Avoiding Errors in General Practice

Kevin Barraclough, Jenny du Toit, Jeremy Budd, Joseph E. Raine, Kate Williams and Jonathan Bonser

CLINICAL CASES

EXPERT OPINION

LEGAL COMMENT

LEARNING POINTS

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General Practice

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General Practice

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Preface

Like most general practitioners, I am anxious about being sued. It is clearly necessary to have such a process in society to right clinical 'wrongs', but as a doctor it is difficult to be very enthusiastic about it.

However, negligence cases – whether justified or not – do provide an extraordinarily rich source of material from which to improve one's clinical practice. I have learnt a great deal over the last decade of examining such cases, and it has certainly changed my practice.

I have learnt to be very wary about the spectrum of presentations of those conditions that come up recurrently in medico-legal practice – appendicitis, ischaemic feet, subarachnoid haemorrhages, pulmonary emboli etc. The 40 case studies in Part 2 cover over 95% of all conditions that end in litigation against general practitioners.

I suspect that an awareness that I could be sued does also encourage me to second guess my clinical reasoning – 'could I be wrong here?' That process is, I think, an essential part of being a good clinician. Part 1 examines in more detail the techniques which help a clinician to avoid errors.

Being a good general practitioner is, as we all know, difficult. There is a fine line between being over cautious (and medicalizing everyone) – and being under cautious (and missing serious illness). I hope this book provides some help in walking that tightrope. Part 3 provides some guidance if you fall off the tightrope!

Kevin Barraclough
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Abbreviations

A&E	Accident & Emergency
ABPI	Ankle Brachial Pressure Index
ACE	Angiotensin converting enzyme
ACS	Acute coronary syndrome
ALT	Alanine transaminase
AMUSE	Amsterdam Maastricht Utrecht study on safety and cost-effectiveness of a diagnostic decision rule for suspected deep venous thrombosis in general practice.
AST	Aspartate transaminase
βhCG	Beta human chorionic gonadatrophin
BJGP	*British Journal of General Practice*
BMI	Body mass index
BMJ	*British Medical Journal*
BNF	British National Formulary
BP	Blood pressure
BPPV	Benign paroxysmal positional vertigo
BSG	British Society of Gastroenterology
BTA	British Thyroid Association
BTS	British Thoracic Society
BUPA	British United Provident Association
CAP	Community Acquired Pneumonia
CBE	Clinical breast examination
CDH	Congenital Dislocation of the Hip
CES	Cauda equina syndrome
CKD	Chroinc kidney disease
COCP	Combined oral contraceptive
CPR	Clinical Prediction Rules
CPS	Crown Prosecution Service
CRC	Colorectal cancer
CRP	C-reactive protein
CRT	Capillary return time
CT	Computerised tomography
DDH	Developmental Displasia of the Hip
DGH	District general hospital
DKA	Diabetic ketoacidosis
DOH	Department of Health
DRE	Digital rectal examination
DVT	Deep vein thrombosis
ECG	Electrocardiogram
ED	Emergency Department
ELISA	Enzyme-linked immunosorbent assay
ESR	Erythrocyte sedimentation rate
FBC	Full blood count
FOBs	Faecal occult bloods
GCA	Giant cell arteritis
GMC	General Medical Council
GORD	Gastro oesophageal reflux disease
GP	General practitioner
GPRD	General Practice Research Database
GTN	Glyceryl trinitrate
Hb	Haemoglobin
HCG/L	Human chorionic gonadatrophin per litre
HIV	Human Immunodeficiency Virus
HPA	Heath Protection Agency
HSC	Health Service Commissioner
IMB	Intermenrtrual bleeding
ICU	Intensive care unit
IOP	Interim Orders Panel
IT	Intrathecal
ITU	Intensive therapy unit
IV	Intravenous
JAMA	*Journal of the American Medical Association*
LFT	Liver function test
LR−	negative likelihood ratio
LR+	positive likelihood ratio
MCV	Mean corpuscular volume
MDDUS	Medical and Dental Defence Union of Scotland
MDOs	Medical Defence Organizations
MDU	Medical Defence Union
MPS	Medical Protection Society
MRI	Magnetic resonance imaging
MSU	Mid stream urine

NAD	Nothing abnormal detected
NCAS	National Clinical Assessment Service
NEMC-PCR	New England Medical Centre Posterior Circulation Registry
NHS	National Health Service
NHSLA	NHS Litigation Authority
NICE	National Institute for Clinical Excellence
NNT	Numbers needed to treat
NSAIDs	Non-steroidal anti inflammatory drugs
O/E	On examination
OOH	Out of Hours
OSCE	Objective Structure Clinical Examination
PCB	Post-coital bleeding
PCRS	Primary Care Respiratory Society
PCTs	Primary Care Trusts
PE	Pulmonary embolism
PEFR	Peak expiratory flow rate
PIOPED	Prospective Investigation of Pulmonary Embolism Diagnosis study
PR	Per rectum
PSA	Prostate specific antigen
PTSD	post-traumatic distress
RCP	Royal College of Physicians
SAH	Subarachnoid haemorrhage
SEA	Significant Event Analysis
SHO	Senior House Officer
SnOUT	when a **sen**sitive test is **n**egative, it rules the diagnosis **out**
SOAP	Subject, Object, Assessment, Plan
Sp	Specificity
SpIN	when a **sp**ecific test is **p**ositive, it rules the diagnosis **in**
SUFE	slipped upper femoral epiphysis
TFT	Thyroid function test
TIA	Transient ischaemic attack
TPO	Thyroid peroxidise
TSH	Thyroid stimulating hormone
U&E	Urea & electrolytes
UTI	Urinary tract infection

Introduction

In 2000, a committee established by the Department of Health, chaired by the then Chief Medical Officer, Professor Liam Donaldson, published its report *An Organisation with a Memory*. The report recognized that the vast majority of NHS care was of a very high clinical standard and that serious failures were uncommon, given the volume of care provided. However, when failures do occur their consequences can be devastating for the individual patients and their families. The healthcare workers feel guilt and distress. Like a ripple effect, the mistakes also undermine the public's confidence in the health service. Last, but not least, these adverse events have a huge cumulative financial effect. Updating the figures provided in the report, in 2010/11, the NHS Litigation Authority (the NHSLA is the body that handles negligence claims against NHS Trusts in England) paid out nearly £863 000 000 for medical negligence claims (these figures take no account of the costs incurred by the Medical Defence Organisations for General Practice and private health care). The report commented ruefully that often these failures have a familiar ring to them; many could be avoided 'if only the lessons of experience were properly learned'.

The Committee writing the report also noted that there is a vast reservoir of clinical data from negligence claims that remains untapped. They were gently critical of the Health Service as being par excellence a passive learning organization; like a school teacher writing an end of term report, they classified the NHS a poor learner – could do better. On a more positive note, the report stated that 'There is significant potential to extract valuable learning by focusing, specialty by specialty, on the main areas of practice that have resulted in litigation.' It acknowledged that learning from adverse clinical events is a key component of clinical governance and is an important component in delivering the government's quality agenda for the NHS.

The NHSLA has reported that its present (as of 2011) estimate for all potential liabilities, existing and expected claims, is £16.8 billion. At the time *An Organisation with a Memory* was written, this figure stood at £2.4 billion. (These sums are actuarially calculated figures that are based on both known and as yet unknown claims, some of which may not surface for many years to come. They should not be confused with the figure of £863 000 000 mentioned above, which was the sum actually paid out in one year.) The NHSLA also reported that the number of negligence claims rose from 6652 in 2009/10 to 8655 in 2010/11. While the increases in these figures may be due to the increased readiness of patients to pursue negligence claims and the very significant costs of claims inflation, rather than any marked decline in the standard of care provided by the NHS, the statistics clearly show that

there is still room for improvement in the care provided to patients. It is this gap in the standard of care that we, the authors, wish to address through this book, and the series of which it is a part.

An Organisation with a Memory as a report tried to take a fresh look at the nature of mistakes within the NHS. It looked at fields of activity outside health care, such as the airline industry. The committee commented that there were two ways of viewing human error: the person-centred approach and the systems approach. The person-centred approach focuses on the individual, his inattention, forgetfulness and carelessness. Its correctives are aimed at individuals and propagate a blame culture. The systems approach, on the other hand, takes a holistic view of the reasons for failure. It recognizes that many of the problems facing large organizations are complex and result from the interplay of many factors: errors often arise from the cumulative effect of a number of small mistakes; they cannot always be pinned on one blameworthy individual. This approach starts from the position that humans do make mistakes and that errors are inevitable, but tries to change the environment in which people work, so that fewer mistakes will be made.

The systems approach does not, however, absolve individuals of their responsibilities. Rather, it suggests that we should not automatically assume that we should look for an individual to blame for an adverse outcome. The authors of *An Organisation with a Memory* acknowledged that clinical practice did differ from many hi-tech industries. The airline industry, for example, can place a number of hi-tech safeguards between danger and harm. This is often not possible in many fields of clinical practice, where the human elements are often the last and the most important defences. 'In surgery,' they wrote, 'very little lies between the scalpel and some untargeted nerve or blood vessel other than the skill and training of the surgeon.' We believe that this difference is key to understanding the nature of error in healthcare and why we have placed such great emphasis on case studies that show how doctors make mistakes in treating their patients.

The committee felt that the NHS had for too long taken a person-centred approach to the errors made by its employees and that this had stifled improvement. They called for a change in the culture of the NHS and a move away from what they saw as its blame culture. More than a decade has passed since the writing of the report and there has been little change in attitudes. A sea change is required. We want to see an NHS that promotes a safety culture, rather than a blame culture, a culture where there are multiple safeguards built into the system.

However, the legal system in which the medical services operate does not foster such an approach. Although coroners can now comment on the strengths and weaknesses of systems in the form of narrative verdicts, in general, the medical complaints and litigation process still tends to focus on the actions of individuals rather than the failings of the system. Perhaps the most glaring example of this person-centred approach can be seen in the way the General Medical Council treats medical practitioners, when they receive a

complaint. In that forum, doctors are expected to meet personal professional standards and will be held to account if they fall short of them in any way. Yet they may find themselves working in an environment that at times seems to conflict with those professional standards.

In Reason (2000) Professor James Reason (originator of the well known 'Swiss Cheese' explanation of how errors sometimes lead to damage) stated:

> The longstanding and widespread tradition of the person approach focuses on the unsafe acts – errors and procedural violations – of people at the sharp end: nurses, physicians, surgeons, anaesthetists, pharmacists, and the like. It views these unsafe acts as arising primarily from aberrant mental processes such as forgetfulness, inattention, poor motivation, carelessness, negligence, and recklessness. Naturally enough, the associated countermeasures are directed mainly at reducing unwanted variability in human behaviour. These methods include poster campaigns that appeal to people's sense of fear, writing another procedure (or adding to existing ones), disciplinary measures, threat of litigation, retraining, naming, blaming, and shaming. Followers of this approach tend to treat errors as moral issues, assuming that bad things happen to bad people – what psychologists have called the just world hypothesis.
>
> The basic premise in the system approach is that humans are fallible and errors are to be expected, even in the best organisations. Errors are seen as consequences rather than causes, having their origins not so much in the perversity of human nature as in 'upstream' systemic factors. These include recurrent error traps in the workplace and the organisational processes that give rise to them. Countermeasures are based on the assumption that though we cannot change the human condition, we can change the conditions under which humans work. A central idea is that of system defences. All hazardous technologies possess barriers and safeguards. When an adverse event occurs, the important issue is not who blundered, but how and why the defences failed. (Reproduced from J. Reason (2000) Human error: models and management, *BMJ* 320:768, with permission from BMJ Publishing Group Ltd.)

As authors, we believe that the Committee of *An Organisation with a Memory* were right when they wrote that many useful lessons can be learnt from the bitter experience of errors and litigation and that this can best be done by looking specialty by specialty at those areas of practice where errors are most frequently made. Thus, we have produced a book looking at errors in general practice. It will fit into a series of such books, each concentrating on a separate specialty.

If doctors are to learn lessons from their errors and litigation, then they must have some understanding of the underlying processes. Thus, in Part 1, Section 1 we discuss the key legal concepts and how they interact with medical practice. We will examine the document *An Organisation with a Memory*, published in 2000. This was the report of an expert group on learning from adverse events in the NHS that was chaired by the Chief Medical Officer. One

hospital negligence case was examined in some detail to identify how system failures contribute to personal error. We will look at that case briefly.

Most litigation cases in general practice concern failure to diagnose or delay in diagnosis or referral. In Part 1, Section 2, we will examine aspects that contribute to this. We will look at evidence about how general practitioners reach diagnoses, and evidence about where cognitive errors arise. We will suggest a simple six-step strategy for minimizing those risks.

In Part 1, Section 3, we will briefly examine how Bayesian reasoning can illuminate the process of clinical reasoning and where the errors are likely to occur. We will examine 'SnOUTs' and 'SpINs' and likelihood ratios (these will be explained later!).

In Part 1, Section 4, we will examine a potpourri of issues that lead to errors: problems with the history and examination, telephone consultations, communication problems, knowledge failures, the unexpectedly abnormal result, note-keeping, drug or prescribing errors and the issue of consent. We will flag up 'frequent fliers' in negligence cases and how to avoid them. Lastly, we will deal with the crucial aspect of 'safety netting'.

The heart of the book is in fact in Part 2. Here, we set out a number of case studies on common mistakes in general practice. Each case is drawn from real scenarios, anonymized to protect patient confidentiality and is supplemented with legal comment. Most cases concern failures to diagnose an illness, the commonest source of error in medical treatment and the commonest cause of litigation against general practitioners.

Finally, Part 3 provides a practical guide to the various forms of complaint that a general practitioner may encounter, how they may affect her and what she can do to protect her interests (gender pronouns will be used indiscriminately!).

Our aim is to provide a book that will go some way to meet the challenges laid down at the turn of the millennium in *An Organisation with a Memory*. We hope that it will reduce the number of clinical errors and improve the standard of care provided by individual general practitioners and practices throughout the country.

References and further reading

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PART 1

Section 1: The legal structure of negligence

A few words about error

If our aim is to reduce the number of clinical errors, then we must explain what we mean by 'error'. The Oxford English Dictionary defines 'an error' as a mistake. This is self-evident and does not really help us, the authors, to define our goal.

We could define our aim by looking at the end-result of errors and say that we want to prevent poor patient outcomes. That must be our primary concern, but our aim is broader; many mistakes can be rectified before any serious harm is done.

We could look at the seriousness of the error, how 'bad' the mistake actually was. Some errors could be so crass and the consequences so serious that they can be labelled 'criminal' by one and all and in fact some cases are investigated by the police and come before the criminal courts, as we shall see later. Other errors are the sort that only become obvious with the benefit of hindsight and could be made by anyone, even the best of doctors. In short, we want to look at all errors across the spectrum. What we hope to achieve is to raise the standard of care provided to patients, so that mistakes of all kinds are reduced.

But as soon as we mention error, the word negligence also springs to mind. The law has defined negligence in specific terms and not all errors will be considered negligent. But since the law looms large in any discussion of clinical error, we will now provide a brief explanation of what negligence in a legal context actually means and on how the compensation that we mentioned in our Introduction is calculated, when negligence occurs.

Medical negligence

If a doctor makes a mistake in the treatment of a patient, then he or in the case of a child, his family, may decide to pursue the doctor for compensation. Generally speaking, in order to win compensation, the family will have to prove that the doctor (or the collectively the practice, or Trust) were negligent.

Negligence

Before looking in detail at what is relevant to this book, medical negligence, we need to know the basics that lie behind what is called the tort of negligence

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(tort is simply the old French word for wrong; in modern legal terms, it forms a branch of legal study).

In principle, a person is liable in negligence if he breaches a duty owed to another in such a way as to cause damage to that person. What does this mean? In practical terms, in order to decide whether an act is negligent, a lawyer will break this formula down, looking at each of its constituent parts, phrase by phrase, word by word. For example, he will ask himself whether a duty of care exists between the injured person and the alleged defendant.

It may not always be clear whether a duty exists in a given set of circumstances, but as far as medical treatment is concerned, it is assumed that a doctor owes such a duty to his patient. The key questions in any medical negligence case are whether that duty to take care has been breached and then if it has, whether any damage has been caused as a result of that breach.

Has there been a breach of duty?

When the treatment of a patient comes under scrutiny in a potential negligence claim, the first question that will be asked is: was that treatment in accordance with the standards of a body of reasonable or responsible general practitioners? If it was, then the general practitioner will not have breached their duty of care; but if the treatment does not accord with the standards of a reasonable body of general practitioners, then they will have breached that duty.

This test was first formulated by the House of Lords in the case of *Bolam v Friern Hospital Management Committee* in 1957. Hence the *Bolam* test.

Over the years, a body of cases has built up that indicates how this *Bolam* test should be applied. How, for instance, should we look on a case, where in a given set of circumstances, one set of general practitioners may treat a patient in a certain fashion, while others would adopt a different approach? Answer: it is enshrined in case law that so long as both bodies of general practitioners are reasonable/responsible, then it would not matter which of the two approaches the doctor adopted. In other words, it is possible to have more than one correct approach to treatment.

But this begs the question: who determines whether you have breached your duty of care?

If a general practitioner has received a letter of claim from the solicitors representing the family concerning the treatment of a patient, this should indicate that the family have investigated the case and gone to medical experts who have written reports critical of the care provided. At first blush, there is a case for the doctor to answer.

In response, the defence organization of the general practitioner, or the lawyers for the Trust, will instruct experts to look at the allegations made against it. The experts will be asked to consider both breach of duty and causation. So in the first instance, the answer to the question is that the