Loss of Chance of a Better Outcome: Medical Considerations

Professor John Watson is an Associate Professor in the Discipline of Medicine at the University of Sydney. He is a neurologist at Hornsby, the Mater and the Sydney Adventist Hospitals and Director of the Stroke Unit at Hornsby Hospital. He has recently retired from three years as Chair of the Ethics Committee at the University of Sydney.

Professor Watson commenced his medical studies in 1973. He was a New South Wales Rhodes Scholar in 1977. In 1990, he travelled to London, where he was a Lecturer and Senior Registrar in Neurology at the Hammersmith Hospital. He has published 55 peer reviewed original articles, supervised several masters and doctoral candidates, presented clinical and research material many times on radio and is a visiting scientist at the Howard Florey Institute in Melbourne.

Introduction

It seems that, although the loss of chance doctrine appears in tort law in many jurisdictions, and over many years, that its current greatest interest in application is in the area of medical negligence.

One of the main strands relates to the making or not making of a correct diagnosis and the timing (and alleged delay) of this diagnosis. In addition, there appears to be an interest in the choice of treatment, the timing of the treatment and similar lines of enquiry. Furthermore, it is possible to conceive that other areas of interest might be in the monitoring of treatment over time, particularly in cases involving children and adolescents.

Although the concept of loss of chance has been around a good while (see the influential 1981 article by Joseph King[1]), with the growth in evidence-based medical practice and the publication of authoritative guidelines for management and similar, along with the development of large registers of illnesses and/or treatments, and the conduct and publication of large clinical trials, the climate exists for lawyers and courts to put more than their toes in the water in the consideration of loss of chance, and for the provision of data to allow estimating at least some of these losses with some confidence.

1. Neurological case examples

Birth defects and the use of anti-epileptic medications

As a rough guide, about 2% of pregnancies will have as an outcome some kind of birth defect affecting the newborn baby, ranging from very minor to very severe.

We have reasonable levels of evidence from published studies and from large scale prospective national registers of pregnant women with epilepsy and/or taking antiepileptic drugs, to start to estimate better risk estimates for birth defects due to different drugs. Many different medications can be used alone or in combination for epilepsy management. It is a reasonable truism to state that, the more difficult the epilepsy is to manage, the more likely it is that the patient will be on more than one anti-epileptic medication.

Let us suppose we have one particular medication, 'A'. When used alone, 'A' is associated with a newborn baby birth defect rate of approximately 3.5%. Let us suppose there is another anticonvulsant medication, 'B', that has a risk of approximately 6%. Before deciding on whether medication choice has been appropriate and/or whether a poor birth outcome relates to negligence, other information is needed. This includes an idea of what the risk of birth defects may be in the epileptic population, ideally the untreated epileptic population, and in addition, other factors such as the risk of death of the mother and/or the foetus, in the setting of uncontrolled or major seizures.

At first approximation, some kind of grossed-up risk for birth defects, brain injury to the baby, death of the baby and death of the mother in an untreated epileptic population might come to about 3%.

Assuming that there has been a finding of negligence when drug 'B' was used, what is the correct way to calculate the loss of chance, if the court wished to proceed down this line? For example, is it the difference between the risks if medication 'A' was used compared with if 'B' was used? What account is taken of the better epilepsy control by medication 'B' (if any)?

Multiple Sclerosis

Another area of interest that I can demonstrate from neurological experience is in the emerging list of active treatments for multiple sclerosis. Multiple sclerosis is a life-long condition affecting more women than men and affecting people within a higher socio-economic group than lower (and affecting those living further away from the equator than those nearer).

In a nutshell, we have moved in the space of 20 years, from not having any effective treatments for this condition (we still do not have a cure), to one in which we have a number of disease-modifying agents which appear relatively safe in a 15-20 year experience; there are also other medications which might turn out to be more effective but are

potentially more dangerous. As a doctor, getting the trade-off correct in advising patients is always crucial and one can see potential problems developing in this area.

Acute Stroke

Another interesting area is stroke medicine. Many examples from the acute stroke and secondary prevention stroke literature allow quantification of risk with respect to the nature and selection of treatment, and the timing of treatment. The latter is particularly important for the acute administration of thrombolytic ('clot busting') treatments for acute stroke.

The acute stroke medicine literature, particularly with the development of intravenous thrombolysis with tissue plasminogen activator (tPA), affords good statistics, particularly with respect to the timing of this treatment. The pivotal study was published more than ten years ago and indicated net benefit in terms of death and disability if this medication were given within a three-hour time window. A further study, published only six weeks ago, indicated that the time window can be extended to 4.5 hours, still with net benefit, but there is strong evidence that the maxim "time is brain" holds, as indicated in the following diagram[2].

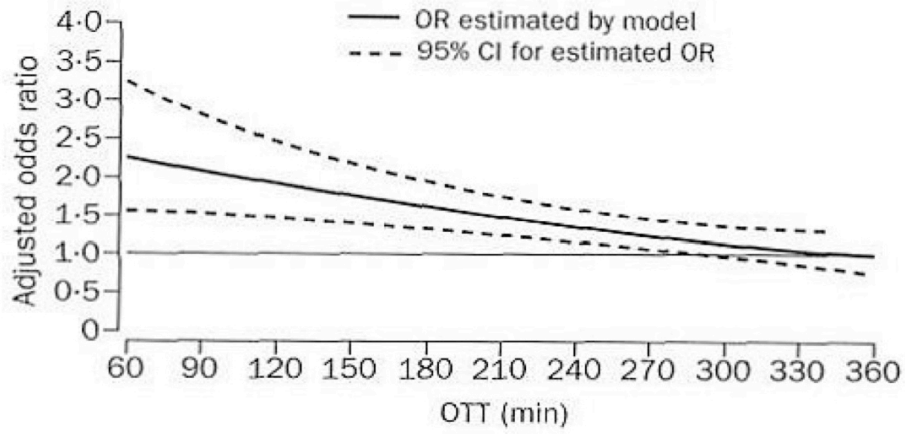

Figure 3: **Model estimating odds ratio for favourable outcome at 3 months in rt-PA-treated patients compared with controls by OTT**

Adjusted for age, baseline glucose concentration, baseline NIHSS measurement, baseline diastolic blood pressure, previous hypertension, and interaction between age and baseline NIHSS measurement.

This is an interesting area of medicine. Prompt delivery of this treatment requires prompt recognition and action by the patient, the family, the ambulance service, primary care practitioners, emergency departments doctors, rapid triage and completion of certain important laboratory tests and a brain scan prior to the administration of the medication. At the same time, there has to be good quality informed consent from the patient or other appropriate consent giver.

Why all the rigmarole? The problem with this treatment is that up to 7-10% of people who receive this medication, even if it is given within all appropriate guidelines, develop major intracranial haemorrhage, usually with a fatal outcome.

There have been a number of cases already litigated with respect to this treatment. The majority relate to failure to consider or to give this treatment rather than to the administration of this treatment with a disabling or fatal outcome.

Of course, it may be that a fatal outcome, for example after devastating intracranial haemorrhage, whilst upsetting to an elderly person, is preferable. There is evidence that patients and their families in such a position would rather accept death with little prior suffering, than face the horrors of living the next two to three years fully dependent on others, in a nursing home, not able to move in bed unaided, not able to communicate properly, and requiring a tube directly into the stomach for feeding and medications. There is no question that the cost of such care is much higher than if someone were to die within a few hours of such treatment.

There are good data now allow the calculation of benefits and probable risk with respect to the timely administration of tPA, almost down to the minute. Consequently, if the courts are minded to go down the pathway of loss of chance, this is another area where information is available.

Cardiopulmonary resuscitation (CPR)

Another area of interest is that of cardiopulmonary resuscitation for cardiac arrest. Only slightly tongue in cheek, it is worth pointing out that, in the stratification scheme of evidence-based medicine from the highest to the lowest level of evidence, there is very little evidence to suggest that it is better to carry out CPR than not, and certainly nothing from a randomised controlled study No ethics committee would allow such a study. If someone has a cardiac arrest and no attempts were made at resuscitation, then it is virtually certain that the person will be dead within a few minutes. However after the resuscitation of such patients, often elderly, already with vascular disease, probably with brains more vulnerable to the insults of hypoxia and hypotension, it is important to realise that many do not do well. There is a fair amount of information that a significant number of people resuscitated after a cardiac arrest make a poor recovery with major brain injury, being totally dependent and never able to return to their homes, let alone to any semblance of independent living. In the USA, there is a National Registry of Cardiopulmonary Resuscitation (NRCPR): some of the figures from this register indicate an overall survival rate to discharge from hospital of about 17%. About half of these patients die within 6 months. Perhaps 5 to 15% of survivors have significant brain damage.

So it is not enough to consider whether a person survives or not. One has to consider in what state the person survives - of course, this goes to the heart of the determination of quantum. An action for wrongful life is unlikely to succeed in this context, and without contemporaneous evidence about the conduct of the CPR it probably would be difficult to establish negligence. However, at the level of the health care system and considering the high burden of necessary care, it would not take many such survivors for an economic analysis to conclude that CPR is likely a burdensome and costly treatment, especially in the elderly. This has been recognised in the practice of advance discussion with patients and family about whether CPR is to be commenced in particular circumstances.

2. Relevant terms and concepts

(a) Statistical properties of diagnostic tests

The properties of diagnostic tests are interesting. Medical students are lectured on such notions, namely the sensitivity of a test, the specificity of a test, its false positive rate and false negative rate, and two other notions: the positive and negative predictive value of a test.

The positive and negative predictive values depend on the sensitivity and specificity of a test, and the prevalence or likelihood of the illness existing in the test population. These concepts are not always easy to get across and often require a number of lectures and practical exercises before the medical student's penny drops. But these concepts are not esoteric and should apply, even in the traditional test situation, let alone the loss of chance situation.

In particular, one could look at the false negative test rate. Suppose a plaintiff contends that there is a failure to diagnose his cancer because the doctor did not conduct a particular test. Suppose there is a 15% chance of a false negative test result (with no prospect of another cause of action being argued in respect of this false negative rate, for example against the pathologist) and that the plaintiff is able to determine that he has lost a 40% chance of survival because of the failure to diagnose. There are probably a couple of ways one can look at the mathematics of this particular calculation, but it seems clear that the patient who has lost a 40% chance of survival has to be compared properly, and not with the assumption that the test properly conducted would always have discovered the cancer. It would only have discovered the cancer 85% of the time because there is a 15% false negative rate - consequently the percentage loss of chance would have to be reduced. One calculation would place this at 40% x 85%, equalling 34%.

(b) Mathematical expectation

It is worth mentioning the concept of mathematical expectation. This is essentially the sum of all the individual probabilities (which themselves must sum to 1.0) of each different outcome, each multiplied by a measurement of interest (such as life expectancy, or cost of care for each different outcome). Something like this has to be used to try to calculate the considerations as precisely as possible. After such a calculation it is possible to conceive, for example, that widespread deployment of CPR (as is the case in Seattle where one only has to trip and fall on the ground for someone to jump on one's chest) at the population level would lead to higher costs in terms of caring for the very disabled survivors, as compared with doing nothing. However, for the few individuals, particularly of working age with younger families, who might make a good recovery after a cardiac arrest, it would be difficult to convince them and their families of the lack of utility of CPR

Quality of life

Not only in this context, but in a more general context of illness burden and the results of treatment, including pharmaco-economic submissions to government for the subsidy of new medications, health care economists try to look at the quality of people's future lives in units such as the 'quality adjusted life year' (QALY). To many, the determination and correct measurement of the QALY is to a great extent arbitrary and often nebulous, but such

estimates can be brought into the equation if one is to determine loss of chance (or even with the non-loss of chance doctrine) and then to calculate the quantum.

Life expectancy

Many of the cases of loss of chance relate to the loss of chance, or loss of opportunity, to live a particular length of time, usually in the context of missed or delayed diagnosis of cancer.

Life expectancy is a vexed issue. There are probably few medicos and lawyers who understand how life expectancy is calculated. However, it is a most crucial estimate of the length of time a person is likely to live and has a great influence on the quantum. The courts seem happy to take such a population-derived 'epidemiological statistic' and apply it to the individual plaintiff, with nary a judicial murmur about inapplicability. The concept of a quantifiable life expectancy has notions of chance and opportunity built into it.

Pre-existing notions of chance and its loss

Courts do use (with a greater or lesser degree of sophistication, sometimes no more than the 'folk statistics' level) notions of loss of chance, certainly in the valuation of damages, if not in determining causation. Life expectancy estimates themselves are just that - they are figures taken from the relevant population, ideally adjusted for individual patient/plaintiff characteristics, to work out an individual's life expectancy; however they remain estimates and estimation is all about chance. When a court determines contributory negligence and thereby reduces an award by a certain percentage, it is in effect using, even if it does not recognise it, a statistical approach.

The judge might decide on a particular percentage, e.g. 33%, and imbue his or her determination with an apparent precision that might not be justified. However, in reality, the judge is making a point estimate of the likely contribution to a person's particular outcome of his or her own actions (or in the case of co-defendants, the different liability proportions as between the defendants), which estimate itself has an unstated spread or 'confidence interval'. When judges assign a 33% contributory factor in such a case, they are really saying that the action has caused the minority of the outcome and that this contribution might spread, say, from 15% to 48%. It is an interesting thought experiment to speculate how much more consideration might be given to such issues if judges were expected to provide real estimates in such cases, and to express their confidence in these estimates, and therefore the spread function for such estimates. This could herald a new era. Perhaps one could call it 'evidence-based law'?

Population-based epidemiological studies

Although it is important to recognise that population-based epidemiological statistics can never fully apply to any single individual running his or her course in life, many commentators on this topic have at times been too precious in how irksome they find this attempt. They do not recognise what we all do daily in relating individual human experience to the population at large and vice versa. The acceptance of the concept of estimated population-based life expectancy is a very clear acceptance of the application of population-derived statistics to individuals - if one cannot do this, then one might as well pull judicial answers out of a hat. (In fact there is a powerful statistical modelling process that does just that, when predictive algorithms are lacking; the reader might be amused to learn that this is called the Monte Carlo method).

There is an anecdote that is actually impossible to source but usually seems to involve Winston Churchill, George Bernard Shaw, and a female London socialite, often Lady Astor. The anecdote goes as follows: Churchill/Shaw/generic male asked Lady Astor/generic London socialite if she would sleep with him for a very large sum of money e.g. £1,000,000, to which she agrees with varying degrees of readiness, according to the different anecdotes. Then the male protagonist asks if she would sleep with him for a very small sum, variously a halfpenny to a few pounds, to which she replied, "What do you think I am." Then comes the reply: "We've already established what you are, ma'am. Now we are merely haggling over the price."

The implication of this might be a little harsh to apply to any member of the legal and medical professions. However as, when it suits them, knowingly but often unknowingly, the courts do use statistics and do use population-based estimates to bring information to bear on individual cases, to recoil at times in horror does seem odd.

As an outsider to the methods of judicial reasoning, it seems to me that the concept of loss of chance and the use of statistics is already embodied in determining issues of damage and quantum.

Life expectancy

Interestingly, the High Court in Australia has even decided, as very few other jurisdictions in the world have decided, that we must use the Commonwealth Statistician's projected life expectancy figures rather than current (historical) derived figures. They were persuaded in the case of Golden Eagle International Trading Pty Ltd v Zhang [2007] HCA 15, 19 April 2007, to follow this approach on the basis that this was a better estimate. Perhaps it is, but

a lot of statistical methodology is used in how the Statistician calculates these projections. It will be an interesting exercise over the next ten to twenty years to see how close the projected estimates of life expectancy match the real figures as they become available. Although the judges presumably were confining their thoughts to the matter of life expectancy tables, the non-legally trained medico might think that the following has broader applicability: "...the 'best evidence rule' has not fallen completely into desuetude. Subject to the exigencies of litigation, the circumstances of the parties, and the other settled and statutory rules of evidence, it has vitality. An aspect of the rule is that courts should act upon the least speculative and most current admissible evidence available. To prefer the prospective, rather than the historical, life expectancy tables is to do no more than that."

Employment

Another example of a 'folk' or everyday statistical approach arises in terms of quantum calculations for employment and employability. A plaintiff might have had very little scholastic aptitude, an appalling school academic and attendance record and achievement, and a host of immediate family with very similar characteristics. Moreover, this plaintiff might have an established very poor employment history and achievement. Such a plaintiff is unlikely to have his quantum calculations for future loss of earnings based on the earnings of a CEO of a large merchant bank, or of a medical practitioner at the pinnacle of his profession, or of Sydney's leading Senior Counsel.

In such a case, there is very likely to be a decision, whether explicit or implicit, that the expectation of earnings is likely to be below the average of unskilled workers on the basis of the concept of "more probable than not". That might be the likely outcome. However, a modern medico interested in estimates of risk, benefit, confidence intervals etc. would understand that if this likelihood estimate were, for example, 70% and if a confidence interval or spread function were applied to this point estimate, it might vary from 51% to 99% (for the commonly accepted 95% confidence interval). What this means, on a population basis, is that there is a very small percentage who might in fact have an entirely different income outcome. Once in a blue moon an apparent 'ne'er-do-well' comes good and surprises everyone - that is what the notion of confidence interval in this context tries to take into account. However, the chance is low, so the Court is able to hide under the skirts of the balance of probability without thinking about it much further.

Statistical significance and real-world effects - Stroke medicine example

Here is another example from stroke medicine. We know from two very large studies[3] that the administration of aspirin within 48 hours of the onset of stroke confers a beneficial outcome. The very large numbers involved in the studies (40,000) made the statistical significance very high. There was a net decrease of 9 per 1000 in the overall risk of further stroke or early death in hospital (8.2% versus 9.1%, 2P<0.001). This is one of the more statistically significant results in modern stroke treatment trials4.

However the net benefit is not very high. On average a much better outcome is achieved in about 1% of stroke patients if they all are treated this way (9.1% to 8.2%). There are plenty of strokes, approximately 40,000 a year in Australia; consequently, if all are given aspirin within 48 hours of the stroke, 400 such patients will do much better and will be much less burden to themselves, their families, and to the state, in terms of nursing home care etc. These studies have been around for some time, so it is highly likely that failure to give aspirin to such a patient without appropriate contraindications being present would be considered negligent. If so, and if a loss of chance doctrine were followed, the quantum calculation might be small as the attributable risk to the failure to give aspirin is also low at about 11% (calculated as (9.1 - 8.2)/8.2).

Statistical significance and real-world effects - High dose radiation example

Another example is the administration of high dose radiation to the vulnerable brains of very young children. This treatment is usually given with curative intent for various solid central nervous system tumours and for certain childhood leukaemias. Along with other advances in paediatric cancer medicine, such treatments have seen a massive improvement in survival.

However, the adverse consequences of such treatments can be very severe. In many ways this type of treatment can be considered a Faustian bargain. There is clear evidence that high-dose whole-brain irradiation in young children leads to massively reduced cognitive capacity. Almost universally the endocrine axis, so dependent on the pituitary gland, is effectively destroyed. Physical growth is stunted severely. At a cosmetic level, there is often significant failure of scalp hair growth. There is a significant increase in the chance of other cancers developing, even as early as the mid-teens. How does one measure the quantitative aspects of such an outcome in these children should they find themselves in a position to sue successfully for some act of negligence in their treatment?

3. Special areas of consideration when evaluating loss of chance in a medical context

How widespread is the appropriate scientific and mathematical knowledge?

It is possible that members of the legal profession, including judges, might feel that they do not have an adequate training and knowledge of the concepts of chance and probability. Many members of the medical profession would feel similarly under-prepared or unprepared. With the move to evidence-based medicine (EBM), along with the conduct of randomised control trials for the past 50 years or so, there is probably more understanding among the medical profession than perhaps across the legal profession.

An interesting paper by Gatowski and colleagues "Asking the gatekeepers: a national survey of judges on judging expert evidence in a post-Daubert world"[5] refers to the USA Supreme Court's examination of criteria for the admissibility of 'scientific evidence', following the case of Daubert v. Merrell Dow Pharmaceuticals, Inc, 1993 (509 U.S. 579). This case has an antipodean angle for its expert witnesses; it concerned the action by two young men against Merrell Dow Pharmaceuticals, claiming that the drug *Bendectin* (also known as *Debendox*) had caused their birth defects. In this study, the authors undertook a national survey of USA State Court judges, in the light of the new rules laid down in Daubert. Half the judges believed that their education had not prepared them adequately to deal with the range of scientific evidence that they encountered. About 60% reported that they had not received instruction about general scientific matters and principles. Very few judges understood the concept of scientific falsifiability, and the concept of error rate.

It seems entirely plausible that an empirical study of judges' lack of understanding of population-based epidemiology, individual risk, estimates of risk and benefit, relative and absolute risk, confidence intervals etc would reveal a similar level.

Recognition of mathematical errors in estimating causation

There is an interesting and helpful article by Lars Noah, "An inventory of mathematical blunders in applying the loss-of-a-chance doctrine,"[6] which discusses in some detail notions of proportional recovery for loss of chance - whether the calculations should be symmetrical or asymmetrical - and notions of optimal deterrence (some of the critics of the idea of loss of chance argue that the function of deterring negligence may be lost). As with other areas of risk estimation, Noah discusses in detail notions of absolute loss, relative loss and attributable risk. He also considers the issues involved in delays in diagnosis, stages of disease, and change in chance of survival. He particularly examined some of the errors which he argues have been made in various cases and articles. He points out that in King's first article[7], by promoting the notion of loss of chance, King was in effect proposing "converting the question from one of causation to one of valuation."

Part 3 of the article by Noah[8], with a subheading, "Tackling some of the conceptual and computational errors," points out that a number of judges, lawyers and commentators have made errors in dealing with loss of chance claims. These include mistakes related to comparisons across the stages of the disease, flawed assumptions about background mortality rates, and faulty calculations related to changes in the chance of survival. Noah also pointed out, "over time, these errors propagate and become more difficult to correct. If nothing else, the experience with loss-of-a-chance claims offers a case study in the hazards associated with judicial innumeracy."

Comparative negligence

In many cases, the loss of chance approach is adopted in trying to decide on damages in situations where a pre-existing condition has been aggravated by negligence. Noah[9] pointed out, "courts now routinely allocate responsibility to reflect causal contributions among multiple tortfeasors and with comparatively negligent victims, which means that a particular defendant assigned less than half the share may pay precisely that amount. No one really has emphasized the parallel between loss-of-a-chance claims and rules of comparative negligence..." He went on to write, "in jurisdictions that have adopted the so-called 'pure' comparative negligence rule, a victim found to be 90%. ...responsible for his injuries can recover 10%...damages from the negligent defendant even though such an apportionment would appear to defeat the necessarily prior finding that the defendant's negligence more probably than not caused the injury. The courts seem to view this matter "as one of valuation rather than causation."

Relative and absolute changes in risk

Noah[10] discusses a number of errors relating to the misapprehension of risk and chance estimates, and the issues of relative and absolute changes in risk. At the end of his article, he has a number of illustrative tables indicating how one might calculate the loss under different scenarios concerning the underlying baseline risk/loss of chance (whether high or low) and the change in this risk as a result of a negligent act.

Deterrent effect?

King[11] argued, "The loss of chance of achieving a favourable outcome or avoiding address compensable should be valued appropriately, rather than treated as an all or nothing proposition." He also argued that the traditional rule that

barred recovery when a chance of recovery is less than 50% was arbitrary, and that it was contrary to the deterrent objectives of tort law because it denied recovery for statistically demonstrable losses resulting from negligent acts.

Weigand[12] summarised King's reformulation of his doctrine along the following lines:

- the defendant failed in his duty to protect or preserve the victim's prospects for a more favourable outcome;
- either the duty owed was based on a special relationship, undertaking or other similar bases, or the only question is how to reflect the presence of a pre-existing condition in calculating the damages for a materialised injury that the defendant is proven probably to have caused;
- the defendant's conduct reduced the likelihood of the victim's otherwise attaining a more favourable outcome;
- the defendant's conduct was the reason that it was not feasible to determine precisely whether or not the more favourable outcome would have materialised, but for the defendant's conduct.

King[13] does not limit this approach to medical malpractice, but it is important to note that risk of future consequences caused by negligent conduct is not recoverable unless the harm actually materialises.

Policy considerations

Weigand[14] goes on to discuss policy issues for and against adopting the loss of chance doctrine. As with other commentators, he points out that it is a powerful idea that human life is precious and that even the loss of only a small chance of cure or survival is a significant loss. He and other authors point out that the traditional threshold, when applied to a patient who is very old or who has such a poor prognosis because of an underlying condition, might mean that acts of negligence might pass without redress, and that this was fundamentally unfair. Although he accepts the idea of a threshold, he does point out the countervailing argument that it seems unfair that recovery is permitted when negligence has a 51% possibility of producing the alleged harm but denying any recovery when the proof is only a 50% possibility.

Errors

In an interesting use of statistics, Weigand[15] echoes the Maryland Supreme Court, which concluded that the loss of chance doctrine produced "more errors than the traditional causation principles."

Consider the following somewhat artificial example used by Weigand. Assume that there are 99 patients with cancer and each has a 33 1/3 % chance of survival. Each of the 99 is subject to a failure of diagnosis and, as a result, all 99 patients died. Under the traditional principles of causation none of the patients would be able to recover damages because it was more probable than not that the underlying cancer caused their deaths. However, if all 99 patients had received proper treatment, 33 would have survived, and 66 would have died as a result of their underlying condition. Thus the traditional principles of causation would result in 33 errors by denying recovery for 99 patients. However, if the loss of chance rule were applied, allowing for discounted recovery and damages there would be errors "in all 99 cases". That is, with proper care, 33 of the 99 patients would have recovered, but each would have received only 1/3 of the appropriate quantum. The remaining 66 patients who would have died as a result of the pre-existing condition would then receive a windfall by receiving 1/3 quantum. To a lawyer, this seems to mean a 100% error rate.

To a doctor who works in a system which regularly uses statistics for purposes such as determining funding by Medicare, the Department of Veteran's Affairs, and various health funds on the community rating principle, this argument seems somewhat misapprehended. At a system or population-based level, the transfer of 99 discounted sums from the negligent doctor, totalling 33 full sums of damage, is exactly the right method, given that one cannot determine in any single patient whether the negligence was the [single] cause of that person's death.

Symmetry

At the same time, it seems to the author that, if such a doctrine were adopted, it has to apply symmetrically, as implied in the example just discussed. For example, if a patient has a 49% chance of survival, lost through misdiagnosis and therefore entitled to recover 49% of the value of his life under the pure chance or proportional damage theory, then a patient who has a 51% chance of cure lost through exactly the same negligence ought to be limited to recovering only 51% of the value of the life lost. It is interesting that commentators speak about the erroneous and/or windfall gains which would flow to plaintiffs if the loss of chance doctrine were adopted, but often do not mention the current situation (which clearly must be the case on many occasions), namely that, by only just exceeding the threshold on the traditional test, many patients, looking at this on a proper economic and statistical basis, gain windfall over-compensation.

4. Other epidemiological issues to consider

The patient still being alive at the time of trial

The medico with knowledge of epidemiology and statistical methods can bring to account other important issues discussed in articles on this topic, for example, how survivability statistics in illnesses like cancer are measured from

the time of diagnosis. Commentators such as Weigand[16] note that we do not have figures for survivability at other points in the diagnosis (this is not always true as survival curves do exist from registries and patients can be plotted on such curves) and therefore they argue that, for someone who has lived three years, for example, after the time of diagnosis, by the time of their trial, the loss of chance of survival "is now completely irrelevant" with respect to the survival rates at the time of diagnosis.

In many ways, this fundamentally misrepresents the concept of loss of chance in this situation, for both survivability and life expectancy. In most cases, such patients will always be worse off as compared with patients who were diagnosed and treated appropriately in a more timely manner. The fact that someone has lived some years by the time of their trial does not, in the author's opinion, negate the notion that they remain in an inferior position. This is to mistake the current situation for the future. If we really believed this, we would have to say that we should not construct life expectancy tables for anyone, because she is alive today (having for example not been hit by a car yesterday) and will therefore remain alive indefinitely into the future. (There are some conditions in which this might not be the case. For example, if there were a cancer with very steep early non-survivability rate, which then plateaus to the horizontal, and for whom we had many years of data on cancer registries, it may be possible to argue that such a person, in the minority of the cohort at the beginning, has survived so long that she can be considered cured.)

Lead time bias

There is a related problem, 'lead time bias'. If one does not recognise this, then the valuation calculation for loss of chance can be skewed. This issue relates to the exact timing of the diagnosis with respect to the natural history of the illness. In general, when cancer is detected earlier, the survival from the very time of diagnosis is likely to be longer, because of a longer lead time. Suppose we know that a type of brain cancer that has grown to a particular size has a median survival rate of 36 months, and is uniformly fatal. If through extremely keen diagnostic abilities or through coincidental brain scanning, such a tumour is picked up when it is smaller, it might be that the diagnosis is made twelve months earlier than is typical and so the apparent survival is twelve months longer than 'normal' survival from diagnosis. The patient, however, effectively lives to the same age with his tumour - it is just that he knows about it twelve months earlier. Bias of this type can be taken into account.

Does early diagnosis always lead to better outcomes?

It is possible that early diagnosis does not necessarily lead to better outcomes. This is certainly the public perception and it is encouraged by many colleagues who work in the area of cancer and cardiovascular medicine, with varying degrees of objectivity. However not all disease processes are linear, particularly not cancer.

For example, surgeons used to perform the very disfiguring operation of radical mastectomy for breast cancer on the assumption that this particular cancer behaved linearly, which it might well do in its very early stages. However, we know that, in many cases, the cancer has spread by the time of diagnosis and that radical mastectomy makes no difference to the nature of the systemic cancer or to survivability. Consequently, this operation has very much disappeared.

Another area of debate which might be more settled in the next few years, is the role of the screening test for the prostatic specific antigen (PSA) in male all-comers, say above the age of 50. Many imponderables remain with this test, including its sensitivity, specificity and predictive value, the biology of the underlying condition, and especially the utility of various treatments, including radical treatments. There is conflict between a number of learned authorities on whether or not the test should be done routinely and how to deal with the test results. There is a very interesting short article by a young American doctor who dealt with exactly this issue in discussion with a patient, using the latest evidence-based medicine approach and using a model of shared-decision making as between the reasonably well-informed patient and himself, then subsequently being sued ("Winners and Losers," by Daniel Merenstein, JAMA. 2004; 291: 15-16). If you have a spare fifteen minutes, it is worth reading this article and the follow-up correspondence.

5. Conclusion

There are many aspects of the practice of medicine, and even in the practice of law, in which a loss of chance approach is already adopted. For someone who works in a system underpinned by the community rating principle, there is some attraction in this path, but the wholesale adoption of such an approach would represent a fairly radical change. It would need authoritative guidance, presumably by the High Court and/or legislative change.

However, for many conditions and many situations, we have at our disposal reasonably good data, and a reasonably good understanding of appropriate statistical procedures to make more rational decisions about the most likely result for a particular patient, including notions of the range or confidence in such estimates. It would be nice to speculate that the adoption of such approaches could reduce legal costs and speed up decision-making - indeed it is possible to

find articles that suggest this. However, the author is not naïve enough to believe that, on balance of probabilities, such an outcome is likely.

1 King JH (jnr). "Causation, valuation, and chance in personal injury torts involving pre-existing conditions and future consequences". Yale Law Journal, May 1981

2 Taken from Hacke W et al., for The ATLANTIS, ECASS, and NINDS rt-PA Study Group Investigators. Association of outcome with early stroke treatment: pooled analysis of ATLANTIS, ECASS, and NINDS rt-PA stroke trials. Lancet 2004; 363: 768-774

3 The International Stroke Trial and the Chinese Acute Stroke Trial

4 Liu LS et al., Analysis of 40 000 Randomized Patients From the Chinese Acute Stroke Trial and the International Stroke Trial; Stroke 2000; 31: 1240-1249

5 Published in Law and Human Behavior in 2001, 25:433-458

6 Review of Litigation, 2005, 24:369-408

7 Ibid footnote 1

8 Ibid footnote 6

9 Ibid footnote 6

10 Ibid footnote 6

11 Ibid footnote 1

12 A partner in the Boston law firm Morrison, Mahoney and Miller and his article "Loss of chance in medical malpractice: the need for caution" appeared in the Massachusetts Law Review, 2002, Volume 87, No 1.

13 Ibid footnote 1

14 Ibid

15 Ibid

16 Ibid