January 2016

Pharmacists' Defence Association Response to

'A professional duty to support patient safety culture through reporting, sharing and learning' Consultation,

Led by the Royal Pharmaceutical Society

| representing **your** interests |

pda
the pharmacists' defence association

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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 25,000 individual pharmacist members. The PDA Union was inaugurated in May 2008 and achieved independent certification in 2011.

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
- Provide insurance cover to safeguard and defend the reputation of the individual pharmacist

In 2015 alone, the PDA supported pharmacists in nearly 5,000 episodes where they encountered a variety of conflicts and critical incidents during their practice. Almost 1,000 of these interventions involved pharmacists who had experienced situations involving dispensing errors. Many of these episodes created learning opportunities. Some resulted in civil claims for compensation, regulatory investigations, employer-mediated disciplinaries and even criminal investigations. These experiences provide the PDA with a rich vein of experience upon which to build a policy platform. The PDA's response to this consultation is significantly informed by the expertise gathered in defending pharmacists involved in these matters.

Executive Summary

The Royal Pharmaceutical Society (RPS), Pharmacy Forum NI, Association of Pharmacy Technicians UK (APTUK), a consultant and representatives from two large multiple pharmacies have drafted an 'error reporting standard' entitled 'A professional duty to support patient safety culture through reporting, sharing and learning'. The RPS asked for feedback on the document from the PDA.

Our key recommendations are below.

- The content must be fundamentally revised so that, whilst a focus on error reporting is maintained, it does not misinform pharmacists about the true potential for criminal sanctions for dispensing errors. The authors must take great care not to make unrealistic assertions about the impact and scope of changes to the Medicines Act arising from the current outputs of the Rebalancing of Medicines Legislation and Pharmacy Regulation programme.

- The government must go 'back to the drawing board' to commission work which comprehensively removes the prospect of criminal sanctions for inadvertent dispensing errors. This would help reduce the fear of reporting errors, facilitate learning and improvement and ultimately improve patient safety.

- The document must set out a vision for patient safety, encompassing reporting and learning from incidents through action research, sharing of what was learned and taking effective action to achieve sustainable, long-term improvements. The vision should incorporate the ethos that activities enhancing patient safety should be so deeply ingrained in a pharmacist's working practice and culture that there is a desire to actively engage in them as a natural part of their routine practice. Pharmacists must be appropriately supported and enabled to do so; the vision must therefore refer to the duties of pharmacists, pharmacy owners, employers, staff in employer support roles (such as Area Managers and superintendent's office staff) and other positions of authority, pharmacy bodies, the regulator, the NHS and central government in this regard.

- The overarching purpose of the document needs to be carefully thought through and set out clearly within it. The purpose of each section must also be set out clearly.

- In order to improve the quality of the document, its acceptance, engagement with its use and ultimately the outcome of improved patient safety, the composition of the working group needs review. In particular, it needs relevant legal expertise or access to it and the support of those bodies who are involved in managing and defending against the consequences dispensing errors. Additionally, it requires the wider representation of relevant expertise in the sector, including fuller representation of individual patient-facing pharmacists and independent pharmacy contractors.

- In order to maximise the benefit to patient safety, the time and energy of the working group would be meaningfully spent lobbying for community pharmacy access to the National Guardian and IPSIS functions.

- The RPS and Pharmacy Forum NI should lead an initiative that supports employers to publicise, on a named organisation basis, their aggregated pharmacy incident data (anonymised for individual person(s)). This would enable and support broader learning in the public interest and would help employers to focus and devote significantly more time and attention to reducing the risk of pharmacy incidents. Their work should also include input into the design of incident data sets which capture the necessary details, including the true underlying causes, of pharmacy incidents.

- The document needs to set out a clearer, fuller logical progression showing how error reporting results in improvements to patient safety.

- The document must better describe the fundamental support mechanisms and environmental standards conducive to a good error reporting culture and the ability to effectively implement sustainable changes. These must include adequate staffing levels, high quality training, effective leadership, adequate facilities in the pharmacy, professional autonomy, suitable dispensary environment / layout, inclusion of pharmacists in the investigation, management and response to pharmacy incidents, sharing of learning between employers and good organisational culture. It must clearly set out the responsibilities of pharmacists, pharmacy owners, employers, staff in employer support roles (such as Area Managers and superintendent's office staff) and other positions of authority, pharmacy bodies, the regulator, the NHS and central government in establishing that environment and culture.

- The inclusion of community pharmacy within the scope of the National Guardian for NHS whistleblowing and the pharmacy sector's access to the IPSIS function must be included as enablers for better error reporting culture.

- The responsibilities of pharmacy owners and superintendents described within the GPhC's Standards for Registered Pharmacies must be set out within the table summarising the existing regulatory framework related to error reporting and candour.

Introduction

Patient Safety in Pharmacy

Patients rightly expect that pharmacy services will be delivered safely. The activities involved in assuring and enhancing patient safety should not be merely unhindered. They should be so deeply ingrained in a pharmacist's working practice and culture that there is a desire to actively engage in them. Pharmacists should experience professional fulfilment from doing so.

Reporting of near misses and pharmacy incidents, alongside analysis of root causes, is crucial to understanding what can be learned. Undertaking and sharing learning and implementing actions to create effective, sustainable reductions in the risk of reoccurrence are fundamental to a healthy approach to patient safety.

These activities, however, should not be the result of an organisational policy or culture that mandates them or which creates sanctions for not engaging in them. This, surely, would be a recipe for grudging compliance rather than active engagement. Pharmacists must want to report incidents rather than being afraid of not reporting them or being 'battered into submission' through repeated emphasis on individual professional duty. Improvements in patient safety otherwise would be limited to the extent of the grudging compliance that could be secured.

We take the view that pharmacists should engage in action research as a natural part of their routine practice and that they must be adequately supported to do so. As professionals, they should be able to work collaboratively with others to analyse and understand the root causes and trends of mistakes. Analysis should extend to monitoring and understanding the success of the actions taken as a result. They should feel confident to lead, coach and engage others to achieve the same. This would lead to well-informed actions which enhance the safety of patients in an effective way.

The Document

Substantial revisions must be made to the content and focus of the document. As it is currently written, its purpose is unclear and it is overly focused on the responsibilities of individual pharmacists, most likely as a result of the composition of the working group. The reasons put forward to explain why professionals should report and learn from errors concentrate too heavily on their compliance with rules, duties and obligations; a better approach would be to say that these activities should be a natural product of their engagement, participation in action research and well-supported routine professional practice. The document does not adequately describe the responsibilities of other parties. It fails to adequately reflect the breadth of the factors affecting incident reporting, learning from incidents and the ability to take effective, sustainable actions as a result. The tone of the document currently could provide inappropriate assurances to pharmacists and consequently the public that necessary protections afforded through the decriminalisation of inadvertent dispensing errors are already in place – or that matters are 'in hand' (in reality they are not).

These issues presented challenges in structuring our response to the consultation within the confines of the questions asked. However, we have endeavoured to categorise our concerns in detail under appropriate headings.

Decriminalisation of Dispensing Errors

Between 2007 and 2010, the PDA defended pharmacist Elizabeth Lee following an inadvertent dispensing error. The patient sadly passed away 6 days after the incident. A charge of gross negligence manslaughter was considered by the police but was not brought since the patient was found to have died of natural causes. Elizabeth was ultimately charged with 2 breaches of the Medicines Act 1968 under sections 64.1 (sale of a medicinal product not of the nature or quality demanded by the purchaser) and 85.5 (labelling which falsely describes a product or is likely to mislead about its nature, quality, uses or effects).

Due to the nuances of the legal process and pleading arrangements, the charge under 64.1 was left on the table at the initial trial, as the judge declined to decide on the legal arguments made. Elizabeth was convicted of an offence under section 85.5 and shockingly given a 3-month suspended prison sentence. The PDA took the matter to the Royal Court of Appeal and secured a new interpretation of section 85.5; the charges against Elizabeth under this section were dropped. An offence could only be committed under that section by individuals who were carrying on a business (i.e. business owners). However, the Crown Prosecution Service (CPS) asked for the conviction to be substituted with a conviction against 64.1 as part of a legally established process. Elizabeth would have had to return to court on a separate occasion to challenge that prosecution, but understandably did not want to do so. She had already endured an arduous legal process and made a decision to leave the profession. She therefore pleaded guilty to an offence under section 64.1 and the sanction was reduced to a £300 fine.

As part of its extensive legal defence efforts, the PDA obtained assurances that changes to the law were afoot which would remove the fear of criminal sanction for inadvertent dispensing errors in the interests of patient safety, but understood that this would take years to complete. It proposed an additional interim measure – a protocol for the CPS to use to guide prosecutors as to the course of action they should take for pharmacists where a gross negligence manslaughter charge had been excluded. The PDA's view was that it would be appropriate to refer the matter for consideration by the regulator rather than pursuing criminal prosecution, consistent with the approach taken for other healthcare professionals. The protocol was published on the 21st of June 2010. [1] It was not at all what the PDA had proposed and could have either increased or decreased the likelihood of prosecution for inadvertent dispensing errors depending on the circumstances of the case, but overall it was unhelpful. It is currently being rewritten.

On the 30th of November 2011, the RPS sent an email alert to its members announcing that an amendment to the Medicines Act 'to end the automatic criminalising of dispensing errors' was to be tabled in parliament. It declared that the society had 'seized the initiative' to ensure that it used the opportunity presented by the Health and Social Care Bill to 'resolve the issue for [its] members and their patients'. It published an article in December 2011 claiming that it had been doing the work over the past two years. [2]

The RPS had proposed an *'all due diligence'* defence to certain parts of the Medicines Act 1968. It had not sought the guidance of other organisations with the expertise to advise on the implications of its proposals. The PDA was in the vanguard of the movement to decriminalise inadvertent dispensing errors, but necessarily opposed the changes the RPS had put forward. It obtained unambiguous legal advice from a member of the Queen's Counsel which made it clear that the 'all due diligence' defence would be very difficult to engage. Had the changes gone through, in court it would have been almost impossible to argue that a pharmacist had exercised 'all due diligence' if any error or omission by them had been a factor in an incorrectly dispensed item being supplied to a patient. Failure to follow an SOP or following a poor quality SOP might have rendered the defence ineffective and if unsuccessful, the pharmacist's defence could have lost credit in the eyes of the court. Had a pharmacist chosen not to engage the defence, this would also have been apparent to the prosecution and the court. It could well have increased the prospect of a successful criminal prosecution, heightened fear of reporting errors and thereby reduced patient safety. As a result, a statement was put together on the 6th of February 2012 on behalf of Pharmacy Voice, the RPS, PSNC, PDA, IPF and the GHP withdrawing support for the proposed amendments. The proposals were subsequently withdrawn in parliament in March 2012.

A recent example highlights that the risks that still exist. A pharmacist was given a police caution in 2015 following the implication of a dispensing error in a patient's death. The CPS said there was 'sufficient evidence for a realistic prospect of conviction against the pharmacist'. [3] Nevertheless, they still pursued a criminal investigation and imposed a criminal sanction.

This occurred during a time when the Department of Health was working to address the issue of criminal sanction. The Rebalancing Medicines Legislation and Pharmacy Regulation programme board was established in early 2013. [4] The Pharmacy Legislation on Dispensing Errors and Standards consultation was conducted in 2015. It was heralded as the initiative which would remove the prospect of criminal prosecution for inadvertent dispensing errors. Its brief, however, was limited to introducing a defence to only two specific sections of the Medicines Act – sections 63 and 64. The rebalancing board lacked the requisite expertise to fully recognise and advise others as to the limitations of the scope and impact of the changes. The consultation document unhelpfully stated 'the intention is to remove the threat of criminal sanction for inadvertent preparation and dispensing errors', which may have contributed to confusion as to what it has achieved. [5]

We would counsel extreme caution with respect to references to the Pharmacy Legislation on Dispensing Errors and Standards consultation, carried out in 2015. We are particularly concerned about the first paragraph of the introduction: 'The Royal Pharmaceutical Society, Pharmacy Forum NI and Association of Pharmacy Technicians UK have supported changes to the law in the interests of improving patient safety and to promote increase error reporting, by removing the fear of criminal sanction for inadvertent dispensing errors.' It must be made clear to all who read the document, many of whom will rely on the authors and their organisations for advice, that inadvertent dispensing errors are set to remain a criminal offence for the foreseeable future and that this threat has not been removed.

The consultation document proposed a conditional defence to two specific sections of the Medicines Act 1968, 63 and 64, through legislative changes which have not yet been enacted by parliament. Even if the changes are enacted, the criminal offence will not be removed. In addition, legal opinion indicates that a criminal offence will be committed in the event of an inadvertent dispensing error as a result of other legislation not addressed by the consultation, to which the proposed defence will not apply. [6]

There are distinct parallels between what is written in the draft document and the proclamation from the RPS in November 2011. We are disappointed that the lessons of history appear not to have been learned. In both cases it appears that the RPS supported initiatives and gave the impression all was well, without consulting properly to establish a position supported by appropriate legal expertise.

The wording should not be left as it currently stands since it could provide a false sense of security to pharmacists that the dangers of criminal prosecution have been removed – they have not.

Recommendation

The content must be fundamentally revised so that, whilst a focus on error reporting is maintained, it does not misinform pharmacists about the true potential for criminal sanctions for dispensing errors. The authors must take great care not to make unrealistic assertions about the impact and scope of changes to the Medicines Act arising from the current outputs of the Rebalancing of Medicines Legislation and Pharmacy Regulation programme.

Focus of the Key Statement / Vision

We are concerned about the key statement, which is repeated several times within the document. It reads 'All pharmacists, pharmacy technicians and members of the pharmacy team need to uphold a professional duty to support a patient safety culture and a culture of learning and improvement by being open and honest when things go wrong and reporting actual errors and near misses to the appropriate reporting programme.'

The statement has been given paramount importance within the document but says nothing of the duties of pharmacy owners, employers, staff in employer support roles (such as Area Managers and superintendent's office staff) and other positions of authority, pharmacy bodies, the regulator, the NHS and central government. Each has a duty to enable and support patient-facing pharmacists and their teams to create an excellent patient safety culture (as opposed to a patient safety culture of unspecified quality). For some of the aforementioned parties, that duty is written; in the case of employers, for example, it is conferred by the GPhC's Standards for Registered Pharmacies. In other cases, that duty arises by extension of a responsibility to protect the public, the success of which is made far more likely by supporting a group of professionals who, on the whole we submit, chose that profession and continue to practice it because they care about patients (the public).

In addition, the key statement incorrectly asserts that *members of the pharmacy team* have a *professional duty* to support a patient safety culture etc. Other members of the pharmacy team – which we assume includes dispensing assistants and healthcare advisors since pharmacists and pharmacy technicians are identified separately - have no legally defined professional duty, professional body, professional registration or otherwise which would justify this assertion. In this way the statement could undermine the professional status of pharmacists.

The document must set out a broad vision for patient safety in pharmacy, including how error reporting contributes to that vision and the responsibilities of all relevant parties. Whilst one of the foci of the document is the removal of barriers to open and honest reporting of mistakes, this in itself will not result in the *desire* to report and learn from them – and it is that desire which should form part of the overall vision.

Recommendation

The document must set out a vision for patient safety, encompassing reporting and learning from incidents through action research, sharing of what was learned and taking effective action to achieve sustainable, long-term improvements. The vision should incorporate the ethos that activities enhancing patient safety should be so deeply ingrained in a pharmacist's working practice and culture that there is a desire to actively engage in them as a natural part of their routine practice. Pharmacists must be appropriately supported and enabled to do so; the vision must therefore refer to the duties of pharmacists, pharmacy owners, employers, staff in employer support roles (such as Area Managers and superintendent's office staff) and other positions of authority, pharmacy bodies, the regulator, the NHS and central government in this regard.

Purpose of the Document

The overall purpose of the document, as it is currently written, is unclear. The document includes commentaries on professional obligations, factors affecting patient safety culture, barriers and enablers to error reporting and applicable regulatory frameworks. A single, unifying, overarching purpose must be clearly defined, set out explicitly and used to form the basis of all content in the document.

The RPS states on its website that the goal is to create 'professional standards for error reporting' and to 'define the professional duty for pharmacists, pharmacy technicians and pharmacy teams to be open and honest when things go wrong, and to report actual errors and near misses'. If this is the overarching purpose, we would make the following points:

- It should be set out in the document (currently it is not)
- The highlighted statement in the document 'all pharmacists, pharmacy technicians and members of the pharmacy team need to uphold a professional duty…' achieves this aim, but then all other content is superfluous to that aim and may potentially appear to have various other purposes
- It is too narrow in scope since it does not address major issues affecting the ability to openly report, learn from and take action as a result of an incident, each of which is necessary to give the ultimate outcome of improved patient safety
- The RPS, APTUK and Pharmacy Forum NI, whose logos feature at the top of the document, collectively have no remit to define individual duties. They are in a position to provide guidance to their members and we are supportive of their doing so. Their members are pharmacists (RPS and Pharmacy Forum NI) and pharmacy technicians (APTUK) and do not include other members of the wider pharmacy team

Under the heading 'Barriers and enablers for error reporting', it states 'The table below summarises barriers to reporting and corresponding system enablers which encourage teams and organisations to report errors and share learning. To promote error reporting as part of a culture of patient safety, it is important that these barriers are eroded and enablers supported by all stakeholders.' Whilst there are explanations such as this which describe what the content is, the purpose of that content is not defined, for example how it is to be used and by whom. Each section may have a slightly different purpose as part of the overarching one, but if so this should be stated clearly.

Possible Perceived Purposes of the Document

The document could be interpreted to serve multiple purposes. We have set these out in the following table and illustrated each *possible perceived purpose* with an example of the content which could lead to that perception. The purpose of doing so is to help the authors revise the content of the consultation document to ensure all content achieves a clear, stated and appropriate purpose.

Possible perceived purpose	Example(s) of content which could lead to this perception
A position statement or press release advancing the image / reputation of the authors	'The Royal Pharmaceutical Society, Pharmacy Forum NI, and Association of Pharmacy Technicians UK have supported changes to the law in the interests of improving patient safety and to promote increased error reporting, by removing the fear of criminal sanction for inadvertent dispensing errors.' (Introduction)
A set of expectations for the respective members of the authors' organisations. We recognise that it may be the intention that these expectations apply more widely to all pharmacists, but if so the current composition of the working group needs review to include broader representation of the sector.	'It is our and the public's expectation that pharmacists, pharmacy technicians, and the teams they lead, report, share and learn from dispensing errors and near misses.' (Introduction) Table summarising the existing regulatory framework related to error reporting and candour
A reference document for pharmacists and / or employers	Table summarising the existing regulatory framework related to error reporting and candour (it is unclear whether this table is intended as a reference guide or set of expectations)
A guide for pharmacy employers	'The error reporting system needs to be able to provide feedback to pharmacy teams reporting those errors. This reinforces the perception that reporting is worthwhile and valued.' (System enabler, Barriers and enablers for error reporting table) 'Encourage error reporting behaviour e.g. local praise for reporting, sharing and learning as positive for patient safety but also discourage non-reporting as unacceptable and detrimental to patient safety culture.' (System enabler, Barriers and enablers for error reporting table)
A call to action for pharmacy organisations to lobby for change	'Campaigns to educate and raise awareness with the public and stakeholders that encouraging error reporting improves patient safety but to also expect that more errors will be reported as a result.' (System enabler, Barriers and enablers for error reporting table)

Recommendation

The overarching purpose of the document needs to be carefully thought through and set out clearly within it. The purpose of each section must also be set out clearly.

Practical Use and Target Audience of the Document

It is unclear how the document will be practically helpful to pharmacists and / or patients. This is perhaps because its overarching purpose is unclear; however, its practical use must be given particular consideration in order to inform its purpose. If the document is to inspire pharmacists, help them understand their accountabilities and change their behaviours as a result, it must describe the environmental enablers much more effectively. If employers are to use it to advise pharmacists, we suggest that it will fail to engage those professionals unless it also sets out the responsibilities of employers very clearly. If it is a reference document with multiple purposes, the intended use and target audience needs to be made clear for each section. If it is intended to galvanize pharmacy organisations to achieve common goals, those goals need to be carefully considered and made the focus of the document.

We take the view that within the 'Barriers and enablers for error reporting' table the appropriate stakeholder(s) should be identified. It should clearly state for each enabler whether it pertains to pharmacists, employers, the regulator, the NHS or central government, for example.

Relevance of Content

Some of the enablers referred to in the 'Barriers and enablers for error reporting' table are not relevant to all areas of practice. For example, the current intention is that Freedom to Speak Up Guardians will be based in NHS trusts; there is no clear plan for them to be accessible to community pharmacy. With respect to the 'Care Quality Commission National Guardians' referred to in the document – the current plan is to have a single National Guardian acting independently of the CQC (though given the government's current proposals we would concur with the authors' implied assertion that the Guardian will not be independent).

As a further example, Medicines Safety Officers are not expected to be employed by community pharmacies not part of a multiple. This leaves large numbers of pharmacists who would have difficulty in accessing the 'Medicines Safety Officers Network'. Access to the network is theoretically beneficial, though the network does not appear to be operational at present. An update in November 2014 highlighted 'Patient Safety First' as an online portal for MSO networking. [7] The website **www.institute.nhs.uk/safer_care/general/patient_safety_first.html** refers to the Patient Safety First initiative but makes no mention of Medicines Safety Officers. It provides a link to **www.patientsafetyfirst.nhs.uk**/. This website was registered in 1996 but is not in use; for some time, it has linked to an entirely unrelated website. Internet searches for 'medicines safety officer' and / or 'patient safety first' do not produce any results indicative of an accessible or operational network of MSOs. We understand that the network is an enabler but if, 18 months after its inception, it is not functioning effectively, visibly or accessibly as a network, then its inclusion on the list of enablers is nothing more than fanciful and it serves only to fill the table with content. The authors' time would be meaningfully spent on coordinated lobbying for the creation of an effective MSO network.

Composition of the Working Group

Those who become pharmacists enter their profession knowing they will be involved in caring for patients. Collectively they are well placed to advise on the best means of achieving and enabling that.

The working group includes 4 members of the RPS including highly regarded representation from a professional development perspective, a consultant, a representative from APTUK, a representative from Pharmacy Forum NI and two representatives from large pharmacy multiples. A corporate-employer-esque patient safety paradigm is evident within the document – illustrated by the focus on the individual pharmacist, sparse mention of employers' responsibilities and the failure to acknowledge fundamental enablers known to be difficult and challenging to the interests of employers.

We are supportive of the professional leadership bodies for pharmacists, the RPS and Pharmacy Forum NI, showing leadership of the patient safety agenda. However they must ensure that advice they take and the statements they make are well informed and balanced by consulting with the appropriate individuals and organisations. Both the PDA and the NPA, for example, provide advice on incidents involving dispensing errors, represent pharmacists in hearings related to the commission of errors and advise on pharmacy law and ethics, patient safety and risk management on a daily basis and would have been well placed to support the working group.

Recommendation

In order to improve the quality of the document, its acceptance, engagement with its use and ultimately the outcome of improved patient safety, the composition of the working group needs review. In particular, it needs relevant legal expertise or access to it and the support of those bodies who are involved in managing and defending against the consequences dispensing errors. Additionally, it requires the wider representation of relevant expertise in the sector, including fuller representation of individual patient-facing pharmacists and independent pharmacy contractors.

Focus of the Working Group

As a group keen to improve patient safety in the pharmacy sector, the time and energy of the members of the working group would be well spent lobbying for the National Guardian and Independent Patient Safety Investigation Service (IPSIS) functions to be fully accessible to community pharmacy.

Anonymity of Error Reporting

In the 'Barriers and enablers for error reporting' table, one of the system enablers is 'Proportionate levels of anonymity for people or organisations reporting errors are built into local or national reporting systems'. We do not agree that anonymity is required for public authorities reporting dispensing errors.

The Freedom of Information Act 2000 creates a public right of access to information held by public authorities. The ICO has previously considered how the act applies to community pharmacy. In a decision notice pertaining to pharmacies in Wm Morrisons Supermarkets Plc in 2013 it stated 'Morrisons is a public authority under the terms of the FOIA in respect to the provision of NHS pharmaceutical services.' [8]

ICO guidance on the Freedom of Information Act states that where a public authority is satisfied that the information requested is a trade secret or that its release would prejudice someone's commercial interests, it can only refuse to provide the information if it is satisfied that the public interest in withholding it outweighs the public interest in disclosing it. The bias is in favour of disclosure.

Generally speaking, the public interest is served where access to the information would;

- further the understanding of, and participation in the debate of issues of the day;
- facilitate the accountability and transparency of public authorities for decisions taken by them;
- facilitate accountability and transparency in the spending of public money;
- allow individuals to understand decisions made by public authorities affecting their lives and, in some cases, assist individuals in challenging those decisions;
- bring to light information affecting public safety. [9]

Anonymised or aggregated data is not regulated by the Data Protection Act.

Our view is that the publication of aggregated pharmacy incident data which identifies the organisation is in the public interest. It would inform the public about the issues contributing to pharmacy incidents and allow them to make informed choices about healthcare provision.

Pharmacists have a duty of candour applicable to pharmacy incidents - to report them in an open and honest way. Indeed, it is a requirement within the SOPs set by many employers that they do so. The act of reporting an incident should be possible without fear of retribution from the employer, the public or other public authorities, since each should be adequately informed about the importance of doing so for the purposes of learning, improving safety and protecting the public.

We see no reason why the same duty of candour should not apply to organisations providing NHS pharmaceutical services in respect of aggregated incident data. This would be of huge benefit and significance from a public interest perspective, since it would facilitate better cooperation and sharing of learning between organisations, enable public and regulatory oversight and intervention where a risk to the public was apparent.

Incident data submitted to the National Reporting and Learning System (NRLS) is published on a named organisation basis for 'NHS organisations'. [10] Since community pharmacy contractors are public authorities with respect to the provision of pharmaceutical services, there is a public interest in this being done on a named basis, to help identify where support is required to improve the standard of service or where wider public confidence needs to be maintained. Commercial interests must be secondary to the interests of the public and organisations should not fear disclosure of that information. Just as a pharmacist relies on recipients of an incident report submitted by them on a named basis being well informed so that it is received in a manner which leads to an appropriate response, providers of pharmaceutical services must also rely on an appropriate response if they are to extend the same standards and expectations of candour to the individual.

Recommendation

The RPS and Pharmacy Forum NI should lead an initiative that supports employers to publicise, on a named organisation basis, their aggregated pharmacy incident data (anonymised for individual person(s)). This would enable and support broader learning in the public interest and would help employers to focus and devote significantly more time and attention to reducing the risk of pharmacy incidents. Their work should also include input into the design of incident data sets which capture the necessary details, including the true underlying causes, of pharmacy incidents.

Questions

1. *Is the draft clear in explaining why it is important that pharmacists and the wider pharmacy team needs to support patient safety through reporting, sharing and learning from errors and near misses (introduction, patient safety culture, value of reporting, duty)?*

NO

The document states 'the value in [sic] error reporting is to gather information and data which can used [sic] to identify the root causes of an incident. The information results in learning…' There is a significant gap in the logic within this paragraph – information does not automatically result in learning. It does not say how the information results in learning, how learning results in action or how action results in improvements in patient safety locally and more widely.

As already stated, the purpose of the draft document is not clear. On one hand, some of the content appears to directly address pharmacy teams; on the other hand, individual patient-facing pharmacists and their teams will have limited influence over some of the system enablers – such as 'create a defence to criminal sanction for inadvertent dispensing errors through the Rebalancing Medicines Legislation and Pharmacy Regulation programme'. Since the purpose of the document is not clear, the explanation referred to in this question does not come across clearly.

2. *Have we captured the main barriers and system enablers that promote error reporting (Barriers and enablers for error reporting table)?*

NO

The focus of the document is on the responsibilities of individuals and not those of the pharmacy owner, employer, superintendent, staff in employer support roles (such as Area Managers and superintendent's office staff) and other positions of authority, pharmacy bodies, the regulator, the NHS and central government. As such, it is silent on some of the major barriers to error reporting.

The barriers to reporting say nothing of the fundamental support mechanisms which enable and support a good incident reporting culture, facilitate learning and allow appropriate, sustainable actions to be implemented effectively. These include:

- Adequate staffing levels – to provide sufficient time for incident reporting, management and subsequent learning, enable SOP compliance / concordance, support other patient-safety focused activities and reduce pressure to create an environment conducive to safe working
- High quality training
- Effective leadership
- Suitable dispensary environment / layout
- Adequate facilities in the pharmacy
- Professional autonomy

These factors are not described adequately by 'error reporting is actively promoted and supported by employing organisations', if these are to what this phrase refers.

With reference to the Elizabeth Lee case, Lord Howe observed in 2009 that 'The risk to the public comes not from dodgy pharmacists, but from potentially dangerous working practices. Tesco seems to be noticeably reticent in admitting that they may have had some contribution to the error that occurred.

When a pharmacist is made to work regular 10-hour shifts, you cannot put the entire blame on that one individual. Supermarkets and major pharmacy multiples cannot wash their hands of the health and safety implications which their pharmacists are subject to.' [11]

The document focuses heavily on the responsibilities of individual patient-facing pharmacists and fails to adequately address the responsibilities of the employer and others. The authors must not be afraid to put these responsibilities in writing.

An example of where the responsibilities of employers with respect to dispensing errors are not fulfilled to a satisfactory standard may be helpful. It is not just the reporting of dispensing errors which is important, it is the culture and the response to them which has an impact on the public, the profession and the ability of individuals to learn and improve. An issue encountered by the PDA all too often involves letters being sent by employers to patients following dispensing errors, without involving the pharmacist or making them aware that they were doing so. As an example, a PDA member employed by a large multiple contacted the PDA because he had been treated in an extremely rude and condescending manner by a non-pharmacist store manager, who blamed the pharmacist for being rude to a patient following a dispensing error. The member told the PDA that he had been polite and when apologising to the patient for the error over the telephone, had acted strictly in accordance with advice from his employer. He raised a grievance about the matter. It transpired that a letter featuring stock phrases and platitudes had been sent from head office. The member had never seen it, let alone had any input into its contents. During the grievance hearing it became clear that none of the steps promised in the letter to the patient, designed to prevent a reoccurrence, had been implemented. No safety review had ever taken place, despite cast iron assurances to the patient that it had. It focused on his actions as the pharmacist, referred to disciplinary action and made no reference to a severe lack of trained staff (which was a significant factor in the error) or that he had in fact sought and followed the advice of head office when dealing with the patient.

In cases such as this the employer must engage in active learning to improve its own processes. Unfortunately, there is no wider oversight or public visibility of such issues to facilitate shared learning between pharmacy employers with respect to practices affecting patient safety. We believe this illustrates the need for a wider focus in the document.

Recommendation

The document must better describe the fundamental support mechanisms and environmental standards conducive to a good error reporting culture and the ability to effectively implement sustainable changes. These must include adequate staffing levels, high quality training, effective leadership, adequate facilities in the pharmacy, professional autonomy, suitable dispensary environment / layout, inclusion of pharmacists in the investigation, management and response to pharmacy incidents, sharing of learning between employers and good organisational culture. It must clearly set out the responsibilities of pharmacists, pharmacy owners, employers, staff in employer support roles (such as Area Managers and superintendent's office staff) and other positions of authority, pharmacy bodies, the regulator, the NHS and central government in establishing that environment and culture.

The document refers to the National Guardian as an enabler to a healthy patient safety culture. We would like to see the inclusion of community pharmacy within the scope of the National Guardian as an enabler. Additionally, we would like to see the accessibility of the proposed 'Independent Patient Safety Investigation Service' (IPSIS) to all areas of the pharmacy sector as an enabler.

Recommendation

The inclusion of community pharmacy within the scope of the National Guardian for NHS whistleblowing and the pharmacy sector's access to the IPSIS function must be included as enablers for better error reporting culture.

3. *Have we adequately described the existing regulatory framework that sits alongside our proposed professional standard (table summarising the existing regulatory framework related to error reporting and candour)?*

NO

The document does not refer to the responsibilities of pharmacy owners and superintendent pharmacists. Instead it refers to the framework which applies to 'registered pharmacy premises', which are, technically speaking, buildings. The GPhC Standards for Registered Pharmacies are only meaningfully delivered with the support of pharmacy owners and superintendents. As such, the authors must make this clear within the document.

4. *Do you have any other feedback about this document?*

OUR VIEWS ON THE DOCUMENT HAVE BEEN SET OUT IN THE INTRODUCTION AND RESPONSES TO OTHER QUESTIONS.

I am responding as a…

Defence Association

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