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reflect reversible or irreversible myocardial injury and how necrosis could be distinguished from reversible myocardial damage. Further experimental studies are required to clarify this point, which has in recent years been considered in numerous clinical studies that showed that raised troponins are predictors for mortality or worse clinical outcome independently of acute coronary syndromes and myocardial infarction.^{w1 w9 w23 w24 w27 w28 w31 w35 w41 w43}

However, raised cardiac troponins alone will never allow us to make a clinical diagnosis, but they are an important contribution to a complex clinical picture, be it in the context of acute coronary syndromes or other conditions. Above all they contain prognostic information for most of these conditions that may be relevant for the management of patients

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- Braunwald E, Antman EM, Beasley JW, Califf RM, Cheitlin MD, Hochman JS, et al. ACC/AHA guidelines for the management of patients with unstable angina and non-ST-segment elevation myocardial infarction: executive summary and recommendations. A report of the American College of Cardiology/American Heart Association task force on practice guidelines (committee on the management of patients with unstable angina). *Circulation* 2000;102:1193-209.
- Myocardial infarction redefined—a consensus document of the Joint European Society of Cardiology/American College of Cardiology committee for the redefinition of myocardial infarction. *J Am Coll Cardiol* 2000;36:959-69.
- Ammann P, Fehr T, Minder EI, Gunter C, Bertel O. Elevation of troponin I in sepsis and septic shock. *Intensive Care Med* 2001;27:965-9.
- Heidenreich PA, Alloggiamento T, Melsop K, McDonald KM, Go AS, Hlatky MA. The prognostic value of troponin in patients with non-ST elevation acute coronary syndromes: a meta-analysis. *J Am Coll Cardiol* 2001;38:478-85.
- Shave R, Dawson E, Whyte G, George K, Ball D, Collinson P, et al. The cardiospecificity of the third-generation troponin T assay after exercise-induced muscle damage. *Med Sci Sports Exerc* 2002;34:651-4.
- Tucker JF, Collins RA, Anderson AJ, Hauser J, Kalas J, Apple FS. Early diagnostic efficiency of cardiac troponin I and Troponin T for acute myocardial infarction. *Acad Emerg Med* 1997;4:13-21.
- Bertinchant JP, Larue C, Pernel I, Ledermann B, Fabbro-Peray P, Beck L, et al. Release kinetics of serum cardiac troponin I in ischemic myocardial injury. *Clin Biochem* 1996;29:587-94.
- Christenson RH, Apple FS, Morgan DL, Alonsozana GL, Mascotti K, Olson M, et al. Cardiac troponin I measurement with the ACCESS immunoassay system: analytical and clinical performance characteristics. *Clin Chem* 1998;44:52-60.
- Hamm CW. New serum markers for acute myocardial infarction. *N Engl J Med* 1994;331:607-8.
- Brett J, Gerlach H, Nawroth P, Steinberg S, Godman G, Stern D. Tumor necrosis factor/cachectin increases permeability of endothelial cell monolayers by a mechanism involving regulatory G proteins. *J Exp Med* 1989;169:1977-91.
- Piper HM, Schwartz P, Spahr R, Hütter JF, Spieckermann PG. Early enzyme release from myocardial cells is not due to irreversible cell damage. *J Mol Cell Cardiol* 1984;16:385-8.
- McDonough JL, Arrell DK, Van Eyk JE. Troponin I degradation and covalent complex formation accompanies myocardial ischemia/reperfusion injury. *Circ Res* 1999;84:9-20.

Data protection, informed consent, and research

Medical research suffers because of pointless obstacles

Cancer Research UK and other medical research charities have warned the government that the human tissue bill will cause damaging confusion among doctors and hamper medical research unless crucial sections are clarified.¹ The Data Protection Act, another well intentioned but loosely drafted law, has also been in the news. The Bichard inquiry has been investigating the decision by Humber-side police to erase the records of Ian Huntley's sexual offences involving children because he had not been convicted, and Richard Thomas, who as information commissioner is responsible for interpreting the Data Protection Act, has announced a public information campaign to prevent such embarrassing "misinterpretations" of the act.² He says that "data protection principles are largely a matter of common sense," and told the Bichard inquiry that the decision to erase Huntley's records was "astonishing." This decision, like the General Medical Council's instruction to doctors that they might face litigation under the Data Protection Act if they notified their patients to cancer registries without obtaining fully informed consent, stemmed from the legal muddle that the Data Protection Act has engendered. To blame the muddled majority is to miss the point. It is the law, not police or medical training, that must be amended. Access to

personal records should not require informed consent in certain circumstances, and these should be specifically exempted. The criterion of an overriding public interest has proved to be too ambiguous to be useful.

The deaths that will occur because of the effects of data protection law on British medical research attract less publicity than child murders; but the pointless obstacles that bona fide researchers, particularly epidemiologists, face when they seek access to individual medical records are now causing serious damage. An important recommendation of the new Wanless report is that the forthcoming white paper on public health "should address the possible threat to public health research which arises from the difficulty of obtaining access to data because of the need to strike a balance between individual confidentiality and public health research requirements."³ Lord Falconer says: "Data can be used for any medical research purpose under the [Data Protection] Act, without the need for the consent of individuals. So Professor Julian Peto is simply wrong when he states that the Data Protection Act is preventing data from being passed to medical researchers."⁴ That those who enact and interpret radical social legislation should be so ignorant of its actual effects is

alarming. Custodians of medical records are fearful of litigation if they allow any access for research or even audit without each patient's informed consent. The effects on British epidemiology are illustrated by two of our current studies.

The NHS cancer screening programme commissioned us to abstract the screening records of women who had died of cervical cancer and an anonymised 1% random sample of all British women. We had to correspond with the director of public health or the Caldicott guardian in almost 100 former health authorities for permission to obtain these data. These negotiations occupied much of a senior researcher's time for two years, and the data have still not been released in a few areas.

The Health and Safety Executive commissioned us to conduct a national case-control study of patients with mesothelioma. We asked the Department of Health to provide the names of clinicians with newly diagnosed eligible patients (not the patients' names) from the hospital inquiry system, but this was refused for over two years. The information commissioner's office finally advised the hospitals that it is not illegal to put medical researchers in touch with doctors. To obtain random population controls from general practitioners' lists again entailed protracted correspondence with NHS data custodians in each region before the project could begin, and several areas, including the whole of Scotland, still refuse to participate.

At a public meeting in November 2002, organised by the Parliamentary Group on Cancer and opened by Alan Milburn, then secretary of state for health, the audience were provided with an electronic voting facility. After a discussion of the restrictions on access to medical records that British epidemiologists now face and their effects on our work, the audience were invited to vote for or against the following proposed law: "Consent is not required for access to medical records for non-commercial medical research that has no effect on the individuals being studied and has been approved by an accredited research ethics committee."

The vote in favour was 93%. The audience included members of the general public, patients' support groups and cancer charities, doctors, nurses, and public health workers. The widespread belief among politicians and senior civil servants that the public would no longer tolerate access to their records by bona fide medical researchers is assiduously promulgated by many medical ethicists and lawyers, but it is not true. Even the tiny minority of patients and controls who express any concern that we have identified and contacted them through their medical records are almost always satisfied when we explain our work to them.

The only substantive difference between the proposed exemption for medical research that this audience supported so overwhelmingly and the relevant parts of the 1998 Data Protection Act and the 2001 Health and Social Care Act is the requirement that permission for medical researchers to access individual records without informed consent must be granted by the Patient Information Advisory Group. Multicentre research ethics committees typically include general practitioners, hospital specialists,

nurses, ethicists, lay members, and patients or their representatives. The government has not explained why the Health and Social Care Act usurped the authority of this effective national network of highly professional committees by creating the Patient Information Advisory Group.

None of the hundreds of data custodians in hospitals, cancer registries, and primary health care trusts with whom we have corresponded has ever indicated that our access to their records might raise ethical concerns. These are resolved in discussion with the multicentre research ethics committee before a research protocol is approved. Their concern relates solely to their legal liability, and it can be allayed only by clarifying the law. The Data Protection Act was intended to accommodate medical research, as Lord Falconer claims it does. In practice, however, data custodians are increasingly cautious, and the current government seems unlikely to grant the explicit exemption for non-commercial medical research that would resolve their fears.

Lord Falconer further asserts that it is the common law, not the Data Protection Act, that demands informed consent for medical researchers to access named patients' records "unless there is an overriding public interest."¹ This suggests a practical solution. Medical researchers have been allowed confidential access to medical records throughout the ages, and until recently such access without informed consent was explicitly allowed under the Medical Research Council's guidelines on research. To reverse this ancient tradition in the name of the common law seems absurd, and a high court judge could presumably restore the status quo by simply stating in a test case that the novel demand for informed consent to access records for non-commercial medical research has no basis either in law or in established common practice. He or she would become a minor icon of 21st century medical research, for many lives and a great deal of public money would be saved.

But no such remedy can rescue British medical research from the ambiguities of the Human Tissue Bill. Doctors who store any human tissue that may be used for future research without obtaining informed consent could face punitive criminal sanctions, and many will simply discard it.

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- 1 Cancer Research UK. *Call for clarity on human tissue bill*. Press release, 14 January 2004. www.cruk.co.uk/news/pressreleases/humantissuebill_14jan04 (accessed 18 Feb 2004).
- 2 Information Commissioner. *Data protection—helping organisations to get it right*. Press release, 14 January 2004. www.informationcommissioner.gov.uk/cms/DocumentUploads/Data%20protection%20-%20Helping%20organisations%20to%20get%20it%20right.doc (accessed 2 Mar 2004).
- 3 Wanless D. *Securing good health for the whole population. Final report, 25 February 2004*. www.hm-treasury.gov.uk/consultations_and_legislation/wanless (accessed 31 Mar 2004).
- 4 Lord Falconer of Thoroton. Privacy law and medical research [letter]. *Times* 2001 May 17:21.