

## ● Medico-legal advice

# Proposals for a Human Tissue Bill



**Aisling Gannon** of Beauchamps Solicitors takes a look at the proposals for the Human Tissue Bill 2009, which will regulate the removal, retention, storage, use and disposal of human tissue

**O**n April 9, 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'). The latest date for receipt of responses to the public consultation was May 29, 2009.

The proposed Bill 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.

## Transplantation

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.

In this regard the report states that 'an appropriate legislative framework must be put in place to govern hospital post-mortems', which must 'set out clear safeguards for patients and their families, and encourage medical education and research'.

Another objective of the draft proposal 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,



Technician checking the endothelial viability of a cornea to be used for transplantation

research and import/export of human tissue from deceased donors.

## Draft proposal

The draft proposal is divided into six parts:

1. The preliminary and general matters section sets out the guiding principles and defi-

nitions used throughout the draft Bill and also define the scope of the legislation.

2. The transplantation section sets out the requirements that are specific to the donation of organs and tissues for transplantation including the prohibition on the commercialisation of organs and

tissues for transplantation. It also addresses the issue of consent for donation of organs for transplantation. The proposals are drafted on the basis of the 'opt-in' model of consent, however four possible models of consent ('opt-in', 'opt-out', 'mandated choice' and 'required request') were the subject of a separate public consultation earlier this year and the Department of Health and Children (the Department) is currently considering the submissions received.

3. The pathology practice section covers the regulation of hospital post-mortem examinations and the use of tissue from living and deceased donors for the purpose of research.
4. The anatomical examination part regulates the practice of anatomy. It also provides for a system of licensing of appropriately qualified medical practitioners who practice anatomy, the appointment of an inspector of anatomy and sets out the conditions under which the public display of bodies will be permitted.
5. The regulation and administration section provides that

the Minister may appoint one or more regulators and sets out the functions of the regulator.

6. The last section sets out offences and penalties for non-compliance.

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 has decided to keep the proposals together for the purpose of this consultation process.

## What happens next?

The Department will analyse all submissions received and aims to present the final General Scheme to Government for its approval in the autumn. Once Government approval is received, a Human Tissue Bill based on the provisions of the General Scheme will be drafted and introduced into the Dáil.

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## ● Investing in patients

# Quicker 'door to balloon' treatment for patients

A hospital initiative in Texas means that 83 per cent of its heart-attack patients are treated within 90 minutes, while the state average is 69 per cent

**A** hospital in the US has set itself a goal to treat heart-attack patients in fewer than 90 minutes. Between July 2007 and June 2008, Huguley Memorial Medical Centre, Burleson, Texas treated 83 per cent of patients within 90 minutes, compared to a Texas average of 69 per cent.

Since then, the hospital has vowed to further reduce the time it takes a heart-attack patient to be treated. Over the last six months, it has treated all its patients more quickly.

Care Manager of Huguley's Heart Catheterisation Lab, Julie Songy, said physicians, nurses and technicians in the emergency room and the Heart Catheterisation Lab have col-



laborated to get patients with chest pain evaluated and treated as soon as possible. "We're focusing intently to improve the outcomes of patients with heart attacks," she said.

The initiative originated with the American College of Cardiology and the American

Heart Association. In 2008, they set a national goal that heart-attack patients entering the emergency room would have blood-vessel blockages opened within 90 minutes.

More than 800 hospitals are signed up to the 'door to balloon' campaign. It was a

response to studies, which showed death rates from heart attacks rose by 42 per cent in patients who waited more than 90 minutes for an angioplasty. Their message is 'every second counts', and can impact on how much heart muscle is saved.

In some hospitals, as few as 30 per cent of patients have their blocked arteries opened within 90 minutes.

## Don't wait – call 911

"The faster a heart attack is treated, the less damage occurs in the heart. Patients who might be experiencing a cardiac event need to get to the emergency department as soon as possible. If you have chest pain, don't wait. Call 911," Songy said.

Almost half a million Americans have a STEMI (segment elevation myocardial infarction) each year, which is caused by a completely blocked artery.

Chair of the guidelines writing group and Director of Coronary Care at Brigham and Women's Hospital, Boston, Dr Elliott Antman, said the recommendation for the initial treatment reinforced the goal of restoring blood flow to the heart as quickly as possible.

"Data shows that better systems of care, leading to faster times to reperfusion, result in better outcomes for patients with STEMI. One under-utilised but effective strategy for improving STEMI systems of care is to expand the use of pre-hospital 12-lead electrocardiography programs by emergency medical systems (EMS) that provide advanced life support. This provides the early diagnosis that can set into motion the appropriate treatment strategy," he said.

Evidence has shown that P12ECG technology can be readily used to identify patients with STEMI before a patient's arrival at hospital.

Under the recommendations, after emergency room staff determine that a patient

is experiencing an acute heart attack, they are taken to the heart catheterisation lab.

A cardiologist determines the location of the blockage and opens it using one of two common methods – angioplasty, which inflates a balloon to open the blood vessel, or stenting, which places a small wire tube in the blood vessel to hold it open.

The recommendations clarify that the emphasis on angioplasty should not obscure the importance of fibrinolytic (clot-busting) therapy. STEMI patients presenting to a hospital with angioplasty capability should be treated with primary angioplasty within 90 minutes of first medical contact as a systems goal.

The 90-minute goal also stands for hospitals without angioplasty capability, as long as a patient can be transferred and receive treatment within the 90-minute window.

However, patients who cannot be transferred to an angioplasty centre and undergo the procedure within 90 minutes should be treated with fibrinolytic therapy within 30 minutes of hospital presentation as a systems goal, unless fibrinolytic therapy is contraindicated.