Professor Sir Norman Williams Review into Gross Negligence Manslaughter in healthcare

About the Community Pharmacy Patient Safety Group

Patient safety is a fundamental priority for everyone working within community pharmacy. The Community Pharmacy Patient Safety Group was set up in February 2015 to advance patient safety culture and practice across the community pharmacy sector, including by increasing the reporting of patient safety incidents and enhancing the learning opportunities available when things go wrong. The Group has representation from community pharmacy Medication Safety Officers (MSOs) on behalf of all community pharmacies in England. Most of these individuals are Superintendent Pharmacists, or senior members of their team.

The Group meets bi-monthly to openly share and learn from each other, as well as from other safety-conscious industries. We consider how this learning could be applied and disseminated across the pharmacy network and wider health system, and then work together to create the opportunities to do so.

Every group member, and their employer, has committed to reducing the occurrence of patient safety incidents, sharing good practice and improving the overall approach people take when things go wrong. We have worked on a range of safety topics over the past few years including; introducing common principles for reporting and learning from incidents, understanding the role of community pharmacies in safeguarding vulnerable people, looking at how medication delivery services can be made safer, and disseminating information and resources about serious national risks to pharmacy teams.

Application of Gross Negligence Manslaughter in healthcare

At its meeting on 21 March 2018, the Community Pharmacy Patient Safety Group had an open and constructive discussion about the tragic death of Jack Adcock and the subsequent conviction of Dr Bawa-Garba of Gross Negligence Manslaughter, which has prompted this Review.

A summary of the key themes from our discussion and subsequent reflections, concerns and suggestions are outlined below, for the consideration of the Review panel. We welcome this Review and its efforts to ensure healthcare professionals, and the public, are better informed about where and how the line is drawn between gross negligence manslaughter (GNM) and negligence, what processes are gone through before initiating a prosecution for GNM, and the processes used in cases of GNM.

Openness and honesty

In commissioning this Review, the Rt Hon Jeremy Hunt stated that the Review will consider "how we ensure the vital role of reflective learning, openness and transparency is protected so that mistakes are learned from and not covered up". This is something members of the Community Pharmacy Patient Safety Group have invested heavily in over the last few years and we have seen a cultural shift across the sector, a shift in open and honest reporting, as well as the application and sharing of learning. We would be extremely disappointed if an unintended consequence of this tragic case was the regression to a blame culture in any part of the health and care system. One member of our Group commented: "After many years of progress in developing openness and honesty within the healthcare community and its' accompanying improvements in patient safety, a pursuance of recriminatory processes now would set back the patient safety agenda at least ten years."

We understand that Dr Bawa-Garba's reflections about the incident and her admission of culpability were used against her by the prosecution during her criminal trial. We are also aware of police investigations into pharmacy professionals where disclosure of all incident report forms relevant to particular individuals under investigation has been demanded, regardless of whether they were relevant to the particular incident under investigation. This has led some pharmacy team members to raise concerns about reporting any incident in view of the fact that it could be used in the future in an attempt to try and prove negligence.

We believe that this undermines the work that we have all been leading to embed our Report, Learn, Share, Act, Review principles. There is no 'correct' or 'safe' number of patient safety incidents. A 'low' reporting rate should not be interpreted to mean that a pharmacy is 'safe'. Similarly, a 'high' reporting rate should not be interpreted to mean a pharmacy is 'unsafe' and may actually indicate a culture of greater openness and a commitment to patient safety improvement. However, this context is not always clear to those involved in investigations, especially criminal investigations.

The General Pharmaceutical Council (GPhC) and employers require pharmacy professionals to be honest in reporting and providing statements about incidents during an internal investigation, yet the information that they provide internally for the purpose of root cause analysis can then be demanded as part of the criminal investigation. There is currently no 'safe haven' for pharmacy professionals to provide a full and frank account of an incident to support root cause analysis and learning alone. For the future healthcare professionals may want to take legal advice when being open and honest during their internal investigations, to ensure that they do not inadvertently say something that is later held against them in a criminal investigation or disciplinary hearing.

An appropriate balance must be struck to ensure that we continue to drive professionalism, openness and honesty, whilst allowing professionals to be confident that these behaviours will not then be used against them by the criminal courts or their professional regulator.

Professional regulation

We have confidence in the GPhC's regulation and revalidation of pharmacy professionals to protect, promote and maintain the health and safety of the public. We are confident that the Professional Standards Authority will also challenge the GPhC on any decisions which have been deemed to be too lenient for public protection in this regard. We welcome the GPhC's evidence submitted as part of this Review and their statement issued following the Dr Bawa-Garba case itself, which we hope has offered some assurance to pharmacy professionals, though the risks outlined above remain.

In many ways, the regulator has a far wider range of powers to uphold standards and handle potential GNM cases than the police. The GPhC also has a greater understanding and experience of what standard a healthcare professional should be operating at within their field of expertise and what constitutes whether or not the individual is fit to practise. Every case must be considered on its own merits to be proportionate and fair to all involved.

In light of the Bawa-Garba case, our Group members feel it is now difficult to see an instance where a doctor has been convicted of manslaughter and the General Medical Council does not strike them off. We are concerned by the approach taken by the GMC in this case, especially in the context that the Department of Health and Social Care recently consulted on proposals to merge several of the healthcare regulators.

Consistency of criminal investigative approach

There is currently inconsistency across police forces for handling investigations into incidents involving healthcare professionals. It is not clear who advises police forces on proportionality and reasonable expectations with regards to these incidents. Consideration could be given as to how the Criminal Prosecution Service or police forces could liaise with healthcare regulators on how to handle particular incidents that have resulted in the death of a patient, before they make a decision on investigating, charging and/or prosecuting.

Pharmacy professionals and employers have a clearer understanding of what to expect from their regulator (due to available decision-making guidance) for serious incident investigations, but the processes for criminal investigations are not well known. This means that the line between GNM and negligence is not clear. We would support the creation or review of guidance on what forces should assess or consider before investigating, charging, and/or prosecuting healthcare professionals for GNM, to drive consistency in this regard. Investigations and guidance should include a focus on whether the death of a patient is caused by a systems failure or individual failure. Contributory factors should be taken into account when making decisions about the prosecution of individual healthcare professionals. Our current experience is that investigations, certainly those undertaken by the police within community pharmacy, are heavily focussed on the failure of an individual, which can make the Responsible Pharmacist particularly vulnerable.

Impact on professionals

A threat of GNM conviction and subsequent removal from the register could lead to a more defensive or risk-averse form of healthcare, which does not enable professionals to confidently put their patients first. We would not wish to see healthcare professionals discouraged from trialling progressive treatments in this context.

We are aware of cases whereby pharmacy professionals have been investigated for manslaughter for incidents which have occurred during the course of their professional practice. Whilst it is rare for charges to be brought, the impact of the threat of charges and the full investigation has an obvious and detrimental effect on a healthcare professional's mental health and wellbeing. This impact may be immediate or delayed, can also affect their families and colleagues, and can potentially impact patient care where they are continuing to deliver healthcare services.

Improved public understanding

Public understanding and awareness of healthcare regulatory action and the application of learning or prevention of future incidents across healthcare should be improved. It is not always clear to patients and the public what actions are taken within an organisation when a patient safety incident occurs. Guidance for the public to drive better understanding of the actions and steps taken by individuals, employers and regulators when incidents occur would be valuable. This should include examples of the actions or sanctions that impact the individual professional, their employer, and potentially their entire profession.

Where any system issues are identified, there are investigations into pharmacy owners and Superintendent Pharmacists which need also to be considered. In these cases, it can become virtually impossible for the company involved to act in a way which is seen to be supportive of both their employee and the patient (or their family).

It seems as though the ultimate goal of regulatory action is to improve public safety and patient care, yet in contrast the ultimate goal of a criminal investigation is usually to punish an individual. It should be made clearer to the public that a lack of conviction does not equate to a lack of action or learning. Similarly, a conviction does not automatically lead to improved patient safety. Healthcare regulators usually put regulatory action on hold whilst criminal investigations are taking place. If these criminal investigations do not lead to a successful conviction, the healthcare regulator will still take appropriate and proportionate action to determine whether the individual is fit to practise.

Next steps

The recent case of Dr Bawa Garba v General Medical Council was both enlightening and perturbing for everyone who works in health and social care. This Review has helped stimulate a constructive debate. Members of the Community Pharmacy Patient Safety Group are the leads on patient safety for their respective organisations and have significant expertise and experience in handling investigations when things go wrong. We would be well-placed and pleased to input to wider discussions on this challenging area of regulation and legislation, either as part of this Review or the activity that follows it. To access the Group, please use contact@pharmacysafety.org.