Litigation Versus Science: What's Driving Decision-Making in Medicine

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Litigation against doctors and hospitals in so-called 'medical malpractice' suits is having a devastating effect both on patient welfare and scientific research. A leading paediatrician and epidemiologist, Dr Fiona Stanley, explains the consequences of subjecting doctors' medical decisions to legal review.

A spermicide used with most barrier contraceptives causes birth defects; the whooping cough vaccine causes brain damage; incompetence by obstetricians is a leading cause of cerebral palsy; the morning sickness drug Debendox caused an epidemic of birth defects; environmental pollutants cause chemically induced AIDS. All of these stories have been reported and all are false. But, as Peter Huber wrote: 'They were not reported only in the gutter press and on television midday quasi-documentaries; they were reported in the annals of US and UK jurisprudence'.[1] One amazing case was a successful $1million award to a soothsayer who, with expert testimony supporting her, claimed that a CAT scan had removed her psychic powers. Imagine the epidemiological study we would need to do to prove that one! Imagine the debate over the outcome measures!

Most of us in public health research practise our science with the sincere hope that our research will result in information which, if properly applied, could make major improvements to the health of the community, either

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[1] P Huber 'Galileo's Revenge: Junk Science in the Court Room' Forbes 8 July 1991, 68-72.

through improved outcomes from better treatments of disease or through preventive programs that avoid the disease altogether. The vast array of diseases which affect humans are complex to understand in their aetiology and in the variety of possible solutions. It is with increasing concern and frustration that we hear of the way that litigation is now influencing parents to avoid vaccination, what drugs doctors can prescribe, what is an appropriate rate of obstetric interventions and when they should be carried out, and whether screening for cancer is helpful to the population. These decisions are not based on science — more on what Peter Huber calls 'junk science'.

Litigation, by use of selective or misleading evidence and fanned by the media whose aim is to sell rather than to inform, can drive us away from making the best decisions in medicine — decisions which have the potential to help the majority but rarely may harm or not benefit the individual.

The modern sciences of public health (ie epidemiology and statistics) are now of enormous importance. They have a population focus. They determine, as rigorously as possible, whether associations are real and whether they are likely to be causal. Court room trials are quintessentially singular, framing facts in isolation and demanding that scientific truths be rediscovered anew every time. They are often influenced by biased expert witnesses, who present an extreme and outrageous view which is not the general consensus of knowledge. 'Let's not ignore the next Galileo' pleads the plaintiff's lawyer (hence the title of Peter Huber's book) — 'many at the frontiers of medicine or science were ridiculed to start with'.[2] But science has changed profoundly since the days of Galileo.

I now want to tell you four stories, each of which illustrates the extraordinarily negative effect which litigation has had on the practice of medicine or public health. These are not isolated cases: both the number and variety of cases coming to litigation and the damages being awarded are increasing alarmingly. There are some similarities and some differences between the four but the message is clear. We have to change the way such things are handled if we want to continue to advance the public health. Society has established a system of judging medical care in the courts which is not serving society well.

CERVICAL CANCER SCREENING

Cervical cancer is the seventh commonest cancer in Australian women, with 1700 new cases per year. It is preceded over a period of years by a spectrum of asymptomatic abnormalities graded as I, II or III. Only a proportion of women with these lesions, even grade III, will progress to invasive cancer, but those with these lesions are at a higher risk of getting

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[2] Ibid.

cancer eventually. Screening healthy women to assess their precursor status by taking a smear from the cervix and looking at the cells so obtained was introduced in Australia and many other developed countries in the mid 1960s. It attempts to identify these abnormalities in women who have no symptoms and thus give them and their doctors an idea of their risk status. It is important to understand that these screening tests are not 'diagnostic' of cancer (some women call them 'cancer tests'). But even some doctors do not seem to understand that the majority of women who have abnormalities on the Pap smear will *not* get cancer and that some women who have no abnormalities will get cancer.

But it gets even more difficult. The tests themselves are not 100 per cent accurate in terms of detecting abnormalities and some report abnormal cells when they are not really abnormal ('false positive') and some report normal cells when the woman really has an abnormality ('false negative'). In any screening test there are both false positives and false negatives and a good screening test is one where these are kept to reasonably low levels.

Most women who are screened will be told accurately that they have either abnormal cells (justifying further action) or that their smears were normal and that they should come back for another smear in two years' time. Those with false positives will have additional, unnecessary and sometimes invasive investigations to rule out cancer; those with false negatives will be falsely reassured they are not at higher risk. It is when these women have a rapidly progressive cancer that they feel cheated by the system.

By changing the cut-off levels for 'abnormality requiring further investigation', you can reduce the false negatives and thus pick up more that are more likely to become cancer, but it is at the expense of more false positives with their problems. Cervical cancer screening aims to reduce illness and death from a common cancer in women. It was introduced with the knowledge that the benefit of the program would be less than 100 per cent. Pap smear screening has the capacity to reduce the incidence of cancer of the cervix by 90 per cent and thus is a major public health benefit to women and their families.

Recent litigation has involved women who have claimed that their cancers were not picked up by the screening process. These situations are tragic for the women concerned and their families, but it is not a failure of the screening program and it is not negligence on the part of the laboratory; it is expected as part of a normal screening activity. These women were the unfortunate few, the rare cases, the 'false negatives' which occur in any screening program.

The effects of this litigation have been negative in the following ways:

- a marked increase in referrals for slightly abnormal smears, 'the reluctance for overdiagnosis, with its increased costs and anxiety to women, has

now been outweighed by the need to avoid any responsibility for missing a case';[3]
- major increases to the cost of the program (more repeat tests, more doctors' examinations, more colposcopy, more biopsies, etc);
- fewer women coming for screening, having been put off the program by the adverse publicity, which is usually damaging to the service and the profession whether they are eventually found liable or not;
- trained people leaving gynaecology or pathology as they do not like being sued;
- increased accuracy but with considerable increases in costs.

It is not beyond the realms of possibility that the costs of the cervical cancer screening programs could become so great that they are abandoned altogether. Yet we have no other way of preventing deaths from these diseases. If society wishes to allow women and their lawyers to sue and be awarded huge damages then it will have to accept that there will be more women dying of this disease because cervical cancer screening will become too expensive to continue. Who do we blame if it stops — the media, the lawyers, the legal system or the lack of proper education from the medical profession? And what can we do to avert a similar fiasco in the future?

And now to my second story:

WHOOPING COUGH VACCINE AND BRAIN DAMAGE

As you would all be aware, the most cost-effective public health measure after provision of fresh water and sanitation is vaccination. The success stories of smallpox, polio and measles are legends in the history of international public health. AIDS has made the public even more aware of how wonderful the solution of a vaccine would be. However most developed countries have in the past or are still now facing major problems with their childhood vaccination participation rates and in the United States and Australia it has been called a shambles. Why? The sources of this reversal have been, first, vaccine liability leading to exorbitant costs or loss of supply of vaccines as companies decide that the costs and risk of litigation are too extreme and they decide not to make vaccines any more, and secondly, the belief of certain groups and an increasing number of parents that vaccines cause major problems such as brain damage, cot deaths, AIDS, chronic fatigue syndrome and allergies. Not only are none of these allegations born out by rigorous scientific study, but the damage and death from the disease

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[3] AE Raffle, B Alden and EFD McKenzie 'Detection Rates for Abnormal Cervical Smears: What Are We Screening For?' (1995) 345 Lancet 1469-1473.

itself and the power of vaccines to virtually eradicate it appears to have been ignored. The resulting epidemics of the disease demonstrate — too late — the devastation that infectious diseases can still wreak amongst our infants. Whooping cough epidemics are currently sweeping the Eastern seaboard of Australia where vaccination levels have fallen so low that less than 50 per cent of our children are protected. In one state in 1990: 143 cases; in 1994: 1 940 cases (287 hospitalised, and seven cases of encephalopathy (brain damage)).

The story of brain damage and whooping cough vaccine is a tragic one; again decisions made by the courts have done the public health a major disservice by dealing with vaccine injury in an irregular and unpredictable manner. I also feel angry that as a profession we as doctors did little to counter the highly emotive and very well publicised cases of so-called vaccine brain damage which we could have done by showing dying and brain damaged children with whooping cough on television and publicising the statistics which demonstrated what some parents found out too late; that the disease is far far worse than the vaccine.

Whooping cough killed five of every 1 000 children in the 1930s and 1940s. Many were left disabled from haemorrhages in their brains and many developed bronchopneumonia. The vaccine was initially welcomed. In the 1970s in the United Kingdom and early 1980s in the United States there were suggestions from parents of children with neurological disabilities that the vaccine may have been responsible for their child's condition as they had noticed fits after the vaccine and the children did not recover. Many children with disabilities are not diagnosed or even noticed to be abnormal until about 6–12 months of age. Thus it was easy to demonstrate coincidence of the exposure (vaccination) and the problem. A television documentary in the United Kingdom in 1974 showed 36 such children who it was claimed had been brain damaged (encephalopathy) over the last 12 years. The parents demanded and eventually were granted vaccine damage payments and the Vaccine Damage Payments Act (UK) was introduced in 1979.

In the meantime there was a dramatic fall in immunisation rates in the United Kingdom, dropping from 80 per cent in early 1974 to about 30 per cent in 1975; then followed the worst outbreak of whooping cough since vaccination became available, with 5 000 children hospitalised, 200 cases of pneumonia, 83 cases of encephalopathy and 28 deaths. If you feel litigation is the way to go, parents of these children should have sued the television station which ran the documentary!

In the United States, following the first law suit in 1978 for $10 million there was a dramatic increase in vaccine brain damage suits, particularly following widespread media coverage of (still scientifically unproven) adverse vaccine effects. In 1984, 73 suits were filed with an average of $46 million per claim and rising to 255 suits in 1986 averaging $16 million per suit. Over the same time period the cost of the whooping cough vaccine rose from 15 cents to $8.50 per dose. Two of the major companies making vaccines (Wyeth and Lederle) pulled out leaving Connaught the only United States supplier of whooping cough vaccine. Liability insurance rose dramatically with further increases in vaccine costs and a real emergency in terms of vaccine supplies. As in the United Kingdom, vaccination levels fell with resulting major epidemics of whooping cough — 10–12 000 cases in 1987 with 40 deaths.

In 1987, the Childhood Vaccine Injury Act (US) was passed following determined lobbying by such organisations as the American College of Paediatrics and the American Public Health Association. This ensured the supply and eventually brought down vaccine costs as the number of suits started to fall — by 1990, there were less than 20 suits per year with lower claims as the parents were attracted by offers to obtain compensation more quickly and fairly than if they went through the lengthy and expensive court system. This system of compensation is funded through a tax on each vaccine. It is national in scope, and optional not mandatory as lawyers wanted to leave going to court as an option though parents would have to go through this system first before they were allowed to pursue a legal route and they would then forfeit any compensation from this system once they had chosen to sue.

Well, does whooping cough vaccine cause brain damage? There were very few data anywhere which allowed a comparison between vaccinated and unvaccinated children in terms of disabilities. Hence the well funded National Encephalopathy Study was conceived and conducted in the United Kingdom. All cases of encephalopathy (over 1 000 children) were compared in terms of their vaccination status with over 2 000 control children without encephalopathy. The final analyses, summarised beautifully by the judge in the class action suit in the United Kingdom, demonstrate that vaccination 'actually protects' against encephalopathy rather than causes it. So after many thousands of cases, hundreds of deaths and complications later, and following numerous court cases worth millions of dollars, with science hardly having a look in, science eventually did win. How can we stop this happening again?

There was excessive media 'hype' about the adverse effects of vaccines with many television documentaries showing brain damaged children and their parents. Very rarely were epidemiologists consulted for these programs. In contrast, there was barely a page on the day when the news broke (if you can call it that) that there was no evidence that whooping cough vaccines caused permanent brain damage.

As with the cervical cancer story there have been enormous amounts spent on research into new whooping cough vaccines. This may be a good thing but it may have been unnecessary, as it was not really driven by science but more by the fear of litigation. Money spent on the development of these vaccines could have been possibly better spent on other more important vaccines such as against Hib meningitis for example. Research money also was earmarked for encephalopathy research if it involved vaccines: other encephalopathy research of perhaps higher scientific priority remained unfunded.

And so to my third story:

CEREBRAL PALSY AND OBSTETRIC CARE

In 1975 the 'new obstetrics' began. Two obstetricians wrote in an obstetrics journal that early recognition and elimination of fetal distress should reduce by half the incidence of handicapping conditions or mental retardation and with caesarean sections they could now promise the delivery of a baby in perfect condition following a low risk pregnancy. Their promises were not backed up by any research findings, but by a growing belief that most of the cases of cerebral palsy in childhood are due to birth asphyxia (ie, lack of oxygen at birth) and that new machines which electronically monitored the baby's heart rate during labour could accurately diagnose asphyxia. One can only speculate how this belief arose as most data over the last 100 years suggest that only a small percentage of children with disabilities had had birth asphyxia. I am sure that those obstetricians rue the day that they made these rash promises!

The new obstetrics relied on improved methods of detecting fetal distress and then responded by delivering the baby by caesarean section if distress was noted. Babies in poor condition at birth were resuscitated. These birth interventions were much more invasive than anything done to mother or child up until that time. The aims were to reduce deaths and prevent brain damage. The increased income to both obstetricians and those selling fetal monitors may have contributed to this trend somewhat.

From the late 1970s, and increasing dramatically in number and in amount claimed per suit, parents (via their lawyers) have sued their obstetricians for negligence if their child was diagnosed as having cerebral palsy, irrespective of the real cause of that child's condition. The effects have been devastating for obstetricians and obstetric care; litigation has driven up the costs of care, particularly in the United States but also now in Australia and in the United Kingdom. In Australia insurance premiums have risen from $50 per annum in 1975 to $25 000 in 1995. In the United States, where some individual cerebral palsy settlements have been as high as $100 million, insurance premiums are over $100 000 per annum. Hospitals have also been hit — one in South Australia has been forced to close because of the payment for one case. Pregnant women, their families and society have paid and will continue to pay for these increases in the costs of care.

Obstetricians are leaving obstetrics and fewer of them are available to deliver babies; general practitioners have decided against doing GP obstetrics, and midwives, once a cheaper option for mothers, now have to get malpractice insurance and have raised their fees too. Some rural GPs do too few deliveries to even cover the cost of their premiums. Where do rural women go for obstetric care? Those most affected are the poor and the high risk women whose chance of a poor pregnancy outcome is greatest. And as a backdrop to this sad and sorry tale, lawyers continue to advertise to encourage parents to sue.

Has all this improved obstetric care? Do obstetricians and other doctors practise better care of women in labour? All evidence to date suggests that litigation has increased the intervention rate — in the face of no evidence to demonstrate the effectiveness of either electronic fetal monitoring or caesarean section to reduce cerebral palsy or birth asphyxia. Obstetricians are ignoring science and because of fear and exposure in the courts are practising what is called 'defensive obstetrics'. A recent study in the United Kingdom analysed questionnaires from over 3 000 practising obstetricians and found that nearly 100 per cent felt that fetal monitors were inaccurate but still used them for medico-legal reasons. Other studies have shown an increase in caesarean section rates for the same reasons. As there are considerable risks still associated with caesarean sections, all agree that it would be best to avoid unnecessary ones.

Well, does intrapartum asphyxia cause cerebral palsy? And can obstetric care aimed at diagnosing and treating such asphyxia reduce the occurrence of cerebral palsy? My own group in Perth have contributed to this international debate because we have data on all cerebral palsy cases. Thus for the total population we have accurate cerebral palsy rates from 1956 to 1990, and the capacity to conduct case-control studies to investigate trends and causes.

In spite of dramatic increases in the use of electronic fetal monitoring (none in 1970 to well over 50 per cent of all births in 1990) and caesarean sections (4 per cent in 1970 to over 20 per cent of all deliveries in 1990), the occurrence of cerebral palsy actually rose over the same time period. The message was clear: widespread use of aggressive obstetric interventions has not reduced the occurrence of cerebral palsy as promised by the practitioners of the 1970s.

For obstetric care in labour to reduce the occurrence of cerebral palsy, first, birth asphyxia or other intra-partum problems must cause a significant proportion of such cases, and secondly, obstetric care must be able to avoid the problem. Neither of these seems to be true. The most damaging aspect is the reliance on the electronic fetal monitor. This was introduced by enthusiasts who did not evaluate it. The science has now been done: the main effect is a rise in intervention rates but no reduction in cerebral palsy.

What is even more embarrassing for the obstetricians is the considerable observer variability in interpreting the electronic traces. There was only 22 per cent agreement to do a caesarean section or not in one study of 50 traces by four experienced obstetricians. Six months later 21 per cent of the same traces were interpreted differently by the same obstetricians. With such poor levels of agreement, how can an expert witness get up in a court of law to say with confidence that such a tracing was indicative of incipient encephalopathy? Or by not doing a caesarean section that a clinician failed in their duty? What is amazing to me is that the courts are still relying on these traces as the mainstay of evidence in cerebral palsy litigation and that doctors are using monitors more than ever, because not using one is a reason for parents to sue. If it was proposed to introduce a test for anaemia which was wrong often more than it was right, it would be rejected.

The truth is that at the moment we do not have the capacity to accurately diagnose birth asphyxia and an electronic tracing of the fetal heart rate may be at best a rather poor screening test. However, screening tests should only be used if they can be followed by: (i) an accurate diagnostic test, and (ii) an effective intervention to avoid the problem.

Neither of these prerequisites can be met with birth asphyxia. It is acknowledged that we cannot accurately diagnose asphyxia in the human fetus either before or during delivery.

Research now suggests that most cerebral palsy cannot be prevented. No individual case of cerebral palsy can, in my opinion, be attributed with confidence to a birth asphyxial episode. It is even less scientific to say that a different level of care may have changed the outcome. We have several case histories: one child with severe cerebral palsy who had had a poor birth history. Later investigation showed a family tree with three first cousins similarly affected.

Expert witnesses in the area of cerebral palsy litigation have done enormous damage to their profession, pushed by lawyers who only have to prove it is probable that the brain of a severely handicapped child was damaged during the birth process. Parents who are promised perfection in a world where realistic expectations of pregnancy outcomes and the limitations of medical care are never fully explained, continue to seek someone to blame for the tragic problems in their child.

Now, my final story:

DEBENDOX AND BIRTH DEFECTS

Debendox was a drug given to pregnant women to prevent severe nausea and vomiting in pregnancy; such symptoms are very common in pregnancy and can be very debilitating. Thus it was prescribed commonly — about 30 per cent of pregnant women in Australia may have been on the drug. Birth defects also occur frequently — 5 per cent (12 500) of all Australian births have a major abnormality. Thus it is relatively easy to collect a series of exposed cases and suggest a relationship. This was done by a Canadian physician in 1969.[4] The importance before going public with such information, of course, is to obtain a group of control children (without birth defects) to ascertain the level of exposure in them. Alternatively one could compare the occurrence of birth defects between two large cohorts of pregnant women — one who had taken Debendox and another similar group who had not. Only then could we estimate a relative risk of exposure in relation to birth defects. This was done time and again and showed no association, but this information did not influence the courts or the media.

As soon as the first case went to court in Florida in the late 1970s, the Australian obstetrician and researcher, Dr William McBride, suggested that the association was causal, based on both animal and human data. Until animal data in a key experiment was eventually shown to be fraudulent by the Australian Broadcasting Commission's Norman Swan, McBride was used extensively by lawyers in the United States and Australia as an expert witness for the plaintiffs. His human data never had a control group. Juries of non-epidemiologists were influenced by clever lawyers for the plaintiff (the tragedy of the disabled child is the emotive factor which seems to influence many juries in favour of the plaintiff) . The presentation of good scientific evidence against Debendox being a teratogen did not appear to influence them. Thirty trials over 13 years from 1 700 suits with many being settled out of court resulted initially in a 30 per cent success rate for the plaintiffs, one as recently as 1991.

The effects of this litigation were: women believed that Debendox was a teratogen and they stopped taking it, the costs of litigation were not being met by the falling sales of the drug and eventually, in spite of no evidence of teratogenicity, Marion Merrill Dow stopped making the drug and took it off the market. There is now no good and safe drug for use in pregnancy nausea, women are too scared to take anything else so they just suffer or go into hospital for intravenous fluid replacement, and no drug company is ever likely to make or market another drug given the Debendox fiasco. So who won? The lawyers were the only ones as eventually most of the court cases were thrown out on appeal, so the families of affected children lost everything as well. The litigation also spawned a huge number of research studies (over 40) so that the safety of Debendox has been proved conclusively and somewhat unnecessarily over and over again. It is one of the best researched drugs in relation to pregnancy outcomes, but is not able to be used as it is no longer available. Based on biological plausibility, suggestive evidence, animal data and the other measures we scientists use

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[4] DC Paterson 'Congenital Malformation' (1969) Can Med Assoc Journ 101, 175-6.

to develop hypotheses, it was not on my list of teratogens needing investigation.

The media labelled scientific reports as 'cover ups' and 'white washes' as did some of the women's health lobby groups. As some of the studies were funded by the company that made the drug, this further supported a white wash. The US National Women's Network (representing 1 000 women's health organisations in the United States) was outraged when Debendox was eventually removed from the market; enraged not because a useful and safe drug for nausea in pregnancy had been taken from women, but because it was still allowed to be sold until all stocks had run out. The women's movement has had so many beneficial effects for both women and men; but it is sad when misinformation can have such a negative effect.

Why did the courts handle the Debendox issue so badly? It seems that there was a reluctance to use primary researchers and researchers are often reluctant to become expert witnesses; lay juries were unable to weigh the evidence and undervalued epidemiological research, often giving it the same weight as animal data, cellular effects or case studies; it was easy for the clever plaintiff lawyers to confuse juries and to discredit the defence expert witnesses; story telling held more sway than epidemiological evidence and there was always the tragic evidence of the abnormal child to push them towards a sympathy vote. It was the translation of science into evidence that was particularly flawed.

Debendox was removed from the market in 1983 for economic reasons and not because it was a proven teratogen. Debendox wasn't a teratogen, it was a 'potent litogen'. Judges and juries now tell doctors how to practise and what drugs to prescribe rather than any scientific studies.

HAS LITIGATION SERVED ANYONE WELL?

Who are the winners and who are the losers in these fiascos? The community and medical care are losers. Doctors cannot avoid litigation by practising defensively as litigation is illogical and unpredictable. There is no evidence that the increasing litigation has resulted in better obstetric care, fewer cases of brain damage following vaccines, fewer birth defects or better and cheaper screening programs to prevent cancer. Litigation has had the reverse effects. Medical interventions and their associated costs have spiralled as a result of litigation and useful and safe drugs and vaccines have been unfairly blamed for disasters. People avoid them, sometimes at their peril as in the case of falling rates of immunisation followed by devastating epidemics. Individual families may have benefited from huge payouts and they can look after their disabled children without worry of financial hardship, but many did not succeed. Those who are awarded damages often end up getting far less than the published settlements, after paying fees. They have spent years of their lives involved in long and emotionally draining court cases instead of getting on with adapting their lives to accepting and caring for their disabled child. It has been shown that excessive litigation retards the healing and adaptive process for parents, family and even the child. The vast majority of families with disabled children are not eligible for such compensation and have to cope by themselves or with help from the welfare system.

So the lawyers have won? Well, it may be a short lived victory as they face increasing criticism, even from their own profession; and reform or alternatives to litigation are high on the agenda in most developed countries. One could argue that lawyers are only responding to the demands of their clients, reflecting our society.

How can we change the legal system? There are two general responses — one to avoid the courts altogether (as occurred with vaccine damage compensation Acts in the United Kingdom and the United States) and the other is to improve the way in which the courts handle evidence, so that science is better converted into evidence that can be assimilated by judge and jury alike. In all Australian states except Victoria and New South Wales juries are no longer used and civil cases are tried by judge alone.

COMPENSATION WITHOUT PROOF OF FAULT

The concept of fast-tracking compensation outside the court system for those inevitable but unpredictable, very rare and non-negligent cases of adverse consequences of public health interventions has been implemented overseas and suggested for Australia. It was suggested by Professor Charles Watson and Dr Aileen Plant in the *Australian Journal of Public Health* in 1992 for any adverse effects from vaccination and for cases of viral infection from missed screened blood transfusion tests. Such compensation would be quick, fair and helpful and should be introduced immediately. People will need to debate how it should be funded — possibly by an additional levy on medicare similar to motor vehicle insurance. The courts could then be reserved for those cases where negligence was provable.

CHANGES TO COURT PRACTICES

I have fewer problems with cases for which there is absolutely no scientific evidence of adverse effects (as with Debendox) than with cerebral palsy and birth asphyxia (where we know it can happen though it does so very rarely and is difficult to prove). No court case against Debendox should now succeed or even be contemplated, but some cases of cerebral palsy are difficult to decide upon. Mediation, structured settlements, capping of payments and statutes of limitation have all been suggested along with changes to improve the evidence from expert witnesses such as court appointed witnesses, peer reviewing of witnesses and scientifically conducted consensus statements.

I suggest using rigorous overviews such as the Cochrane collaboration to decide on standards of care rather than a biased witness who can give any opinion favourable to the plaintiff.

Heather Mitchell[5] puts it very well: 'Science is downgraded in the courts; it seems to me the antithesis of justice and fairness when out of 10 expert opinions on a difficult Pap smear, the plaintiff's lawyer is allowed to choose only those three which favour the plaintiff. They then attempt to discredit the scientific evidence. The damage (to screening) is done as all this legal action is eagerly reported in the media accompanied by pictures of a dying woman; the populace observe the public hanging of an excellent screening program'.

It is important, however, to remember that the courts can sometimes get it right, as with the judge in the United Kingdom in the whooping cough vaccine and encephalopathy class action.

WHAT ABOUT THE RESEARCHERS?

The lessons are there for us as medical researchers. The most important and obvious ones for me are: (i) do the research well; (ii) publicise it widely; and (iii) be prepared to participate.

Rigorous randomised trials of new techniques, drugs and screening tests should be mandatory. The possibly devastating consequences of not doing so must be widely disseminated amongst doctors and health policy makers.

AND THE MEDICAL PROFESSION?

We must ensure the use of scientific proof of effectiveness in the practice of medicine in Australia. Every way of encouraging doctors to use evidence to guide their practice must be investigated. We must remove barriers to the conduct of randomised trials in our major centres of excellence, our teaching hospitals. In public health programs, we must strive to minimise individual risk; good public health does not preclude care for the individual.

We must be honest and open with the people whom we serve as public health and clinical practitioners. We must give them 'realistic expectations' of what their biology can deliver and the considerable limitations of modern

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[5] DD of the Victorian Cytology Service.

medicine to change that. It is not letting our disciplines down to tell people what we can't do in medicine; there have been great successes in medical science but we have not solved even a quarter of medical problems and we certainly cannot promise a perfect baby.

REALISTIC EXPECTATIONS

Based on the best available Australian data with 'optimal' obstetric care — 15–20 per cent (= 45 000 pa) of pregnancies will end in spontaneous miscarriage; 6 per cent (= 17 500 pa) will be born pre-term; 5 per cent (= 14 500 pa) will have a baby with a major birth defect whether they take Debendox or not; 0.25 per cent (580 pa) will have a baby with a diagnosis of cerebral palsy by age five and 0.4 per cent (= 1156 pa) will have a baby who will be diagnosed with moderate or severe intellectual disability by age six. This is biological reality; this is normal life in Australia and no-one is actually currently to blame for these problems. If pregnant with triplets either naturally or following an IVF conception, the risks of either a perinatal death or cerebral palsy — based on our Western Australian data — may be as high as 15–30 per cent. Are pregnant women told these risks?

If parents are given realistic expectations rather than promises of perfection, possibly given to justify increased interventions and charges, then they are less likely to be angry and to sue when an abnormality occurs. If the population in Australia were accurately told about screening and what it involves (ie, its realistic objectives and outcomes) then they would understand that there are swings and roundabouts. Screening does not eradicate disease; it classifies people by their probable risk of disease.

Don't 'keep it simple' because it isn't. Don't patronise an increasingly well educated public who have a right to know because they will feel betrayed when you can't deliver those things which should never have been promised.

People die from cancer even if they have been screened in the best place in the world because screening does not detect all cases (particularly those that are growing rapidly) and treatment is not 100 per cent effective. But avoiding cervical cancer by 90 per cent should be good news. If people understand that, they may accept the few screening failures. If not, then we cannot offer them anything better.

Obstetric care cannot prevent most cases of cerebral palsy, birth defects, pre-term births or many other pregnancy problems (we are researching these things but apart from a very few we don't even know what causes them). But obstetrics has had a significant impact on reducing stillbirths, neonatal deaths and many other causes of illness in early childhood and on making childbirth safe for the mother and more pain-free. This is now threatened. Vaccines have been the most effective and safest methods of preventing major infectious diseases this century and there is no evidence that they cause permanent brain damage in childhood. If you choose not to vaccinate your child against whooping cough then you put him/her at risk of serious illness which could cause brain damage and even death. It is your choice but you can only make informed choices if you have correct information.

CAN THE MEDIA CHANGE?

The popular press have played a devious role in these fiascos: good news is no news whereas bad news is front page. Science showing that a drug does not cause birth defects is not interesting; it is a white-wash or a cover up and need not be published. Junk science showing disabled kids in wheelchairs and a mother who took a drug in pregnancy 'proves' causation and is front page news and all over the television. They tend to stimulate unrealistic expectations from research or unjustified alarms concerning adverse reactions. The media coverage of the advances of science clearly demonstrate both the writer's view of them as magic and the public's need to see them in this light. Scientific theories which are riddled with controversy are presented as cut and dried, rather than tentative and uncertain. The magical thinking which pervades the 20th century is that we understand everything. The fault may lie with the scientists as much with the media; we must be prepared to talk to journalists and to explain the complexities of our methods and their limitations.

I have no solutions to this but my hope is that via such public forums as this one, we generate some shame in enough journalists and editors that the reporting may start to become more balanced. One thing they may wish to do is to peer review their sources of evidence. Rigorous scientists, of course, are often too busy to be interviewed as they are off seeking the truth, or the elusive research dollars which have largely gone to these political, media hype issues rather than to proper research!

It is important to remember that the media can get it right too; Bill Birnbauer wrote an excellent editorial which acknowledged the tragedy of the situation for Rhonda O'Shea.[6] He then went on to summarise the issues in terms of cervical cancer screening and called for immediate changes to compensation before we see such valuable albeit imperfect public health programs disappear.

Whatever the solutions we seek we must act soon. There is general agreement that we have a litigation crisis in medicine which has wrought enormous devastation and may wreak even more unless 'something is done'. In Brecht's play, Galileo said: 'The aim of science is not to open the door to everlasting wisdom but to set a limit on everlasting error'.

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[6] B Birnbauer 'Judge Awards $442 000 to Cancer Victim' *The Age*, 7 May 1994.

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