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Informed consent: edging forwards (and backwards)

Informed consent is an unavoidably complicated issue

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The issue of informed consent within medical practice, research, and publication is coming increasingly to the fore as the balance of power in the doctor-patient relationship tips towards patients. Last week Britain's General Medical Council heard a case in which a paediatric cardiologist was accused of going beyond the consent that he was given to treat a child. The child died, and he was found guilty of serious professional misconduct and erased from the medical register for six months (p 955).[1] When, last year, we published a cluster of articles asking whether we should decline to publish studies where patients had not given fully informed consent we prompted a flood of correspondence. We received over 50 letters, most of them argued with unusual care and clarity. Authors split down the middle between those who argued that we should always insist on informed consent (except in very limited circumstances) and those who thought that there were occasions when we need not. Today we try to advance the debate by publishing further responses to last year's debate, including some from patients' representatives. Within the broad context of informed consent we also explore the particular issue of consent for publication of material that emerges from the doctor-patient relationship.

Informed consent in research

In our first cluster Len Doyal made the case for insisting on informed consent with only a few narrow exceptions,[2] while Jeff Tobias argued that the *BMJ* should sometimes publish papers that did not include fully informed consent.[3] Both reflect on the subsequent debate, but neither has changed his position (pp 1000,1001).[4]

Mary Warnock, a philosopher who chaired Britain's Committee of Inquiry into Human Fertilisation, argues that "the principle of non-exploitation has come to seem to many to be by far the most important moral principle that should govern research using human subjects" (p 1002).[4] She thinks it a "misuse of words" to suggest that not obtaining informed consent in itself constitutes a harm: "sometimes it amounts to exploitation, sometimes it does not." She encourages editors to continue to live in a morally hazardous world, to shun dogma, and to follow a prayer from Hertford College Chapel "to distinguish things that differ." This encouragement is hard to resist because morally hazardous worlds are, I believe, right and proper for journals. Dogma is not only dangerous but also boring. We are in the debate not the certainty business.

We have specifically asked patients' representatives to contribute because patients' voices were not being heard—because the *BMJ* is read mainly by doctors and other health workers. Heather Goodare argues that we should take a strong line and reject all studies that do not include informed consent (p 1004).[4] Lisa Power asks us to consider the broader issue of patients in planning research and thinks that "any hard and fast rule that the *BMJ* made about publication would probably have to be broken at some point" (p 1003).[4]

In a separate article Richard Lindley argues that researchers should be educating the public about trials and that "we introduce a new type of card—the randomised controlled trial card—to be carried by people who understand randomised controlled trials and wish to be considered for future appropriate trials" (p 1005).[5] David and Solly Benatar from South Africa attack both Len Doyal's position and that adopted by the ethics committee in Natal that approved a trial that did not have informed consent (p 1008).[6] In a personal view Josephine Venn-Treloar describes how she felt abused by undergoing an investigation without consent (p 1027).[7]

None of this provides a simple solution to our dilemma: rather, it complicates it further. For now we are continuing our pragmatic policy of considering each case on its merits, and we have ourselves conducted studies on papers submitted to us without seeking consent from either authors or reviewers (and been criticised for it). Our next steps are to hold a conference in London (see accompanying note) and then to invite a small group of representatives of all views to advise us on what policy to adopt. If, as seems likely, they cannot agree, then we will decide our own policy and announce it to readers. Any policy we adopt will, of course, be reviewed.

Consent and publication

While continuing to swither over the broad question, we have advanced on the particular question of consent for publication of material that emerges from the doctor-patient relationship.[8 9] Now we are proposing to retreat—a little. It used to be, and in many cases still is, that medical journals and books were relaxed about publishing material that emerged from the doctor-patient relationship—pictures, radiographs, case reports, or whatever. Weak attempts were made to anonymise the material, but generally nobody was worried. Then editors and others began to receive complaints, and we realised that anonymity is impossi-

Previous articles and comment on informed consent are available on our website (see Collections)

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ble to guarantee (particularly to the patient himself or herself). The inevitable logic was to move to informed consent for all such material, and that is the position adopted by the International Committee of Medical Journal Editors.[10] Now Britain's General Medical Council is adopting the same line. Proposed guidelines state: "You must obtain consent from patients before publishing personal information about them as individuals in journals, textbooks, or other media in the public domain, whether or not you believe the patient can be identified. Consent must therefore be sought to the publication of, for example, case histories about, or photographs of, patients."

Catherine Hood and others show in detail how consent can be obtained from patients in 85% of cases (p 1009).[11] There are, however, a growing list of cases where patients have been distressed by information about them being disclosed without consent, and at least one case led to charges of serious professional misconduct.[12] Those doctors were not found guilty, but under the new guidelines a similar case might result in the charge being sustained. The *BMJ* has recently been embroiled in a further case.[13] We published—without revealing the patient's name and with written consent—a radiograph and photograph of a patient who had been attacked with a machete. Later, when the case came to court, the pictures were reproduced in most of Britain's national newspapers and on television. Journalists had made a link between the case and the *BMJ* pictures. All but one of the newspapers reproduced the pictures without written consent, and we have complained to the press and broadcasting regulatory bodies. Our argument is that by reproducing these pictures without consent the media have invaded the privacy of the patient, undermined the doctor-patient relationship, and made it less likely that patients will consent to have material about them published in medical journals.

David Bullimore accuses us of hypocrisy and naivety in relation to this case (p 1022)[14]: hypocrisy because we placed the pictures on our website and had obtained inadequate consent, and naivety for not recognising that journalists would make the connection between the case and the pictures. Our response is that material on the website is copyright just as in the paper journal and that we published the material without a name attached. This case has, however, prompted us to start asking patients to sign specific consent forms that give information about the *BMJ*. The form is available on our website (www.bmj.com), and we will modify it in the light of readers' and patients' comments.

The GMC's proposed guidelines are brief and clear, but they may oversimplify, be hard to implement, and undermine scientific publishing. Particular—and unresolved—problems arise, for instance, with the publication of family trees. Information, sometimes very sensitive, may be given about large numbers of people, and some of those people may not know that they have a particular genetic trait. Is consent required from everybody? In the process of obtaining consent might people be given information they would rather not have? Series of cases also present a problem. We published a series of cases of patients who had recovered after being diagnosed as being in the persistent vegetative state.[15] In one case permission was denied, causing a critic in *JAMA* to ask whether "a journal that knowingly omits scientific information from a report because of the lack of consent [can] still be called a scientific journal."[16] The implication that science may demand that patients' rights be overridden is perhaps unfortunate, but that author attacks the editors of *JAMA* for declining to publish his paper on an outbreak of drug resistant tuberculosis because patients had not consented. Few if any ethical rules can be absolute, and a case may arise where editors would choose to publish without consent "in the public interest." Certainly there are occasions when doctors break confidentiality in the public interest.

Similar problems arise over confidential inquiries into patient deaths. This methodology began in Britain with maternal deaths and has been extended to surgical and other deaths. The information that arises is extremely valuable but has so far been published without consent from surviving relatives. Will the GMC allow these to continue? Almost by definition, these are identifiable cases.

Relaxing our absolutism

We have also been criticised for becoming too absolute in our rules. James Rankine bemoans on p 1026 the fact that a personal view he published in the *BMJ* in 1994 would not now be allowed because of the problem of consent.[17] The fillers that we publish on doctors' interactions with patients are popular with readers, and many make an important point. Yet many

Publishing information that emerges from the doctor-patient relationship

Our general policy is that we require written consent from patients to publish material that emerges from the doctor-patient relationship. This is because the doctor-patient relationship must be confidential and because attempts to anonymise information about patients may fail. In papers describing recent experiences with patients consent will thus always be necessary: thus, in almost all scientific papers consent will be needed. Sometimes, however, it may be possible to publish material about patients—particularly general anecdotes—without consent. We cannot produce completely specific guidelines on this subject, but the decision depends on balancing the importance and interest of the information against the likelihood that a patient might be damaged.

Publication without consent may be acceptable in the following cases.

- The patient is long dead and has no living relatives.
- The interaction with the patient was long ago—perhaps more than 15 years.
- Because the interaction was long ago and the patient was elderly or terminally ill, the patient is likely to be dead.
- The piece is to be published without the authors' names attached, making it unlikely that anybody could identify the patient.
- All extraneous information that might help identification is excluded. We must be careful about removing information from scientific papers because it is difficult to tell what is important, but these "let outs" will rarely apply to scientific papers. They are more likely to occur with fillers or stories in essays.
- Even if the patient were to identify himself or herself, the events described are unlikely to cause offence. We must remember, however, that it is difficult to know what will cause offence: some patients will be offended simply by the fact that the information they gave to their doctors was published without consent.
- Sometimes authors—particularly Soundings authors—fictionalise material: they mix stories from different patients together. This is not acceptable in fillers because people read these as true. It may be acceptable in Soundings columns, but the author should make clear that the account is fictionalised.

The *BMJ* and the Committee on Publication Ethics are hosting a conference in London on Friday, 15 May on informed consent in research, teaching, and clinical practice. Contact the BMA's conference unit. Tel 0171 383 6605. Fax 0171 383 6663. Email eoliver@bma.org.uk

describe events that happened years ago and where the patients are almost certainly dead and their relatives untraceable. Should we reject these because we don't have consent? We have been doing so, but we think that we have gone too far. So just as the GMC is introducing clear but strict rules we are proposing to soften ours. The box contains our proposed guidance, and we welcome readers' comments. In essence, the guidelines ask authors and editors to balance the importance and the interest of the piece against the possibility of harm to patients.

This continuing debate over informed consent illustrates clearly that most ethical conundrums don't submit to simple solutions. Doctors are practical folk who like to get on with things, and many will be frustrated by the expanding complexity of this debate. But doctors will have to learn to inhabit the complicated world in which philosophers feel comfortable. Clearly ethical training is important, which is why our surveys of readers' wants always show ethics second to education. We are trying to oblige.

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Improving the health of NHS workers

Would make a strong contribution to "Our Healthier Nation"

News p 958

At 50 years of age the NHS might be excused for undergoing a mid-life crisis. For most of its life its existence, albeit turbulent, has been unchallenged. The past few years have brought into focus its role as a public service while its professional ethos has been eroded by the doctrine of business management. The vision of universal health provision that is free for all has been replaced by an increasing awareness of inevitable restrictions in service delivery, while the rapid development of information technology is likely to change radically access to health information and models of health care. This might explain why attention is now being paid to the health of the people who work in the NHS and who make the service what it is.

The publication by the Nuffield Trust of a report on improving the health of the NHS workforce[1] is the latest document to encourage NHS trusts to take occupational health seriously. It comes at a time when trusts have been criticised for their health and safety management,[2] and one has been prosecuted by the Health and Safety Executive under the Management of Health and Safety Regulations 1994. The report builds on the theme of the English green paper *Our Healthier Nation,*[3] which highlights the responsibility of the NHS, as the largest employer in Britain, to set an example by showing that it is serious about environmental health and occupational health and safety. NHS trusts are now seen as places which should actively improve everyone's health, and it is to be hoped that the messages from this report are received and acted on accordingly.

One of the strengths of the report is the involvement of NHS stakeholders: the report was commissioned by a partnership of leaders of nursing and medical bodies and representatives of trust managments. Another strength is that the report is based on an evidence based review of the literature, which the partnership hopes will be the basis of actions to be taken by ministers, the NHS Executive, individual trusts, and staff to protect and promote the health of all categories of staff. The evidence base included 131 papers, selected using Cochrane methods of systematic review; 98 reports; and 25 interviews with key individuals.

The results show that the main burden of ill health in the NHS is due to psychological illness, much of which appeared to be associated with unsatisfactory workplace organisation and employment practices. While such a high level of morbidity is consistent with anecdotal reports from occupational health services, 52% of the references quoted were concerned with psychological aspects of occupational health, which may indicate a research or publication bias. Musculoskeletal disorders featured in certain groups, such as nurses and ambulancemen, but occupational dermatitis, asthma, and infections were barely mentioned, or absent. This indicates the lack of a reliable and comprehensive research base and of the need for more studies using acceptable methods. Of particular importance will be longitudinal studies to investigate causal relations between work factors and health outcomes and randomised controlled trials of interventions. A good measure of ministers' response to this report would be amendment of the NHS research and development strategy in the light of these recommendations.

Indeed, for this to be anything more than just another well intended report it will have to influence the people who make things happen. In particular, it

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will have to feature on the agendas of trust boards. The impact of previous guidelines on occupational health issued by the NHS Executive[4] has been variable, particularly in health surveillance. The report dares to mention resources: "It is clear that much ill health arises from workload, which is a resource issue." What is required now is leadership that will be capable of looking innovatively at occupational health, changing management cultures and employment practices, and seizing the opportunity to invest in the health of one in 20 of the working population. Health authorities or trusts should fund pilot schemes, perhaps as part of health action zone initiatives, which are subject to rigorous evaluation. Here is a window of opportunity for the NHS and other publicly owned organisations to take responsibility for promoting the health of the nation.

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Chernobyl and public health

The nuclear industry should fund an international foundation to learn from Chernobyl

In 1992, when the first effects of the Chernobyl accident on the prevalence of thyroid cancer in children were reported,[1] they were met with scepticism by the radiological community.[2 3] Some of this scepticism was undoubtedly scientific ("iodine-131 has a low carcinogenic potential"), though some was not. These reservations have now mostly been resolved by re-examination of the data on the relation of exposure to *x* rays and thyroid cancer and a realisation of just how many children were exposed. It is a cautionary tale of how scientific instinct can mislead: help could have been provided more quickly had it not been for this debate. Nevertheless, similar debates are now obscuring our ability to learn longer term lessons from Chernobyl and provide further help to its victims.

Some sceptics, relieved that the fallout had not originated and fallen in western Europe or America, where populations are litigious, were reluctant to concede that environmental sources of radiation could be strongly associated with serious disease. Childhood thyroid cancer has a very low spontaneous incidence in most countries ($<1/1\,000\,000$/year). Thus, the appearance of several tens of cases in the region round Chernobyl from a population of under half a million children, giving relative annual incidences of $\geqslant 100/1\,000\,000$, should have left little room for doubt that something was seriously amiss.

Today there is little dispute that a real increase in thyroid cancer occurred among young people in Belarus, the Ukraine and, to a lesser extent, the Russian Federation, and that it was associated with the Chernobyl accident.[4] Indeed, in a recently published study of post Chernobyl cases[5] the risk is found to fall within the confidence limits for the absolute risk for thyroid cancer after external radiation exposure,[6] thus contradicting the widely held assuption that ^{131}I is only weakly carcinogenic. This was apparently based more on lack of evidence than definitive findings. Perhaps it is no coincidence that one of the last bastions of this belief is in America, where deliberate releases of ^{131}I were made from the Hanford complex in the late 1940s to study the behaviour of fallout clouds.[7] More recently, we have learnt that weapons testing in the atmosphere over Nevada in 1950-62 appears to have left few parts of America unaffected by releases of ^{131}I three to four times greater than those from Chernobyl.[8] Neither is Europe without its weapons testing legacy. The Soviet Union has made extensive atmospheric tests in the Arctic, possibly the cause of the increased incidence of thyroid cancer reported in Norway.[9]

In America a report from the National Cancer Institute on the Nevada releases is currently being reviewed by the National Academy of Sciences and Institute of Medicine to assess the public health implications and advise the government on how to communicate these risks to doctors and the public. Had it not been for the dramatic increase in the incidence of childhood thyroid cancer in the Chernobyl region the health risk from the Nevada testing might have been dismissed as negligible, based primarily on the evidence for adults treated with ^{131}I, which points to a very low risk.

Even so, questions remain about the health effects of ^{131}I exposures. How far the risks seen in the former Soviet Union can be extrapolated to the American population is unclear. We still do not know how long the increased incidence of thyroid cancer will continue (12 years have elapsed since the Chernobyl accident), or the accident's impact on thyroid conditions other than cancer and non-thyroid disease, such as breast cancer. These uncertainties serve only to emphasise the importance of the Chernobyl populations to our understanding of the health effects of such exposures.

However, the prospects for learning from the Chernobyl accident over the necessary time scale (the next 40 or so years) are bleak. Firstly, their economic and political upheavals have made it difficult for countries of the former Soviet Union to respond to the immediate public health problems of the increase, let alone conduct rigorous epidemiological studies. Secondly, the initial scepticism and acrimonious debate in the international scientific community did little to encourage collaboration between international agencies supporting either the humanitarian aspects

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or research. Thirdly, despite scepticism about the origin of the increased incidence of childhood cancer, a prominent aim of research has been to seek characteristics, at molecular level, that might signal radiation as the cause of the cancer. So far no such markers have been identified for any tumour. Such markers would have obvious benefits in helping to determine eligibility for compensation for radiation induced cancers, and this financially motivated aspect of the research has produced an unproductively competitive atmosphere in some research circles.

If the lessons of a disaster on the scale of Chernobyl are to be learnt an international effort is essential. For the results to be meaningful independence from vested interests must be guaranteed; the compensation issue in America and for the nuclear industry is potentially so large that significant sums could be spent to frustrate legitimate research in the hope of avoiding much larger sums in compensation. How can these two objectives be met?

After the atomic bombings in Japan a joint Japanese-American study was initiated and continues today as the Radiation Effects Research Foundation. It is the main source of knowledge about the effects of radiation on human health. The situation in Japan, involving only two principals, is simple in comparison with that in Chernobyl, where three independent states are involved together with tens of international, national, and private agencies. Nevertheless, if the opportunities to learn from this disaster are not to be irretrievably lost some kind of initiative along the lines of the Japan-American foundation is required. Improved coordination has been universally advocated over the past five or six years, yet the position has not improved. Either no one organisation commands both the authority and the confidence of the other organisations to allow it to coordinate effectively, or the participating organisations do not want to cooperate as their real aims differ from those they proclaim.

The humanitarian aspect to this problem should also not be forgotten. Whatever the decision about an international effort to learn about the course of the epidemic, speculative research to identify a marker of radiation causation will continue—because the rewards are so high. This research impinges negatively on the lives of those exposed and is rumoured to have led to a market in tumour tissue. Bringing all research under a single coordinating body would additionally serve to minimise the impact on the affected populations.

A significant proportion of the global population, particularly in western Europe and America, obtain electricity from nuclear sources. Had the Chernobyl accident occurred there and affected those populations, they would have expected to be compensated, either individually or on the basis of a national health care programme. Given the economic circumstances in the former Soviet Union, those exposed have little chance of compensation but would benefit from international help to obtain adequate treatment. The global community needs to learn from their experience: those who benefit from the production of nuclear electricity should finance an independent international foundation to coordinate research and provide humanitarian aid.

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Inflammatory responses and coronary heart disease

The "dirty chicken" hypothesis of cardiovascular risk factors

The "dirty chicken" hypothesis was proposed by Solomons to explain why children reared in poverty, though appearing healthy and receiving adequate nutrition, end up as short adults.[1] Based on the observation that antibiotic supplementation reverses poor growth in chickens reared in overcrowded unhygienic conditions, he suggested that chronic subclinical infection induces a low grade systemic inflammation and that this produces a qualitatively similar effect to full blown acute inflammation—that is, chronic anorexia and increased basal metabolic rate, with cytokines being the mediators. What does this have to do with humans reared in relatively overcrowded unhygienic conditions and cardiovascular disease?

There is an increasing interest in the relation between chronic low grade systemic inflammation, as indicated by serum levels of C reactive protein, and mortality from coronary heart disease.[2 3] There has, however, been little knowledge of the determinants of this response and its importance in the pathogenesis of atherosclerosis. Chronic subclinical infection with *Chlamydia pneumoniae*, *Helicobacter pylori*, chronic bronchitis, and chronic dental sepsis have been associated with raised values of C reactive protein within the normal range[3] and have been implicated as risk factors for

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coronary heart disease. Non-infective conventional environmental risk factors also associated with low grade acute phase responses include age, low adult social class, smoking, obesity, and childhood social class (a possible mechanism for the association of short stature and coronary heart disease).[3]

If the dirty chicken hypothesis is true—that is, that qualitatively similar effects are observed during chronic low grade systemic inflammation (occurring in all of us) as in severe acute inflammation—many biological risk factors should be associated with raised serum C reactive protein values in normal subjects. This is indeed the case: raised serum C reactive protein values are associated with raised serum fibrinogen, plasminogen, factor VIII, white blood cell count, fasting insulin, and serum triglyceride values; depressed high density lipoprotein-cholesterol; and raised fasting blood sugar concentrations.[3 4] (The latter cast light on the pathogenesis of non-insulin dependent diabetes.) These associations are not diminished by controlling for body mass index. A common underlying mechanism such as inflammation may explain why different types of cardiovascular risk factors cluster in the same subject—for example, in syndrome X. It might also explain why many environmental cardiovascular risk factors produce changes in several different biological risk factors—for example, smoking or obesity. Nevertheless, atherosclerosis is clearly a multifactorial condition, since not all contributory factors show a clear relation to inflammation—for example, low density lipoprotein cholesterol and hypertension.

We have recently extended these observations on inflammation. Interleukin 6 and tumour necrosis factor α play a key part in regulating the acute phase response by the liver. They also affect lipid metabolism in vivo. Raised serum concentrations of both have similar associations to those observed with serum C reactive protein and were linked to chronic coronary heart disease.[5]

Inflammatory type reactions and, particularly, cytokines may not deal only with the body's response to tissue damage or environmental stress. Body mass index is correlated with serum concentrations of tumour necrosis factor α, which is consistent with increased synthesis of tumour necrosis factor mRNA by adipocytes from obese subjects.[6] Oestrogen has inhibitory effects on interleukin 6 synthesis and on levels of cardiovascular risk factors, perhaps through this mechanism. Alcohol consumption is associated with diminished serum concentrations of tumour necrosis factor α,[5] and polyunsaturated fatty acids inhibit cytokine synthesis. Hence levels of inflammation may respond to metabolic change and be influenced by various dietary factors.

But what relation does systemic inflammation generated in response to environmental or metabolic change bear to the risk of coronary heart disease? Cytokines and activated white blood cells originating in the lungs or gut in response to environmental stress could influence the process through effects on conventional risk factors such as fibrinogen. In addition, tumour necrosis factor α and interleukin 6 generated at these sites could have direct effects which promote atherosclerosis and thrombosis at distant sites.[7] Alternatively, inflammation may be principally located at the site of the atherosclerotic lesion, being directly influenced by environmental factors that can reach that location, such as smoking, alcohol, diet, and *C pneumoniae,* with the systemic inflammatory response being an epiphenomenon of this process. Obesity, *H pylori* infection, and chronic bronchitis cannot act directly at the site of atherosclerotic lesions, supporting the notion that distant inflammation may be important. Whatever the balance of effects between locally and distantly generated cytokines, agents which can influence inflammatory processes are likely to have important therapeutic effects in atherosclerosis, as has recently been suggested for aspirin.[2]

These observations provide new insights into how environment can influence the risk of atherosclerosis and reduce growth in children. Inflammation and inflammatory cytokines play a fundamental role in the whole body response to environmental stress (infective and non-infective) and metabolic change. These mechanisms are likely to be continuously active, but more so in some who die sooner from coronary heart disease. The dirty chicken hypothesis has the pleasing property of unifying many previously disparate observations about the clustering of cardiovascular risk factors and also of identifying new risk factors such as chronic bronchitis and dental disease. It suggests simple ways in which a whole set of environmental stressors—infective agents—can be treated to reduce risk of coronary heart disease, as well as providing a mechanism for the association of poverty with coronary heart disease. The growth of dirty chickens is augmented by antibiotics, and preliminary studies suggest that inflammatory responses[8] and coronary events[9 10] after myocardial infarction are reduced by antibiotic administration.

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