Saturday 28 February 1998

BMJ

The Swiss heroin trials: testing alternative approaches

Prescribed heroin is likely to have a limited role

Over half a million heroin misusers receive oral methadone maintenance treatment worldwide[1] but the maintenance prescription of injectable opioid drugs, like heroin, remains controversial. In 1992 Switzerland began a large scale evaluation of heroin and other injectable opiate prescribing that eventually involved 1035 misusers.[2 3] The results of the evaluation have recently been reported.[4] These show that it was feasible to provide heroin by intravenous injection at a clinic, up to three times a day, for seven days a week. This was done while maintaining good drug control, good order, client safety, and staff morale. Patients were stabilised on 500 to 600 mg heroin daily without evidence of increasing tolerance. Retention in treatment was 89% at six months and 69% at 18 months.[4]

The self reported use of non-prescribed heroin fell signifianctly, but other drug use was minimally affected. The death rate was 1% per year, and there were no deaths from overdose among participants while they were receiving treatment. There were limited reports of problems in the local neighbourhood, despite the high frequency of daily attendance. Heroin diversion was not a major problem, although some trial participants were expelled for attempting to remove heroin from the clinic or to smuggle cocaine into the clinic.[4]

The Swiss trials have encouraged proposals for similar trials in other countries, including Australia,[5] and, more recently, Denmark, Luxemburg, and the Netherlands. Any country that contemplates a trial of heroin prescription will need to address several problems that arose in the Swiss trials. Firstly, the participants' preference for heroin over any alternative opioid undermined the randomised controlled design that was originally planned and resulted finally in a descriptive outcome study. Secondly, in the Swiss trials heroin was prescribed as part of a comprehensive social and psychological intervention. In the absence of any comparison treatment it was impossible to disentangle the pharmacological effects of heroin from the effects of providing treatment in well resourced clinics with highly motivated staff. An assessment of this issue requires an appropriate comparison treatment. Thirdly, the unique social and political context of the Swiss trials makes it uncertain how to generalise their findings to other countries. Switzerland is a wealthy society that has a comprehensive healthcare system that includes a well developed drug treatment system whose staff have substantial experience with opioid substitution treatment. Even so, heroin prescription in Switzerland has been an addition to existing treatment approaches: it has not replaced the methadone maintenance still prescribed for 15 000 Swiss heroin misusers but has been an expensive option for a minority of severely dependent misusers who have not responded to existing treatments.

Given this limited role, the controversy surrounding heroin prescription in Switzerland and elsewhere has been out of all proportion to its likely role as a treatment option. A recent debate about heroin prescription in Australia, for example, dominated public discussion of drug policy for nearly a month before the government decided against proceeding with the trial. The debate also had other untoward effects: supporters of the trial argued that something radical was needed, thereby encouraging the view that Australia was in the midst of a national heroin crisis. Their opponents agreed but countered that this was evidence that the national policy of harm minimisation, which sanctions methadone maintenance and needle and syringe exchange, had failed.

These issues have not been resolved by the Swiss trial. There are clearly still questions that remain unanswered. The most important is what is the comparative usefulness and cost effectiveness of injectable heroin and oral methadone maintenance? A convincing answer to this question would substantially improve our understanding of the role of this controversial treatment.

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BMJ 1998;316:639

Deaths related to intrapartum asphyxia

Largely unexplained but probably preventable

Fetal death in labour is extremely rare. Although the total fetal death (stillbirth) rate has more than halved over the past 30 years, and is now about 5.5 per 1000 total births, the rate of intrapartum fetal death in babies above 1500 g is only 0.3 per 1000 total births.[1 2] Hypoxia is thought to be a factor in 90% of intrapartum deaths,[2] and much of the reduction has been credited to continuous fetal heart rate monitoring, introduced into clinical practice about 30 years ago. Use of continuous fetal heart rate monitoring was soon found to be associated with significant falls in perinatal mortality,[3 4] and further evidence for an inverse association between the level of perinatal technology and the incidence of intrapartum fetal death came from the 1980 American national fetal mortality survey.[5] Interestingly, the Dublin randomised controlled trial of fetal heart rate monitoring in labour found no differences in intrapartum stillbirth rates, or long term outcome, between groups monitored by intermittent auscultation and by continuous fetal heart rate monitoring.[6] However, this study was performed against a background rate of 0.3-0.4 intrapartum fetal deaths per 1000, and this very low rate remains the present challenge to attempts to reduce it still further.

The confidential inquiry into stillbirths and deaths in infancy focuses on preventable factors in intrapartum related perinatal deaths. The fetuses who die are more likely than controls to have had placental abruption, cord prolapse, fetal distress, or an unhealthy placenta.[7] The inquiry found that 75% of intrapartum related deaths showed examples of suboptimal intrapartum care which might have contributed to the outcome. Over 90% of these examples related to failure to recognise a problem, act appropriately, or communicate adequately. A long delay between the onset of fetal compromise and delivery has been highlighted as a major contribution to intrapartum fetal deaths.[8]

Intrapartum asphyxia accounts for both fetal deaths in labour and neonatal deaths. Analysis by cause was recommended by Wigglesworth in 1980[9] and is used by the confidential inquiry. It was also the approach taken by Stewart and colleagues in their study of the frequency of asphyxial deaths according to time of birth, published on page 657.[10] They looked at 33 intrapartum deaths (rate 0.31 per 1000 registrable births), 42 neontal deaths in the first week (0.39 per 1000), and 4 deaths at days 8-28 (0.04 per 1000) identified from the confidential inquiry in Wales in 1993-5. They limited their study to babies born with a birth weight of 1500 g or more and found that twice as many of the babies who died from intrapartum asphyxia had been born between 9 pm and 9 am; the relative risk was similarly doubled for births in July and August. They did not, however, find higher rates of total perinatal mortality at the weekend, as found in a previous study.[11]

The study of Stewart et al raises an intriguing question. Is staff performance at night, and in July and August, sufficiently different to account for this twofold increase in asphyxia related mortality, or does fetal asphyxia during labour at night present differently? Spontaneous labour is known to occur more often at night, and such labours may be associated with a different presentation of chronic fetal compromise from the iatrogenic compromise more likely to be associated with induction of labour.[12] Although it is tempting to conclude that night staff may be less able to identify fetal compromise, further study is essential before this conclusion is accepted. In 1970 data from the collaborative perinatal study in America showed that 57% of term stillbirths were unexplained.[13] UK data from the confidential inquiry show that 51% of intrapartum deaths remain unexplained.[1] This figure has not changed in over 25 years, despite a halving of perinatal mortality.

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A deep rooted ambivalence exists among professionals about the use of continuous fetal heart rate monitoring in labour. Much is expected of this simple tool, and much difficulty results from its use. The recent confidential inquiry report shows that most adverse comments about continuous fetal heart rate records in labour related to poor education.[1] If continuous fetal heart rate monitoring is to stay[14] there is a clear need to achieve an improved understanding of the physiological basis for control of the fetal heart rate.[15] Only with better knowledge and understanding of how the fetal heart provides information about fetal oxygenation can staff hope to address the epidemiological question of whether serious intrapartum asphyxia presents in a way that is less obviously recognised at night.

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Subcutaneous apomorphine in Parkinson's disease

Effective yet underused

Over 40 years have passed since Schwab and colleagues reported the beneficial effect of apomorphine hydrochloride in Parkinson's disease.[1] In 1979 Corsini et al reported the successful use of subcutaneous apomorphine in combination with domperidone,[2] and this was confirmed by a series of experiments by Hardie et al.[3] More recently, in 1988, Stibe et al described the successful use of continuous subcutaneous infusion of apomorphine in overcoming refractory on-off oscillations in Parkinson's disease.[4] Since then at least 16 papers, mostly using open label designs (except two double blind placebo controlled studies), have been published confirming the efficacy of apomorphine given as subcutaneous "rescue" injection or continuous infusion using an automated syringe driver in Parkinson's disease.[6] Apomorphine received regulatory approval in Britain in 1993, but, despite its efficacy, it remains largely underused.

The motor response to apomorphine is indistinguishable from that to levodopa, and subcutaneous apomorphine is almost 100% bioavailable with a rapid onset of action (3-20 minutes) and duration of 20-40 minutes. It is indicated in Parkinson's disease when levodopa responses become erratic and marred by fluctuations in motor responses, on-off oscillations, and dyskinesias.[2 5]

Counselling of patients and liaison with the general practitioner are important before prescribing apomorphine because there are commonly held misconceptions that it is addictive and a respiratory depressant. An apomorphine challenge is required for determining the right dose of the drug, dopaminergic responsiveness, and occasionally for diagnostic purposes as tremor-dominant Parkinson's disease may mimic essential tremor. Apomorphine challenge should be carried out after pretreating the patient with domperidone for three days and after an electrocardiogram has ruled out serious cardiac arrhythmia. Young motivated patients with short (less than one hour) off periods may prefer to inject apomorphine up to 10 times a day with a penjet, while more disabled patients may need a subcutaneous infusion for 12-24 hours a day. Once the patient has been stabilised on apomorphine, the dose of levodopa can be reduced by 20%-80%.[2-6]

Apomorphine has other benefits. It appears to have an antagonistic effect on side effects of levodopa such as dyskinesias and nausea. Colzi et al reported continuous subcutaneous apomorphine given as single therapy to severely dyskinetic patients resulted in a reduction of dyskinesia scores comparable to that produced by pallidotomy over a mean of 2.7 years of apomorphine therapy).[7] Apomorphine has a low incidence of neuropsychiatric problems, and it has thus been used in patients with severe neuropsychiatric complications due to oral anti-Parkinsonian drugs.[8] Timed injections of apomorphine may help specific symptoms such as off-period pain, belching, screaming, anismus, constipation, nocturia, restless legs syndrome, dystonias, erectile impotence, and post-surgical state in selected patients who may not otherwise be candidates for apomorphine.[5 6] At a cellular level, recent evidence suggests that the combined D_1 and D_2 receptor agonist action of apomorphine may be more desirable for optimal anti-parkinsonian and anti-dyskinetic action than selective D_2 agonism.[9]

In 1970 Cotzias et al reported that the benefits of apomorphine may be limited by its short duration of action and peripheral side effects.[10] Patients must be pretreated with the extracerebral dopamine antagonist domperidone before apomorphine is started, to prevent nausea and postural hypotension. Tachyphylaxis may develop to these peripheral side effects, allowing discontinuation of domperidone after a time. Subcutaneous nodules complicate therapy and may be avoided by good hygiene, changing injection sites, avoiding reuse of injection lines or needles, and local ultrasound therapy.[2-5] Rarely an autoimmune haemolytic anaemia may occur in patients on long term treatment.[2] Other modes of administration such as intranasal, rectal, buccal and transdermal iontophoresis and subcutaneous implants are being investigated.[6] A prefilled variable dose pen injector has recently become available for self injection.

Neurologists' reluctance to use apomorphine may be due to the need for parenteral delivery and dislike of prescribing a treatment perceived to be expensive. Cost benefit analysis, however, shows that successful apomorphine use helps to reduce "crisis" visits to surgeries and clinics and admissions to hospital as well as allowing reductions in the dose of levodopa.[2 6] Neurologists, physicians, and general practitioners should now ensure that suitable patients are not denied apomorphine therapy.

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Communication among health professionals

Human factors engineering can help make sense of the chaos

Last year, my father was told by his family doctor that the cardiologist had found aortic stenosis during a diagnostic evaluation for hypertension. Some time later it transpired that the specialist's diagnosis had been wrongly transmitted. Instead of a major valve defect, my father actually had atherosclerosis, a much more benign diagnosis. The kind of culture that makes this sort of unfortunate miscommunication possible is examined in a paper in this week's *BMJ* and a recently published government report.[1 2] Their conclusions will come as no surprise to many *BMJ* readers—that communication between health professionals is a mess.

Both sets of authors offer a series of insightful recommendations on what might be done to improve things. However, there is also a pressing need to define the role of applied research in this area and to accept that other disciplines have a lot to teach health professionals on how to design, evaluate, select, and set up efficient communication systems. Without this dialogue between disciplines, useful concepts and theories will simply languish in journals instead of being used by doctors and managers to improve efficiency and reduce mishaps in medical practice.

Coiera and Tombs' observational study confirms that face to face, telephone, or pager based communication is common in hospitals and often driven by events.[1] They found that hospital communications commonly interrupt tasks, including patient consultations, and are inefficient. They suggest that we evaluate and consider investing in asynchronous methods of communication, such as electronic mail or message boards, which are potentially less disruptive to professionals' work and patients' welfare.

The Clinical Systems Group, set up in 1996 to advise the NHS on information management, used questionnaires to study patients' and doctors' views on how health professionals talk to each other and what they say.[2] Despite finding that both groups wanted most types of patient information shared freely, doctors estimated that most of the time important patient details were missing. Similar to Coiera and Tombs, the authors recommend procedural and educational measures to improve communication and urge the NHS to pursue research in this area. A further study in the same report also concludes that documentation in several healthcare delivery systems, and communication between the health professionals in those delivery systems, is chaotic. The authors' recommendations to doctors include more training in information technology, more structured data collection, and adoption of new technology.

These authors should be congratulated for trying to inform and improve policy, education, and deployment of technology. The inefficiencies they uncover may even be enough to prompt some action in the most deficient areas. Poor communication is not only a waste of time, it can threaten patient care and is the chief culprit behind avoidable errors in clinical practice, which can lead to injury and even death.[3 4] We should therefore push for more and better research into clinical communication and, of course, more funding. We should also heed the Clinical Systems Group's advice for education to fill the gaps in doctors' knowledge about collecting, sharing, and analysing clinical information.

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The authors of the study and report agree that their methods were limited (small unrepresentative samples) or potentially misleading (reporting anecdotes and self reported survey data), but once again other disciplines can help.[5] We must be more open to the theories and methods used in subjects like cognitive psychology and linguistics.[6] Methods that go beyond questionnaires and interviews, like applied ethnography, are often unfamiliar to medical informatics researchers.[7 8] Human factors engineering, also known as cognitive ergonomics or usability engineering, is another discipline that applies knowledge of human capabilities and limitations to the design of devices and software.[9 10] Such methods of research and development have been useful in high risk domains (aerospace), complex systems (nuclear power), and consumer products.[11]

You, as purchasers and users of information systems as well as the guardians of patients' interests, hold the key to changing this situation. Your influence will encourage researchers, administrators, and developers to base their projects on your information needs and use human factors engineering methods that result in usable and useful systems. My father seems to think that your influence surpasses his.

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BMJ 1998;316:642

New government, same narrow vision

It's time to move beyond the numbers on waiting lists

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Reduced waiting lists for NHS hospital treatment was one of the five main promises Tony Blair made to the British electorate before his election. Last week we learnt that since he came to power the numbers waiting have increased by 100 000. The time has surely come for the government to acknowledge the inevitability of rationing health care and to shift the debate on the NHS to something more important than numbers on waiting lists. Even on waiting lists, there is scope to copy New Zealand and do a better job of managing them.

Britain experienced a disorientating period of optimism after last May's election. Many sensible people, including observers of the health service, deluded themselves into thinking that all would be different. Old problems would be solved and a new Britain—and a new health service—would emerge. In fact most problems, including those of the health service, are deep rooted and not easily solved. Furthermore, the seemingly unstoppable process of globalisation means that economies are controlled by international economic forces and governments have ever less room to manoeuvre: they have to occupy a middle political ground whether they like it or not. Globalisation is also tending to increase the gap between rich and poor both within and among countries, with serious effects on health.

Gradually reality has dawned in the new Britain. Waiting lists have risen. The winter crisis has been averted not by a new government but by a mild winter. The government appointed a new minister of public health but then vacillated over banning tobacco advertising. Smoking rates are now rising among young people. The government accepted that inequalities in health are important but declined in its green paper to set any targets for reducing them. The white paper on the health service cleverly steered a route between keeping the Conservatives' changes and returning the NHS to its old monolithic structure, but it may well prove to be a triumph of spin rather than of substance. As always, the devil is in the detail, and we must be sceptical that substituting white coats for suits will save money, that primary care groups will function well, that clinical governance will prove to be more than this year's phrase, and that NICE and CHIMP will be more than clever acronyms.

To Americans the NHS is "health care run by the Post Office," distinguished by long waits and brusque service. Almost since the NHS began the main political battles have been over money and waiting lists, with the implication that more money means less waiting. Politically the main output of the NHS seems not to be better health but shorter waiting lists.

In fact, waiting lists have some things to recommend them. Delay is one of the main ways that the health service rations care, and it has to be rationed somehow. The health service also rations by dilution (two nurses on a ward not three, 8 minutes for a consultation, not 12), diversion (sorry, we don't do acute dentistry or long term care anymore), and denial (no tattoo removal, no assisted conception, no donezepil). The NHS's problem is not only that this rationing is fudged but also that the government denies its existence. The fudging leads to inequity, lack of accountability, and poor decisions, while the government's line that all clinical needs can be met leads to a credibility gap—felt acutely by those working in the service. The politicians at the top, like some occupying power, talk of providing everything within a high quality service, while those on the ground are conscious of cutting corners and denying. In last week's *BMJ* David Sellu described graphically the pressures on his outpatient clinic: "How," he asked, "do you explain to a patient in six minutes that the tumour in his rectum is cancer—what is cancer anyway?" [1]

The good things about waiting lists are, firstly, that they are rationing for all to see and, secondly, they are rough justice. So long as they are not arbitrarily manipulated (as with the last government's requirement that no one should wait longer than a year) generally those with the greatest need come to the top of the list, although any local newspaper will be able to find some poor person who has waited in pain for a year or more. If waiting lists were acknowledged as a crude form of rationing they could then be managed much better—as has happened in New Zealand.[2] The public could debate the criteria to be applied to decide who waits how long, and the lists could be openly managed. The trouble with concentrating simply on reducing the numbers on lists is that rationing by dilution, diversion, and denial increases. Furthermore, giving priority to those who have been on the list longest often means giving priority to those with the least clinical need.

New Zealanders have generally welcomed their government's attempt to tackle waiting lists creatively. The *Dominion* described the move as "a welcome step toward reducing waiting lists for non-urgent surgery in a responsible way… .The new system is designed to ensure that people with the biggest need and greatest potential benefit will have their surgery first, that the same rules apply throughout New Zealand… .All this is light years ahead of rationing surgery by making people wait indefinitely for it, and with marked regional variations." [3] Britain is still light years behind.

The first challenge to the government is to change their thinking on waiting lists. The aim should not be to reduce them at all costs but to manage them openly as a form of rationing. The second—ultimately more important—challenge is for the government to redefine its political vision for the health service. It should be about much more than reducing waiting lists.

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Lessons of a hip failure

If we want improved prostheses we must regulate their use

News p 650

The hazard warning issued this month by the Medical Devices Agency in Britain on the 3M Capital hip system evoked emotion but no surprise among hip surgeons.[1] Previous reports of failures have suggested the need for better surveillance,[2] and five years ago a *BMJ* editorial warned, presciently, "This 'fashion trade' in joint replacements is costing the health service many millions of pounds each year and, even more important, is causing patients unnecessary pain and distress through early failure of unproved implants."[3] The 3M Capital hip was introduced in 1991 as a low cost hip replacement. Adverse reviews have already been reported, and its failure rates of 19-21% at five years[1] are four times what would normally be expected and suggest an intrinsic problem. Yet over six years 4669 have been implanted in 95 centres throughout Britain. For a new and untested hip to have ben introduced into so many clinical centres in such a short period highlights the lack of regulation of both the orthopaedic industry and orthopaedic surgeons.

One response to the failure of the Capital hip is to insist that only old tested designs should be used. Hips such as the Charnley prosthesis, when inserted into patients in the sixth decade of life, will survive for 10 years in 90% of cases, for 20 years in 70%, and for 30 years in 50%.[4 5] Yet not all units using this prosthesis will achieve such good rates of survival, for the longevity of any hip depends not only on prosthetic design but also on surgical technique. If we want to ensure good results we may also need to insist that hip replacement is performed only by specialist hip surgeons. Moreover, the argument for using only tested designs implies they are so good there is no need to try to improve on them. This argument does not apply to drugs: nor should it to prostheses. But drugs are introduced into clinical practice only after extensive clinical trials and a licensing process, and their introduction is accompanied by postmarketing surveillance. None of these apply to prostheses.

The need for improved prostheses is clear. Younger patients have long life expectancies and require more durable prostheses that will last for 30 years or more. In any hip replacement debris disease poses the biggest problem: the body's cellular response to tiny particles of polyethylene from the socket, metal from the prosthesis, or cement produces a reaction that destroys bone. It can occur in patients with mechanically well fixed joints and may be asymptomatic. The process can occur with any artificial joint and is the strongest argument for all hip replacements being kept under radiological review so that, if necessary, revision can be performed as soon as possible. In practice the need for such long term review is continually challenged by budget holders. The Medical Devices Agency is advising all patients with Capital hips to undergo clinical and radiological review.

Huge amounts of energy have been spent by research departments to counter aseptic loosening and debris disease. Modern designs of uncemented sockets will reliably osseointegrate in the pelvis, and the addition of better surface finishes and hydroxyapatite ceramic coatings to uncemented femoral stems now means that they are at least equal to their cemented counterparts in terms of function and durability. The weakest link in joint replacement is the bearing surface, which has traditionally been metal on plastic. Other bearing surfaces using ceramic on plastic, metal on metal, or ceramic on ceramic have smaller wear rates (Mckellop H et al, 10th annual symposium of International Society for Technology in Arthroplasty, San Diego, 1997).[6] Much research is carried out worldwide to develop and validate new technology, with mechanical testing, finite element analysis, and animal experimentation. But, as with drugs, a prosthesis can only really be tested when it is used in patients.

If we are to combine improvement with safety we have to find a better way than the present system of introducing new prostheses—which is no more evidence based than the fashion industry.[3] New designs should be introduced only in specialist centres, where careful follow up and special research methods, such as early migration measurements, can reveal problems before huge numbers have been inserted. Such formal evaluations of safety and efficiacy should then be followed by the prosthesis being licensed for wider use—though there should still be a requirement for surgeons to record standard data on all their joint operations. Younger patients with longer life expectancy and higher functional demands should be referred to specialist units. And surgeons who do not have a special interest in joint replacement should use only well tried and tested joints. Orthopaedic surgeons have made previous calls for better regulation of the "hip industry."[3] Now that such a failure has happened, the public will not forgive a failure to act.

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BMJ 1998;316:644