Incident reporting and patient safety

Emphasis is needed on measurement and safety improvement programmes

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Incident reporting should ideally communicate all information relevant to patient safety. Local incident reporting systems in hospitals typically use an incident form that comprises basic clinical details and a brief description of the incident. Such systems are ideally used as part of an overall safety and quality improvement strategy, but in practice they may be dominated by managing claims and complaints.[1]

Specialty reporting systems[2] and large scale systems, such as that of the UK National Patient Safety Agency (www.npsa.nhs.uk/), allow wider dissemination of lessons learnt and emphasise the need for parallel analysis and development of solutions. In this week's *BMJ* a case note review by Sari and colleagues finds that local reporting systems are poor at identifying patient safety incidents, particularly those involving harm,[3] echoing the findings of similar studies.[4] Does this mean that these reporting systems are of no value? It depends entirely on the purpose of reporting and what is hoped to be achieved by reporting.

The comparisons between health care and aviation are often overstated, but the experience of large scale reporting systems in aviation has proved instructive. Reflecting on 20 years of running NASA's aviation reporting system, Charles Billings made many thoughtful comments on past success and failure and the implications for health care.[5] Billings stated that counting incidents is largely a waste of time, that reporting systems capture a fraction of the true number of incidents, and that the underlying population from which the reports are drawn is seldom known.

The study by Sari and colleagues is an important corrective to the widespread misunderstanding that the purpose of reporting is to provide an accurate reflection of harm to patients.

Billings warns that "Too many people thought that incident reporting was the core and primary component of what was needed. These people thought that simply from the act of collecting incidents, solutions and fixes would be generated sui generis and that this would enhance safety."[5]

Of course, defining some aspects of incidents is feasible and desirable. But Billings cautions that the real meaning of the incidents is apparent only in the narrative. To make real sense of an incident the story must be interpreted by someone who knows the work and knows the context. Thus, if healthcare incident reports are to be of real value they should be reviewed by clinicians and, ideally, by people who can tease out the human factors and organisation issues. Analysing a small number of incidents thoroughly is probably more valuable than a cursory overview of a large number of incidents.[6] In health care we are learning slowly and painfully that safety is a tough intractable problem that will take much more than reporting to resolve.[1]

It is hard to see why it may be thought that reporting could be a substitute for systematic data collection. One reason, perhaps, is that it seemed as if aviation and other industries were using reporting to establish rates of serious incidents. In fact, aviation already had established the epidemiology of harm in the form of comprehensive databases of accidents and other systematically collected information. Reporting was always complementary to systematic data collection, providing warnings and additional safety information.

In health care we need systematic assessment of error and harm collected from a wider range of sources, and hopefully a move towards active surveillance of salient events. At local level this means a shift in emphasis from analysis of cases to systematic measurement of known problems and most importantly to safety improvement programmes (www.health.org.uk/ourawards/service/index.cfm?id=41).[7] At national level, whether in the United Kingdom or elsewhere, priority should be given to developing safety indicators and measuring harm and other safety issues, a process already begun by the National Patient Safety Agency. When the move to electronic medical records is achieved, records could be routinely monitored to detect those with a high probability of an adverse event. If such routine monitoring could be developed, patient safety initiatives could be much more proactive, with adverse events and patient outcomes being monitored in near real time.[8]

Reporting will always be important, but it has been overemphasised as a way to enhance safety. Reporting systems can provide warnings, point to important problems, and provide some understanding of causes. They serve an important function in raising awareness and generating a culture of safety. However, a functioning reporting system should no longer be equated with meaningful patient safety activity. Organisations must move towards active measurement and improvement programmes on a scale commensurate with the human and economic costs of unsafe, poor quality care.

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Protection of sex workers

Decriminalisation could restore public health priorities and human rights

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Between 2 and 12 December 2006, the bodies of five young women—Gemma Adams, Tania Nicol, Anneli Alderton, Paula Clennell, and Annette Nicholls (aged 19-29)—were discovered near Ipswich.[w1] Their involvement in street prostitution created a media controversy over whether labelling them as prostitutes was dehumanising, as well as raising questions about our duty to protect such women, and how this can be best achieved.[w2] Sex workers and their families have spoken of abuse and violence, and they have added a human face to these women's lives. This has provoked an overdue debate, but the same stereotyping, prejudices, myths, and a failure to appreciate the complexity and diversity of sex work and its social contexts persist.[1]

Sex workers around the world continue to be murdered, including about six each year in the United Kingdom.[w3] Standardised mortality rates for sex workers are six times those seen in the general population (18 for murder), the highest for any group of women. Death and violence are but part of a spectrum of physical and emotional morbidity endured.[2 w4-w7]

At issue are human rights and repressive legislation in the UK, thus inviting comparisons with how other countries protect sex workers. Governments and health and social services have a duty of care without discrimination.[3] The UK government failed these women[4 w2 w8] by ignoring their voices,[w9] and those of researchers, service providers, and organisations,[2 5-7] including the *BMJ*,[8 9] and by promoting discriminatory laws and practices.[4 9] Recent policies on prostitution (such as *Paying the price*)[10] are disturbingly reminiscent of the Victorian Contagious Diseases Acts,[11] and specialist services state that these have increased the vulnerability of sex workers.[4 9]

Marginalisation and the "violence of stigmatisation"[w10] invite victimisation and create barriers to accessing health and social care. The UK government was warned of the consequences of its actions from many quarters, but persisted.[4 9] Analysis of 150 years of failed policies in the UK requires an understanding of the barriers to implementing effective broad social policies,[12] which do not fit well within the narrow remit of the Home Office.[4]

The moral debate on sex work is deeply divisive, often denying both a voice and the ability to make choices to the women at its centre.[w10] Radicals and abolitionists believe that prostitution can be eradicated and that removing criminal proscription would institutionalise violence against women and their objectification in sexual slavery. The liberal viewpoint recognises the inevitability and legitimacy of sex work and that choices, even when constrained, are still legitimate.

Fundamentally this is the wrong debate, because the morality of prostitution is not the issue,[w8] for morality is "not the law's business."[13] It is state oppression, constraints of autonomy, and the resulting abuse and exploitation of marginalised women (whatever their occupation) that are the real moral issues, as those who work and care for these women know all to well.

Ethical analysis of prostitution is further obscured by links[4] with other issues including people trafficking, underage sexuality, substance misuse, sexually transmitted disease, and organised crime. These issues must be uncoupled. Even if these claims of related social harm can be verified (and many are disputed[4 9]), prostitution does not cause these; it is prohibition that turns social issues into criminal ones.[14] Prostitution requires no unique legal remedy. The harm then is to the sex workers themselves. John Stuart Mill, who campaigned for repeal of the UK's prostitution laws during the 19th century, stated that demonstration of harm (the harm principle) should be the basis of defining crime, and therefore the basis of law.[15] Legal remedies are neither appropriate nor effective in enforcing moral norms or resolving social issues.[6] The welfare of these women must always be our primary concern, and the first priority in harm reduction[4 14] is the removal of prostitution from criminal law.[12 16 w10]

The use of antisocial behaviour orders by the Home Office to control prostitution has also forced women into more dangerous locations and isolated them from support services.[4] This must stop,[16] together with suspension of the relevant laws, to enable policing to focus on protection rather than prosecution.

Comparisons have been made with the Netherlands and Germany, but we should be cautious before transposing models between social systems. These approaches have not eradicated harm to workers, but merely shifted its focus. The Swedish model, based on abolition, which criminalises men who purchase sex rather than women who provide it, has influenced the UK government's philosophy, but this model is not grounded in reduction of harm to women,[14 16] ignores the welfare of sex workers, and drives markets into more dangerous areas, as in Ipswich.

Surprisingly absent from most proposals is discussion of New Zealand's decriminalised model.[w11] Decriminalisation will not completely eliminate street prostitution, which poses most dangers for women,[w4] but it will enhance women's choices, and help to make the streets safer, develop community based support programmes, and improve relations between sex workers and residents.[7] Policy details will need to include discussions around issues such as setting aside areas for working (managed zones)[7 14] and regulation of premises. In New Zealand and parts of Australia sex work is an occupation with its own health and safety standards. Public health measures must be built on evidence based best practices.

Health and social services have an ethical obligation to ensure universality of access to care, to minimise harm to all, and to be advocates for those they provide care for. Criminalisation of prostitution limits access to health and social care and contravenes United Nations' guidelines on human rights.[w10] Only by moving prostitution out of the criminal justice system and focusing on public health and social care can we provide optimum support and help to break the cycle of violence.

The status quo in the UK is unacceptable moral cowardice. The prime minister has opposed reform[w8] and stalled demands for the protection of women; he must show leadership and restore human rights by decriminalising all aspects of sex work now.[4 12] Legal precedent exists for suspending legislation on prostitution in the 19th century and Helen Clark, New Zealand's Labour prime minister, emphasised that her country's decriminalisation in 2003 was not related to sexual morality but to a duty to place the welfare of the vulnerable and marginalised first.

Remedies for social issues surrounding prostitution lie not in legislative measures but in social determinants that limit women's choices, such as wage disparities, access to welfare, and domestic violence.[14 w9] Labour politicians remind us that the morality of a society will be judged by the way it treats its most vulnerable members,[17] yet UK government policies discriminate against the most disadvantaged. Gemma, Tania, Anneli, Paula, and Annette were each some mother's daughter[w7] and some were mothers. Their deaths were almost inevitable.[9] They deserved better, but we failed them.[4 w2 w8] We will honour them best by now doing the right thing.

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Preventing falls in elderly people living in hospitals and care homes

Inconclusive evidence means uncertainty remains

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Falls are common in elderly people living in institutions, and they often cause serious injuries such as hip fracture.[1 2] The clinical and economic costs of such injuries are high,[3] and numerous guidelines have been developed to reduce falls and related injuries. A variety of approaches have been used in different countries and it is not known whether these have been effective. Current literature suggests that some interventions may be effective, based on lower levels of evidence, and these have been combined into multifactorial interventions in many studies.[4] In this week's *BMJ* a systematic review by Oliver and colleagues evaluates interventions to prevent falls and fractures in people living in hospitals and care homes.[5]

It is important to review the effectiveness of interventions in these settings as most studies of falls have been conducted in the community.[6] People in institutional settings have different risk profiles to those living in the community because their activity is limited and they often have cognitive impairment. Also, interventions in institutions are often dependent on the involvement of staff rather than the individual. The most recent Cochrane systematic review[6] and clinical guidelines on preventing falls[7 8] consider prevention programmes in general and do not provide specific guidance for institutional settings.

The review by Oliver and colleagues provides limited evidence of the effectiveness of multifaceted interventions in hospitals (13 studies, relative risk 0.82, 95% confidence interval 0.68 to 0.99) and of hip protectors in care homes (11 studies, 0.67, 0.46 to 0.98). Only these two of the eight categories of intervention in the two settings showed some evidence of effectiveness; the others were inconclusive.

Part of the reason for the inconclusive results may have been the variety of interventions used in the studies, which ranged from exercise programmes to hip protectors. Institutional settings also varied between countries. These differences in approach are reflected in the heterogeneity of results.[9]

Interpretation of the review is complicated by differences in the outcomes measured: the percentage of people who fall, the total number of falls, the number of falls per participant, and falls as a time dependent variable. The best outcome measure is number of falls because interventions are probably better at preventing multiple falls in one person than reducing the overall number of people who fall. The meta-analyses

in the review present data to support this.

Why did Oliver and colleagues examine dementia in the meta-regression? Dementia (or cognitive impairment) increases the risk of falls and fractures. The prevalence of dementia in elderly people in institutional care is high, and evidence is lacking that programmes aimed at preventing falls are effective in this group.[10] The review shows that the presence of dementia does not influence the effectiveness of strategies to prevent falls and fractures in institutional settings. In addition, the review found no evidence that effectiveness is increased by improved adherence (www.rdg.ac.uk/ihs/bmj_falls.htm).

Interventions to prevent falls may paradoxically increase the risk of falls and injuries, or have other side effects, in elderly people in hospitals and care homes. These potential harms are not directly considered in the review, although they have been documented elsewhere. For example, one randomised controlled trial found that the rate of falls was increased in the intervention group (incidence rate ratio 1.34, 1.06 to 1.72).[11]

It is not clear what effect these results should have on clinical practice. Although there is an emerging consensus that multifaceted interventions and exercise programmes prevent falls in community settings,[12] we cannot be confident that the same applies to preventing falls and fractures in hospitals and care homes.

Clinicians will need to apply the available evidence in the context of the institutional setting, local policies and guidelines, and available resources. Key interventions are those that are cornerstones of appropriate care for elderly people. These include adequate supervision, encouragement of supervised mobility and exercise, individually prescribed aids, a safe institutional environment, avoidance of psychotropic drugs where possible, and recognition of changes in health status that predispose to falls, such as delirium. The combination of these can be considered a multifactorial intervention. Researchers should use the available evidence to design focused studies that can answer the question of how to prevent falls in institutional care. Ideally a large multicentre study will examine a standardised multifactorial intervention (including the components outlined above) with falls and peripheral fractures as key outcomes. This should be a cluster randomised trial with hospital and residential care facility strata.[9] Economic analyses will be required to guide implementation. Until further research is completed, uncertainty remains about the prevention of falls and fractures in hospitals and nursing care facilities.

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Chronic hepatitis C

Antiviral therapy is approved by NICE but too few patients receive it

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Hepatitis C infection is a treatable disease.[1] Generally, people with chronic hepatitis C are relatively asymptomatic but risk progression over time to cirrhosis and its complications. Combination antiviral therapy with pegylated interferon and ribavirin achieves sustained virological response rates of 42-80% depending on genotype.[2] In August 2006 the National Institute for Health and Clinical Excellence (NICE) published updated guidelines for the management of patients with this infection.[3] The guidance allows antiviral therapy for patients with hepatitis C viral RNA without the need for liver biopsy. This is a major change to the traditional practice of restricting treatment to patients with moderate or severe disease on liver biopsy.

Specialists in the field, who are keen to increase the uptake of treatment in eligible patients, will welcome the new guidance. However, they together with people infected with the virus and those who seek to deliver appropriate medical care will remain frustrated. Although the new guidelines will increase the number of people eligible for antiviral therapy, the broader public health and service provision issues associated with viral hepatitis have still not been recognised and tackled adequately.

Between 200 000 to 400 000 people are infected with hepatitis C virus in England and Wales.[4,5] Lack of education in primary care physicians has meant that fewer than half of patients with antibodies to the virus are referred for specialist care.[6] Even if patients are referred, specialist clinics are overburdened and antiviral therapy is often unavailable. In 2005 the Department of Health estimated that just 47 000 people had been diagnosed and only 7000 had been treated successfully.

What has been done so far to remedy this situation? In recognition of the importance of this virus as a public health issue the Department of Health released a hepatitis C strategy document for England in 2002.[7] It recommended strategies to prevent and minimise harm, along

with the implementation of clinical managed networks and specialist treatment centres. In 2004 an "action plan for hepatitis C" set out required actions for primary care trusts and National Health Service hospital trusts.[4]

In 2006 concern about the slow implementation of this action plan prompted the All Party Parliamentary Hepatology Group to audit hepatitis C healthcare provision in England.[8] It found that only 8% of primary care trusts were approaching full implementation of the recommendations: only 33% had tried to estimate the number of cases in their area, 34% had a protocol for testing and screening, and 26% had protocols for monitoring treatment. In secondary care, 46% of clinics and hospitals reported considerable delays in starting antiviral therapy; the time to starting treatment varied from one week to one year. Reasons for delay included staff shortages, budget or contractual problems, and delays in accessing liver biopsy.

In a healthcare environment where financial pressures and short term targets are paramount, antiviral therapy (pegylated interferon and ribavirin) for hepatitis C virus might seem relatively expensive. The cost of treating one patient varies from £6000 to £8000 (€9-12 000; $12-16 000) per course in the United Kingdom. However, cases of compensated cirrhosis, decompensated cirrhosis, and hepatocellular cancer related to the virus more than doubled between 1995 and 2005 and are predicted to more than double again by 2015.[5] Deaths from hepatitis C almost tripled from 1997/8 to 2004/5[5] and hepatitis C is one of the most common indications for liver transplantation (UK Transplant, personal communication, 2006). Hepatitis C thus already places an important and increasing clinical and financial burden on the NHS.

At present service provision for viral hepatitis is piecemeal, disjointed, and poorly resourced.[9] Knowledge within healthcare professionals remains suboptimal: 42% of primary care providers in East London were unaware that treatment for hepatitis C has good treatment outcomes.[10] To change this will require a coordinated approach by primary care commissioners, primary care providers, and hepatology specialist services and must be based on an accurate assessment of local disease burden. In practice, this means improved knowledge at the primary care level and improved case ascertainment across a range of settings, including prisons.

Integrated primary and secondary care networks that provide counselling, appropriate testing, and seamless care pathways to specialist assessment and treatment should be established. Furthermore, innovative strategies and environments for service provision need to be examined for a population that does not always interface well with traditional models of health care. Incentives may need to be considered, given the considerable public health problems and disease burden surrounding viral hepatitis.

Hepatitis C is currently underdiagnosed and undertreated. Antiviral treatment is cost effective—it decreases the risk of progression and liver related complications.[11] Provision of adequate resources to fund NICE approved therapy, as well as the infrastructure to deliver it, merits a higher priority.

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Food and Drug Administration

More independent resources and ways to identify adverse events are key

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The Food and Drug Administration of the United States is now the patient on the examining table, with no shortage of attending doctors or nostrums. Months ago, the agency sought the advice of the National Academy of Sciences' Institute of Medicine on its drug safety system. The resulting report echoed previous suggestions that the agency should be given more money and power and proposed altering current industry approaches to drug development.[1-4] The drug industry, already smarting from tightened FDA drug safety standards, went into defensive mode.

The Institute of Medicine report will certainly play a key part in an upcoming debate in Congress over renewal of legislation that empowers the FDA to collect fees for a portion of the cost of reviewing applications for drug approval. The current user fee legislation expires on 30 September 2007 and must be reauthorised by then; this will provide a vehicle for new drug safety legislation if Congress decides it is necessary. With the recent US election results giving the Democratic Party control of both houses of Congress, it seems certain that the user fee extension law will include provisions to tighten drug safety law.

The current controversy is the latest in a series of drug safety crises. We could start with the infectious horse serum that led to the 1902 law on biologicals,

continue to the sulfanilamide tragedy that resulted in the 1938 law on new drugs, or look back on the horrors of thalidomide and how they led to the 1962 drug amendments. Drug safety issues are not new, and calamity often stimulates reform. The question is, what form it should take. So what are the key proposals made by the Institute of Medicine?

More resources? Flat line budgets coupled with increased costs have effectively eroded the agency's non-user fee base, including its drug safety programme. The majority of funds should come from taxpayers money as it is unreasonable to expect drug companies to bear a disproportionate share of the cost of monitoring product safety.

Separation of premarket evaluation of drugs from safety after marketing? This would dilute relevant expertise since two sets of experts would be needed for each stage. Other mechanisms are already in place to guard against loss of objectivity by those who originally recommend approval of a product. None the less, the proposal that each drug review team should include someone from the agency's drug safety office deserves attention and could easily be implemented.

More independence? The recommendation that the commissioner should have a six year term seems solid, although it would be difficult to force those who want to pursue other opportunities to stay. For example, Mark McClellan's departure after only a few months left the agency leaderless for a long period, during which Vioxx and other drug safety issues made headlines. The FDA's status as part of the vast Department of Health and Human Services should also be re-examined. Surely the FDA is as important as other independent regulatory agencies like the Environmental Protection Agency and the Consumer Product Safety Commission.

Earlier and better communication? The idea that the FDA and drug companies should talk more, and sooner, about trial design and endpoints is laudable. Better understanding of regulations should help speed approvals and ensure earlier attention to safety signals. And European regulators need to join this dialogue. A potential problem is that the FDA is generally reluctant to be bound by its own early advice, and industry fears that the agency will take an excessively cautionary approach and recommend unnecessary studies. Both the FDA and drug companies need to find ways to pinpoint what testing will be needed for a given product or product class. Uncertainty about what it takes to win approval impedes development of useful products.

Authority for the FDA to order that manufacturers change the labelling of their products? This proposal is unnecessary because it underestimates the existing leverage that the FDA has at the pre-market stage. A company with an application pending before the FDA is desperate to get its product on the market and almost always gives in to agency requests on labelling. Even for a marketed product, the FDA can yield enormous power over a sponsor by threatening to publicise any disagreements about labelling.

Authority for the FDA to fine companies that fail to carry out the required post-market studies? This proposal deserves a closer look, but the agency only recently made full use of its existing and effective authority to publicise ("name and shame") those drug companies that had not kept promises to carry out post-market studies.

More authority in the area of adverse events? The reporting system for adverse reactions is fundamentally flawed. Although we cannot scrap such reporting systems as they do provide safety signals, we should pay more attention to well designed post-marketing studies, sentinel studies, patient registries, and other mechanisms that are better able to identify valid drug safety issues. Useful ideas are found in an International Conference on Harmonisation guidance document developed by the FDA and its European and Japanese counterparts (and industry in these three regions).[5]

More government funded studies of drugs? This idea is not new. I believe that large scale involvement of government in testing of drugs would be a mistake. Government needs to operate as a check and balance overseeing research done by others. If government is in charge of testing, the objectivity needed at the stage of data review will be lost.

In summary, additional resources for the FDA and alternatives to reporting of spontaneous adverse events would be key steps forward. The International Conference on Harmonisation should be used as a forum in which the FDA can collaborate with industry experts and international counterparts to develop harmonised approaches to drug safety, truly an issue without borders. The FDA recently indicated that it is sceptical about new initiatives from the International Conference on Harmonisation until it knows more about the implementation of previous ones.[6] This position is understandable, but the agency should avoid becoming isolated from other regulators or industry experts. The notion that the response to the drug safety crisis is a matter for the FDA and Congress only fails to consider the stake that people outside the US have in its outcome, and the global nature of the drug industry.

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