Letters

Data protection, informed consent, and research

Data Protection Act does not bar medical research

Editor—The Data Protection Act 1998 does not prohibit the processing of personal information for medical research purposes. Indeed, it is clear from section 33 of the act that such processing is expressly permitted. If it were otherwise, then the act would be in direct conflict with the core aims of the laws that underpin it—namely, the Council of Europe Convention of 1981 and the European Union Directive of 1995. These laws seek to facilitate data processing activities, primarily "free flows" of information, rather than suppress data processing.

The problems to which Peto et al refer in their editorial on data protection, informed consent, and research are not Data Protection Act problems but, rather, problems caused by ignorance and misunderstanding.[1] With basic training on the key mechanisms of the act the problems of which the authors complain can be easily overcome. Training need not be an expensive task either. Legal compliance can be achieved at comparatively modest cost.

There are two additional points of note.

Firstly, the Data Protection Act regulates the processing of personal information relating to living individuals. Thus, research following death is not regulated.

Secondly, the act and case law make clear that information will not be "personal data" if it does not identify a living person or if it does not have the individual as its focus or is not significantly biographical. So, if medical researchers do not actually need or seek identification information the act should not be engaged. Data can be anonymised.

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Competing interests None declared.

1 Peto J, Fletcher O, Gilham C. Data protection, informed consent, and research. *BMJ* 2004;328:1029-30. (1 May.)

Interpretation of legislation should reflect patients' views

Editor—Peto et al report the result of a vote at a public meeting whose audience included the general public, patient support groups and cancer charities, doctors, nurses, and public health workers.[1] All of them, except the general public, have a professional interest in medical research. As a group of medical students, we undertook an epidemiological study building on previous studies exploring patients' views about confidentiality with regard to general practice medical records.[2 3] In addition, we studied public knowledge and opinion about the use of medical records for research purposes.

The study was carried out between February and April 2004 at two general practices in England (Birmingham and Blackburn). A total of 200 questionnaires were given to consecutive patients at each centre. The questionnaire was designed to elicit patients' knowledge of who is able to access their medical records, who they think should be able to, and whether they would allow access to anonymised, or patient-identifiable, data for research purposes or otherwise.

In all, 316 people approached (79%) completed the questionnaire. An overwhelming proportion of patients (250) thought that it was acceptable for their medical records to be used for research to improve health care, but only 27 (8.5%) held this view if the objective of the research was to make a profit. In asking about access to medical records, more patients thought that access should be given for research purposes than they thought was the current practice. This was consistent across all groups included in the study: doctors, practice nurses, health authorities, drug companies, etc.

Our results support Peto et al's statement that it is not true that the public no longer tolerate access to their records by bona fide medical researchers. They also suggest that the balance between research requirements and patient confidentiality should be reassessed to bring the interpretation of legislation into line with patients' views.

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Competing interests: None declared.

1 Peto J, Fletcher O, Gilham C. Data protection, informed consent, and research. *BMJ* 2004;328:1029-30. (1 May.)
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Sharing electronic health records

Confidentiality is big issue

Editor—The central Hampshire electronic health record project raises important issues, with implications for the national spine network.[1 2] The authors assert, after 20 web based responses from a population of 225 000, that most people support linked records. No informed consent was obtained to records being available across health and social care, driving a coach and horses through the General Medical Council's guidance on confidentiality and consent.[3] This makes no exception for computerised dissemination undermining confidentiality between professional and client.

The authors' second paper, on data quality, considers coding and data unavailability, but not accuracy. Speculative diagnoses such as Munchausen syndrome by proxy, for example, may be withheld from patients because of potential harm. Thus informed consent to dissemination is unobtainable, and "garbage in, garbage out" inevitable.

Booth wrote that if safeguards to confidentiality and accuracy of patient information prove insufficient, then the caring professions will not use the spine network, and the money will have been wasted.[4] However, the national programme for information technology is technically and managerially driven. Clinical considerations are mostly ignored, and the programme's clinical adviser network has been disbanded. It is classic group think, like London's Millennium Dome, but much bigger, with £2.6bn committed after minimal debate.

Our research showed no support for such information sharing between NHS and social services, which have different legal frameworks.[5] No non-military public sector information technology project anywhere on this scale has worked. The NHS is unlikely to break this mould with this solution in search of a problem, given its poor track record in large scale computerisation. The government should think again.

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1 Adams T, Budden M, Hoare C, Sanderson H. Lessons from the central Hampshire electronic health record pilot project: issues of data protection and consent. *BMJ* 2004;328:871-4. (10 April.)
2 Department of Health. *Delivering 21st century IT support for the NHS: national specification for integrated care records service consultation draft.* Version 1.22 (26 July 2002). www.dh.gov.uk/assetRoot/04/07/16/77/04071677.pdf (accessed 18 Apr 2004).

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Author's reply

EDITOR—As we described in our first paper, we took great pains in the central Hampshire electronic health record project to discuss issues of confidentiality with the General Medical Council, BMA, Wessex Local Medical Committee, and Information Commission and we made considerable efforts to ensure that people in the community were aware of the project and were able to withdraw their record if they wished to. Despite these efforts, we had very low levels of response. Although the majority of those responses were in favour of record sharing, we did not "assert that most people support linked records" but rather observed that the issue of record sharing seemed not to be an important issue for the majority of people.

Pheby also raises concerns about the risks associated with the national programme for information technology.[1] Although we would not disagree that this is a risky programme, we wished to draw attention to several specific problems associated with the National Care Record Service, which can and should be addressed.

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1 Department of Health. Delivering 21st century IT support for the NHS: national specification for integrated care records service consultation draft. Version 1.22 (26 July 2002). www.dh.gov.uk/assetRoot/04/07/16/77/04071677.pdf (accessed 18 Apr 2004).

Managing nocturia

Nocturia is a symptom, not a diagnosis

EDITOR—The review of nocturia by Marinkovic et al is comprehensive and clear.[1] Although I am not a doctor, my knowledge of medicine gained through many years of working in medical education has taught me that a description of a symptom or a group of symptoms (syndrome) is not a diagnosis. I was taught that the term "nocturia" was used to describe the symptom of increased nocturnal voiding. When taking a history or writing on a patient chart one would write nocturia×3 to describe the three voids at night. This symptom may be indicative of a variety of underlying conditions.

These conditions can be classified as those that cause nocturnal polyuria *v* nocturnal overactive bladder. As described by Marinkovic et al, nocturnal polyuria may be the simple consequence of excessive fluid intake at night time or fluid redistribution due to congestive heart failure. Many other underlying diseases might give rise to increased urine production at night. The underlying cause of the excess urine production must be diagnosed and treated appropriately. However, patients experiencing increased day time frequency and urgency with or without urge incontinence may also experience these symptoms at night. These patients may have nocturnal overactive bladder and may respond to treatment with antimuscarinic drugs (although results from clinical trials to date are not that compelling).

The term nocturia should not be used as a diagnosis that can be treated when it is a symptom of an underlying condition or disease. After all, proteinuria and haematuria are not diagnoses, but doctors certainly look for the cause of such symptoms and treat them accordingly.

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Competing interests: NWM's company develops educational programmes for Pfizer in support of Detrol LA and Detrusitol.

1 Marinkovic SP, Gillen LM, Stanton SL. Managing nocturia. *BMJ* 2004;328:1063-6. (1 May.)

Article is removed from clinical practice

EDITOR—I have some concerns about the article on managing nocturia by Marinkovic et al.[1]

Firstly, claiming that melatonin is effective in men with nocturia is misleading. The study quoted included only 20 patients. The authors themselves say that the clinical importance of melatonin is uncertain.

Secondly, for an article entitled a clinical review, little mention is made of the common causes or treatments of nocturia—for example, bladder overactivity, prostatic disease, and urinary tract infection

Thirdly, sacral neuromodulation is not a widely suitable and recognised treatment for nocturia. It is very expensive. The success rate of 85% quoted does not reflect the literature. On an intention to treat basis the overall success rates are in the order of 33% (similar to a placebo response). Nocturia itself is evaluated only as a secondary end point in most studies on neuromodulation. It is an important research tool, studied and used in a small group of patients whose nocturia fails to respond to simple treatments. The long term effects and results are not yet known.

The article seems removed from everyday clinical practice. It reads as a wonderful promotion tool for the sacral neuromodulation company Medtronic and their InterStim device (figure). I'm surprised at the *BMJ* for publishing such a blatantly commercially biased and incomplete article on such an important subject.

Lightweight (50 g), implantable sacral neuromodulation device (InterStim, Medtronic) from Marinkovic et al[1]

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1 Marinkovic SP, Gillen LM, Stanton SL. Managing nocturia. *BMJ* 2004;328:1063-6. (1 May.)

Authors' reply

EDITOR—The goal of our article was to highlight briefly and thoroughly the underlying causes and treatment options for nocturia and present a useful algorithm for patients with the disorder. Matheson's comment about the term "nocturia" as a symptom rather than a condition highlights the difficulty in defining and categorising this often misunderstood and underdiagnosed disorder.

Doctors must determine the underlying causes of excess urine production at night and treat them appropriately. In clinical practice, the term "nocturia" is a diagnosis for which causes are determined and treatment appropriated to improve patients' quality of life. In our article we offer several treatment options, including restriction of fluids in the evening, time release diuretics, afternoon naps, elevation of the legs, compression stockings, antidiuretic hormone therapy, melatonin treatment, and sacral neuromodulation.

Although Walker asserts that our "claim of effectiveness" of melatonin is misleading, our intention was not to imply a categorical claim of effectiveness, but rather to offer melatonin as a possible option for patients with benign prostatic enlargement. The patient's symptoms and previously attempted treatments would indicate the appropriate course of treatment. For patients whose condition is seemingly recalcitrant to all medical treatment, sacral neuromodulation is a promising alternative.

Although Walker says that sacral neuromodulation is not a widely suitable or recognised treatment, it offers a source of hope for patients who have found relief difficult or impossible to obtain or sustain. One of us (SPM) has performed 150 sacral neuromodulation procedures in the past three years and has experienced a success rate better than 85% in patients with urgency, urge incontinence, and nocturia.

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Hypocalcaemia after intravenous bisphosphonate

Read the product information first

EDITOR—Peter et al describe hypocalcaemia after intravenous bisphosphonate administration.[1] Reference to the recommendations given in the summary of product characteristics for the products in question may have abrogated the occurrence of this well known and well documented side effect.

The patient in case 1 had a low adjusted serum calcium concentration before zoledronic acid was given, and no calcium and vitamin D supplementation was given at the start of treatment despite the recommendation in the summary of product characteristics.

Hypercalcaemia was treated very effectively with zoledronic acid in case 2. The summary of product characteristics gives the incidence of hypocalcaemia as an adverse event as 1-10%. The patient developed this common, documented side effect. Hypomagnesaemia is also listed as an uncommon side effect. This patient had a low magnesium concentration before treatment. Early correction may have mitigated the hypocalcaemia.

The patient in case 3 was treated with 60 mg pamidronate for an adjusted calcium concentration of 2.96 mmol/l, yet the summary of product characteristics recommends a dose of 15-30 mg for this calcium value. This relative overdose may have resulted in, or at least contributed to, the subsequent hypocalcaemia.

The patient in case 4 was treated appropriately with 90 mg pamidronate for hypercalcaemia. On the following day another 60 mg pamidronate was administered against the advice in the summary of product characteristics to wait before giving a further dose. This overdose may have contributed to the ensuing hypocalcaemia.

The responsibility lies with prescribers to familiarise themselves with all available information on medicines that they prescribe.

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1 Peter R, Mishra V, Fraser WD. Severe hypocalcaemia after being given intravenous bisphosphonate. *BMJ* 2004;328:335-6. (7 February.)

Lesson to be learnt

EDITOR—Peter et al discuss the risk of hypocalcaemia after intravenous bisphosphonate.[1] Case 4 of their series provides the opportunity for a further lesson to be learnt.

The patient in this case was given 90 mg pamidronate as treatment for hypercalcaemia of malignancy. A further 60 mg was given on the following day when her adjusted calcium values had decreased marginally. Pamidronate takes several days to work, and the usual recommendation is to recheck calcium concentrations five days after treatment. A common mistake is to recheck the level the day after treatment and re-treat on the basis that the patient is still hypercalcaemic, as happened in this case.

At this stage the calcium concentration is usually beginning to decrease but is unlikely to be back in the normal range. The only benefit from checking the calcium value before five days is to ensure that the concentration is not rising despite treatment. If this is the case there is an argument for repeating the treatment. In case 4 the calcium concentration was normal five days after treatment but continued to drop. This may not have happened had the patient received only the initial 90 mg pamidronate.

In general, the temptation to re-treat a raised calcium concentration before the initial bisphosphonate treatment has had a chance to work should be resisted. The effect of an unnecessary second treatment can be severe, as is illustrated by this case.

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1 Peter R, Mishra V, Fraser WD. Severe hypocalcaemia after being given intravenous bisphosphonate. *BMJ* 2004;328:335-6. (7 February.)

Adjuvant bisphosphonate is not currently accepted practice

EDITOR—Peter et al say that bisphosphonates can be used as prophylaxis against metastatic bone cancer[1]; this statement is incorrect. Although nitrogen containing bisphosphonates such as zoledronic acid can inhibit specific enzymes in the mevalonate pathway and thus affect tumour growth by inducing apoptosis,[2] their use as adjuvant therapy against bone metastasis is controversial and is not currently accepted practice.

To date, three randomised controlled trials have investigated the benefit of adjuvant bisphosphonates: all entailed giving clodronate for two to three years in women with early breast cancer.[3–5] The study by Diel et al reported significant reduction in bone metastases and improved disease free and overall survival in the clodronate group.[3] Powles et al found a reduction in the occurrence of bone metastases in women receiving clodronate that was significant only while clodronate was being administered, although mortality was significantly reduced.[4] Conversely, Saaro et al found no benefit of adjuvant clodronate with regard to bone metastases[5]; moreover, they found a detrimental effect with a significantly higher incidence of non-osseous metastases as well as significantly worse disease free and overall survival in the clodronate group.

Given these inconsistent results, adjuvant bisphosphonate use should be limited to clinical trials. Several such trials are ongoing, including the national surgical adjuvant breast and bowel project trial B34 and AZURE in the United Kingdom. These trials should define the clinical role, if any, of bisphosphonate in managing early breast cancer.

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1 Peter R, Mishra V, Fraser WD. Severe hypocalcaemia after being given intravenous bisphosphonate. *BMJ* 2004;328:335-6. (7 February.)
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4 Powles T, Paterson S, Kanis JA, McCloskey E, Ahley S, Tidy A, et al. Randomized, placebo-controlled trial of clodronate in patients with primary operable breast cancer. *J Clin Oncol* 2002;20:3219-24.
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Authors' reply

EDITOR—The word limit for lessons of the week can result in removal of discussion points during editing. We considered several of Breay's and Fergus's comments in early versions of our article. Their points are valid, and doctors prescribing bisphosphonates must read the product information and understand what can happen if the prescribing guidelines are not followed.

Our cases highlighted severe hypocalcaemia after bisphosphonate treatment, and, although mild hypocalcaemia is a well documented side effect, we are sure that Breay would agree that such dangerously low serum calcium values are not seen in 1-10% of patients treated with bisphosphonates. Experienced doctors treating hypercalcaemia of malignancy commonly use doses of 60-90 mg pamidronate for a calcium concentration around 3.0 mmol/l, and the Novartis sponsored study comparing zoledronic acid and pamidronate in patients with values ≥3.0 mmol/l used 90 mg pamidronate.[1] Although failure to comply with prescribing recommendations may have contributed to the effects seen in our cases, the inability to mount a normal physiological response as described played a large part in the severe hypocalcaemia.

Palmieri et al misquote and wrongly interpret us. At no point did we advocate that "bisphosphonates can be used as prophylaxis against metastatic bone cancer." We wrote: "Bisphosphonates are increasingly used to treat metabolic bone disease and as prophylaxis against metastatic cancer."

Reviews and meta-analyses of bisphosphonates in cancer have shown clear advantages in terms of reduced skeletal morbidity.[2] Guidelines outline the accepted use of these drugs.[3] Recent studies have further defined the value of bisphosphonates such as zoledronic acid in several clinical settings and show treatment advantage in reducing skeletal related events in some cancers.[4] The study by Saarto et al seems to contradict these findings, but the methodological

problems, including a randomisation schedule that resulted in a significant imbalance of hormone receptor positive breast cancers in the two treatment groups,[5] are greatly discussed at international meetings. The adverse effect of clodronate on overall survival lost significance in multivariate analysis. Further trials should clarify the position of adjuvant bisphosphonates in treating and preventing cancer related bone disease.

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1 Major P, Lortholary A, Hon J, Abdi E, Mills G, Menssen HD, et al. Zoledronic acid is superior to pamidronate in the treatment of hypercalcemia of malignancy: a pooled analysis of two randomized, controlled clinical trials. *J Clin Oncol* 2001;19:558-67.
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Hospital management of self harm in adults in England

Study contains important data not reported in the paper

Editor—Bennewith et al studied variations in the hospital management of self harm in adults in England.[1] Unusually, they do not comment on several important facets of their own data. They mention one non-predictor of overall low service score (hospital size), but, in addition, a poor score was predicted by a service that had a low turnover of patients who had harmed themselves ($P<0.026$), although it was independent of the proportion of patients that received a psychosocial assessment ($P<0.922$) or whether patients were seen by a senior house officer alone ($P<0.692$).

At hospitals with a designated self harm service, assessments were less likely to be undertaken by junior psychiatrists alone, but whether this is desirable is unclear and presumably depends on experience. From the data of Bennewith et al, services in which a high proportion of cases were seen by a senior house officer alone were more, not less likely, to result in admission both medically ($P<0.022$) and psychiatrically (P for trend <0.062), whereas services with a psychosocial assessment alone were more likely to result in admission medically ($P<0.005$) but not psychiatrically ($P<0.73$).

Of course the patients who were medically admitted would be more "available" for assessment, and nothing is known about the appropriateness of any admission. Nevertheless, when multiple regression is used the only variable that significantly relates to the likelihood of medical admission is the proportion of cases seen by a senior house officer in psychiatry alone ($P<0.049$). A similar result is found using psychiatric admission as the outcome (although this is in turn linked with the proportion offered psychosocial follow up).

If patients are admitted medically they seem more likely to be the recipient of either a psychosocial or a solo assessment by a senior house officer. However, only psychiatric admission is linked with referral for specialist follow up. Therefore, if avoiding psychiatric admission and follow up is desirable then a dedicated team seems to work best, whereas if the opposite applies use of a psychiatric senior house officer alone seems favourable.

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Competing interests: None declared.

1 Bennewith O, Gunnell D, Peters T, Hawton K, House A. Variations in the hospital management of self harm in adults in England: observational study. *BMJ* 2004;328:1108-9. (8 May.)

Authors' reply

Editor—Mitchell states that our paper is unusual because we have not reported in more detail on our data, but the editorial decision on our original manuscript was to restrict us to a short report focusing on the wide variation in the management of self harm and the lack of compliance with national guidelines. More detailed analysis of factors influencing management and outcome after self harm will form the basis of future publications.

Mitchell seems to assume that in our analyses assessments by a senior house officer in psychiatry were not included in the proportion of attendances leading to a psychosocial assessment. As assessments by a senior house officer in psychiatry are a subset of this group the two processes cannot be compared as though they are mutually exclusive. Furthermore, in analysing factors associated with medical admission, such as levels of psychosocial assessment, our data cannot be used to distinguish cause from effect.

We did not comment on good or bad practice as there is no research evidence to indicate what this might be, although there is some indication that people who have had a psychosocial assessment are at lower risk of repeating harm to themselves.[1]

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1 Kapur N, House A, Dodgson K, May C, Creed F. Effect of general hospital management on repeat episodes of deliberate self-poisoning: cohort study. *BMJ* 2002;325:866-7.

Am I breaking the law again?

Editor—Huxtable refers to my arrest by the Isle of Man police last December for conspiring to assist in the possible suicide of my terminally ill Manx friend, Patrick Kneen.[1] When I finally saw him, Patrick was too ill to commit suicide, and he died after being heavily sedated by his general practitioner.

However, when terminally ill people have travelled from the United Kingdom and where, with the help of Dignitas (an organisation based in Zurich), they have committed suicide, the relatives who assisted them have not been prosecuted in this country.

Since June 2003, when I joined Dignitas, I have advised three other members in the United Kingdom, who are seriously ill, how they can get, from their doctors here, the medical reports that the Dignitas doctors require if an assisted suicide is to occur. I counselled one terminally ill person last November on how to make her final journey to Zurich.

So, in the past year, I have "aided, abetted, and counselled" one suicide, and I am involved in possibly three future suicides.[2] But, as the suicide occurred, or perhaps will occur, abroad, am I guilty of committing a crime in this country? It seems that no one currently knows the proper legal answer.

I was questioned by the Manx police last December. Also, I was interviewed at Guildford police station (near my home) last March. The police are aware of my activities with Dignitas. But, so far, nothing has happened.

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Competing interests: MI is a former chairman of the Voluntary Euthanasia Society, England and Wales.

1 Huxtable R. Assisted suicide. *BMJ* 2004;328:1088-9. (8 May.)
2 Suicide Act 1961.