IRISH MEDICAL ORGANISATION

Ceardchumann Dochtúirí na hÉireann

Submission to the Health Information and Quality Authority (HIQA) on the Draft National Standards for Safer Better Healthcare

18 November 2010

IMO Submission to HIQA on the
Draft National Standards for Safer Better Healthcare

The IMO as the representative body for doctors in Ireland and is committed to the development of a caring, efficient and effective health service. The IMO welcomes measures to improve quality and safety in health care provision, however the *Draft National Standards for Safer Better Healthcare* represent a number of concerns including funding and contractual issues as well as medico-legal and ethical concerns.

The stated objective of the Consultation Document is to describe quality and safety requirements for healthcare service providers, with the plan to introduce licensing of services based on such requirements. The Document notes that the competence and performance of individual practitioners is not within the remit of HIQA, and is covered by other agencies such as the Medical Council, An Bord Altranais etc..

> *"These draft national standards are designed to be applicable to all healthcare services (excluding mental health). These services include, but are not limited to: hospital care, ambulance services, community care, primary care and general practice".*

> *"…the Government has proposed the introduction of a statutory licensing system that applies to both publicly and privately funded healthcare services. Under such a system, a service would need to obtain a licence in order to deliver healthcare. It is intended (subject to legislation currently under development) that these national standards will provide the basis of such a licensing system and so in the future will be applied as enforceable requirements to a wider range of healthcare providers, including private and independent healthcare providers. The Authority will provide detailed information about how the standards will be applied within a licensing system in due course".*

Once approved by the Minister for Health and Children, the standards will have immediate effect. HIQA will begin monitoring compliance with the Standards in 2011 and licensing from 2012.

1) Applicability

The IMO understands that HIQA will begin monitoring compliance with national standards in 2011 beginning with publicly funded hospitals. The IMO believe that Standards should apply to both public and private hospitals simultaneously. In the context of Government policy which is actively promoting the development of healthcare provision through private hospitals, the IMO is concerned that national standards will be used as an excuse to close publicly funded hospitals while private hospitals will be afforded a "regulatory holiday". Currently many private hospitals are contracted to provide services to public patients under the National Treatment Purchase Fund and therefore should automatically be subject to the Standards.

2) Consistency in Approach

There is a need for consistency in language throughout the document. Definitions for standards, providers, etc should be more precise and reflect international terminology.

For example the document defines standards and criteria as:

> ***Standard:*** *a statement which describes the high level outcome required to contribute to quality and safety*
>
> ***Criteria:*** *Measures which, taken together, will enable progress towards achieving the standard*

These definitions are inconsistent with definitions *National Quality Standards for Residential Care Settings for Older People in Ireland* produced by HIQA:

> ***Standards and criteria:*** *a standard is a measure by which quality is judged. It sets out an expected or desired level of performance. The criteria are the supporting statements that set out how a service can be judged to meet the standard.*

And differ from international terminology (ISQua Glossary of Terms 2008):

> ***Standard:*** *a desired and achievable level of performance against which actual performance is measured.*
>
> ***Criteria:*** *specific steps to be taken or activities to be done, to reach a decision or a standard.*

In this context it is difficult to see how some of the criteria may be measured.

Example:

> ***Criteria***
>
> *1.1.2 Care is provided at a time and place that is accessible and convenient to service users, where this can be achieved safely, effectively and efficiently.*
>
> *3.1.2 Care meets the individual service user's assessed needs while taking account of the needs of other service users.*

Within the document the terms "service provider", "healthcare provider" and "healthcare service provider" are used interchangeably and in some instances it is unclear whether standards and criteria apply to the institutions or to the professional staff delivering the care.

Example:

> ***Standard 3.1 - Care meets service users' assessed needs and is based on best available evidence and information.***
>
> ***Standard 1.3 - Service users are treated with consideration and respect.***

3) Ethical and Medico-legal Considerations – Patient Consent

There is no reference in the Consultation Document to the need for service user consent in the area of information sharing. This is an important ethical and medico-legal consideration. There are a number of references to the need to obtain service user consent but only with regard to the provision of care and treatment. There are multiple references encouraging information sharing but without references to the issue of service user consent to do so.

Example:

> ***Standard 1.1- Service users' needs and preferences are at the centre of service design, planning and delivery.***
>
> *1.1.3 Service providers coordinate care delivery and share information within and between services to provide the best possible experience and outcome for service users.*
>
> ***Illustrative examples of steps service providers may take towards meeting the standard.***
>
> *This includes the sharing of information when the service user moves from one service to another or within the same service.*

There is no reference to the need to obtain patients consent to information sharing and detailed consideration needs to be given to the obtaining of patients consent in accordance with Medical Council Guidelines.

4) Cost Implications

Practically every one of the criteria outlined for each of the standards in the document will have significant cost implications (with smaller providers subject to greater relative imposition) under each of the following headings:

1. Measurement by "service providers" of deficiencies in their service compared to what will be statutory standards
2. Implementation of change measures both in the clinical and non-clinical setting to achieve compliance
3. Demonstration of compliance, probably on a recurring basis (Biennially in the case of nursing homes) in a future licensing regime.

There is exclusive reference to compliance with clinical guidelines and protocols within the Document as the desired form of healthcare service system provision. For GPs providing publicly funded services adherence to appropriate guidelines/protocols may be dependant upon:

a) optimally functioning secondary / tertiary and community services and
b) necessary funding.
c) contractual negotiations or agreement between the HSE and the IMO

The burden that these standards impose on the HSE in terms of resource allocation should be flagged to the HSE. For services that are not publicly funded GPs would be forced to fund this from their own pockets or to pass on costs to service users.

To retain a licence as a service provider, GPs could/would be obliged to implement (and, it appears, fund) guidelines which are usually aspirational and designed as best-practice protocols

which assume the cost of implementation is not an issue. There should be an acknowledgement within the Document of service users' rights to individualised informed clinical assessment and care plans by healthcare professionals as distinct from adherence to guidelines and protocols.

Example:

> ***Standard 3.1 - Care meets service users' assessed needs and is based on best available evidence and information.***
>
> ***Criteria***
> *3.1.1 Service user's individual care needs are assessed promptly by the practitioner best placed to plan for and deliver their care.*
> *3.1.2 Care meets the individual service user's assessed needs while taking account of the needs of other service users.*
> *3.1.3 Care responds to individual service user's ongoing needs based on continuing review - it is timely and clinically appropriate.*
> *3.1.4 Service providers plan and provide care that takes into consideration the priorities and needs of all its service users.*
> *3.1.5 Care reflects national and international evidence of what is known to work best, where it exists.*
> *3.1.6 Care is delivered according to national clinical guidelines.*

5) <u>Contractual Issues for GPs</u>

It is the opinion of the IMO that the *Draft National Standards for Safer Better Healthcare* are premature given that contractual arrangements have yet to be agreed between the IMO and the HSE for what are essentially preventive, pre-emptive and chronic care integrated system requirements. There must be guarantees that the Standards will not supersede contracting arrangements.

Examples are:

> ***Standard 3.1 - Care meets service users' assessed needs and is based on best available evidence and information.***
>
> ***Criteria***
> *3.1.3 Care responds to individual service user's ongoing needs based on continuing review - it is timely and clinically appropriate.*
> *3.1.6 Care is delivered according to national clinical guidelines*
>
> ***Illustrative examples of steps service providers may take towards meeting the standard****.*
> *information, advice and support is given to service users to enable them to take steps to improve their own health*
>
> ***Standard 3.3 - The quality of care is continuously monitored and improved.***
>
> ***Criteria***

3.3.3 Service providers conduct local, targeted audits, which are in line with service requirements and priorities, and participate in national audits, and implement improvements based on the findings.

3.3.4 Service providers disseminate information and report publicly about the quality and safety of their care and their quality improvement programmes.

3.3.5 Service providers provide requested information to relevant agencies, including national statutory bodies, in line with relevant legislation and good practice.

Standard 3.5 - Care achieves best possible clinical outcomes for service users.

Criteria

3.5.4 Service providers implement and act on the findings of an annual clinical audit forward plan which is in line with service requirements and priorities. This plan is reported against, and monitored by, the clinical governance arrangements of the service, and includes local audits and participation in national audits.

Standard 8.1 - Service providers promote, protect and improve the health of service users.

Criteria

8.1.3 Service providers actively develop and deliver programmes or initiatives to promote better health, in line with their objectives and in partnership with service users. These are proportionate to the context, nature and scale of services provided and take account of national policies, stakeholders' views, the needs of the population served and the best evidence and resources available.

8.1.4 Service providers actively identify the health priorities of service users and develop initiatives to minimise inequalities in health outcomes.

8.1.5 Service providers actively collaborate and work in partnership with each other, with national agencies and with non-healthcare organisations (where appropriate) to promote the health of service users.

6) Status of GPs within Primary Care Teams

Many references relevant to GPs within the Document are to 'primary care teams'. What primary care teams are functioning currently do so in varying fashion around the country. The status of the GP and his/her practice within teams from clinical, administrative and a medico-legal viewpoints remains unclear. All other team members are HSE employees, serving additional populations not served by the GP. There is no contractual facility for GPs with regard to their engagement in primary care teams. The quality and safety requirements within the Document appear to presume such a team based structure of service.

7) Over-regulation of Service Provision

Continuation and enhancement of the current efficient, adaptable and cost effective delivery of services should not be compromised by unproductive over-regulation. For example General Practice is subject to the regulatory requirements of the Medical Council, the Competition Authority and soon HIQA. The IMO is concerned that over-regulation could lead to stagnation and non-cooperation from doctors.

8) Licensing

In our view it is not possible at this stage to give a full response to the impact of the Standards in the absence of details being furnished concerning the licensing system. For instance it is not clear whether the licensing system is intended to relate primarily to Private Clinics or would relate to General Practice?

Similarly details need to be furnished concerning how the licensing system will impact upon the existing regulatory framework. Currently the ***Medical Practitioners Act*** provides for a Register of Doctors which is broken into various divisions. It is not clear whether the licensing system is intended to impact upon the role of the Medical Council.

In these circumstances we would ask that the implementation of standards would be held over pending details being furnished relating to the licensing system and a detailed consideration of how both the standards and licensing system will operate and interface with other healthcare legislation.

We wish to reiterate that the IMO is fully supportive of the introduction of standards for the improvement of healthcare however the Draft Standards furnished have raised a number of concerns for Medical Practitioners. We are anxious to ensure that any system which is put in place will be workable and will achieve its stated aim of improving healthcare in Ireland however H.I.Q.A. has queried whether those consulted consider the standards suitable to be used as the basis for the future healthcare licensing system. In order to respond in a meaningful way to this, details of the licensing system must first be forthcoming.

9) Specific Response to Individual Standards

Theme 1: Person-Centred care

Standard 1.1 Service users' needs and preferences are at the centre of service design, planning and delivery.

Criteria

1.1.1 Service providers, when planning and delivering care, take into account the needs and preferences of service users and provide feedback to them.

1.1.2 Care is provided at a time and place that is accessible and convenient to service users, where this can be achieved safely, effectively and efficiently.

1.1.3 Service providers coordinate care delivery and share information within and between services to provide the best possible experience and outcome for service users.

1.1.4 Service providers communicate with, and involve, service users at all stages of the planning, delivery, monitoring and evaluation of care.

1.1.5 Service providers continuously improve the service-user experience, based on the feedback of service users.

As the criteria are the actions to be taken and measured in order to achieve a standard it is difficult it is difficult to see how criteria 1.1.2 might be measured.

With regard to criteria 1.1.3, there is no reference here to the need for patient/service user consent in the area of information sharing here. Whilst elsewhere in the document there are a number of references to the need to obtain service user consent with regard to the provision of

care and treatment, there are multiple references encouraging information sharing but without references to the issue of patient/service user consent to do so. This is an important ethical and medico-legal consideration and the rights of the patient must be respected in this regard.

It is the IMO position that a secure national system of Electronic Medical Records (EMR) is vital for coordination of care, information sharing between services as well as quality and safety issues. The IMO is calling for the urgent publication of the Health Information Bill to clarify the legal framework in relation to EMRs and information sharing between health services.

In relation to criteria 1.1.4 and 1.1.5 it is important to distinguish between different categories of service users. For instance individual service users admitted for emergency treatment may be unconscious or lack the cognitive ability to communicate with the service provider or clinician. Services may also be provided to minors. A blanket requirement that service providers communicate with and involve service users does not take account of this and recent case law such as ***Fitzpatrick & Anor v K & Anor (2008) IEHC 104***. The criteria requires elaboration to deal with such situations.

Standard 1.2 Service users actively participate in the provision of their own care.

Criteria

1.2.1 Service providers actively communicate with service users and enable them to participate in making informed decisions about their own care and treatment, and in maintaining and improving their own health and well being.
1.2.2 Service providers provide service users with accessible, clear and relevant information about their condition and treatment options.
1.2.3 Service providers provide service users with accessible, clear and relevant information about the services and how service providers interact with service users.

The general nature of the criteria does not take account of situations where a patient may have an inability to communicate or lack of capacity in certain circumstances. This should be addressed.

Standard 1.3 Service users are treated with consideration and respect.

Criteria

1.3.1 The views, values and preferences of service users are actively sought and respected. These are taken into account in the provision of their care.
1.3.2 Service providers openly and actively communicate with service users.
1.3.3 Complaints, concerns and compliments are promptly, effectively and fairly received, addressed and acted upon. Service users are communicated with and supported throughout this process.
1.3.4 Service users are facilitated, insofar as is reasonably practicable, to exercise civil, political and religious rights as enshrined in Irish law.
1.3.5 Service users' dignity, privacy and autonomy are respected and protected.
1.3.6 Service users receive care based on need, and which is respectful of their age, gender, sexual orientation, disability, marital status, social class, family status, race, religious belief, or membership of the Traveller Community (not an exhaustive list).
1.3.7 Service users' informed consent to care and treatment is obtained in accordance with legislation and current evidence-based guidelines.

1.3.8 Service providers are clear in advance with individual service users regarding any direct costs to them of services provided.

For criteria 1.3.1, and 1.3.3 to 1.3.7, the person responsible for achieving the criteria is not identified. In these instances it appears to be the professional staff delivering the care rather than the service provider and this highlights the need for clear and appropriate distinctions to be drawn between institutions and professionals providing care.

Theme 2: Leadership, Governance and Management

Standard 2.1 Service providers develop and implement clear plans that incorporate the views of clinicians, service users and the public.

Criteria

2.1.1 Service providers set clear direction for delivering quality and safety using short, medium and long term plans. These plans take into account national standards and policy, stakeholders' views, the needs of the population served, best available evidence and resources available.

2.1.2 Service providers review and identify gaps in their core capabilities required to achieve their planned objectives and take actions to address these gaps. These core capabilities include (but are not limited to):

- workforce – incorporating workforce planning, recruitment, performance management, leadership, education and development
- communication – incorporating communication with service users and the public, within the service, and with other service providers
- information management – incorporating knowledge management, information technology, information governance and data quality
- risk management – incorporating management of risk to service users and to service providers
- patient safety incident management – incorporating serious reportable event policy
- service quality improvement – incorporating performance monitoring, patient safety improvement programmes, service design improvement and innovation
- physical assets and environment management
- resource management – incorporating financial risk and viability management, investment and disinvestment, productivity and value for money.

2.1.3 Service providers have in place management arrangements, structures and mechanisms, including annual business plans, to achieve their planned objectives for quality and safety.

2.1.4 Service providers plan and manage change and service transition effectively through:

- identifying a named accountable person responsible for leading the change process
- setting clear objectives for the change and service transition
- prior assessment of service interdependencies at local, regional and national levels
- modelling of demand and capacity
- assessing staffing implications and determining requirements
- consideration of impact on stakeholders
- implementation of communication and engagement strategies
- development and monitoring of performance indicators relevant to change and service transition.

The development and implementation of plans for delivering quality and safety in accordance with national standards will depend significantly on the resources available. The immediate burden that these standards impose on the HSE in terms of resource allocation should be flagged to the HSE.

Again here there is no reference to the need for patient/service user consent in the area of communication and information sharing. There should also be a reference to patient confidentiality and data protection legislation under information management.

Standard 2.2 Service providers have clear leadership, accountability, governance and management arrangements to achieve the delivery of high quality, safe and reliable healthcare.

Criteria

2.2.1 A named individual with the overall responsibility for the service (for example, the Chief Executive or Lead Clinician) is accountable for the quality and safety of healthcare provided and formally reports on the performance through relevant governance structures including, where relevant, directly to board level or equivalent. This information is clearly communicated with all stakeholders.

2.2.2 Service providers delegate clinical responsibility and accountability for patient safety and quality to a Lead Clinician at Clinical Directorate level or equivalent. This Lead Clinician formally reports on the performance through relevant governance structures.

2.2.3 Service providers have in place governance arrangements including a code of governance which clearly defines roles, accountability and responsibilities throughout the service, and which provides assurance arrangements for the quality and safety of health services provided.

2.2.4 Leaders at all levels demonstrate and embed a culture of quality and safety throughout the service.

2.2.5 Service users are routinely represented and involved in decision making within the service, including at board level or equivalent.

2.2.6 Service providers delivering publicly-funded healthcare put in place contracts of agreement for the provision of services between themselves and funding organisations and third party providers. The contracts of agreement include scope of service provided, resources, quality assurance and governance arrangements.

2.2.7 Service providers monitor the performance of the service against their objectives including resource management, and benchmark, manage, and report this performance through the relevant governance structures.

In circumstances where clinicians capacity to provide services may be limited by administrative decisions and budgetary factors it should be clarified that such criteria apply to administrative officers and not simply clinicians. Criteria 2.2.2 also requires clarity as to what is meant by a "service provider" as clinicians will already have ethical and professional responsibilities for patients. Again the role of administration needs to be considered in greater detail.

Standard 2.3 Staff at all levels are enabled to take responsibility for the quality and safety of care through transparent and effective accountability arrangements.

Criteria

2.3.1 Clinical and managerial responsibility, accountability and authority regarding quality and safety of healthcare is clearly stated and implemented at every level of the service.

2.3.2 Service providers support and manage teams and individuals in effectively exercising their personal and professional accountability for the provision of high quality, safe and reliable healthcare.
2.3.3 Service providers ensure that the conduct and provision of services are compliant with relevant Irish and European legislation.

Standard 2.4 A structured quality improvement and learning system is in place which enables the delivery of high quality, safe healthcare.

Criteria

2.4.1 Service providers actively promote and support a positive culture of high quality and safety, and take measures to embed this culture.
2.4.2 Service providers review the quality and safety of their services and actively develop, participate in and continuously evaluate quality and safety improvement programmes.
2.4.3 Service providers act on standards, guidance and recommendations as formally issued by the Health Information and Quality Authority when planning and delivering services.
2.4.4 Service providers safeguard service users and their workforce by proactively identifying, managing, minimising and eliminating risks, including clinical, financial and viability risks.
2.4.5 Service providers proactively identify, document, monitor, analyse and learn from patient safety incidents and implement and communicate learning internally and externally.
2.4.6 Service providers support and enable open communication with service users.
2.4.7 Service providers actively promote open communication within the service, with service users, with independent patient advocacy groups, with external agencies and with other service providers.
2.4.8 Service providers actively manage and monitor complaints and feedback from service users. This information is communicated and used to promote learning and improvement.

Theme 3: Effective care

Standard 3.1 Care meets service users' assessed needs and is based on best available evidence and information.

Criteria

3.1.1 Service user's individual care needs are assessed promptly by the practitioner best placed to plan for and deliver their care.
3.1.2 Care meets the individual service user's assessed needs while taking account of the needs of other service users.
3.1.3 Care responds to individual service user's ongoing needs based on continuing review - it is timely and clinically appropriate.
3.1.4 Service providers plan and provide care that takes into consideration the priorities and needs of all its service users.
3.1.5 Care reflects national and international evidence of what is known to work best, where it exists.
3.1.6 Care is delivered according to national clinical guidelines.
3.1.7 All relevant information necessary to support the provision of effective care is available at the point of clinical decision making, including information provided by the service user.
3.1.8 Service users are actively supported to maintain and improve their own health and well being.
3.1.9 Service providers support clinicians to make clinical decisions that maximise benefits to patients and minimise unnecessary treatment and care.

The protocol model of care delivery should be restricted and constrained as it ignores the framework for good medical practice long-enshrined in the concept of trust and the doctor-patient relationship. Instead guidelines should be issued reflecting best practice which can be adjusted to meet individual patient need. There should be an acknowledgement within the Document of service users' rights to individualised informed clinical assessment and care plans by healthcare professionals as distinct from adherence to guidelines and protocols.

For GPs providing publicly funded services adherence to appropriate guidelines/protocols may be dependant upon:

a) optimally functioning secondary / tertiary and community services and
b) necessary funding.
c) contractual negotiations or agreement between the HSE and the IMO

The burden that these standards impose on the HSE in terms of resource allocation should be flagged to the HSE. For services that are not publicly funded GPs would be forced to fund this from their own pockets or to pass on costs to service users. To retain a licence as a service provider, GPs could/would be obliged to implement (and, it appears, fund) guidelines which are usually aspirational and designed as best-practice protocols which assume the cost of implementation is not an issue.

In the case of General Practice the GP is both the service provider and the deliverer of care. In the case of hospitals, primary and community care settings responsibility lies with the healthcare professionals for the delivery of care.

Standard 3.2 Service providers deliver care using service models designed for high quality, safe and reliable healthcare.

Criteria

3.2.1 Service providers clearly define their service model and openly communicate the scope, objectives and intended quality outcomes of their services.

3.2.2 Service providers deliver care using high quality, safe and reliable service models that have the required clinical services, meet legislative requirements and take into account best available evidence, national policies and local population health needs.

3.2.3 Services are provided to sufficient numbers of patients to maintain the skills and competence of clinical teams and to give clinical teams adequate experience of the management of complex and rare conditions and complications.

3.2.4 Service providers deliver sustainable healthcare services able to meet legislative requirements within available resources and recruit the necessary number of competent staff to deliver the defined service model.

3.2.5 Service providers have the appropriate clinical services and support arrangements, facilities and a sufficient number of competent staff and clinical teams to deliver their defined service model.

3.2.6 Services are effectively planned, managed and delivered to maintain the quality and safety of care when demand, service requirements, resources or capabilities change.

3.2.7 Service providers operate within their stated scope and purpose of care and proposed changes are communicated to relevant stakeholders and necessary approval is sought, where applicable.

Again the status of the GP and his/her practice within Primary Care Teams from clinical, administrative and a medico-legal viewpoints remains unclear.

Standard 3.3

The quality of care is continuously monitored and improved.

Criteria

3.3.1 Service providers monitor and evaluate the quality and safety of the care they provide and its outcomes, using appropriate benchmarks and performance indicators.

3.3.2 Service providers act upon the findings from monitoring and evaluation to demonstrate learning and improve care. This includes, where necessary, discontinuing ineffective or unsafe care.

3.3.3 Service providers conduct local, targeted audits, which are in line with service requirements and priorities, and participate in national audits, and implement improvements based on the findings.

3.3.4 Service providers disseminate information and report publicly about the quality and safety of their care and their quality improvement programmes.

3.3.5 Service providers provide requested information to relevant agencies, including national statutory bodies, in line with relevant legislation and good practice.

Criteria 3.3.3 to 3.3.5 are subject to existing contractual arrangements between the IMO and the HSE in respect of delivery of publically funded services.

Standard 3.4 Care is actively coordinated and integrated within and between services.

Criteria

3.4.1 Service providers actively coordinate the provision of care in partnership with service users, in particular when care is provided by more than one service provider.

3.4.2 Service providers actively cooperate with each other, in particular when service users are transferring within and between services.

3.4.3 Service providers share necessary information to facilitate the transfer or sharing of care in a timely and appropriate manner.

3.4.4 An identified lead practitioner is accountable and responsible for the coordination of care during an episode of care.

The development of a national system of electronic health records which protects and respects patient confidentiality is vital to support patient safety as well as the coordination and integration of care within and between services.

Standard 3.5 Care achieves best possible clinical outcomes for service users.

Criteria

3.5.1 Service providers deliver clinical care that reflects best available evidence, according to agreed national clinical guidelines, protocols and pathways.

3.5.2 Service providers deliver clinical care according to locally agreed protocols and pathways that are clearly described, based on evidence and needs-specific.

3.5.3 Service providers monitor and evaluate their clinical performance by conducting regular clinical audits in accordance with national guidelines and good practice, and implement improvements based on the findings of these audits.

3.5.4 Service providers implement and act on the findings of an annual clinical audit forward plan which is in line with service requirements and priorities. This plan is reported against, and monitored by, the clinical governance arrangements of the service, and includes local audits and participation in national audits.

Again the protocol model of care delivery should be restricted and constrained. Instead guidelines should be issued reflecting best practice which can be adjusted to meet individual patient need. There should be an acknowledgement within the Document of service users' rights

to individualised informed clinical assessment and care plans by healthcare professionals as distinct from adherence to guidelines and protocols.

For GPs providing publicly funded services adherence to appropriate guidelines/protocols may be dependant upon:

a) optimally functioning secondary / tertiary and community services and
b) necessary funding.
c) contractual negotiations or agreement between the HSE and the IMO

Clinical audit will also require resources. Data controllers in addition to enhanced data systems will be necessary to produce crucial meaningful audit.

Theme 4: Safe care

Standard 4.1 Service providers protect the safety, health and welfare of service users.
Criteria

4.1.1 Service providers actively support and promote a culture of quality and safety including patient safety.

4.1.2 Leaders at all levels, including clinical leaders, are responsible for demonstrating and embedding a culture of quality and safety including patient safety.

4.1.3 Service providers develop, implement, evaluate and publicly report on a formal patient-safety improvement programme, as part of an overall quality improvement programme.

4.1.4 Service providers actively develop, implement and monitor the impact of annual patient-safety improvement programmes which are based on assessed local priorities and national initiatives incorporating specific evidence based interventions.

4.1.5 Service providers plan, organise and deliver services, including the care environment, to protect the health and welfare of service users and staff.

4.1.6 Service providers minimise the risk to service users of abuse from service providers and other service users, including physical or psychological ill-treatment, theft, misuse or misappropriation of money or property, sexual abuse, neglect and acts of omission which cause harm or place at risk of harm, while receiving care.

4.1.7 Service providers obtain informed consent from service users and act in accordance with it in providing care and treatment.

4.1.8 Service providers develop, implement and monitor relevant programmes to maximise the safety and quality of core care processes. These core care processes should include:

- protection of children and vulnerable adults from abuse
- continuity of care, including transfers between and within service providers
- prevention and control of healthcare associated infections
- medication management, including safe prescribing and reconciliation
- haemovigilance
- tissue viability management
- nutritional care (in particular for inpatient/residential services)
- equipment and medical devices management
- falls prevention
- healthcare records and information management
- end-of-life care.

Standard 4.2 Service providers plan and deliver services to minimise risks to service users associated with the delivery of care.

Criteria

4.2.1 Service providers safeguard service users by proactively identifying, managing and minimising the risks associated with the design and delivery of services and implement the consequent improvements.

4.2.2 Service providers have arrangements in place to identify, manage and respond to patient safety incidents to minimise their effects.

4.2.3 Service providers effectively document, report on and respond to patient safety incidents in a timely manner and in line with national legislation, policy, guidelines and guidance. These patient safety incidents include:

- serious reportable events
- adverse events
- near misses
- no harm events.

4.2.4 Service providers monitor, analyse and trend and respond to patient safety information including patient safety incidents and ensure that lessons are learnt and disseminated.

4.2.5 Service users are informed as soon as practicable after an adverse event affecting them has occurred or becomes known and they are actively informed at all further stages.

4.2.6 Leaders at all levels facilitate a culture of quality and safety which includes 'open communication' with service users, and where applicable their families and carers, following an adverse event.

4.2.7 Service users are supported by the service provider following an adverse event and they are informed of and receive information on support services, including independent patient advocacy services, and how to access them.

4.2.8 Service providers actively promote learning both internally and externally to the service to minimise the risk of patient safety incidents from reoccurring.

Theme 5 Workforce

Standard 5.1 Service providers plan, organise and manage their workforce to achieve their objectives for high quality, safe healthcare.

Criteria

5.1.1 Service providers plan, configure and manage their workforce to deliver high quality, safe healthcare. In planning, configuring and managing their workforce service providers take the following into account:

- needs assessment of service users
- skill-mix requirements
- the time and resources needed to provide care
- the size, complexity and specialties of the service
- national and international evidence-based practice, policy and guidelines
- risk analysis
- resources available
- changes in workload.

5.1.2 Service providers facilitate multidisciplinary team-working to deliver integrated and coordinated care.

Standard 5.2 Service providers recruit people with the required competencies to provide high quality and safe care.

Criteria

5.2.1 Service providers ensure that the workforce have the required experience, registration (where relevant), credentials and competencies to deliver high quality, safe care.
5.2.2 Service providers select, recruit and manage the workforce in accordance with legislation and informed by evidence-based human resource practices.
5.2.3 Service providers provide a formal mandatory induction programme for their workforce, including a module on patient safety and team working.

Standard 5.3 The workforce have and maintain the competencies required to deliver high quality and safe care.

Criteria

5.3.1 Service providers facilitate each member of the workforce in maintaining and improving their skills, knowledge and competencies to fulfil their roles and responsibilities in delivering high quality and safe care.
5.3.2 Service providers facilitate members of the workforce to maintain the relevant professional registration requirements.
5.3.3 Service providers regularly review the development needs of their workforce to deliver high quality and safe care and take appropriate action to address any identified gaps.
5.3.4 Service providers have in place an education and development programme that enables their workforce to deliver high quality and safe care. This programme includes clear programme objectives, with a specific focus on patient safety and team working.
5.3.5 Service providers supervise, monitor and review the provision of care to ensure all members of the workforce work within the boundaries of their skills and experience.
5.3.6 Service providers facilitate members of the workforce to seek support or advice, including seeking advice from decision makers and senior team members.
5.3.7 The workforce has the skills, attitudes and behaviours to work as part of a multidisciplinary team in order to deliver safe and integrated care within and between services.
5.3.8 Each member of the workforce adheres to a code of governance with a code of conduct and behaviour which promotes the achievement of high quality and safe care. This code includes guidance on advocacy, ethics, probity, patient safety, respect and consideration and managing complaints.

Service providers must ensure that adequate time is provided to ensure that registered medical practitioners can meet and comply with at the minimum requirements of the Medical Council Professional Competence Scheme.

Standard 5.4 Service providers support their workforce in delivering high quality, safe care.

Criteria

5.4.1 Service providers support and promote a culture that values, respects, actively listens and responds to the views and feedback of the workforce.
5.4.2 Service providers monitor, manage and develop the performance of their workforce, at individual and team level, and take action to address identified areas for improvement.

5.4.3 Service providers maintain a working environment that supports and protects the workforce in delivering care. This includes taking measures to minimise the risk of violence, bullying and harassment by other staff or people using the services.

5.4.4 Service providers inform the relevant professional body where they consider that the performance or conduct of a professional may be below the requirements of the professional body.

Demands placed on clinician time need to reflect some time - protected from direct clinical responsibilities and preserved for audit and quality control, teaching and/or research etc.

Theme 6 Use of Resources

Standard 6.1 Service providers plan and manage the use of resources to achieve quality and safety efficiently and sustainably.

Criteria

6.1.1 Service providers effectively and efficiently allocate their available resources, including human resources, to achieve their objectives for quality and safety using clear financial and capital plans.

6.1.2 Service providers regularly assess the potential impact of their financial performance on the quality and safety of service provision.

6.1.3 Service providers consider explicitly the quality and safety implications of financial decisions and undertake a risk assessment of such decisions, taking account of clinical and service users' views.

6.1.4 Service providers plan and manage their physical assets based on analysis of what is needed to deliver their objectives for quality and safety.

6.1.5 Service providers delivering publicly-funded healthcare plan and manage the use of resources to achieve their objectives in line with national policies

Standard 6.2 Service providers have effective arrangements in place to deliver the best possible quality and safety for the money spent.

Criteria

6.2.1 Service providers plan, design, develop and maintain their resources to deliver value for money.

6.2.2 Service providers regularly review and assess the efficiency and cost-effectiveness of services and technologies using best available evidence in order to maximise quality and safety and to inform investment and disinvestment decisions.

6.2.3 Service providers delivering publicly funded healthcare have transparent and effective decision making arrangements for the use of resources.

6.2.4 Service providers delivering publicly funded healthcare actively promote individual and collective responsibility for resource management and raise awareness within their workforce of the resource consequences of delivering services.

6.2.5 Service providers delivering publicly funded healthcare procure external goods and services which deliver the best possible outcomes for the money spent.

6.2.6 Service providers actively manage the use of natural resources to reduce the impact on the environment through setting targets and implementing plans to achieve these.

In relation to criteria 6.2.2, in the current economic climate HIQA's role in evaluating the clinical and cost effectiveness of health treatments and technologies is vital in promoting a modern, quality healthcare system that provides value for money.

Both health technology assessment and investment in health technology is dependent on available funds.

Theme 7 Use of Information

Standard 7.1 Service providers actively collect, manage and use quality information as a resource in delivering and improving the quality and safety of healthcare.

Criteria

7.1.1 Service providers protect the security, privacy and confidentiality of personal health information and the right of service users to access their own records.

7.1.2 Service providers ensure that healthcare records and information, both in paper and electronic format, are of a high quality. In particular this includes information that is up-to-date, accurate, easily accessible at all times, relevant, comprehensive and legible.

7.1.3 Service providers ensure necessary information is shared between and within services to facilitate the delivery of high quality, safe care.

7.1.4 Service providers ensure service users are identified uniquely to avoid duplication and misidentification.

7.1.5 Service providers make decisions based on quality information, that supports effective:

- delivery of care
- strategic planning, including an assessment of the needs of the population served
- performance monitoring and audit
- use of resources.

7.1.6 Service providers manage data and information, including healthcare records, reflecting best available evidence and in line with legislation, national health information standards and nationally agreed definitions, where they exist.

7.1.7 Service providers monitor and evaluate the effectiveness of their information management arrangements and take steps to address any identified areas for improvement.

Privacy and confidentiality of personal health information are fundamental principles of medical professional ethics and the Guide to Professional Conduct and Ethics for Registered Medical Practitioners offers guidance in relation to medical records and confidentiality. The IMO is calling for the urgent publication of the Health Information Bill to clarify many issues in relation to the collection, use storage and disclosure of personal health records.

Theme 8 Promoting Better Health

Standard 8.1 Service providers promote, protect and improve the health of service users.

Criteria

8.1.1 Service providers, in partnership with service users, identify and take opportunities to promote better health while delivering care.

8.1.2 Service providers actively promote and support a culture of quality and safety including promoting better health and take measures to embed this culture.

8.1.3 Service providers actively develop and deliver programmes or initiatives to promote better health, in line with their objectives and in partnership with service users. These are proportionate to the context, nature and scale of services provided and take account of national policies, stakeholders' views, the needs of the population served and the best evidence and resources available.

8.1.4 Service providers actively identify the health priorities of service users and develop initiatives to minimise inequalities in health outcomes.

8.1.5 Service providers actively collaborate and work in partnership with each other, with national agencies and with non-healthcare organisations (where appropriate) to promote the health of service users.

Contractual arrangements have yet to be agreed between the IMO and the HSE for preventive and pre emptive care.