Summary Note on the Report of the Commission on Patient Safety & Quality Assurance

Background

The Commission on Patient Safety and Quality Assurance was established in January 2007 and reported to the Minister in July 2008. The report was considered by government in January 2009 which agreed the implementation process. The overall objective of the Commission was to develop clear and practical recommendations to ensure that safety and quality of care for patients is paramount within the healthcare system. The Commission's report set out a wide range of policy measures that will drive the safety and quality agenda in Irish healthcare in the coming years. The establishment of the Commission was prompted by an increasing awareness of patient safety issues in general and high profile health service system failures at home and abroad and in particular by the Lourdes Hospital Inquiry. These have underlined the need for an increased focus on patient safety and quality.

Terms of Reference

Having regard to the findings of the Lourdes Inquiry and to responses to health system failures in other jurisdictions, the Commission will develop proposals for a health service wide (encompassing both the public and the private sectors) system of governance based on corporate accountability for the quality and safety of health services. These proposals should constitute a framework which includes mechanisms and arrangements that will enable the verifiable implementation of nationally agreed managerial and clinical standards. The framework should include any necessary legal, managerial, administrative, technical, human resource measures.

As a component of any proposed framework, the Commission will inter alia examine and make recommendations in relation to:

- a system of leadership for clinicians and managers which would underpin robust corporate accountability for institutional and clinical performance;
- a statutory system of licensing for public and private health care providers and services;
- the process of quality assurance of clinical services (with an emphasis on clinical outcomes) for public and private health care providers and services;
- procedures for healthcare professionals and managers to anticipate risks and promote good performance through effective risk identification, near-miss and critical incident reporting;
- the participation of patients and carers and support staff in engaging with health care providers on health services planning and the quality of care received;
- the participation by all health care staff in audit programmes which will aim to ensure quality improvement and that trends in adverse clinical events, complaints, adverse drug reactions and adverse events with medical devices are effectively analysed and disseminated;
• the means to ensure that evidence-based practice is supported and applied routinely in everyday practice;
• the governance of regulatory bodies in the health system and ways in which effective integration can be enabled between the various bodies.

Membership of the Commissions

• Chair: Dr. Deirdre Madden, Senior Lecturer, Faculty of Law, University College Cork
• Dr. Richard Brennan, General Practitioner, Kilkenny
• Tracey Cooper, CEO, Health Information and Quality Authority
• Dr. Eibhlí Connolly, Deputy Chief Medical Officer, Department of Health and Children
• Mr. Tim Delaney, Head of Pharmacy, Adelaide & Meath Hospitals, Dublin incorporating the National Children’s Hospital, Tallaght
• Ms. Mary Duff, SRN, Director of Nursing St Vincent’s University Hospital, Dublin
• Ms. Edwina Dunne, National Head of Quality and Risk, Office of the CEO, Health Services Executive
• Mr. Paul Fox, Process Engineering Manager, Bausch and Lomb, Waterford
• Dr. Mary Hynes, Director of Quality and Risk, National Hospitals Office, Health Services Executive
• Ms. Margaret Murphy, Patient/Carer representative, Cork City
• Dr Alf Nicholson, Consultant Paediatrician, Our Lady of Lourdes Hospital, Drogheda
• Mr. Tiberius Pereira, Patient/Carer representative, Dublin
• Dr. Ailis Quinlan, Head of Clinical Indemnity Scheme
• Dr Gabriel Scally, Regional Director of Public Health for the South West Region of England, Bristol, England
• Mr. Dermot Smyth, Assistant Secretary, Department of Health and Children
• Prof. Muiris X. FitzGerald, Physician, Dublin

Consultation process

The Commission undertook a public consultation exercise to gather information from those working in the healthcare system, patients, service-users and any member of the public with views on the issues within its Terms of Reference. Submissions were received from 59 groups/organisations and individuals (listed at the back of the report) which the Commission classified as follows: risk management; participation of patients, carers and the public; audit; quality assurance systems; licensing; clinical governance and leadership; evidence-based practice; collaboration between healthcare regulators; medication safety; use of information technology; education and continuing professional development; physical environment and resources; and some others. These submissions are summarised in the Report.

Commission's Recommendations

The Commission made 134 recommendations concerning the provision of a high-quality health service delivered in an effective way in a safe environment. The recommendations may be grouped as follows
**Involvement of Patients, Carers and Service-Users (25)** Includes communications and open disclosure

**Leadership and Accountability in the system (27)** Includes governance, management and reporting structures, education, training and research

**Organisational & Professional Regulatory Framework (24)** Includes licensing of healthcare facilities, regulation of healthcare professionals and credentialing

**Quality Improvement and Learning Systems (55)** Includes evidence-based practice, clinical audit, adverse event reporting, medication safety, health information and technology

**Implementation (3)**

At national level, the key recommendations include the following:

- **Licensing** Legislation should be enacted to introduce a mandatory licensing system in Ireland to cover both public and private healthcare providers, to be operated by HIQA and to apply to existing and new bodies, with time being given for compliance.

The licensing system should commence with application to the acute hospitals and other facilities based on analysis of potential risk to patient safety. This list should include facilities where the following treatments are provided:

- medical treatment under anaesthesia or sedation
- dental treatment under general anaesthesia
- obstetric services
- cosmetic surgery
- other techniques/technologies such as laser and intense pulse light therapy, hyperbaric oxygen chambers, private dialysis, In Vitro Fertilisation and endoscopies and any others to be prescribed by the Minister for Health and Children.

Licences should apply to healthcare facilities and also service-specific licences within the facility e.g. cancer services, radiotherapy, cardiology services.

**Governance of healthcare organisations**

The minimum governance arrangements envisaged by the Commission for licensed healthcare organisations include a Board of Management with representatives from the medical, nursing and other professions, patients and the public on it. The CEO and Board should be made legally accountable for Patient Safety and a senior Clinical Leader at Clinical Director level or equivalent should be given specific delegated responsibility for all matters relating to patient safety and quality.

**Clinical audit**

The Commission recommends that all clinicians, both as individuals and as members of teams or networks, must actively participate in clinical audit in compliance with national standards and priorities. As part of the licensing process, all licensed healthcare facilities must demonstrate active participation in local and national clinical audit as appropriate to their services. The Commission is also recommending the establishment of a group to develop national programmes of and standards for clinical and other forms of audit which support the safety and quality of health services and are linked to national health priorities.
Adverse event reporting

The Commission concluded that adverse event reporting systems that rely wholly on spontaneous or voluntary reporting are ineffective and result in underreporting. It believes that a mandatory system will improve patient safety and ensure greater accountability by requiring specific reports of serious injury to be made by healthcare providers, and disseminating lessons to be learned throughout the system. The development of a complementary voluntary system of reporting of close calls or near-misses will contribute to further learning and dissemination of best practice.

Protection from disclosure for Patient Safety data

The Commission recommends the introduction of an exemption from Freedom of Information legislation and the granting of legal protection from disclosure to data related to patient safety and quality improvement that are collected and analysed by healthcare organisations for internal use or shared with others solely for purposes of improving safety and quality.

Credentialing

Credentialing is a process whereby healthcare organisations review the qualifications and track record of doctors and other professionals. The Commission recommends the establishment of a group to implement a system of credentialing, initially on a pilot basis. The Commission recognises the need for international collaboration for optimum efficacy.

Patient Advocacy

The Commission report points to the advantages of a system of patient advocacy and recommends that a national network of patient advocates be established to work in partnership with healthcare organisations.

Professional Regulatory Bodies

The Commission recommends a group be established through which the professional regulatory bodies will collaborate on areas of common interest including matters relating to fitness to practise and in that context to develop plans to achieve greater separation between their investigation and adjudication functions. It will also consider the establishment of a first point of contact for patient concerns about clinical care.

Education, Training and Research

The Commission recommends that an active research programme on patient safety related issues be undertaken. It recommends the development of education and training suites and modules at undergraduate and postgraduate level for all healthcare workers. It also recommends a skilled vocational management training programme which will become a prerequisite for appointment to management positions.

Implementation
The implementation plan endorsed by the Commission recommends the immediate establishment of an Implementation Steering Group (ISG) with clear and regular reporting obligations to the Minister for Health and Children regarding progress on the implementation of the recommendations of the report. This also requires the establishment of expert sub-groups comprised of representatives of relevant stakeholders, each of which will be required to report to the ISG on the practical and detailed implementation of the recommendations within their remit.

The 5 sub-groups recommended by the Commission are:

- Credentialing sub-group
- Patient Safety Audit sub-group
- Adverse event reporting sub-group
- Professional regulatory bodies sub-group
- Advocacy sub-group

The Commission sets out proposed terms of reference for each of the groups as well as the bodies which should be represented on the sub-groups. Depending on the sub-group, the composition would be drawn from the HSE, independent hospitals, professional regulatory bodies, Clinical Indemnity Scheme and professional indemnity providers, training bodies, the Higher Education Authority, patients, the Irish Medicines Board, the Mental Health Commission and the Irish Blood Transfusion Service.

The Minister has appointed the Department's Chief Medical Officer, Dr Tony Holohan, as Chair of the Implementation Steering Group. Minister Harney has also asked him to consult with the sector as a first step and revert to her with recommendations in relation to the wider membership of the Group and the various sub-groups. It is intended that the implementation process will now be commenced as quickly as possible.