The Pharmacists' Defence Association's Response to NHS Improvement's Consultation on Developing a patient safety strategy for the NHS

February 2019

| representing **your** interests | | defending **your** reputation |

About the Pharmacists' Defence Association

The Pharmacists' Defence Association (PDA) is a not-for-profit organisation which aims to act upon and support the needs of individual pharmacists and, when necessary, defend their reputation. It currently has more than 28,000 members. The PDA Union was inaugurated in May 2008 and achieved independent certification in 2011.

The PDA is the largest pharmacist membership organisation and the PDA Union is the only independent Trade Union exclusively for Pharmacists, in the UK.

The primary aims of the PDA are to:

- Support pharmacists in their legal, practice and employment needs
- Represent the individual or collective concerns of pharmacists in the most appropriate manner
- Proactively seek to influence the professional, practice and employment agenda to support members
- Lead and support initiatives designed to improve the knowledge and skills of pharmacists in managing risk and safe practices, so improving patient care
- Work with like-minded organisations to further improve the membership benefits to individual pharmacists
- Arrange insurance cover for individual pharmacists to safeguard and defend their reputation.

Summary

NHS Improvement is consulting on a patient safety strategy for the NHS.

The consultation runs from 14 December 2018 to 15 February 2019.

The PDA generally welcomes and supports the proposals in the consultation. There is a significant need for increased focus on systems issues affecting medicines safety in pharmacy.

In the spirit of taking a systems approach to patient safety, some of our recommendations may be beyond the direct remit of NHS England and NHS Improvement, but they may be things that those organisations could help to influence.

Questions

Q1: Principles

A. Do you agree with these aims and principles? Would you suggest any others?

Yes, we agree with the principles, but make the following recommendation.

Recommendation

A fourth aim should be added as an aim for the NHS:

To foster a systems approach to patient safety which considers organisational and wider systems issues and involves staff working in patient-facing roles, on the front line of care, in systems design and decision-making.

We would also add a fourth principle: *systems improvement*.

B. What do you think is inhibiting the development of a just safety culture?

Regulation

Our view is that pharmacy suffers from poor regulation of pharmacy premises due to the inadequate performance of the General Pharmaceutical Council. In pharmacy, the unfair targeting of staff is not just an isolated matter; it does not just happen in pockets or with certain employers, but is also permitted by and present in the behaviour and focus of the regulator.

The GPhC regulates both individual pharmacists and pharmacy premises. According to the GPhC's annual reports up to an including 2018, it has issued 4,111 sanctions against individual pharmacists since its inception in 2010 – but according to its response to a Freedom of Information request in August 2018, had never issued a single sanction against any pharmacy owner or superintendent for a failure to comply with the Standards for Registered Pharmacies. Nor had it disqualified, removed, or sought to disqualify or remove, any pharmacy premises from the register. It did not even have a category in its fitness to

practice database for recording complaints which relate to compliance with the Standards for Registered Pharmacies. [1]

By way of context, the PDA also discovered through the GPhC's response to a Freedom of Information request in June 2018 that it has issued 667 overall "poor" ratings following pharmacy inspections between Nov 2013 and 24 June 2018. The GPhC says that a poor rating signifies that it had "major concerns about patient safety… that require immediate improvement" and that the pharmacy is "*likely to present an* ***unacceptable risk of harm to patients and the public.*** *This means the* ***risk is likely to occur and/or will have moderate to high impact.***" (Emphasis as per original documents). [1]

There are of course various consequences that flow from such poor regulation. For example, understaffing is a commonly reported problem in pharmacy and poses a risk to patient safety – yet even where the GPhC identifies understaffing and has concerns itself, its inspection results may still be returned as overall satisfactory. [2] This may mean that there is insufficient time to investigate and learn from incidents properly, undermining the establishment of a just culture. Another consequence of poor regulation we believe manifests itself in the whistleblowing culture in pharmacy: beyond the ordinary challenges facing whistleblowers, a conundrum faces the profession: what is the point of pharmacists raising concerns about systemic patient safety issues to a regulator that has no history of taking action against system failures in pharmacy premises?

Pharmacy ownership

The absence of a just culture in pharmacy is particularly apparent in certain organisations, where the drive for profit may come at the expense of quality. Investment in quality and patient safety improvement can be in conflict with the profit ambitions of the business. For example, the PDA obtained a document from a large pharmacy multiple which shows its staffing levels targets for 2018/19. Any overspend (i.e. overstaffing) at all is marked as red on a traffic-light scorecard system at individual pharmacy, area, regional and divisional level. Overstaffing vs. the budget given is essentially prohibited at each level of the company and any person not complying is likely to find that their performance rating, pay and/or bonus suffers as a result. The document states, specifically in relation to pharmacy staffing*: "Whilst*

over spending on payroll can impact on profitability, under resourcing can have a detrimental impact on both your store performance and the [company] brand image." In essence, overstaffing may affect the company's profitability whereas understaffing may affect performance against corporate targets and damage its brand; there is no mention of the effect on patient safety.

The European Court of Justice said in its determination – C-531/06 and in joined cases C171/07 and C172/07 in May 2009 - that *"[a] pharmacist pursues, like other persons, the objective of making a profit. However, as a pharmacist by profession, he is presumed to operate the pharmacy not with a purely economic objective, but also from a professional viewpoint. His private interest connected with the making of a profit is thus tempered by his training, by his professional experience and by the responsibility which he owes, given that any breach of the rules of law or professional conduct undermines not only the value of his investment but also his own professional existence. Unlike pharmacists, non-pharmacists by definition lack training, experience and responsibility equivalent to those of pharmacists. Accordingly, they do not provide the same safeguards as pharmacists" and member states may therefore take the view that "the operation of a pharmacy by a non-pharmacist may represent a risk to public health".* Furthermore, it was said that *"there is a risk that legislative rules designed to ensure the professional independence of pharmacists would not be observed in practice, given that the interest of a non- pharmacist in making a profit would not be tempered in a manner equivalent to that of self-employed pharmacists and that the fact that pharmacists, when employees, work under an operator [, which] could make it difficult for them to oppose instructions given by him".* [3] [4] It does not appear that the UK government has considered this issue at all.

C. Are you aware of A just culture guide?

No

In some areas of pharmacy (such as community pharmacy), our view is that it is not well-known or used.

D. What could be done to help further develop a just culture?

Addressing the issues outlined in our response to 1 B would help foster a just culture.

We have reviewed the just culture guide and we are particularly supportive of the following statement, since the principle it alludes to is often forgotten in pharmacy: *"Action singling out an individual is rarely appropriate - most patient safety issues have deeper causes and require wider action."*

We believe that the guide would be useful for many pharmacists, because, to quote from it: *"As well as protecting staff from unfair targeting, using the guide helps protect patients by removing the tendency to treat wider patient safety issues as individual issues."*

Recommendation

Ensuring that pharmacists including in community pharmacy are informed about the Just Culture guide, and providing management training on it, would help to develop a just culture.

E. What more should be done to support openness and transparency?

Our view is that Freedom of Information requests are often subject to obfuscation and delay from public authorities.

Recommendation

To improve transparency, the Freedom of Information Act ought to be strengthened by introducing individual and organizational sanctions for a failure to promptly comply. The circumstances under which information must be disclosed by community pharmacy providers should also be broadened and strengthened so that it is easier for the public to access information.

There are serious shortcomings with whistleblowing law in the UK. The EU is developing a whistleblowing directive to help improve the situation, and others have also proposed legal reform. To quote one whistleblower: *"[The Public Interest Disclosure Act 1998] provided protection not for me but for my then employer."* [5]

Recommendation

UK whistleblowing legislation must be replaced to improve the support and protections that enable whistleblowing.

F. How can we further support continuous safety improvement?

Recommendation

Continuous safety improvement could be supported through regular training for management on:

The systems approach to patient safety

Whistleblowing

The duty of candour

Q2: Insight

A. Do you agree with these proposals? Please give the reasons for your answer.

We agree with some of the proposals.

Recommendation

As with any organization, culture has an impact on employees. Care will be needed to ensure that the medical examiner system working for the NHS has its efficacy reviewed independently, periodically.

Recommendation

Medical examiners must be able to investigate deaths involving pharmacy patients, including in community pharmacy. They will need appropriate rights to access premises and information to do so.

B. Would you suggest anything different or is there anything you would add?

Recommendation

The reports submitted to the Patient Safety Incident Management System should be easily searchable by members of the public, so that they can access information and trends about reported incidents, for example by provider.

Recommendation

The Patient Safety Incident Management System for community pharmacy would benefit from independent review. Our understanding is that its predecessor, the National Reporting and Learning System, was reviewed by Pharmacy Voice, which represented pharmacies as businesses and not the profession or pharmacists per se. According to James Reason's *Human Error: Models and Management*, "*Seeking as far as possible to uncouple a person's unsafe acts from any institutional responsibility is clearly in the interests of managers.*" It is important that the incident reporting and management system, by design, is capable of reflecting institutional responsibility where it exists. The PDA would be happy to assist in reviewing the PSIMS.

Q3: Infrastructure

A. Do you agree with these proposals? Please give the reasons for your answer.

Yes – we welcome the proposed patient safety curriculum, senior patient safety specialists and patient advocates for safety.

Recommendation

Senior patient safety specialists may need to be recruited from outside an organization if necessary. Smaller providers such as independent community pharmacies may not be able to employ such a person directly and should have access to an independent network of such specialists.

B. Would you suggest anything different or would you add anything?

There is currently a need for a pharmacy patient safety advisory group which includes representation of front-line pharmacists, independent of their employer. There is a paucity of discussion and representation in this area. It is no good having representation only from senior staff (or those hand-picked by them) as these are the people who are responsible for and presiding over the current safety situation; patient safety would be unlikely to develop and improve at the requisite pace under such conditions.

One of the existing "safety" groups, for example, is the Community Pharmacy Patient Safety Group, which comprises senior staff representing large private organisations in community pharmacy. Amongst the many significant patient safety issues in pharmacy for which pharmacy owners are largely responsible – such as staffing levels, whistleblowing culture, premises layout, targets and general workplace pressure, perhaps unsurprisingly, one of its first recommendations was related to none of these – but rather was for the MHRA to give greater prominence to the strength on the packaging of licensed packs of ranitidine liquid formulations. [6] It seems clear to us that that group is not an appropriate forum for addressing more substantial systemic issues. A focus on placing the responsibility on the individual is not only unlikely to create systemic improvements, but may serve as a distraction and a barrier to addressing more substantial issues.

Recommendation

A patient safety systems advisory group is needed in pharmacy, with significant input from front-line pharmacists and separately from those with expertise in the field who do not have the conflict of working in, reporting to or representing the interests of pharmacy employers or their managers. The group's role would be to make recommendations about and advise on patient safety systems – to employers, the government, pharmacy regulators and MPs.

C. Which areas do you think a national patient safety curriculum should cover?

Recommendation

The national patient safety curriculum should cover at least:

Ensuring a systems approach to patient safety

Medicines safety (including the roles of pharmacists)

Patient safety incident investigation and reporting

D. How should training be delivered?

Recommendation

Training for the patient safety curriculum should be delivered through a variety of methods depending on the needs of individuals in different roles – ranging from face to face recognized courses to e-learning.

E. What skills and knowledge should patient safety specialists have?

Recommendation

Patient safety specialists should be qualified healthcare professionals such as doctors, dentists, pharmacists or nurses.

F. How can patient/family/carer involvement in patient safety be increased and improved?

It would be helpful for patients to have access to data from the National Patient Safety Incident Management System, as per our recommendation at 2 B above.

G. Where would patient involvement be most impactful?

Patient involvement would be most impactful if patients were able to see the data from reported incidents, as per our recommendation in response to question 2 B.

Recommendation

Patient involvement would be highly impactful during investigations of serious incidents in community pharmacy, as part of meetings where the pharmacist was involved alongside other professionals (similar to a safeguarding meeting). At present it is not common for such meetings to take place unless they are organized by others in the health service outside of the community pharmacy sector.

H. Would a dedicated patient safety support team be helpful in addition to existing support mechanisms? If yes, how?

Recommendation

A dedicated patient safety support team would be helpful in addition to existing support mechanisms for the reasons proposed in the consultation documents – for example to help understand the causes of challenges. It would be helpful for community pharmacists and GP practices to have access to such teams as well as NHS hospital pharmacists.

Q4: Initiatives

A. Do you agree with these proposals? Please give the reasons for your answer.

We agree with the proposals.

Recommendation

Front-line pharmacists must be central to the work on medication safety and integral to the other workstreams, such as antimicrobial resistance, mental health safety and infection prevention and control.

B. Would you suggest anything different or do you have anything to add?

The PDA is concerned by the effect on patient safety of the integration of NHS Improvement and NHS England. As set out in the consultation document, *"Both organisations are committed to increased integration and alignment of national programmes and activities: NHS England and NHS Improvement regional teams are coming together into seven joint regional teams."* NHS England focuses on commissioning, whereas NHS Improvement focuses on safety; the PDA regards this as a conflict of interests and is concerned that the integrated organisations may start to take in to account funding decisions when making patient safety recommendations, which will diminish the efficacy of the recommendations and the associated aspirations.

Recommendation

There must be a separate organisation focusing on patient safety in the NHS. This must not be integrated with the NHS commissioning functions.

C. What are the most effective improvement approaches and delivery models?

N/A

D. Which approaches for adoption and spread are most effective?

N/A

E. How should we achieve sustainability and define success?

Our view is that the NHS must hold an honest conversation with the public about public health policy and what is and isn't achievable in respect of patient safety. The NHS requires funding to achieve everything it needs and its quality aspirations are defined by that funding. It is important that the expectations of staff are met with sufficient funding, else those expectations must change. For example, it is not appropriate to hold front-line health professionals to account for errors when the cause of the error was due to insufficient funding (for example insufficient staff).

Success should be defined by better outcomes for patients, but not focused on outcomes alone. In pharmacy, our view is that many incidents and errors likely go unreported. As such, measuring change or "success" becomes more difficult; success might involve more errors being reported.

A reformed system of pharmacy regulation would help to achieve sustainability and is one of the key steps to progress in pharmacy. The PDA has made recommendations in this regard. [7]

References

[1] The General Pharmaceutical Council, "The GPhC identified major patient safety concerns in 667 pharmacy inspections," 27 July 2018. [Online]. Available: https://www.the-pda.org/the-gphc-identified-major-patient-safety-concerns-in-667-pharmacies-across-great-britain/.

[2] "The GPhC's approach to staffing levels," 21 June 2018. [Online]. Available: https://www.the-pda.org/the-gphcs-approach-to-staffing-levels/.

[3] "Apothekerkammer des Saarlandes and Others (C-171/07) and Helga Neumann-Seiwert (C-172/07) v Saarland and Ministerium für Justiz, Gesundheit und Soziales.," 19 May 2009. [Online]. Available: http://eur-lex.europa.eu/legal-content/EN/ TXT/?uri=CELEX:62007CJ0171.

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[5] M. Alexander and C. Sardari, "Alexander's Excavations," 18 October 2018. [Online]. Available: https://minhalexander.com/2018/10/18/whistleblowers-in-their-own-words-whats-wrong-with-uk-whistleblowing-law-and-how-it-needs-to-change/.

[6] "Pharmacy Voice: Reduce ranitidine incidents among children," 31 July 2015. [Online]. Available: https://www.chemistanddruggist.co.uk/news/pharmacy-voice-reduce-child-ranitidine-incidents.

[7] "Pharmacists' Defence Association Response to the Department of Health's Consultation on Promoting Professionalism, Reforming Regulation," January 2018. [Online]. Available: https://www.the-pda.org/wp-content/uploads/dh-promoting-professionalism-reforming-regulation-pda-consultation-response.pdf.