

Pharmaceutical Society of Northern Ireland Response to the report of the Mid Staffordshire NHS Foundation Trust Public Inquiry known as the Francis Report and related Berwick Report.

Introduction

The Pharmaceutical Society NI being the regulator of Pharmacists and Pharmacies in Northern Ireland shares the grave concern expressed by all healthcare regulators in regard to the issues raised in the Francis Report, March 2013.

The failings exposed at the Mid Staffordshire Hospital were truly disturbing and shows what can go wrong when leadership breaks down and professionals fail to put the needs of patients first.

It is fully recognised that the Francisⁱ, Keogh and Berwickⁱⁱ Reports have been commissioned by the Department of Health in London and while there are no direct reference in these reports or recommendations to pharmacy, as a healthcare regulator we fully accept the need for this organisation to consider the wider implications for all healthcare professionals highlighted in these reports.

Consideration of the reports

Since the publication of the Francis report both the Council and the various committees of the Pharmaceutical Society NI have considered the report and have developed a work plan to investigate and consider the key recommendations, exploring ways to improve our procedures and activities to ensure that in all actions and activities, those whom we regulate are fully aware of their responsibilities.

In particular we have focused on the responsibility to put the needs of patients first and working to the highest professional standards and personal integrity.

The Council of the Pharmaceutical Society NI in designing its response has concentrated on the five principles called out by the Minister of Health, Mr Jeremy Hunt MP, namely:

1. Preventing problems arising by putting the needs of patients first;
2. Detecting problems early;
3. Taking action promptly;
4. Ensuring robust accountability; and
5. Leadership.

We also have taken into account the recommendations and principles elucidated in the Berwick Review. We are also mindful of the changes brought about by the introduction of our own revised and update legislationⁱⁱⁱ and the increased powers that we now have.

Fundamentally we agree with the assertion that robust regulation alone will not prevent problems within the healthcare system; however we agree that robust, proportionate, timely and fair regulation can contribute to the development of professionalism and encourage the creation of a safe environment where professionalism is prized, leadership is given and patients are treated with respect and dignity.

This response has been broken down into five sections: Fundamental Standards, Education, Raising the profile of the Pharmaceutical Society NI and it's role , Fitness to Practise and conclusions.

1. Fundamental Standards

What activities and publications does the Pharmaceutical Society NI currently provide which addresses some of the concerns raised in the Francis and associated Reports of 2013?

In designing the Corporate Strategy “A New Era”^{iv} launched on 11th June 2013, the Council of the Pharmaceutical Society NI adopted the following mission statement:

“The Pharmaceutical Society NI will continue to place patient safety at the heart of everything that it does; maintain the confidence of the public and the respect of registrants”

This statement clearly articulates the centrality of patient safety as seen by Council and emphasises and underscores the prominence given to patient safety in the Code of Ethics 2009^v.

The first principle of the Code of Ethics being;

“Make the safety and welfare of patients your prime concern.”

Fundamentally in all the activities associated with the practise of pharmacy, the Council remains of the view that **this overriding principle** remains at the heart of good healthcare regulation.

Recognising that the current Code of Ethics is now four years old, and in light of the recommendations in the Reports, the Education, Standards and Registration Committee (ESR) has, on behalf of the Council, programmed a fundamental review of the Code of Ethics in 2013.

This review is timely in the light of the various reports and will be subject to full public consultation. In keeping with the principles of ensuring that patients and the public are involved at the early stages of policy development, the review will ensure that patient and public representatives have an early input into this review.

Action point 1.

To undertake a fundamental review of the Code of Ethics (2009). This review, to be carried out by the Education, Standards and Registration Committee (ESR) on behalf of Council, will include early, meaningful and appropriate patient and public participation. This review will commence in September 2013, seeking to formally consult in February 2015.

Action point 1.a

A communications campaign for both registrants and members of the public highlighting the revised Code of ethics and a patient guide detailing what to expect from a Pharmacist and who regulates pharmacy in NI

Action point 1.b

Undertake a review, in collaboration with the GPhC, of the Student Code of Conduct in the light of the review of the Code of Ethics

The current Code of Ethics is supported by “Obligations”, Standards and Guidance. The “Obligations” explain and define in further detail how we as an organisation interpret the principles laid out in the Code of Ethics. The standards detail specific rules on issues of importance whilst the guidance documents suggest best practice and recommendations relating to key issues.

It should be noted that currently contained within the “Obligations” the Pharmaceutical Society NI has outlined what it expects registrants to do in relation to safeguarding patients, particularly in relation to challenging and reporting matters of concern in relation to patient safety. For example;

Obligation:

- 4.1 Consider and act in the best interests of the individual patient and the public
- 4.3 Challenge the judgement of colleagues and other health and social care professionals if you have reason to believe that their decisions could compromise the safety or care of others
- 7.1 maintain public trust and confidence in your profession by acting with honesty, integrity and professionalism
- 7.3 Act immediately, to address any situation should someone in your professional care come to harm, by sharing information with other health and social care professionals as appropriate.

In particular the obligation at 7.3, addresses one of the key concerns highlighted in the Francis and associated reports; the need for candour in all circumstances in relation to issues surrounding patient care.

In light of the Francis report the Pharmaceutical Society NI has reminded all pharmacists and pharmacy leaders of the need to be fully conversant with the Code of Ethics and its implications.

Furthermore, on the 7 February 2013, the day after the Francis Report was launched; the Pharmaceutical Society NI re-launched its "Raising Concerns Document".^{vi}

This document designed for both patients and professionals, focuses on the practical outworking of obligation 8.13;

"Make known to relevant persons or bodies any concerns about policies, systems, working conditions, or the actions, professional performance or health of others that are likely to compromise patient care or public safety, or are already doing so".

This document emphasises the need for candour in all activities particularly in relation to patient care, it also explains the obligations and protections available to health professionals in cases where reporting concerns about colleagues or their activities may place patients in danger. This we believe addresses one of the key findings and recommendations of the Francis report specifically in relation to the need for a duty of candour.

Action point 2

Communicate to both registrants and members of the public the need for openness and transparency with patients and carers (as appropriate), ensuring that all pharmacy professionals operate to the highest possible standards of honesty and integrity.

Action point 3

Review, the Raising Concern Guidance document and processes after a year of operation. This review will consider the guidance given and how this has operated, ensuring that pharmacists and members of the public are clear on how to deal with issues of concern. This review will also consider how to empower trainees and junior members of staff to raise issues of concern that they observe.

2. Education

Education and training (including continuing professional development) is a key aspect of the Berwick report. Of the ten recommendations made in this report, the very first recommendation states:

"The NHS should continually and forever reduce patient harm by embracing wholeheartedly an ethic of learning."

As a regulator in our legislative responsibilities, the oversight of undergraduate education remains a priority, as does the running of the pre-registration programme. In addition we have sought and have gained the statutory responsibility to ensure all pharmacists in Northern Ireland undergo annual Continual Professional Development (CPD). This safeguard has been enabled under our new legislation,

and from June 2013 all pharmacists as a condition of registration are statutorily required to undertake and record Continuing Professional Development.

In keeping with the need for professionals to maintain their skills and competencies, the CPD Framework was launched on 20 May 2013 and it highlights the need for all CPD to be relevant to a pharmacist's scope of practise and as such, those undertaking CPD are prompted to consider the impact of their CPD on patient safety. Again this activity we believe will help maintain a focus on patient safety and wellbeing.

Going forward, the Council of the Pharmaceutical Society NI recognises the need to move towards a new, fair and robust method of ensuring registrant "Continuing Fitness to Practice" previously referred to as professional Revalidation. This work continues to be developed by the ESR Committee. Research has commenced on possible models and is expected to report before the end of 2013 with recommendations to Council.

Action point 4

Development, by the ESR Committee on behalf of Council, a proportionate "Continuing Fitness to Practice model"

The ESR committee intends to engage further with the Universities in Northern Ireland around curriculum developments that will be designed to improve graduates ability to interact with patients and carers.

It is accepted that these skills are currently taught, however, we recommend that a review of these activities is carried out in the light of the Francis and the other reports and their recommendations. Further work may also be required in providing training for student and registered pharmacists in the area of complaint management and handling with an emphasis on listening to feedback, particularly in relation to early detection of problems.

Action point 5

Engagement, in particular, with the two local Schools of Pharmacy, at Queens University Belfast (QUB) and the University of Ulster (UU Coleraine), to highlight and discuss how the universities are addressing the issues raised in the Francis Report.

Action point 6

Open discussions with training providers in relation to complaint management and handling

Following the launch of the Francis Report, all pharmacists and pre-registration pharmacy trainees were made aware and notified by email of the Francis Report and the implications contained within it.

We reviewed our 2009 Guidance on Raising Concerns and, in March 2013, reissued revised guidance reiterating to all pharmacists that they have a duty to report concerns about the quality of care being delivered by their professional colleagues or

support workers. We also reemphasised that the code of ethics and the need to place patients at the centre of all that is done.

In 2013-14 at the induction days for new pre-registration trainees, a section of the induction day has concentrated on the Francis report and the key implications for pharmacists. This has been effective and going forward, further work will be done with trainees on the recommendations from the Berwick review and other review which may yet report, including guidance on complaints handling, listening to the patient etc.

3. Raising the Profile of the Pharmaceutical Society NI and its role.

At the time of the inception of the new Council, in October 2012, along with a new brand identity the Pharmaceutical Society NI re-launched its website. As evidenced by increased web traffic and greater public engagement, we believe that we are reaching a wider audience than previously reached. Recognising that there is a need for even greater public awareness, as part of the corporate strategy "New Era 2013-16" we have set, raising public awareness of our activities, as a key objective.

In September 2013 the Council adopted its Communications and Engagement Strategy which aims to ensure that the public and patients know who we are and what our role is. Further to this, the aim of the strategy is to enhance public and registrant awareness and confidence in the standards we set. Ultimately the strategy seeks to promote patient safety through and understanding of pharmacy regulation in Northern Ireland.

Action point 7

[Implementation of the Engagement and Communication Strategy to promote information about pharmacy regulation in an accessible and understandable form, particularly by patients and members of the public](#)

In line with the strategy to increase awareness of the organisation, the Corporate Communications and the Fitness to Practise Committee have undertaken a work stream to review our complaint process and consider any public awareness campaign around this. This work is designed to ensure that in all our activities, the key stakeholders and advocates of patients are aware of our existence and know how we can be contacted.

Allied to this work the Council will investigate the possibility of the creation either at a national or regional level of a simplified, user friendly system to help patients contact relevant regulatory bodies, when they have a complaint or concern about a health professionals. This work is to be discussed and explored with other healthcare regulators and the four Departments of Health. This work can only be taken forward with the support of the other regulators and may require Departmental support to be progressed.

Action point 8

Corporate Communications Committee, on behalf of Council, will undertake a review of the complaints process in conjunction with the FtP Committee and design any promotional activity to enhance public awareness of the process whilst ensuring that all barriers around raising complaints and issues are reduced to a minimum

Action point 9

Develop a programme to increase engagement with patients and carers, ensuring their voice is heard and that their experiences are recognised.

4. Fitness to Practise

In relation to Fitness to Practise, the Pharmaceutical Society NI, being locally based has been able to gather and share information relating to emerging issues in pharmacy with other key stakeholders.

Proactively over the past three years the organisation, with the DHSSPS Pharmacy Inspectorate and other key stakeholders within pharmacy, has worked together in creating an “intelligence network” sharing details of activity designed to give early warning of potential issues, including fitness to practise concerns.

This network not only serves as an early warning system of arising issues but is a key strategy in identifying potential systematic failures before they arise.

In keeping with this exercise of monitoring activity that may not be reported directly to us as a regulator, we also undertake media monitoring as a method of identifying any unreported but noteworthy issues in pharmacy.

The Council, through the Fitness to Practise Committee, is committed to ensuring that the FtP process is both robust and fairly applied. This commitment is underscored by constant review of processes and has recently been enhanced by the introduction of a FtP participant attitudinal survey. This seeks to garner views and experiences of both registrants and particularly other stakeholders involved in the Fitness to Practise process

Ultimately Fitness to Practise cases serve not solely as a vehicle to consider poor or bad practise but they should also serve as a means whereby poor practice can be highlighted to others as a learning exercise. To further the dissemination of learnings following the completion of a Fitness to Practise case the Registrar will issue an FtP learnings bulletin to all registrants highlighting issues of concern and lesson from FtP cases.

Action point 10

Registrar to produce a regular FtP learnings bulletin report on issues arising from FtP cases which will be shared with all registrants and trainees.

The Fitness to Practise Committee is also seeking to develop with other regulators methods of working where failings are identified in multidisciplinary teams. This work-stream will seek to develop greater ties and understanding between regulatory bodies to ensure where issues arise within multidisciplinary teams that a coordinated and consistent approach is used.

Action point 11

FtP Committee on behalf of Council to consider protocols with other Healthcare Regulators, including RQIA, to coordinate approaches to FtP issues arising in multidisciplinary healthcare teams.

11 a Registrar to open discussions with the pharmacy leads in the five health hospital trusts re potential FtP cases in hospital

11 b CEO to liaise with other regulators on issues of joint concern

Action point 12

Review of indicative sanctions guidance, drawing on lesson from the first year of operation.

The Council of the Pharmaceutical Society NI is also committed to progressing the work currently undertaken by the Department of Health London, known as “Rebalancing Medicines Legislation and Pharmacy Regulation^{vii}”.

The Council supports the concept that to fully enable an open and just culture within pharmacy practise, some changes are required to current legislation. This work is currently being headed up by the Department of Health London on a UK wide basis and we continue to have an input to this work.

5. Conclusions

As a regulator, we recognise that not all the issues that would enhance and promote patient safety are within the regulatory remit. However we would make the following recommendations that should enhance patient safety and confidence.

1. Pharmacies and pharmacists should be open and transparent about their internal complaints procedures and should reduce any barriers to patients accessing the services of the pharmacy regulator.
2. All pharmacies and pharmacists should have and promote a complaints/compliments feedback system, which includes pointing patients and the public to the Regulator should the complaint warrant further investigation.
3. All pharmacy staff should be trained to record and handle patient complaints, ensuring appropriate escalation processes for serious incidents
4. Pharmacies and pharmacists should adopt a learning culture whereby near misses and mistakes are viewed as opportunities to improve, in keeping with this recommendation, the Pharmaceutical Society NI continues to be involved in the “Re balancing” working in relation to the Medicines Act 1968 to ensure and promote a “just working environment”
5. The Pharmaceutical Society NI will continue to promote and call for the regulation of Pharmacy Technicians in Northern Ireland, this single step we believe would enhance patient safety and promote good practice in Northern Ireland.

The Council agrees that the Recommendations and outcomes of the Francis and Berwick Reports will have a profound effect on Healthcare Regulation in the years to come. We are fully committed to embracing the changes required and we will work with patients, registrants and members of the public to meet all the challenges set out in these and future reports.

ⁱ <http://www.midstaffsinquiry.com/>

ⁱⁱ <https://www.gov.uk/government/publications/berwick-review-into-patient-safety>

ⁱⁱⁱ <http://www.legislation.gov.uk/nidsr/2012/9780337986338>

^{iv} <http://www.psn.org.uk/about/psni/corporate-strategy/>

^v <http://www.psn.org.uk/about/code-of-ethics-and-standards/>

^{vi} <http://www.psn.org.uk/wp-content/uploads/2012/09/Guidance-on-Raising-Concerns.pdf>

^{vii} <http://www.dhsspsni.gov.uk/index/pas/pas-lie/pas-rebalancing-project.htm>