Submission to the Commission on Patient Safety and Quality Assurance

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Introduction

The Pharmaceutical Society of Ireland (PSI) welcomes the opportunity to present its views to the Commission on Patient Safety and Quality Assurance. The PSI recommends that there is a need to develop an effective governance system and framework through which all health professionals and health care organisations, in the public or private sector, are held morally and legally accountable for patient safety and patient protection. The taxpayer can be no longer expected to meet the costs arising from serious failure on the part of health service professionals or health service providers to meet their obligations to their patients and the public. Patients cannot be expected to continue to suffer unnecessarily and indefinitely because of the failure to put in place a proper patient safety governance system.

1. Leadership for Clinicians and Managers

The evidence base is clear. Strong leadership at all levels will promote patient safety and be effective.

Recommendation

i. Every clinician or service contractor must have their responsibilities clearly defined in their contracts. The levels of accountability expected must be specified for both employees and for those who supply services under contract such as general practitioners, dentists, pharmacists, private hospitals, nursing homes etc.

ii. It is essential that we have in place, on a statutory basis the accountability of supervising clinicians. This is best achieved through codes of conduct that are statutorily enforced through the various professional regulatory systems, for example, the code of conduct for pharmacists under the Pharmacy Act 2007.

iii. The roles and responsibilities of clinical managers/senior managers must be embedded in a statutory registration/licensing system for all service providers.

2. A Statutory System of Licensing

A statutory system of licensing is absolutely essential for all service providers and third party funders such as the VHI, Quinn Direct etc.

Recommendation

i. The evidence base strongly favours embedding the accountability of the key principal or supervising persons in such a licensing/registration system together with specifying the minimum level of competency and experience required from such Principal or Supervising Persons as provided under the Pharmacy Act 2007.

ii. The initial licensing and registration process must make provision for a statutory declaration at the point of application that statutory standards or official guidance in respect of service provision is being complied with in full. Such statutory guidance and standards would be normally provided by a regulator such as the PSI.

iii. Critical incident reporting supported by risk management techniques and systems must also be in place at the time of the initial licensing/registration and a formal legal undertaking that such risk managements systems are in place should be required as part of an annual licensing/registration system. As part of the renewal process service providers and agencies should be required to supply detailed reports to the relevant authority licensing or registering such premises or facilities.

iv. For any licensing/registration system to be effective it must be supported by an inspection, investigative and enforcement regime with provision for the prosecution of both individuals and bodies corporate where such is deemed necessary. This is in line with the Pharmacy Act 2007. Pharmacies are and will be registered by the PSI under the Pharmacy Act 2007. The legislation governing all of the other regulatory bodies will need to be brought into line with the pharmacy sector and they will need to be given similar inspection, investigative and enforcement powers as those provided for in the Pharmacy Act 2007. In addition, they will have to be provided with a similar *Fitness to Operate* system where the beneficial owners of such clinical facilities are held accountable under a parallel system similar to *Fitness to Practice.*

3. The Process of Quality Assurance (QA) of Clinical Services

The payment system and compensation system will have considerable impact on the quality and safety of patient services and the outcomes for patients.

Recommendation:

i. The evidence base suggests that improved outcomes are available for patients where payment systems are directly linked to evidence based care and best practice. Most reimbursement bodies in Ireland do not have the clinical expertise and competency to undertake the essential scrutiny of claims to identify inappropriate prescribing, dispensing care or treatment. Such scrutiny would also provide regulators such as the PSI with

invaluable information to guide policy makers and senior decision makers in particular in pharmacy trends and patterns of dispensing and prescribing should be made available routinely to the PSI.

ii. In order to improve the quality assurance of our clinical services, it is essential that we spend significant resources developing a system for reporting the actual levels of expertise and competency in such areas as Clinical Management and Clinical Supervision. All health service providers should be required to allocate significant resources to maintaining the competency of its clinical workforce.

4. Anticipating Risk and Critical Incident Reporting

This is the key to ensuring that we learn the lessons that are essential to protecting patients.

Recommendation:

i. Every organisation in the public and private healthcare system must embrace a system wide culture that places identification, disclosure and investigation of adverse events and near misses to the fore. Each organisation must put in place an internal audit system to ensure this actually happens. In the context of the Pharmacy Act 2007 the PSI are examining how best to ensure that procedures and protocols are in place to investigate near misses and adverse events.

5. Patient and Carer Involvement

The involvement of patients, carers and support staff in patient safety is a major imperative.

Recommendation:

i. Our Health Sciences Faculties and Training Bodies should facilitate and encourage active direct participation of patient advocates in all their training programmes.

ii. Continuous professional development programmes for all professionals and managers must include a patient advocacy module so that all become sensitive to the needs and concerns of patient's carers and their families.

iii. The Pharmacy Act 2007 makes provision for the exchange of information between statutory bodies on matters relating to the public interest. Similar provision needs to be made in other legislation governing the HSE, HIQA and the other regulators. Where complaints present to one part of the system; it should be possible to facilitate transmission of the complaint to other parts of the system without delay.

6. Health Care Staff and Audit

This is an essential component of any effective patient safety system.

Recommendation

i. Audit is seen by many health professionals including senior clinicians and senior managers as an optional extra. It must be given the status of a 'Mandamus', in contracts of employees, in contracts for service provision in the public or private sector through statutory codes of conduct for health professionals and for those who operate and provide health services. The PSI will examine closely the need to ensure that audit is an essential part of pharmacy practice in Ireland.

ii. It is essential that audit is part of any licensing or registration system for personnel or for premises/facilities. Beneficial owners of premises and facilities must be obliged to ensure that there is an effective audit system in place so that adverse incidents, adverse reactions with medicines or devices are properly investigated and reported to the Competent Authority.

iii. The role of executive management, including clinical management, and ultimately the Board of a hospital or a facility in managing patient safety is paramount. Accountability and responsibility must be clear for this group. Issues of quality, safety and risk must be routinely brought before Boards and laid out before the organisations involved. It is time for all of those engaged at executive level and at Board level to accept the burden of the errors that have occurred in Ireland and to mobilise their energies to secure dramatic improvements.

iv. Health and Welfare of Health Professionals:
    a. Proposed management and enforcement systems in healthcare management must be robust, transparent and fair. They must also take into account that all persons working in this sector suffer from all of the weaknesses and imperfections of the human condition. They get old, they get sick, they die prematurely and suffer all of the stresses and pressures of modern life. It has been estimated that between 10 and 15% of healthcare employees will suffer from the disease of addiction, in one of its various forms, during their working life. However, as diabetes affects carbohydrate and lipid metabolism and asthma affects the respiratory system the principal area of disease manifestation in addiction is on behaviour.
    b. Statistics show that 85% of the health cases brought to the GDC in Britain relate to Dentists who are impaired in practice by addiction to alcohol, drugs or gambling. Functioning addicts exist in the surgeries, operating theatres, pharmacies and hospitals worldwide. The risks posed to patients who are under the care of functioning addicts are self-evident. There is no uniform, international, process for dealing with this problem in healthcare management systems. Many are based on reflex responses which first administer punishment and then, sometimes, dealing with the health and well being of the disease sufferer. Parallel to the activities which have led to the Pharmacy Act 2007, the PSI are developing an independent Unified Health Support Programme for Pharmacy and Dental professionals. This work has been co-ordinated by Dr Joe Mee who has established similar programmes in Great Britain. The approach is one of sympathetic intervention where a trained professional actively intervenes with the addicted health professional and leads them to detoxification, treatment and continuous re-

habilitation. This allows the affected person the opportunity to voluntary cease practice, accept professional help and when appropriate return to practice years before they would have appeared before a fitness to practice hearing. This prevents years of risk to patients and ultimately preserves the integrity of the relevant health system.

c. A related health issue which is slowly becoming noticeable as a significant problem in the health and welfare of health workers is that of self-harm and suicide. Statistical evidence for this is either difficult to find or not available at all. The sources which have been used are from "Suicide in Ireland" by Fergal Bowers 1995 and the early articles in the UK Pharmaceutical Journal by Dr Joe Mee. Both of these studies give evidential proof to the fact that persons working in most health professions are considerably more prone to "successful" suicide than the general population by more than 200% in some cases. This trend has been accepted by The National Office for Suicide Prevention and its Director Geoff Day. Significantly higher proportions of health workers are at risk from self-harm and suicide, which is an extremely worrying trend which requires action. How this will impact on patient safety can only be guessed at as little or no work relating to this in the Irish context has been undertaken or published. Alcohol and drug abuse are well established as being significant factors in the lead up to suicide, so in addressing addiction we are also impacting on this problem.

d. A comprehensive suicide aversion programme for health workers should be built in to any health support programme, also research into how all of this impacts on patient safety as well as the health and welfare of health workers should be undertaken as a matter of urgent priority.

7. Evidence Based Practice

Strong support for HIQA will see the matter of evidence based practice addressed.

Recommendation

i. The PSI recommend that a National Steering Group be established to work with HIQA involving all the regulators and service providers to ensure matters in relation to evidence based practice are addressed.

8. The Governance of Regulatory Bodies

i. The PSI also recommends that there should be a high level of collaboration between the regulators and service providers which could be done through a Memorandum of Agreement between the various agencies involved. The PSI is currently exploring with HIQA and other regulators how best to progress with this.

9. Conclusion

The PSI welcomes the establishment of the Commission on Patient Safety and Quality Assurance and the opportunity to contribute on the issues within the remit of the Commission. Patient safety

and public protection are high priorities and sufficient time, resources and money need to be allocated by both regulators and service providers to ensure these priorities are met.

Dr. Ambrose McLoughlin
Registrar

Dr. Cheryl Stokers
Policy Development Officer