHSI's 'Just Culture Guide'. Our Director of Education and Standards has specifically referred to the guide during conference speeches on accountability and just culture.

Question 4) What do you think could be done to further develop a just culture?

Firstly, we are aware that there is some confusion surrounding the term 'just culture'. The consultation document defines a just culture as moving away from the current blame

culture in healthcare towards a focus on changing systems and processes and encouraging learning. Whilst we fully endorse this view, we believe that a just culture should also take into account issues such as proportionality, fairness and accountability. We would therefore encourage establishing a common and more inclusive understanding of what is meant by a 'just culture' as a way to enable more informed and proactive conversation.

We believe that a strong leadership which embraces the values of a just culture is a vital factor in allowing a just culture to develop and flourish. Leaders need to help foster a work environment that encourages openness, readiness to learn, ability to reflect and confidence to follow through where concerns are raised (and the research we have commissioned Dr Shale to undertake for us will help us better understand the challenges to realising this).

Another essential element of establishing a just culture is ensuring that all healthcare professionals are treated fairly. We understand that there can be instances where hierarchial structures can adversely affect this and are involved in a number of initiatives that aim to addresss this issue. We have developed training, online resources and an associated change programme based on the Vanderbilt model principes, which should help doctors identify and eradicate unprofessional behaviours in themselves and others.[*] We would welcome an opportunity to discuss with NHSI how this programme might be able to support this strategy.

It is also important that professional regulators do not adversely affect the development of a just culture. Whilst the GMC and other regulators should address serious concerns, doctors and other healthcare professionals should not be in constant fear of referral when errors occur. The conversations that our Employer Liaison Advisers have with employers ensure that concerns are only referred to the GMC when they need to be and that, where possible, concerns are addressed at a local level.

We welcome and support NHSI's acknowledgment of the importance of human factors and ergonomics in the investigative process and their role in assisting with the development of a just culture. We have included and prioritised human factors principles in the outcomes set for students and doctors. And in October 2018 we announced that all of the General Medical Council's fitness to practise decision makers, case examiners and clinical experts are to receive Human Factors training and advice on modifying investigation processes, as part of a collaboration agreed with Oxford University's Patient Safety Academy. This action will help ensure that system issues are properly considered in any local or GMC led investigation.

Question 5) What more should be done to support openness and transparency?

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[*] The Vanderbilt Model is an escalation framework developed by the Vanderbilt School of Medicine to address disruptive / unprofessional behaviour in the workplace

We believe that openness and transparency is closely linked to having a just culture. We believe that regulators, professional bodies, providers and education bodies need to work together to embed a culture of candour. Indeed, the GMC worked closely with the Nursing and Midwifery Council (NMC) to develop our joint guidance on the duty of candour. We acknowledge that doctors, nurses and midwives are uniquely placed to encourage partnership working and influence culture across the professional boundaries, and this guidance outlines our joint expectations of our registrants in this regard.

We will be considering recommendations made by PSA for embedding candour, such as working with employers and system regulators to ensure positive reinforcement of skills learnt during practitioners' training are not negatively impacted by environments with poor records of candour.

We also believe that more work can be done to establish processes for ensuring that concerns are acknowledged and acted on routinely, with feedback provided to the individual(s) who raised this. Feedback loops like these will further empower staff to speak out.

Question 6) How can we further support continuous safety improvement?

Engaging clinicians more closely in safety learning and improving the way in which learning is shared across the system could support more effective clinician to clinician safety learning. To facilitate this, we are willing to explore how we can use our communication channels with doctors to share safety measures. And we would be interested in discussing the possibility of joining with NHSI and other interested bodies to carry out further work in this area.

Revalidation may present a further opportunity for supporting safety improvement. As part of their supporting information requirements, doctors are required to evidence their involvement in quality improvement activity. At present, most individual doctors are free to choose which quality improvement activity they participate in on the basis that it must relate to aspects of their area of practice. Although we do encourage, within our guidance, participation in relevant audits and service reviews, there is potentially a greater role here for organisations to consider how this requirement of revalidation could be used to better support and embed patient safety initiatives. In effect, this could involve directing professionals towards particular quality improvement activities that serve wider corporate needs as opposed to the current self-directed approach.

Question 7) Do you agree with NHSI's proposals? (relating to Insight)

Yes, the GMC welcomes NHSI's proposals to improve the way that learning and insight is derived from multiple sources by introducing the new Patient Safety Incident Management System. We are aware of concerns that NHS organisations often have different protocols which may lead to confusion or even inaccurate understanding for trainees and locums moving between organisations. Encouraging a more uniform approach to safety policies and protocols throughout Trusts would represent a big step forward.

Question 8) Would you suggest anything different or is there anything that you would add?

We suggest that further consideration be paid to the thresholds used for the reporting of incidents to allow for the reporting and identification of minor issues before they become more serious. Identifying incidents earlier on may prevent escalation to the investigative stage which may lessen the fear of retribution felt amongst the profession. We also believe that there are opportunities for learning from lower level concerns.

Furthermore, we recognise that the consultation places a lot of importance on the use of patient safety information. We collect data on the medical profession and the organisations where doctors practise and train and are committed to using and sharing this as a means for learning, for addressing risks and for driving improvements in patient care. We would welcome further discussions with NHSI on this point.

Question 9) Do you agree with NHSI's proposals (infrastructure)

Yes, we broadly support the proposals set out in this section.

We agree that a patient safety curriculum will promote understanding of patient safety amongst NHS staff and will help increase alignment and efficiency of safety techniques. However, we believe that particular attention should be afforded to how this curriculum is implemented. Our report 'State of Medical Education and Practice in the UK' found that one of the key strategies used by professionals to deal with pressure is to prioritise certain aspects of clinical care at the expense of other activities such as continuing professional development. We therefore suggest that NHSI consider methods of implementation, to ensure that these measures are proportionate and adequately financed so that they do not burden professionals and organisations already under pressure.

Recognising the potential links between the curriculum and our 'Generic Professional Capabilities' (GPC) framework (launched in 2017), we believe that we are well placed in the healthcare arena to assist the NHSI in developing and implementing the curriculum. We would be happy to provide assistance and, where possible, share knowledge in order to assist with the curriculum development process.

We also welcome NHSI's proposal to develop a Network of Senior Patient Safety Specialists. We have existing posts similar to that which is proposed, for example, Freedom to Speak Up and Safer Working Hours Guardians, and we believe that these can provide important lessons for the establishment of the Network.

However, we have found that those carrying out these posts must be carefully selected and they must be given time within their job descriptions and working days to be able to undertake their roles effectively and carry out sufficient training where necessary. Therefore, simply creating additional responsibilities for existing members of staff (rather than recruiting to these new roles) may undermine the effectiveness of the Patient Safety Specialists.

Question 10) Would you suggest anything further or would you add anything?

In relation to the establishment of a new Network of Senior Patient Safety Specialists, we would like to highlight that our field forces work is of particular relevance here. We have a network of Employer and Regional Liaison Advisors that currently engage with over 40,000 doctors and medical students each year. These teams often provide training and support in practising safely and supporting the wider patient safety agenda. Furthermore, our RLS teams already go to providers who are facing challenges with patient safety and give sessions on topics that will help overcome this. Therefore, there is potential for a much wider strategic partnership here. We believe that our outreach teams could work with the proposed new network and that they could facilitate training and learning. We would thus welcome collaboration between ourselves and NHSI in order to align work in this field.

We would also like to highlight the importance of ensuring that this new Network integrates with any existing networks already in place that form part of the patient safety team - such as the Safer Working Guardians, the Freedom to Speak-up Guardians and our RLS and ELS teams mentioned above. Greater collaboration and integration will also be necessary between the new network and other key organisations that have regional structures such as the NMC and Healthwatch.

Question 11) Which areas do you think a national patient safety strategy should cover?

We would like to point out that all of the above areas are very important, and in particular the following seven areas:

   a. Human factors and ergonomics
   b. Patient / Family / carer engagement
   c. Systems thinking
   d. Delivering education and training
   e. Communication skills
   a. Introduction to patient safety science
   b. Incident reporting and management

Question 12) How should training be delivered?

We recognise the potential for the GMC to assist in the delivery of patient safety curriculum training by engaging clinicians with the safety learning via our communications channels with doctors. There may also be potential for the curriculum to be included in our Welcome to UK Practice Programme, as well as an opportunity to reconsider how these issues are covered in our PLAB and GMC Performance Assessment. We therefore welcome further collaboration with NHSI to understand how our processes may be able to assist in facilitating training delivery.

Question 13) What skills and knowledge should patient safety specialists have?

We believe that all suggested areas are important. However, if pushed to pick just five, we believe that the patient safety strategy should cover the following:

a. Human factors and ergonomics
b. Systems thinking
c. Delivering education and training
d. Communication skills
e. The components of a patient safety culture

Question 14) How senior should patient safety specialists be?

We believe that patient safety specialists should be Executive Level (Executive Senior Manager) in order to ensure the highest level of understanding and experience in patient safety issues. However, we would like to reiterate that additional workloads will need to be managed in a way that will not impact on their existing duties.

Question 15) How can patient / family / carer involvement in patient safety be increased and improved

Ensuring meaningful involvement of patients and their family / carers is central to improving patient safety. For us, we believe that 'meaningful' involvement requires the patient and their family or carers to have a full and correct understanding of our investigative process, an ability to contribute to the investigation, receive regular updates on progress, and that they are aware of the outcome and any actions that are going to be taken. We have adopted several measures to help achieve this including the introduction of our Patient Liaison Service (to share relevant information about the complaint and to explain our investigation process). We would be happy to share our experience in improving how we involve patients and their families/carers in investigations processes.

To increase and improve the involvement of patients and their family or carers, one option could be to more widely publicise existing opportunities for doing so. For example, consideration should be given to holding meetings (with patients) outside of usual working hours. Furthermore, there may also be opportunities to increase the involvement of third parties such as victim support or specially trained staff (similar to our Patient Liaison Service) who could debrief patients or family members on all aspects of the investigative process following a critical event.

Question 16) Where would patient involvement be more impactful

Whilst we believe that patient involvement in all areas suggested would provide great impact, we consider that a dual focus be adopted to address both the whole system / strategic level and to facilitate clinical pathway design.

Question 17) Would a dedicated patient safety support team be helpful in addition to existing support mechanisms?

Yes, we agree that a dedicated patient safety support team would be a helpful addition to existing support mechanisms as this would assist in sharing best practice and supporting those that currently work in the most challenging environments.

However, measures must be taken to ensure that the patient support team integrates effectively with others already working in this area so that they are effective tool and not regarded as an additional regulatory burden by professionals. The support team must also uphold values of a just culture, openness and learning; if the team is perceived as a threat to these values, this is unlikely to achieve the desired outcomes.

Question 18) Do you agree with these proposals? (Initiatives)

We support the proposals set out within the Strategy and share NHSI's ambition to deliver measurable reductions in specific areas of 'harm'. Within our Corporate Strategy 2018-2020, we set out a programme of work to identify, understand and address particular problems which present a risk of avoidable harm to both patients and doctors. As part of a more upstream approach to regulation, our intention is to identify opportunities to intervene before that harm occurs. Given the parallels with the proposed strategy, we would welcome any opportunity to collaborate with NHSI where our areas of work overlap.

Question 19) Would you suggest anything different or is there anything that you would add?

We note the consultation document identifies a number of initiatives in this area, with the potential risk that the system is overwhelmed in attempting to address each of these concurrently. Furthermore, this perhaps limits opportunities to learn from how and why some initiatives are more effective than others, before applying this to new areas of harm.

For our 'harms reduction programme' to be a success, effective collaboration will be critical - recognising that any solution is likely to be multi-faceted in nature and not always for the regulator to deliver. For this reason, and where appropriate to do so, we would encourage NHSI to adopt a broad perspective on how particular harms might be addressed, and how different parties across the health and care system (including providers, professionals, regulators and educators) might play a role in facilitating this.

The consultation notes that programmes will be prioritised where the most significant harm is observed. Further detail on what constitutes 'significant' would also be helpful. We would suggest that any prioritisation exercise also take into account the degree to which that harm is preventable, recognising that not all harm will be avoidable. To this end, NHSI may wish to review our commissioned research in this area, focused on identifying the key types of preventable patient harm.

Question 20) What are the most effective quality improvement approaches or delivery models? (top three)

We would encourage and promote quality improvement, though we do not have any further comments to make in relation to this question.

Question 21) Which approaches for adoption and spread are most effective?

No further comment.

Question 22) How should we achieve sustainability and define success?

It remains a challenge to articulate a clear causal link between an intervention and the outcome – in some cases, the intervention may simply create the conditions for that outcome to occur rather than driving it directly. For example, our expectation is that professional standards will act as an enabler, a benchmark of good practice that supports the development of professional identity – with good medical practice then following on from this.

Analysis we have undertaken suggests that where doctors have a strong sense of professional identity (based on shared values and experience) this has a broadly positive impact on healthcare practice. NHSI may therefore wish to explore how patient safety initiatives can serve to inform and reinforce this professional identity (across all professional groups) in order to promote sustainability.

Recognising that some initiatives may have a more indirect impact on harmful care, we suggest that proxy measures of success could also be considered. This could entail measuring awareness of the extent and nature of the harm, and awareness over the means through which it might be addressed rather than solely focusing on harder outcome measures (e.g. occurrence of harmful care). Where evidence points towards the effectiveness of a particular intervention, additional proxy measures could focus on the rate and level of adoption.

While the goal should naturally be to reduce harm, the value of increasing our collective knowledge over how and why such harms occur (a key objective of our harms reduction programme) should not be underplayed.

A further challenge is to ensure that the wider environment for practice is supporting professionals to deliver these initiatives, allowing time to learn, reflect and act accordingly. A failure to reduce harm may be indicative of a conflict between an individual's motivation to act and an environment in which institutional standards might serve as a barrier to good practice or in which the institutional culture is unsupportive of further action (See our 2012 enablers and barriers to good practice research).

Therefore, in thinking about how impact can be sustained, there is potentially a role for other regulators, training providers and professional bodies (as well as employers) to collaborate on the design and longer term sustainability of these initiatives.