



Healthcare Update Issue 12

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Advance Care Directives

On 16 September 2009 the Law Reform Commission's Report on Bioethics: Advance Care Directives and draft Bill was published. The report makes 46 recommendations and includes a draft Mental Capacity (Advance Care Directives) Bill 2009 to implement these recommendations. The report follows on from its consultation paper on this topic published in October 2008. An advance care directive or 'living will' sets out a person's wishes about what should happen to them in the event of an incapacitating accident or illness that makes it impossible for them to communicate their wishes directly. Advance care directives have been legislated for in a number of states allowing people aged over 18 to specify what treatments they do not wish to have in the event of being incapacitated. There is currently no such legislation in Ireland.

Unique health identifier recommendations

On 29 June 2009 the Health Information and Quality Authority (HIQA) published a report on Recommendations for a Unique Health Identifier for Individuals in Ireland. The recommendations state that currently there is no reliable method of tracking a patient through the healthcare system as healthcare services rely on matching names, addresses and date of birth, none of which are reliable or recorded in a standard format. The report states that the health and social care system requires the introduction of a number, unique to each individual in the country, known as a unique health identifier (UHI) to increase patient safety by offering a secure mechanism by which people can be identified.

Arising from an extensive public consultation process on the Health Information Bill (which will provide the legislative basis for the UHI), the Minister for Health and Children has decided to set up an inter-agency working group to do further work on this issue. Details of the consultation process on the Health Information Bill are available on www.dohc.ie.

Electronic discovery: new rules in the Superior Courts

Both parties in a civil litigation case are obliged to make available all relevant documents within their power or procurement whether or not they support or undermine the respective parties' cases. Discovery entails formally stating that certain documents or classes of documents exist or have existed. New rules in relation to discovery in the Superior Courts came into effect on 16 April 2009 introducing for the first time detailed rules on the discovery of electronic data (e-discovery).

Under the new rules:

1. A party may ask for electronically stored data in a searchable format;
2. Inspection and search facilities for electronic data on its computer systems to the other party can be ordered. If the computer contains sensitive non-discoverable data, an independent expert or person agreed between the parties may be appointed by court to search for the relevant electronic data;
3. The court may vary the terms of a discovery order or agreement where it is satisfied that the discovery originally ordered or agreed is unreasonable having regard to the cost or other burden of providing discovery;
4. Where the requested documents or data is extremely costly or burdensome to locate, the party obliged to furnish these items may apply to court to narrow the scope of the discovery order;
5. All discoverable documents or data must be listed according to agreed categories or in an easily comprehensible sequence.

Also all parties subject to a discovery order must swear an affidavit of discovery confirming that they understand their obligation to give the relevant documents and electronic data in the agreed format.



Designated centres for older people: new regime

The Health Act 2007 (Registration of Designated Centres) Regulations 2009 provides for a new registration and inspection regime for nursing homes. It came into force on 1 July 2009. They underpin the National Quality Standards for Residential Care Settings for Older People in Ireland. The Chief Inspector of Social Services now has the power to inspect all designated centres for older people. As part of the new regime all nursing homes will also now have to be registered.

National Standards for the Prevention and Control of Healthcare Associated Infections

On 27 May 2009 the Health Information and Quality Authority (HIQA) published 12 new standards to combat the spread of healthcare associated infections (The National Standards for the Prevention and Control of Healthcare Associated Infections). The standards are aimed at providing direction for health and social care providers on how to minimise and prevent the occurrence of these infections. They cover governance and management; structures, systems and processes; environment and facilities management; human resource management; communication management; hand hygiene; communicable/transmissible disease control; invasive medical device related infections; microbiological services; outbreak management; surveillance programme; and antimicrobial stewardship.

The standards will apply to all health and social care services in Ireland, including hospitals, community care services, GP and dental surgeries and primary care services. They are applicable to public, voluntary and independent hospitals. They do not replace any of the existing guidelines in place such as the SARI Guidelines for Hand Hygiene in Irish Health Care Settings and the guidelines on "The Control and Prevention of MRSA in hospitals and in the Community" and they build on and complement numerous legislative requirements, policy documents and national strategies.

The implementation of these standards is a top priority and there will be a six month adjustment period to allow all services to consider the local implications of the standards and develop implementation plans. During this period, HIQA will engage with the Health Services Executive and other stakeholders to discuss internal monitoring processes. Following this, HIQA will assess the findings of the internal gap analysis, the development of plans and how priority safety areas have been addressed. It is intended that implementation plans should contain steps to immediately deal with and manage the risk of serious gaps, and put in place measures leading to the standards being implemented within 12 months of their publication. The only exception is standard 3 on environment and facilities management which has a three-year implementation timeframe.

Link to the new standards

http://www.hiqa.ie/media/pdfs/National_Standards_Prevention_Control_Infections.pdf

Proposals for a Human Tissue Bill

On 9 April 2009 the Minister for Health and Children, Mary Harney opened a public consultation on Draft Proposals for General Scheme of the Human Tissue Bill 2009 (draft proposal) which closed on 29 May 2009. The draft proposal will regulate the removal, retention, storage, use and disposal of human tissue from deceased persons and the use of donated tissue from living persons for transplantation and research. The types of activities covered by the proposals include hospital post-mortem examinations and the use of organs and tissues for transplantation, research, anatomy and education. One aim of the draft proposal is to implement the key recommendation of the 2006 Madden report into Post Mortem Practice and Procedures in that no hospital post mortem examination should be carried out and no tissue retained for any purpose whatsoever without authorisation. Another objective is to establish a legal framework for organ donation which can benefit patients through transplantation of organs. Consent or authorisation is the defining principle underpinning any of the specified activities involving human tissue set out in the draft proposal such as pathology practice, anatomical examination, public display, transplantation, research and import/export of human tissue from deceased donors.

There is a view that the proposed legislation should be divided into two Bills – one Bill to deal with postmortem and anatomy practice and the donation of tissue from living and deceased donors for research, and a second Bill to deal with transplantation issues. The Department of Health and Children has decided to keep the proposals together for the purpose of this consultation.

Link to the draft proposals: http://www.dohc.ie/consultations/open/human_tissue_bill/covering_letter.pdf?direct=1



National Quality Standards for Residential Services for People with Disabilities

On 11 May 2009 the Health Information and Quality Authority (HIQA) published the National Quality Standards: Residential Services for People with Disabilities in Ireland. The standards do not apply to residential services for children with disabilities as a separate set of standards is being developed for these services.

The 19 standards follow the same structure as the 32 National Standards for Residential Care Settings for Older People that were launched in March 2009 by HIQA. They are grouped under seven headings or principles which address the following: quality of life; staffing; protection; development and health; rights; the physical environment; and governance and management. They are made up of standard statements and criteria. The standard statements set out what is expected in terms of the service provided to the person living in the residential service. The criteria are the supporting statements that set out how a service may be judged as to whether the standard is being met or not.

Residential services for people with disabilities have not, so far, been subject to registration and inspection. Under the Health Act 2007, the people who provide and manage the residential services must prove that they are fit to do this so that they can be registered. Each residential service will be registered for up to three years and an inspection will be carried out as part of the registration process. HIQA's Social Services Inspectorate will also inspect residential services on an ongoing basis to make sure that they are meeting the new standards. HIQA will also publish all inspection reports and will keep a list of all the services that have been registered on its website.

John Moloney, the Minister of State with responsibility for Equality, Disability and Mental Health has acknowledged that, given the current fiscal situation, it was not proposed to place the standards, including regulation and inspection on a statutory footing yet. However, progressive implementation of the standards would be commenced on a non-statutory basis in all publicly-funded facilities.

Link to the new standards:

http://www.hiqa.ie/media/pdfs/National_Quality_Standards_Residential_Services_People_with_Disabilities.pdf

Biobanking proposals

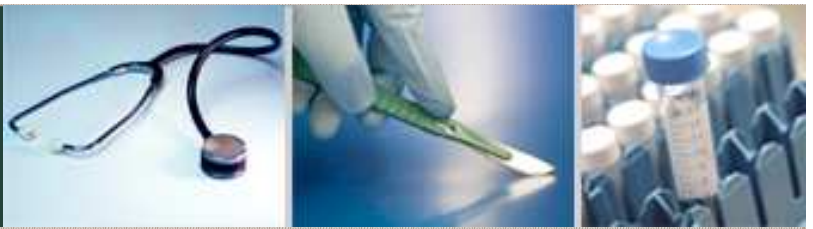
As part of the implementation of the National Cancer Strategy, in 2007, the Minister for Health and Children, Mary Harney nominated members for an expert group to develop proposals for the establishment of a National Cancer Biobank. On 14 May 2009 the report of the expert group on biobanking was published and it contains recommendations for the establishment of a National Cancer Biobank in Ireland. A biobank is a collection of patient samples and related information, and is an essential tool in the advancement of medical research.

Link to the report : <http://www.hrb.ie/publications/hrb-publication/publications//453/>

Recent cases

Third party ownership of pharmacies

The European Court of Justice (ECJ) has recently ruled that while restrictions on ownership and operation of pharmacies constitute a restriction on freedom of establishment and the free movement of capital, these restrictions can be justified by the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality (*Joined Cases C 171/07 and C 172/07 Commission v Italy and Apothekerkammer des Saarlandes and Others, 19 May 2009*). It is important to note that this ruling does not say that pharmacy ownership must be restricted to pharmacists. Each of the 27 EU member states has discretion in this regard. In Ireland, there are no restrictions on third party ownership of pharmacies.



Plaintiff walks away from action at hearing

The Healthcare Department was recently involved in a case that was taken by a plaintiff against the hospital and her consultant obstetrician (who was separately represented and insured). Following the birth of her first child in 1996, the plaintiff alleged complications involving a fourth degree tear that she believed was mismanaged and inappropriately treated subsequent to delivery and prior to her discharge from the hospital. A supportive expert was to be called for the defendant doctor who would clearly say that while the plaintiff suffered a difficult time, this was without any fault on behalf of the hospital or the consultant obstetrician. On the second day of hearing the plaintiff agreed to strike out her claim with no order whatsoever.

Plaintiff's claim statute barred

Generally speaking under the Civil Liability and Courts Act 2004 the statute of limitations for all personal injury actions is two years from the date of the cause of action. This is the maximum period of time, after certain events, that legal proceedings based on those events may be initiated. The Healthcare Department was recently successful in bringing a motion to have the statute of limitations heard as a preliminary issue before Ms. Justice Linnane in the Circuit Court and the plaintiff's claim was subsequently dismissed. The motion had to be adjourned on a number of occasions and it was on the sixth hearing date that Ms. Justice Linnane advised that the plaintiff's claim was dismissed. She had given the plaintiff's solicitors numerous occasions to file an affidavit setting out the reasons why the plaintiff's claim had not been instituted within the limitation period but they had not done so.

MDU indemnity cover issues

We are involved in one of the seminal test cases regarding Medical Defence Union (MDU) issues. The MDU sought to apply their 'discretion' in withdrawing indemnity cover from some doctors in this jurisdiction in 2005 and 2006. The Healthcare Department's Health Board client joined one of these doctors as a third party, who in turn joined MDU Services Ireland. They queried the Irish court's jurisdiction to hear the issues, appealed the unsuccessful ruling to the European Court of Justice and now face the 'discretion' hearing. Thankfully the outstanding issues are being case-managed by Mr Justice Quirke.

Irish Healthcare Awards and breakfast briefing

Beauchamps Solicitors are sponsoring the award "Innovation in Healthcare Management" at the Irish Medical Times' annual Irish Healthcare Awards on 15 October 2009. The award will recognise innovation in healthcare management which is focused on the patient, the carer and the general public. It seeks to reward management which has made a difference and has improved patient care and/or streamlined administrative procedures.

Beauchamps Solicitors are hosting a breakfast briefing on "Damages - yesterday, today and tomorrow" on Friday 9 October 2009 at 8.30am (sharp) which will address the assessment of general and special damages in Ireland and the proposed introduction of periodic payments. Aisling Gannon, Charles Meenan SC and Colm McCarthy, economist at UCD and chairman of the Special Group on Public Service Numbers and Expenditure Programmes will be speaking. To register for this event please email healthcare@beauchamps.ie or contact Maree Kirby at 01 4180600.

The Healthcare Unit

If you have any queries on the contents of this update, or if there are other topics you would like to see us address in future editions, please contact any member of the Healthcare Unit listed below.

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