Expert evidence: civil law, epidemiology and data quality

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1 Abstract

My experience with forensic statistics is largely through providing reports for civil cases. This article introduces the type of cases with which I have been involved, and the issues which have arisen, in a few jurisdictions. I wish to encourage more involvement, and debate on the contribution statistics might make in civil litigation, and what might be learned from criminal forensic statistics.

Keywords: Civil litigation, jurisdiction, statistics, data quality, expert evidence

2 Examples of issues in personal injury civil trials

In criminal cases, the state prosecutes a person for an offence, and a decision on guilt should beyond reasonable doubt. The state provides the laws and infrastructure for civil suits, but cases are often brought by private individuals. In civil law suits, one party sues for damages from a second party, or demands particular actions as recompense for an infringement of rights.

My experience is in personal injury and medical cases. The cases which are based on deciding liability typically concern claims such as, informally expressed: "Metal-on-metal hip replacements are defective";"If anticoagulants had been administered sooner, my client would not have died"; and "This drug damaged the sight of my patient". A report should assist the court in deciding whether the cause of the injury or death can be decided on balance of probability.

Many of my reports relate to life expectancy, as once responsibility for an injury is admitted, part of the quantum or amount of money paid as compensation for the injury is intended to provide appropriate support for the remainder of the person's life. I have generally considered neurological injuries, such as cerebral palsy which arises from damage to the developing brain, or accidental injuries to the head of spine. My life expectancy

reports do not address questions of causation or liability. A statistician might regard the median as the relevant estimates of life expectancy on balance of probability, but means and life tables are also included in reports.

Initial approaches from solicitors who wish to instruct a statistical expert often include an apparently simple and reasonable general question, such as "How long will this child live?" or "Are metal-on-metal hip replacements defective?" In order to respond, you have to agree on the question are you required to evaluate. The general question will usually lead to several more detailed questions. My understanding is that there is a similar need for clarification in criminal cases. For example, given a sample of DNA, the question "Does this DNA profile match that of person X?" might lead to "From what body fluid did this DNA originate?" or "Where was the sample found and how did it get there?".

An agreement on relevant questions leads on to decisions on what data and research publications are relevant, and the relationship between reports from different experts. Again, these considerations are not unique to civil cases. National crime-related data-bases exist, such as a UK National DNA database with profiles from offenders and from crime-related samples DES4929 (2017). For civil cases, national statistics can be a resource.

2.1 Life expectancy

There are arguments, some quite heated, about the relevance of clinical, statistical and epidemiological expertise in assessing life expectancy (Strauss and Shavelle, 1998b). Data on a relevant population is sometimes available, though decisions have to be made on the choice of covariates and methods of analysis. I use the same covariates in all my cerebral palsy reports. Others create composite variables for individual claimants. In the absence of specialised data, national life tables can be modified. Approaches to using estimated mortality rates or ratios from published research to adjust population rates vary.

In one instance, solicitors called me from a court because a medical doctor gave her estimate of life expectancy for a severely disabled ten year old child with cerebral palsy as 16 years from age 45, expected age at death 61 years. This required assuming that the child would certainly live to age 45. The doctor asserted that a severely disabled ten year old child with cerebral palsy would be more likely than not to live to age 15. She then referred to published research to support a claim that the estimated probability of surviving from age 15 to 30 years was greater than a half, as life expectancy was greater than 15 years (Strauss et al., 2008, Table 1). A 30 year old would also live to age 45 on this version of balance of probability reasoning. The life expectancy estimate regarded the successive probabilities as certain, hence the use of life expectancy from age 45. In contrast, I provided an estimate using data from the Mersey Region Cerebral Palsy Register Hutton and Pharoah (2002). As I had access to this data, I could estimate a survival curve from the current age of the child, taking the severity of her impairments into account.

An approach used by another doctor whose reports I often see is to assign percentage increases or decreases of annual death rates, add them together, and then refer to published

life tables which use population death rates adjusted by such percentages (Bowen-Jones et al., 2014). If the claimant had suffered a brain injury, and was obese, had high blood pressure, high cholesterol levels, diabetes and was a heavy smoker, this might lead to the sum +175%+100%+50%+50%+150%+200% = 725%. Three questions occur to me. On what evidence are the percentages based? Is the implicit assumption that obesity, blood pressure, cholesterol levels, diabetes and heavy smoking are not related reasonable, and how can the dependence be evaluated? Is it appropriate to add percentages, rather than multiply them? The response to my commenting that percentages should be multiplied, not added, was that it was obviously ridiculous to use +100% × +100% = +10000%. When I square +100%, I use $2 \times 2 = 4$, and 4 is +300%.

As a statistician, I rely on experts to provide information on pre-existing conditions and co-morbidities, and the severity of the impairments arising from any injuries. If possible, I select essentially similar people from condition specific datasets to estimate a survival distribution. Alternatively, I look for research linking these factors to mortality rates, and use the information to modify population life tables.

In the United Kingdom, the Government Actuary's Department publishes Actuarial Tables for use in personal injury and fatal accident cases (Government Actuary's Department, 2011), which are based on official projections of future mortality rates for the UK. These are known as cohort life tables, and differ from period life tables, which used current observed mortality death rates. The Office for National Statistics publishes both period and cohort life tables. The Australian Bureau of Statistics (ABS) provides period life tables, but not official cohort life tables. A firm of consulting actuaries, Cumpson Sarjeant, publishes life expectancies based on ABS projections of future mortality.

A choice has to be made between using period or cohort life tables for the standard mortality rates. In the United Kingdom, the publication of official tables implies that cohort tables should be used. In Australia, the choice is not so clearly endorsed. If we do not assume that people with chronic conditions or impairments will experience similar general increases in life expectancy as projected for the general population, then cohort life tables might be used. For example, survival rates for most people with cerebral palsy have not shown improvements over time (Hutton and Pharoah, 2002; Strauss et al., 2007), so period life tables might be a more relevant reference standard.

The chosen standard population mortality rates must be modify by estimates of excess death rates or relative risks for particular factors. In general, such estimates are not available for all ages, so one has to consider the effects of, for example, adding a constant excess death rate or multiplying by a constant relative risk for all ages (Strauss et al., 2005). Declining relative risks, which are consistent with clinical experience as well as observations (Middleton et al., 2012), result in higher estimated life expectancy than constant relative risks. Estimates can be substantially different: estimated life expectancy for a 65 year old with serious impairment was reduced by 22%, from 12.1 to 9.4 years, when a constant relative risk instead of a declining risk was used.

Review of the range of approaches taken to estimating life expectancy, and detailed discussion of the evidence and reasoning which supports each approach, could form a

useful contribution to decisions on the appropriate size of compensation payments.

2.2 Liability for adverse events

Claims about adverse effects of drugs or defective medical devices arise after reports of adverse events associated with the product. Post-approval surveillance of drugs is well established, and reports of adverse events can trigger studies aimed at exploring strength of association and causation (Smyth et al., 1994, 1995). There might also be evidence from in-vivo studies and animal testing as well as various phases of clinical trials.

The allegation "This drug damaged the sight of my patient" was simple: the drug vigabatrin caused a gradual loss of field of vision. Claimants sued under personal injury law. In contrast, the UK claim that "Metal-on-metal (MoM) total hip replacements (THR) are defective" was brought under consumer protection legislation. Disentangling the questions was more difficult, as product defect and medical causation were confused. If the prosthesis was not manufactured within the design specification, it might be clearly defective. If a new design of THR performs better than an old design, at some point when sufficient evidence has been accumulated, the old design might be regarded as defective because it has a shorter expected functional life-time.

The main claim was that the metal-on-metal (MoM) components used in total hip replacement (THR) failed: the MoM components led to adverse reactions which caused failure. How should failure of a hip replacement be defined? Without some agreement on what failure is, expert reports might have no common ground.

There are many possible definitions of failure of THRs. The THR might not achieve patients' expectations, such as pain relief, allowing them to walk a short distance or enabling a return to squash or ski races. The THR might wear and release particles, which might lead to adverse reactions. The THR might dislocate, break or get infected easily. A re-operation or revision with replacement might be required, or be required sooner than a patient expected.

A commonly recorded event is revision, so more clinically meaningful outcomes were given limited attention in the UK expert reports. Statistically speaking - in terms of accuracy and reliability - revision as a marker of failure of a THR is worse than death. The date and fact of death are objective and routinely recorded with precision in many countries. Revision surgery is not always recorded and linked to initial surgery (see Data section). Further, whether a revision was due to failure requires careful consideration of the reasons and many factors which might affect the initial THR as well as revision.

Failure and revision are not synonymous: a failed hip may not be revised. A decision whether to revise a THR is not simple decision. Factors which have been associated with different revision rates for various THR components. Age, sex, health, weight, use of earrings, types and placement of joint components, surgical approach and experience, and external events have been associated with different revision rates for various THR components. Other possible factors are the operating team, post-operative care, and

the person's health and lifestyle. The ease of revision may also play a role, and depend on the device. Patients, professionals and health providers might have different utilities and perceptions of the likelihood of risks and benefits. The final decision is made by a combination of patient, family and health professionals.

Failure of a MoM THR defined as a high revision rate, due to adverse reaction to metal debris (ARMD) requires a decision about acceptable revision rates, and a choice of alternatives and comparators. Possible alternatives are not to have a THR, and continue to live with the pain or immobility which the THR is intended to alleviate; to have a hip resurfaced rather than THR, with MoM or other combinations; to have a THR with a non-MoM prosthesis. The latter might include different stems, different heads or different cups. If a patient will definitely have a THR, the relevant comparators might be all other THR, or a particular THR.

Without accurate and agreed definitions of adverse events, it is difficult to synthesise research publications, or to compare the risks and benefits of alternative treatments. Even with clear definitions, one has to decide which covariates should and can be considered, and how should effects be estimated and included in a report.

3 What data are available?

Once - or if! - the questions are agreed, experts have to decide what data are available to address the questions, and to whom the data are available. Data might only be available in summary form in published reports or articles. The quality of data will affect the strength of evidence. Not only might the data might limit the questions, there might simply not be any suitable data available (Bird and Hutton, 2012). A very substantial volume of information raises different problems. Obviously, being provided millions of pages of reports and extensive data can deter experts from involvement. As there are limits to what I can process, my approach is to ask for specific instructions on what to read and what data to analyse.

Both personal privacy and the commercial value of the data are relevant. In litigation which involves commercial companies, data will usually be provided under strict confidentiality conditions. The obvious questions to consider before using a dataset is the size, completeness, accuracy and validity of the data. In my experience, the common view is naive: "bigger is better" without regard to quality.

Compared to specialist geographic cohorts, registers created from lists of people receiving services have a greater risk of bias due to selective entry, and inaccurate diagnoses (Pharoah and Hutton, 2006). Data from the Californian Department of Developmental Services (CDDS) has been used to publish papers on life expectancy of people with cerebral palsy. Articles refer to 52 000 persons with cerebral palsy (Brooks et al., 2014). Data from the United Kingdom Cerebral Palsy Collaboration, which includes under 6000 people (Hemming et al., 2005). These people come from specific geographic areas and a precise definition of cerebral palsy is required for inclusion.

As some lawyers assume the results from large registers are better than those from small cohorts, evaluation of the data is necessary. The CDDS is a service register, originally the Californian Mental Retardation database. It is not even certain that the people included in analyses have cerebral palsy. In 1998, cerebral palsy was identified by severity, type and location of cerebral palsy (Strauss and Shavelle, 1998a). All three items had to be present to define cerebral palsy. This is a classification of cerebral palsy, not a definition of it. The question used in compiling CDDS was 'Presence of Cerebral Palsy', with two options, 0: 'No CP or other significant motor dysfunction' and 1: 'Has CP or other significant motor dysfunction'. Children who did not have cerebral palsy but had other significant motor dysfunction were included as '1.' The database used by Strauss et al. (1998) had 314 children with cerebral palsy 'present' who were born between 1983 and 1985 inclusive and whose mother's residence was in one of four San Francisco Bay area counties (personal communication). Grether et al. (1992) used the same database, but reported 192 children with moderate or severe cerebral palsy and a further 14 with mild cerebral palsy, a discrepancy of 108 children.

Even if the classification were accepted as a definition and all three criteria were required to identify cerebral palsy, severity of cerebral palsy was unspecified in 10%, type of cerebral palsy was unspecified in 21% and location of cerebral palsy was unspecified in 12% (Strauss and Shavelle, 1998a, Table 1). All three criteria had to be specified for the case to be defined as being cerebral palsy. This being so, at least 21% of cases should have been excluded because 'type of cerebral palsy' was unspecified. In response to a letter to the editor the definition of cerebral palsy was changed to state that a case was excluded if 2 out of the 3 items were missing. More recent publications do not provide summaries of missing data (Brooks et al., 2014).

This information has convinced some lawyers that smaller, well-defined cohorts are of greater relevance than large datasets of routinely collected information. I have also used reporting standards (see next section) to frame questions to be put to experts in order to test the quality of the data used.

For hip replacement, one can consider joint registers such as those in UK, Australia, NZ, Nordic countries, some reviews and papers which give the results of cohorts based on patients treated in particular hospitals or by particular surgeons. Completeness of joint registers or other cohorts is a major indicator of quality. Coverage should consider initial operations and follow-up of subsequent operations or death, with details on time lags in reporting, and the difference between notifications, consent and linkage. Headlines or litigation might result in changes to practice or data collection. This was obvious with MoM (Smith et al., 2012, Figure 1), though statistical measures might be required in other cases (Freidlin and Gastwirth, 2000). The UK requires individual informed consent, unless an exemption is obtained. The combined effects of changes in consent, lack of notification and linkage lead to the English National Joint Register having data on only about 25% of operations for the first year, and less than two-thirds of operations performed more than ten years ago. In contrast, the Nordic Registers have very high coverage (98% for Sweden) as those societies have a different balance between privacy and social benefit (Hutton and Ashcroft, 2000; Hutton et al., 2009; Ludvigsson et al., 2015).

I have used the summary of the bias due to selection by Meng (2016) in several of my reports. He shows how, for a population of size N, with X the variable of interest, the choice between a simple random sample size of n_r and a self-selected sample of size n_s, the mean squared error depends on the correlation ρ_s between X and inclusion propensity. The name *data defect index* is given to ρ_s, and is an effective term in explaining the problem.

To have smaller mean squared error for statistics for X from a self-selected sample than a simple random sample of 100 when the correlation between X and the inclusion propensity is 0.05, one requires 320 million in the self-selected sample. This can be calculated from:

$$n_r \leq \frac{n_s}{N - n_s} \rho_s^{-2}.$$

This dramatic illustration of the problems of selective inclusion in a database was included in my expert report, and appreciated by the barristers. The judgement is pending, so the view of the judge is not known.

4 Published research

An expert report will often cite published research, and my experience is that many lawyers use publication in a peer-reviewed journal as an adequate indicator of quality. The health and medical research communities have developed detailed standards for reporting studies: various guidelines are available from the EQUATOR (Enhancing the QUAlity and Transparency Of health Research) network [1]. However, these are not used by all peer-reviewed journals.

The value of reporting guidelines can be illustrated by considering an article on survival of a cohort of people who had had spinal cord injury (Shavelle et al., 2015). The STROBE "Checklist of items that should be included in reports of cohort studies" [2] includes "Study size (No. 10) Explain how the study size was arrived at"; "Participants (No. 13a) Report numbers of individuals at each stage of study ... (b) Give reasons for non-participation at each stage" and " Descriptive data (No. 14b) Indicate number of participants with missing data for each variable of interest".

The cohort considered by Shavelle et al. (2015) was derived from a national US database. The original 50,661 patients were reduced to 31,531 patients. Five exclusion criteria were mentioned; the two relating to missing data on critical covariates are not discussed. There are no details of the numbers excluded under different headings. There is a reference to "the 59% of patients with complete information", but no further information on missing data. It is confusing to find that from fewer than 32 thousand people, the summary descriptive statistics represent a total of 66,940 people (Shavelle et al., 2015, Table 1). With this (lack of) information, the reader has to decide on the reliability of the conclusion

[1] http://www.equator-network.org/

[2] http://www.equator-network.org/reporting-guidelines/strobe/

"There was no evidence of improvement. Long-term survival has not changed over the past 30 years." (Shavelle et al., 2015).

Quantity of publications is another challenge. A search for published research is usually relevant to investigating adverse events associated with a drug, or mortality associated with a chronic disease. Few people understand how much work is required for a full systematic review and meta-analysis. In the case of vigabatrin and visual field constriction, a systematic review was being done at the time. As I was an author, the unpublished review informed my expert report and discussions between experts (Maguire et al., 2010). In general, a choice has to be made between refusing to provide a report because a full review cannot be carried out, or deciding that offering something is better than nothing. I will often have to state what is feasible for me to offer within the time frame. I might set very tight criteria, such as searching only for existing reviews within the last ten years. Alternatively, it might be possible to demonstrate that additional articles will only add further evidence of heterogeneity, and that there is sufficient heterogeneity to prevent any firm conclusions (Hemming et al., 2006).

Adverse events associated with drugs or medical devises can be difficult to define or measure, and without good definitions diagnosis is difficult, which affects the quality of data in studies or registers. This affects both the quality of articles, and the number of articles within the scope of a search. For example, the review of vigabatrin and visual field loss ranked articles in terms of the definition and method of measuring visual field loss (Maguire et al., 2010). This ranking was possible as measurement of visual fields was already established.

In trying to assess how frequent Adverse Reaction to Metal Debris (ARMD) was, I found there was no agreed definition. One definition allowed eight options, not all of which refer to metal debris: "the presence of metallosis; or corrosion at the MoM bearing surfaces; or pseudo-tumour found at revision; or by imaging; or perivascular lymphocytes seen in a histopathological specimen with tissue necrosis; or fibrin deposition; or metal ions significantly elevated; or significant clinical improvement after exchange of the MoM articulating surface." (). This includes people who have metallosis, i.e. staining of tissue by metal, as I have had from a watch in a hot and humid climates, as the only marker for ARMD. No reasons given as to why detectable metal is an *adverse* reaction: I did not suffer from having a dark grey stain on my wrist. Many articles reporting on rates of ARMD did not give a definition of ARMD.

A definition is essential for diagnostic procedures and to evaluate screening methods. In terms of screening for ARMD, blood metal ion levels are used. Various thresholds for raised blood metal ions have been considered, and the best levels have estimated sensitivity of 63%, and specificity of 86%. There is a list of 30 essential items that should be included in every report of a diagnostic accuracy study (STARD 2015)[3]; none of the studies had a high score.As the rates of ARMD are no more than 15%, and perhaps much lower, the positive predictive power of screening is low. Despite this, some surgeons regarded almost all patients with raised blood metal ions as having ARMD. This is, of course, an example of ignoring the transposed conditional probability, or the prosecutor's

[3]http://www.equator-network.org/reporting-guidelines/stard

fallacy.

I did not attempt a systematic review of either prevalence or diagnostic accuracy. I simply reported that prevalence estimates and revision rates from a selection of publications are very variable. This variation means that there is not enough evidence of consistency, strength, specificity or dose-response effects to draw conclusions about the association between MoM and ARMD.

Limited information in publications provide plenty of challenges for the would be expert who has to consider the implications of in accuracy and substantial missing data, and then communicate results in a form which lawyers will accept. Many people prefer a confident declaration of research findings with no caveats about quality. Transferring the improvements in study design and reporting which have happened over the last half century in medicine to personal injury litigation is not easy.

5 Different jurisdictions

I have provided reports in several UK and Commonwealth jurisdictions, but not for cases in the USA. In these jurisdictions, reports are written for the benefit of the court, and should not be influenced by the instructing parties. In my experience, civil litigation rarely results in a court hearing, as there are opportunities and encouragements to settled before a hearing. Expert reports provided to instructing solicitor might not be disclosed to the opposing parties, and do not necessarily reach a court. Out of court settlements often have confidentiality requirements, which makes it difficult to study the impact of expert reports.

In Australia and England & Wales, there is no property in a witness, and I have occasionally provided separate reports to both sides. Of course, the expert cannot disclose information from one side to the other. If the information provided by the two sides is consistent, the reports will be essentially the same. It is also possible for both sides to jointly instruct the same expert. Expert witness reports must be exchanged before trial, and experts can comment on other reports, and raise questions. Such comments and questions can be addressed in supplementary reports. Thereafter, experts can be, and usually are, instructed to provide joint reports. A joint report lists the points of agreement and disagreement. Where there are disagreements, experts explain briefly the reasons for disagreement. In Northern Ireland, the opposing parties might only begin negotiations once the experts are sitting outside the court, which is not a particularly efficient approach. In Scotland, expert reports can be disclosed in advance, and there can be correspondence via the solicitors. However, there is no protocol for joint meetings or reports.

In some jurisdictions, for example, Scotland and South Africa, expert witnesses instructed by different sides are not allowed to communicate, and experts are not allowed to provide reports to both sides. At one time, a set of Scottish solicitors exploited the fact that there were only two sources of expert opinion on life expectancy of people with cerebral

palsy, myself and a USA team. Reports were commissioned from both sources, and a single report was disclosed to the opposing party. I once discussed the disclosed USA expert report with opposing solicitors. An instructing solicitor was present to ensure that I did not disclose any of the content of my own report. I was able to have an interesting discussion, and a settlement was reached not long afterwards. To my mind, if a court cannot trust a person to provide an expert report which is objective, and indifferent to the instructing parties, the person should not be regarded as an expert. It is strange for a report written for a court to be owned and potentially concealed by one party.

Almost all advocates have quickly grasped essentials of a case. My limited experience of judges is more mixed. There can be frustrations when a judge decides between those competing for expert status. A cancer surgeon who provides arbitrary probabilities for causal effects of exposure on a cancer might be preferred to an epidemiologist who specialises in that cancer, or a paediatrician's view of life expectancy preferred to a statistician's detailed analyses.

6 Conclusions

Civil law suits provide many opportunities for statisticians to offer their skills. At the individual case level, statisticians can contribute by clarifying the issues raised, finding evidence relevant to the particular case, evaluating it, and then presenting the information. Perhaps the lack of clarity which can arise with respect to the precise questions and comparisons relevant to a case is the civil law version of the prosecutor's fallacy. Civil trials in the jurisdictions in which I have worked are before a judge, so while I am grateful to have only one person to whom to explain statistical concepts, I cannot make a comparison with giving evidence to a jury.

As a medical statistician, I notice that there is a substantial difference between the evidence required in order for a drug to be licensed, and the evidence which is used in litigation. Regulatory authorities require evidence from a range of studies, including large clinical trials, and statistical analysis of data to defined standards before issuing a product licence which authorises the marketing on a drug or device. A doctor cannot simply say "I will use this new, untested drug because my clinical opinion is that it will be effective for this patient". Tested and licensed drugs can be used for non-indicated conditions within various constraints, but multi-disciplinary science including statistics is an essential part of the normal process.

However, some judges are willing to dismiss statistical and epidemiological evidence McIvor (2013). In an appeal relating to life expectancy, a judge asserted that statistics must not be allowed to interfere with clinical judgement. To reduce the perceived conflict, I think there is considerable value in providing reports written jointly by various experts such as clinicians, pharmacologists and statisticians. Perhaps initially it might be more practical to have mutual acknowledgement of experts. Further discussion of the relevance of standards adopted to make decisions on regulating medical products to evidence used to inform litigation decisions would be helpful. Litigation decisions are

made for known individuals, sometimes a single person, whereas product licences are given to allow advertising for a class of people. Of course, litigation decisions can have consequences for other people who have been exposed to the same agents.

There has been considerable activity in forensic science and statistics. There are monographs (Aitken and Taroni, 2004; Gastwirth, 2000). Guidelines have been published by the European Network of Forensic Science Institutes [4] and the Royal Statistical Society [5]. A series of primers for judges has been launched by the Royal Society of Edinburgh and the Royal Society [6]. The Inns of Court College of Advocates has issued a guide on statistics and probability for advocates [7].

Criminal forensic science has been the main focus. The RSS guides explicitly consider statistical evidence in the administration of criminal justice. The US National Academy of Science report in 2009 on the need to strengthen forensic science National Research Council (2009) was followed in 2016 by a report on Forensic Science in *Criminal* Courts of Advisors on Science and Technology (2016). Debates about who has relevant expertise occur in both civil and criminal forensic matters, and there is as much need for work in civil litigation as in criminal cases (McIvor, 2013). Current enthusiasm for easily obtained large data sets requires clear communication of selection bias.

We should not underestimate the value of simple statistics based on good quality data, presented with clarity.

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[5] http://www.rss.org.uk/practitioner-guides

[6] https://royalsociety.org/about-us/programmes/science-and-law/

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