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NHS Pathology A Valuable Resource Maximising Research Use

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Types of Study

- Pilot
- More in depth analyses comparing multiple samples of normal and diseased tissues
- Information linked to clinical outcome as retrospective
- Prospective and Clinical Trials – Obtaining Consent to use tissue after randomisation does not guarantee access to the tissues
- Why can't I just be given what I want, when I want and yesterday?

Anatomist Gunther von Hagens sells off dead bodies a slice at a time

Mail order business based in Germany will supply human or animal body parts



A 'plastinated' corpse in Gunther von Hagens's Body Worlds exhibition. Photograph: Christopher Furlong/Getty Images

For sale: a smoker's lung, a slice of human head, a piece of hand.

A mail-order service has been set up by a controversial German anatomist offering these and many more human and animal body parts,

Body part prices range from around €600 (£507) for a cross-section of a fish to €1,500 for a sliver of human head or €15,000 for a section of the entire length of a human body. Smokers' lungs are available for €3,600 and a slice of human hand for as little as €185. The objects will be dispatched by post and can be sent around the world.

Main Challenge

CONSENT

Informed Patients



The Key Issues

- The Surplus Tissues that we need is being destroyed as clinical waste
 - The public do not know that currently this invaluable material is being destroyed
 - The obvious answer is an opt - out mechanism, based on widespread public education on the policy, but as we have an opt - in what is the solution?
- We need policies and procedures that will facilitate collection of all tissues not just cancer
 - Generic consent for all patients is the only answer if we wish to access the vast NHS resource to the benefit of all

Obstacles to accessing Tissue in NHS Pathology Departments

- No Consent
 - Not the job of surgeons
 - Not the job of nurses
 - As we are talking about use of tissue that will be otherwise incinerated, what are the consent issues?
 - We need authorisation by the patient or relatives to use surplus, discarded tissue for the common good
- Patients and Relatives are not being given the opportunity to exercise their right to donate the tissue as procedures are not available for generic consent

What have we learnt in 10 years?

- Funding is spent on controlling access and use of the tissues, rather than starting at the beginning and ensuring that everyone has the opportunity to authorise/consent
- **Proposal – Devolve responsibility to NHS for research governance for all operational procedures related to tissues for the living and the dead and hold the R and D Directorate accountable**

Obstacles to Generic Consent

- Legislation? - NO
- The tissue resource lies within the NHS and the NHS are the custodians
- It is not an NHS priority to:
 - Fund distribution of patient information leaflets
 - To train staff on new procedures to obtain authorisation, (staff time and costs)
 - Many different departments involved and thus need for coordinated procedures

Four Key Areas

How, Who, Where, What

- Patient Information.
- Who should seek consent
- Where should patients be asked
- What should be recorded

NHSGGC System Redesign

Patient Information
Posters

Hospital Patient
Information
Officers



NHS
Greater Glasgow
and Clyde

Giving
tissues
helps us Find new
Treatments

Are you willing to give a **GIFT** ?

During your care and treatment we will ask your permission to use any left-over tissues for use in medical research. Contact 0141 211 4531 for further information or to register your gift

onCore

First Fundamental- How To Inform Patients

- **Information**

Develop one standard information sheet. A4

Comply with Health Board's Equality & Diversity Standards

Medical Records to issue with every appointment letter

NHSGGC System Redesign: Use of IT to enable process

- Stand alone screen to record patient wishes and withdrawal:

electronic – Surplus Tissue Authorisation Form (e-STA)

- Information held centrally in SCI store
- This information can be accessed by Pathology and Bio-repository to confirm patients wishes

Tissue Banking Supporting Policy

“Better Cancer Care: An Action Plan” (2008)

Gradual role out of e-STA

- Golden Jubilee
- Ayrshire & Arran

Pilot

- Preoperative Assessment Clinics

Monitor

- Response
- Request for further information
- Impact on clinical appointment time
- Withdrawals of consent

Summary

- Need Generic Consent across NHS
- Need a policy of patient information
- Must come under the priorities for NHS Research and Clinical Governance
- How do you pay for it?
 - Put funds into ensuring that all patients have the opportunity to exercise their rights to donate, which was the underlying problem at Alder Hey and Bristol