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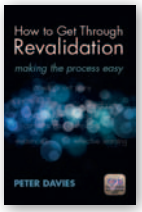

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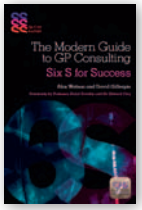

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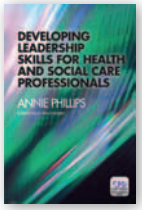

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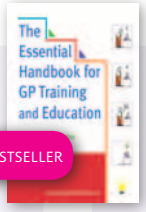

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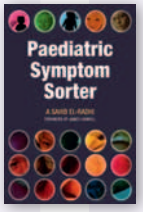

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Presents likely diagnoses, clinical pathways, tips and warnings for 97 symptoms common in childhood and will prove valuable to new and experienced clinicians alike.

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IN THIS ISSUE

NOVEMBER of last year saw the launch of a 670-page white paper setting out a "blue print" for an independent Scotland. This signalled the kick-off of what is promised to be an intense period of campaigning in the run-up to the September referendum. The implications of a Yes vote for the practice of medicine and dentistry in the UK are varied and complex.

How will healthcare professionals be regulated in an independent Scotland and what role would the current GMC/GDC retain if any? What about cross border working and medical and dental education and the current role of the royal colleges in setting standards? Would an independent Scotland continue to attract the same level of research funding? And what about current NHS pension arrangements?

It is fair to say the devolved healthcare system in Scotland has not so much diverged as held a steady course in contrast to the top-down radical shakeup that NHS England has seen over the last few years. But independence is, of course, a whole new ball game. One page 10 of this issue we put some of the issues to representatives on both sides in the debate.

On page 12 Allan Gaw tells the fascinating story of the thalidomide scandal and how medicine, the profit motive and even popular culture intersected in the playing out of this medical tragedy. It's also the story of how one woman's determination may have prevented even greater suffering.

Are dentists wise to treat friends and family members? Dental adviser Doug Hamilton looks at the risks on page 18 while Deborah Bowman considers the ethics of becoming involved in the personal lives of patients on page 9. Is it more a matter of discretion than uncompromising rules?

And on page 16 Professor Charles Warlow highlights some of the common pitfalls in the early diagnosis and management of stroke.

Jim Killgore, editor

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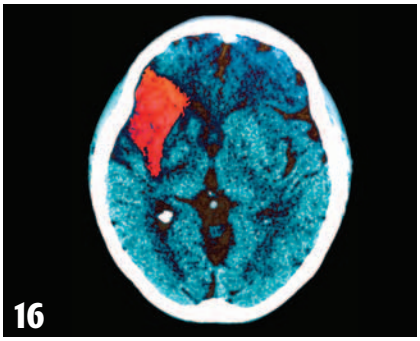
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Cover image: Untitled by Susie Wilson 1991. Medium: lithograph.

Susie's work is in the collection of the City Art Centre, Edinburgh Fine Art Library and Edinburgh College of Art.

Art in Healthcare (formerly Paintings in Hospitals Scotland) works with hospitals and healthcare communities across Scotland to encourage patients, visitors and staff to enjoy and engage with the visual arts. For more information visit www.artinhealthcare.org.uk, Scottish Charity No: SC 036222.
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MDDUS reminder on care.data

MDDUS is reminding GPs practising in England of their obligations to inform patients of the care.data programme that will be implemented this Spring.

Under the care.data programme, patient information will be gathered from various NHS providers and forwarded to the Health and Social Care Information Centre (HSCIC) where it will be used by healthcare commissioners to assess the safety and quality of local services. The information can also be used by NHS organisations to plan and design better services.

In October, NHS England moved to ease concern among GPs by announcing plans for a nationwide publicity campaign to raise awareness of the programme. Leaflets will be delivered to all 22 million households in England throughout January, explaining how care.data will operate. Patients will then have four weeks to tell their GP if they would like to opt out before the first data extraction occurs in March.

Concerns have been raised that public awareness of care.data is low and MDDUS reminds GPs that they remain under an obligation to take their own steps to inform patients that objections can be raised to prevent data extraction.

Guidance from the Information Commissioner's Office explains that, to avoid falling foul of the Data Protection Act, GPs must "actively" communicate information to their patients to ensure that "as far as practically possible" all patients are aware of their right to object.

NHS England has provided posters and leaflets to GP practices and has issued additional guidance that explains GPs' legal obligations to provide data to the HSCIC for the care.data programme. It also sets out measures that can be taken to achieve effective patient notification.

MDDUS would advise GPs to familiarise themselves with the ICO and NHS England guidance and to make use of the information posters and leaflets available. By doing so, we believe our members would be unlikely to find themselves in breach of the Data Protection Act or other rules relating to patient confidentiality.

Former BDA president joins board

THE Board of MDDUS is pleased to announce the appointment of Dr Amarjit Gill (above) as a new non-executive director. The former British Dental Association president will play an important role in strategic development and his appointment further strengthens the dental expertise available to the Union.

Professor Gordon Dickson, chief executive, said: "I am delighted that Amarjit Gill has joined the Board. He brings a wealth of experience that will contribute enormously to the Board's work as it continues to grow and develop the Union."

With more than 30 years' experience in the profession, Dr Gill is one of the most high profile and influential figures in the UK dental field. He was on the executive board of the BDA for 10 years, including a period as deputy chairman, before being elected BDA president in 2010.

Dr Gill qualified at the Royal Dental Hospital, University of London, in 1981 and has since developed an interest in aesthetic dentistry. He works in a successful practice in Nottingham focused on preventive and cosmetic dentistry.

He has lectured throughout the UK and abroad on various topics including the future of UK dentistry, practice management and periodontology. He has also chaired the National Dentistry Awards judging panel and has published numerous articles in the dental press.

Dr Gill said: "I am really pleased to join this extremely respected organisation, which exists to serve its members' best interests. It will be a pleasure to work with highly esteemed colleagues in directing the organisation's ambitions across the UK."

IN BRIEF

● **ENTRY CALL FOR BMJ AWARDS 2014** January 24 is the last day for entries to the 2014 BMJ Awards. MDDUS is proud to be headline sponsor of the awards which are now in their sixth year. For 2014 new categories have been added, there is an enhanced judging process and a strong focus on UK medical talent. Doctor-led teams in the UK can enter 13 categories, with cancer care, diabetes, gastroenterology and primary care among the specialties recognised. Visit **thebmjawards.bmj.com** for more information and to enter.

● **CAN MY DOCTOR BE MY FRIEND?** If you can trust your doctor with your life, can you be their Facebook friend? In a recent "Scrubbing Up" column on the *BBC Health* website, MDDUS medical adviser Dr Naeem Nazem looked at the ethical challenges facing doctors and the implications for the patient relationship when engaging through social media. Read the full article at **www.tinyurl.com/nkhbmcr**

Membership matters

Attention junior or training grade doctors

JUNIOR or training grade doctors will be aware that your membership includes up to £10,000 cover from work that is not otherwise indemnified by your NHS post.

With effect from your renewal date in 2014, this threshold will **not** include cover for the following:

- Primary care services, such as work as a GP, GP locum or GP out-of-hours sessions, with the exception of work done as part of a formal GP training programme.
- Obstetrics
- Spinal surgery
- Cosmetic surgery
- Botox and other non-permanent fillers
- Gynaecology
- Orthopaedic surgery
- Neurosurgery
- Forensic/police physician work (FME)
- Occupational health
- Non-NHS palliative/hospice work
- Pharmaceutical physician work
- Expert medico-legal report writing.

In addition, where a junior/training grade doctor (non-consultant) performs private practice treatment, we would normally expect such practice, for example a resident medical officer, to be performed under the direction of a senior colleague (such as a consultant) with overall responsibility for the patient's clinical care.

The £10,000 limit will continue to provide cover for all other aspects of work outside your NHS contract, including attendance at music and sporting events.

These changes will take effect from your next renewal date, but should you have any questions regarding this matter, please contact our Membership Team.

Private GP indemnity

Please note a separate subscription rate exists for those members working in a private GP capacity, where the GP may be seeing patients outwith an NHS setting, such as a private clinic or walk-in centre. Likewise, our standard GP and private GP rates no longer provide indemnity for cosmetic surgery procedures, with the exception of Botox and other non-permanent fillers. Members should contact Membership to discuss increasing cover to ensure adequate and appropriate indemnity is in place.

Forensic or police physician work

MDDUS recently revised the pricing structure for those members who perform forensic/police physician work. We have already contacted a number of members who we know are working within this specialty to advise of these changes, however if you perform forensic/police physician work and you have not heard from us in the past few weeks, then please contact Membership Services to check the level of cover you have is still sufficient for this type of practice.

This is particularly important for GPs, as in the past we have included cover for forensic/police physician work through the standard GP subscription rate, but depending on your exact circumstances, you may need to increase your membership cover to include these activities.

For questions on these or any other membership matters contact our Membership Team on 0845 270 2038 or email **membership@mddus.com**

■ *Stephen Kelly, Membership Services Manager*

Online video modules mitigate risk

FOUR new online video modules have been launched by the Risk Management Team at MDDUS, offering advice and guidance on some common medico-legal risk areas in general practice.

These resources are among the first to go live as part of a new online risk management service at MDDUS being developed to help doctors, dentists and their wider healthcare teams manage and mitigate business and clinical risk. The new service is exclusive to MDDUS members and builds upon our long history of helping doctors, dentists, practice managers and their teams improve the quality of processes, people and patient service.

Each video is led by one of our experienced MDDUS risk advisers and is accompanied by a relevant risk checklist to help teams work towards building a safer practice. The topics are:

- Maintaining the integrity of your prescribing record
- Managing confidentiality in a practice setting
- Managing test results
- Risk Tools – process mapping.

More video modules will be available soon along with pod casts, blogs and other resources on a variety of risk management topics. To access the videos go to the Risk Management page at **www.mddus.com**

● **CAUTION SWITCHING ANTIEPILEPTIC DRUGS** Prescribers treating patients with oral antiepileptic drugs (AEDs) are being urged to consider carefully any decision to switch between different manufacturers' products for a particular drug. This advice comes in the November MHRA drug safety update. Concerns regard the narrow therapeutic index of some of the drugs and the potentially serious consequences of therapeutic failure. Access the MHRA alert at **www.tinyurl.com/qjrrhez**

● **DENTAL SUBS FOR DIRECT ACCESS** Dental hygienists and therapists will be aware that from May of this year they can see patients without a prescription and without the patient having to see a dentist first (direct access). A supplement to the standard subscription rate will now apply for direct access, varying between £15 - £60 depending on your exact circumstances. Contact MDDUS Membership Services for further details at 0845 270 2038.

Bullying a significant concern among medical trainees

OVER one in 10 trainee doctors report being bullied in the workplace according to the 2013 annual national training survey conducted by the GMC.

In the survey of 54,000 doctors in training in the UK, 13.2 per cent of respondents said that they had been victims of bullying and harassment in their posts and 19.5 per cent had witnessed someone else being bullied.

Over a quarter of respondents (26.5 per cent) also experienced "undermining behaviour" from a senior colleague with doctors in obstetrics and gynaecology most affected. Doctors in years four to seven of specialty training were more likely to report undermining than those in foundation or core training.

In its report on the findings the GMC reiterates that undermining or bullying behaviour is in total contradiction with its values regarding respect for colleagues as set out in *Good Medical Practice*. "It is more than a simple failure to comply. Serious or persistent failure to follow our guidance puts a doctor's registration at risk."

The *National training survey 2013* also found that 2,746 survey respondents (5.2 per cent) raised a concern about patient safety. Doctors near the start of their training are much more likely to raise concerns than those in the later stages: 8.7 per cent in the first year of foundation training (F1) versus 2.8 per cent in year eight of specialty training (ST8).

Commenting on the results, Niall Dickson, Chief Executive of the GMC, said:

"These findings highlight the importance of listening to young doctors working on the frontline of clinical care. They support what Robert Francis said - that doctors in training are invaluable eyes and ears for what is happening at the frontline of patient care.

"They also suggest that more needs to be done to support these doctors and to build the positive supportive culture that is so essential to patient safety. The best care is always given by professionals who are supported and encouraged."

GPs "under pressure" for oral health advice

A SURVEY of over 1,000 GPs across the UK has found that 87 per cent believe that too many patients are turning to them for oral health advice instead of a dentist and this is putting unnecessary pressure on their practices.

The poll was commissioned by the Association of Dental Groups (ADG) to coincide with Mouth Cancer Action Month last November. It also revealed that 96 per cent of GPs think more should be done to encourage patients to go to their dentist rather than their GP for mouth-related health issues. The ADG believes dentists are best placed to spot oral problems – including mouth cancer.

David Worskett, chair of the ADG, said: "People often think that dentists focus purely on teeth and gums, but actually they are specialists in most aspects of oral health and we often find GPs refer patients back to their dentist if there is any treatment required."

Radical reform needed in emergency care

A FUNDAMENTAL shift is needed in the provision of "urgent care" services in the NHS to reduce the strain on A&E centres, according to a first phase review published by the National Medical Director of NHS England.

Sir Bruce Keogh says the current system is under "intense, growing and unsustainable pressure" driven by rising demand from a population that is getting older and faced with a confusing and inconsistent array of services outside hospital. He advocates a system-wide transformation over the next three to five years.

The report highlights that 40 per cent of A&E patients are discharged requiring no treatment and that up to one million emergency admissions were avoidable last year, and up to 50 per cent of 999 calls could be managed at the scene. In the treatment of the UK's two biggest killers – heart attacks and strokes – it has been demonstrated that survival rates are improved significantly by taking patients to specialist centres that provide the best available hospital care.

The report makes proposals in five key

IN BRIEF

● **EU REFORM ON CROSS-BORDER CLINICIANS** An alert system will be introduced across Europe requiring health regulators to warn each other within three days when a doctor or other health professional has been removed from a medical or dental register or had restrictions placed on his or her practice. The system is part of a new agreement made by EU ministers that doctors, nurses and other health professionals moving among EU nations will have to meet new patient safety requirements.

● **NEW TOOLKIT TO RELIEVE REGISTRAR WORKLOAD** A new toolkit has been launched that aims to relieve the pressure on overworked medical registrars. The Royal College of Physicians' *The medical registrar on call* promises to help trainees improve their workload, training opportunities and supervision. Access at **www. tinyurl.com/ow3nzjt**

areas. These include providing better support for people to self-care, thus avoiding the need to see a doctor and also helping people with urgent care needs to get the right advice and ongoing support via the NHS 111 service.

The report also calls for "highly responsive urgent care services outside of hospital so people no longer choose to queue in A&E". This would mean "consistent same-day, every-day access" to primary care and community services and developing the 999 ambulance service into a mobile urgent treatment service capable of treating more patients at the scene to avoid the need for hospital.

In dealing with patients with serious or life-threatening emergencies it calls for the development of two types of hospital emergency departments: emergency centres and major emergency centres. Emergency centres will be capable of assessing and initiating treatment for all patients and safely transferring them when necessary. Major emergency centres will be much larger units, capable of not just assessing and initiating treatment for all patients but providing a range of highly specialist services. The NHS envisages around 40-70 major emergency centres across the country.

The Royal College of Emergency Medicine welcomed the review but pointed out that it is very much future focussed, saying "the crisis is here with us now".

"Over the past decade many efforts have been made to find solutions to try and provide alternative services to help patients whose conditions could be treated outside of the Emergency Department. Our experience is that most of these have been unsuccessful. Almost all were implemented without effective testing or piloting."

The College has published its own "pragmatic solutions, deliverable in a short time scale." To access these go to the RCEM website or **www.tinyurl.com/lh3jqht.**

Call for clarification on direct access

FURTHER clarification is needed from the GDC on the new arrangements for direct access to dental care professionals, according to a group of dental stakeholders who recently met at the BDA.

"Gaps remain in dental professionals' understanding of the complexities surrounding direct access", said the group in a statement.

Members include the British Association of Dental Nurses, the British Association of Dental Therapists, the British Association of Clinical Dental Technology, the British Dental Association, the British Society of Dental Hygiene and Therapy and the Faculty of General Dental Practice.

Among the areas they believe still require further guidance are:

- NHS regulations and the variations in legislation between the devolved nations
- prescribing and reporting on radiographs
- consent and referrals within the dental team to ensure efficient and safe care for patients.

Many of the stakeholders reported uncertainty about how the new arrangements can be implemented efficiently, with patients fully understanding the different roles among dental professionals. The members agreed to work together in future to resolve these uncertainties.

Doctors may face criminal charges for neglect

DOCTORS accused of "wilful neglect" in the care of patients in England and Wales could face criminal charges, according to proposals set out in the Government's recent full response to the Francis inquiry.

The offence would be modelled on one punishable by up to five years in prison under the Mental Capacity Act. A consultation on what scale of sentence should be applied to the extended law will be carried out over the next few months.

The recommendation stems from a report on patient safety led by Professor Don Berwick, commissioned by the Government in response to the Francis inquiry. It called for new criminal offences to be created for "recklessness or wilful neglect or mistreatment by organisations or individuals and for healthcare organisations which withhold or obstruct relevant information". But the report emphasised that the use of such sanctions should be extremely rare and unintended errors must not be criminalised.

Both the RCGP and the BMA are not supportive of the proposal. Dr Mark Porter, Chair of BMA Council, said: "While extending wilful neglect as a criminal offence may go some way towards reassuring the public, it is unlikely to bring around the change in culture we need, and how this will work in practice is something that we will continue to discuss with the Government as there are already criminal sanctions in place in order to hold healthcare workers, including doctors, to account."

● **UPDATED SCOPE OF PRACTICE GUIDANCE NOW ONLINE** Recent changes reflecting the new direct access agreement for dental care professionals have been incorporated in the GDC's revised *Scope of Practice* guidance which is now available to download. The guidance reminds registrants that they must only undertake a task or type of treatment or make decisions about a patient's care if they are sure they have the necessary skills and are appropriately trained and indemnified.

● **COMPLAINTS HIGHER THAN REPORTED** Complaints against NHS doctors and dentists in Scotland increased by 36 per cent last year, according to revised government figures. The original report from information unit ISD Scotland in September indicated complaints had dropped by 15 per cent between 2011/12 and 2012/13. However, these figures were later found to be inaccurate and the result of a "formula error".

INCIDENTALLY SPEAKING

Liz Price

CONSIDER THE SCENARIO. You have just become aware that one of your consultant colleagues has missed a patient's significant result. He is on annual leave so you will take action – but should you report this as a critical incident?

Patient safety relies on individuals, teams and organisations reporting human errors and system defects so that, where possible, adverse events can be prevented and lessons can be learned.

Recent events exposing poor NHS patient safety practice and tolerance of "bad behaviours" have highlighted the importance of both incident reporting and of senior staff acting appropriately on these reports.

Indeed, in September 2013 NHS Scotland launched its national framework document *Learning from adverse events through reporting and review*. It is likely that other NHS organisations (large and small) will also be expected to show they have reporting systems in place, that incidents are analysed to improve learning and that leaders prioritise the resources required to make changes and provide patient safety training.

The problem

Although many organisations already have incident reporting strategies in place, research suggests only five to 30 per cent of incidents are reported. This is attributed to various factors[1].

First, at an organisational level, there is often a lack of universal understanding of what constitutes a "reportable incident". Such understanding is largely dependent on how well the system has been introduced across the organisation.

Alongside this, a lack of understanding about what an effective incident reporting system can achieve may discourage reporting. This is often linked to poor feedback about action taken as a result of an individual's reporting – or where managers or organisations have not acted to change defective systems or support improvement in practice.

Lack of time is another factor. At an organisational level, this could be due to unwieldy, time-consuming or bureaucratic reporting systems. At a team level, it could be a result of heavy workload or a lack of concern for reporting from managers or clinical leads.

Individuals may be reluctant to report for fear of punitive action or in case an incident exposes them to personal liability. This is often related to negative experiences of performance management or the perception of a "blame culture" within the team or organisation.

There also appears to be a general reluctance to report incidents involving doctors. This may be due to junior doctors' concerns about career progression or, for non-clinical staff, founded in a traditional view of doctor status.

The solution

For organisations, there are a number of elements that can improve reporting.

Evidence shows that publishing lists of specific adverse events can improve reporting by 40-60 per cent. Such lists could include acute/repeat medication errors, infection, computer coding, workflow of results, team communication failure, missed results and so on. Providing training in reporting systems can increase reporting further while also allowing for reinforcement of fair performance management policies and practice. This can encourage individuals to report and also open discussions on how analysis and actions taken as a result of reporting will support individuals and focus on system change and training as key results.

Further, simplifying systems can promote reporting. This could include the introduction of drop-down lists for commonly occurring categories, sacrificing detail for speed of notification and the use of a simple severity scale in incident notification (e.g. 0-3 = no injury – serious breach/injury).

It is important to consider who is responsible for receiving and analysing incident reports, how easy it is for them to identify and analyse any trends, and the mechanisms and timescales by which action is taken. This action should include feedback to reporters, system change if required, and communication and training to staff where necessary. Analysis of reporting should consider whether some professional groups or departments report more than others and, if so, why?

One good measure of the effectiveness of reporting systems is that around 70 per cent of reports comprise near misses/no harm events, which can be considered "free safety lessons"[2]. In our significant result example mentioned above, you could simply decide to action the result and feel reassured that patient harm has been avoided – "you are a team after all". You may also choose to note the incident and flag it discreetly with your colleague when he returns from leave. Both of these courses of action support patient safety, however the fact that the incident has not been reported could in some cases conceal a wider problem of stress, overwork or clinical underperformance.

To support a culture of comfortable reporting, organisations should emphasise the importance of raising and acting on patient safety concerns. Requirements for doctors are clearly set out by the GMC in its guidance *Raising and acting on concerns about patient safety*, but senior teams need to reinforce this by making patient safety a clear strategic and operational priority. In larger organisations, senior staff walkrounds can be effective in signalling concern as well as a willingness to listen and act on patient safety concerns. Advice about how to carry these out effectively is available on the Patient Safety First website.

Incorporating some of the elements above into system design, implementation or improvement should result in a measurable change in reporting behaviour, and a corresponding improvement in patient safety.

To create or review your own incident reporting system, visit the risk management section of **www.mddus.com** where you will find our Incident Reporting System checklist. Other online tools and learning opportunities will be available soon.

■ *Liz Price is a senior risk adviser at MDDUS*

Notes

1 *Risk management in healthcare institutions*. Kavaler & Alexander (2012)
2 *Implementing human factors in healthcare: a how to guide*. Patient Safety First (2010)

GETTING PERSONAL

Deborah Bowman

WHEN I WAS AN UNDERGRADUATE I became seriously ill. During that most difficult of times, a GP gave me her home telephone number. At the time, I was touched by her kindness, but thought little of the scrap of paper that she handed me as I left the surgery, saying "call any time". In the 25 years that have passed I have often thought of that doctor and what she did when she offered her personal number to a frightened young woman.

Yet, despite the frequency with which I have returned to that encounter, I remain unsure about what I think. Indeed, I have two distinct and perhaps contradictory responses to how she acted. The rational and academic side of me worries about her decision to give me her home telephone number. In so doing, she indubitably crossed a boundary. She treated me differently from other patients (unless, of course, she was in the habit of inviting all her patients to call her at home whenever they wished – which I doubt). She opened up her private life to someone whose vulnerability might have led to an unhealthy dependence and even damage were she unable to meet my expectations.

This GP might have distorted the ways in which I perceived doctors and their availability to me. Her actions could have created splits within the broader clinical team charged with my care. I worry too about the implications for the doctor herself. By inviting patients into her private life, she ceased to have the time we all need to regroup and relax. In blurring boundaries and compromising her time away from being a doctor, I worry that she may have made herself vulnerable to burnout.

But there is another part of me that has a quite different response. On a human level, I am awed by her compassion, her commitment and the meaning that she gave to the term "care". I was scared and she reached out to me in a way that was transformative. With that small expression of kindness, that GP ensured I felt that I mattered and that I could cope with what was to come, whatever that might be. And, it was significant that I had her support when I needed it and that it wasn't confined to surgery hours and limited by my ability to get past the switchboard. I believed, and continue to believe, that I had been fortunate to meet a doctor who was remarkable in her altruism and unselfishness.

> "Boundaries make resilience possible and resilience makes continued clinical practice possible"

Professional boundaries have received increasing attention, both in healthcare education and clinical practice. The arguments in support of boundaries are well-rehearsed and I find them persuasive. Boundaries reflect the distinct nature of the healthcare relationship and facilitate safe practice for both professional and patient. Clinicians do not respond to their patients as they would a friend and that is important for both parties. For let us not deceive ourselves, boundaries serve the professional as much as the patient: managing expectations and containing difficult emotions within the structure of the consultation. Boundaries make resilience possible and resilience makes continued clinical practice possible.

For me, the negotiation of boundaries is an integral part of the ethical interpretation of professional discretion. Of course, there are some circumstances that constitute an unequivocal boundary violation, for example, financial exploitation of, or a sexual relationship with, a patient. However, most clinicians never come close to such behaviour, but they are required to navigate the complex subtleties of professional boundaries every day as they choose what to disclose about themselves, whether to accept a gift or how to respond to an invitation to a social event.

At the risk of sounding like a stereotypically compromising ethicist, I believe that whilst blanket bans or uncompromising rules may be convenient, they do not capture the essence of what it means to negotiate boundaries in clinical practice. To be professional is to have to use one's judgement and to exercise discretion. Doing so in relation to boundaries is difficult, but necessary.

So, did I ever call that GP's home number? I confess that I did. I remember vividly receiving a letter in the second post which prompted me to call the surgery to discuss its implications. The doctor was, I was told, on leave. I hesitated for several hours, but eventually yielded to the impulse and retrieved that scrap of paper. The phone was answered by a hassled-sounding man whom I guessed was her partner. In the background, I could hear young children playing. I realised immediately what an intrusion my call was into her family life. When she came to the phone, I apologised profusely for the imposition and she, with characteristic generosity, gently reassured me and encouraged me to talk to her about my distress.

For that, I will always be grateful.

■ ***Deborah Bowman is Professor of Bioethics, Clinical Ethics and Medical Law at St George's, University of London***

An independent Scotland?

Yes

By Dr Ian McKee on behalf of the Yes campaign

WHEN forecasting how the health service will develop in an independent Scotland there is an important caveat. The vote in September's referendum will determine solely whether Scotland becomes an independent country – how the country develops thereafter will depend on the political nature of the government which will be elected two years later.

However, there are some useful clues. Since the responsibility for health was devolved in 1999, significant differences have emerged between the way that the NHS is run on different sides of the border. In England and Wales the patient is seen as a customer and health providers are encouraged to compete with each other for business. Within the last year there has been a huge expansion in the role of the private sector in healthcare and this is likely to continue.

In Scotland, on the other hand, patients are regarded more as partners. After all, as taxpayers they do own the service. Instead of competition the emphasis here is much more on collaboration – not only with fellow clinicians but also with the health department. The general view in Scotland seems to be that the time, effort and legal expenses incurred by would-be providers fighting each other would be far better spent directly on patient care. More recently the aim of a service free to all at time of need has been expanded to include free prescriptions. Unless the first government of an independent Scotland is unexpectedly right wing it seems reasonable to argue that these trends will continue.

The No campaign might argue that as this has all happened under devolution, there is no need for independence to develop further a health service sensitive to the particular needs of Scotland. This stance ignores two important points. The first is that the level of allocation of funds to Scotland under the Barnett Formula is under sustained attack from Westminster. It is a fair assumption that nothing has been done until now to alter this allocation because of the coming referendum. If there isn't a Yes vote this reason will disappear and Scotland will face a large net reduction in income in coming years.

> "It is just possible that a central regulatory body might promulgate a policy that is not suited to the needs of Scotland..."

The second is that the Barnett Formula, or its successor, distributes funding according to public expenditure. As England massively increases funding for health and education from private sources, including patient charges and university tuition fees, the amount of public expenditure correspondingly decreases and with it Scotland's share. Whether we like it or not we will be faced with the choice of having either a grossly under-funded health service or one in which rationing, patient charges and private healthcare rapidly come to the fore unless we take our future in our own hands and vote Yes next September.

In an independent Scotland doctors and dentists will be part of a health service in which professionals are expected to work together rather than against each other in competing provider units. This is far more rewarding and involves much less bureaucracy. Under European freedom of movement legislation doctors are free to cross borders and practise elsewhere so it would be foolish of any Scottish government to create working conditions which encouraged large scale medical emigration to England or elsewhere. There will always be scope for private practice for those who wish it but the driver must not be a failing public service. Both the GP and consultant contracts need to be altered to allow for the rural nature of much of Scotland and the health inequalities in our main cities. One size certainly does not fit all.

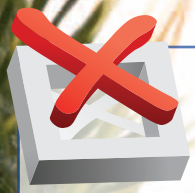
Institutions such as the Scottish Medicines Consortium and NICE already work amicably together and there is no reason why this level of co-operation should not continue and develop between these and other regulatory and professional bodies after independence. Of course it is just possible that a central regulatory body might promulgate a policy that is not suited to the needs of Scotland and in this case an independent Scottish Government is an additional safeguard.

■ ***Dr Ian McKee is a former Member of the Scottish Parliament for the Lothians region. He was a partner in an Edinburgh medical practice and served in the RAF as a medical officer***

Two opposing views on the health and social benefits of Scottish independence

IN November of 2013 the Scottish Government published its 670-page white paper setting out the case for an independent Scotland and kicking off what promises to be a bruising campaign in the run-up to the referendum in September of this year.

***Summons* asked the opposing camps in the debate to offer views on the implications of Scottish independence for health and social care. We posed three basic questions. Why would the health service be better (or not) under independence? Why should doctors and dentists vote for or against independence? What about cross-border working and professional regulation in an independent Scotland? Here are the replies.**



NO

Dr Susan Bowie on behalf of Better Together

IT IS now under 9 months until we will make the biggest political decision of our lives: whether to remain a part of the UK or whether to go it alone. The question isn't whether Scotland could be an independent country; it is a question about what is best for us, our colleagues, friends, our families and mostly our patients, the poor and the vulnerable.

In Scotland today we have the best of both worlds – a successful Scottish Parliament with full powers over our schools and our own NHS. We also have the strength and security that comes with being a part of something bigger.

As a doctor, I am really proud to be both part of and a product of the NHS. I was born only because of it, trained by it, worked for it for 35 years and have been saved by it. I take great exception to anyone or anything that might jeopardise it.

Although the NHS is a uniquely British institution, treasured by people across our islands, right from the start the NHS in Scotland has tailored its care to local needs. The year 2012 marked the centenary of the publication of the Report of the Highlands and Islands Medical Service Committee or the Dewar Report. The report presented a vivid description of the social landscape of the time and highlighted the desperate state of medical provision to the rural population in the Highlands and islands. The report recommended setting up a new, centrally planned provision of care that within 20 years transformed medical services to the area and this acted as a working blueprint for the NHS in Scotland.

Indeed, the fact that Scotland has been able to make some radically different choices from England regarding healthcare has shown the great strength of diversity within the Union and devolution process. But being a part of a Union means we also have access to world class centres of excellence across the UK should we need them. When a patient from Aberdeen travels to the world-leading Freeman Hospital in Newcastle they receive the same quality care that they would if from Aberystwyth. In training we also have the best of all worlds – the flexibility to train anywhere from inner city London to rural Stornoway. What would happen to this mobility and flexibility in a separate Scotland?

> "Our NHS currently doesn't recognise borders but separation could put that at risk"

What would independence mean for doctors in training? How would leaving the UK affect our relationship with the BMA, the GMC and our defence unions? At this stage with 9 months to go, does anyone really know?

Our NHS currently doesn't recognise borders but separation could put that at risk. We would be replacing a straightforward, internal relationship with an international, cross-border one. Being part of a larger UK allows us to pool and share our resources for the benefit of all.

Pensions too are an example of where being part of the UK benefits us all. Right now, across the UK, we pay into the state pension and we all benefit on retirement. Given Scotland's population is ageing faster than the rest of the UK, it makes much more sense to spread the costs associated with caring for an increasing elderly population across 60 million people rather than 5 million.

One of my biggest worries and that of colleagues I've spoken to is what will happen to our NHS pensions under independence. Having done all those years on-call I was pretty secure in the knowledge of a very decent NHS pension (even with the proposed changes). However, no one at this late stage can make any promises about what will happen to my pension in a separate Scotland – what I will be paid or even in what currency.

To vote for independence with all the uncertainty that brings would be a leap in the dark. Even after reading the Nationalist White Paper, I find there are just too many unanswered questions regarding health and social care. Today Scotland has the best of both worlds. Why put that at risk?

■ ***Susan Bowie is a GP in Shetland with 35 years' experience working in the NHS***

Saving Marilyn

Allan Gaw recounts a cautionary tale of how commercial considerations in drug development can sometimes trump patient safety

ON August 5, 1962, Marilyn Monroe was found dead in the bedroom of her home in Los Angeles. While considerable controversy surrounds her death, what is not in question is that she died from barbiturate poisoning. Barbiturates had been widely used for over a century in sedatives and sleeping tablets, but their toxicity in overdose was always a serious problem. Efforts to develop safer, but still effective, sedatives had yet to yield tangible results though the major pharmaceutical companies recognised that any such product would offer a huge commercial advantage.

A drug that seemed to fit this bill was developed by the German company Chemie Grünenthal in the 1950s. Originally developed as an anticonvulsant, its sedative properties were quickly identified, and the apparent safety of the drug was striking. Company scientists found that there was practically no dose lethal to rats.

The drug in question was thalidomide, and it was launched in West Germany as Contergan in October 1957 as an over-the-counter sedative. More than 40 other countries followed, including the UK where thalidomide was launched in April 1958 as Distaval. As the drug also reduced nausea it became a popular sleeping tablet amongst pregnant women suffering from morning sickness.

The first thalidomide victim is thought to have been born in December 1956, before the drug was mass marketed. The child's father was a Grünenthal employee who received advance samples of the sedative, which he gave to his pregnant wife. However, it would be another five years before the link between the deformities and the drug would be made.

An easy one to start

In September 1960, the new drug application for thalidomide landed on Frances Kelsey's desk in Washington DC. Kelsey was a physician and pharmacologist, who had just been appointed as a medical officer and reviewer of new drug applications at the US Food and Drug Administration (FDA). She later recalled: "They gave it to me because they thought it would be an easy one to start on. As it turned out, it wasn't all that easy".

The American drug company Richardson-Merrell had licensed the drug from Grünenthal and was poised to flood the American market once they had dealt with the formalities of the FDA. However, Kelsey, with her rigorous training in pharmacology and meticulous attention to detail, did not view her role as a formality and Merrell's application, which was weak and shoddily put together, failed to impress.

Kelsey responded to Merrell for the first time on November 10, 1960, stating that their application was incomplete. At the time, the FDA had 60 days in order to process a new drug application, and a pharmaceutical company could go ahead with marketing their product if they heard nothing by this deadline. However, the deadline did not apply if the application was deemed by the FDA to be incomplete. On day 58 Kelsey threw out the application, presenting Merrell with their first rejection in a battle that would go on between them for 18 months.

During this time Merrell visited, phoned and wrote regularly trying to influence Kelsey. Their superficial civility wore off fast and she was accused by company officials of stubbornness and simply avoiding making a decision, among other things. Kelsey later told a *Life* magazine reporter: "Many of the things they called me you couldn't print".

Big gun

At one of these many meetings, Merrell brought a hired gun. On September 7, 1961, in her spartan office in the rather ramshackle headquarters of the FDA, Kelsey met with three visitors—two company officials from Merrell and a third man, Dr Louis Lasagna from Johns Hopkins. Lasagna was a respected physician-scientist, an outspoken advocate of controlled clinical trials and evidence-based medicine, and he had recently given evidence against the pharmaceutical industry at hearings in Washington DC. In this context, Lasagna's seat on the corporate side of the table at that meeting might appear puzzling.

As it turns out, Lasagna had conducted one of the few clinical trials investigating thalidomide, and Merrell had enlisted him as a paid expert to help argue their case in front of the 'stubborn' Kelsey. In 1960, he published a randomised placebo-controlled sleep study evaluating different doses of thalidomide. His study was part funded by Merrell, who also supplied the thalidomide he used.

Whatever Lasagna said at the meeting, it made no difference and Kelsey stood firm. Three months later her concerns unfortunately proved to be justified as increased numbers of babies with a range of abnormalities were born in West Germany and in other countries where thalidomide had been sold. A striking feature of these abnormalities was phocomelia, which literally means seal extremities. These children had been born without the proper development of the long bones in their limbs, often giving their arms and/or legs a flipper-like appearance. Sylvia Plath in her poem *Thalidomide* described this succinctly as 'knuckles at shoulder-blades'.

As publications appeared linking the upsurge in these birth defects with thalidomide use in the first trimester of pregnancy, Grünenthal were forced to withdraw thalidomide from the European market on November 27, 1961. In the US, however, Merrell continued to badger Kelsey with claims that there was no proof of a link.

As the evidence grew and the full horror of the tragedy unfolded, Merrell quietly withdrew the new drug application in March 1962.

Frenzied public response

Four months later, the media circus around Kelsey began with an article above the fold on the front page of the *Washington Post*. This piece, carrying a prominent photo of Kelsey, declared her the "Heroine of FDA". The article, which elevated Kelsey to virtual civic sainthood, was engineered by advocates of drug regulatory reform—an astute political move that served to raise the temperature of the debate and to create a public appetite for change. Now events shifted gear.

Momentum growing, the following month there was a call in Congress for Kelsey to be honoured, and remarkably this was realised in less than a week, when President John F. Kennedy presented Kelsey with the Distinguished Federal Civilian Service Medal at a highly publicised White House ceremony on August 7, 1962, 48 hours after Marilyn was found dead.

The spotlight was now on thalidomide, the FDA and everyone concerned. Thousands of column inches were filled with analysis and interviews but not everyone was optimistic about the proposal of tougher new pharmaceutical regulation.

With the prospect of greater control often comes outrage from those who will be controlled. John Osmundsen reported on the front page of the *New York Times* that "many medical authorities" in the US were "concerned that what some call the 'frenzied public response to the thalidomide episode' may adversely affect the nation's drug laws". Their concerns stemmed from the greater controls and accountabilities that they could

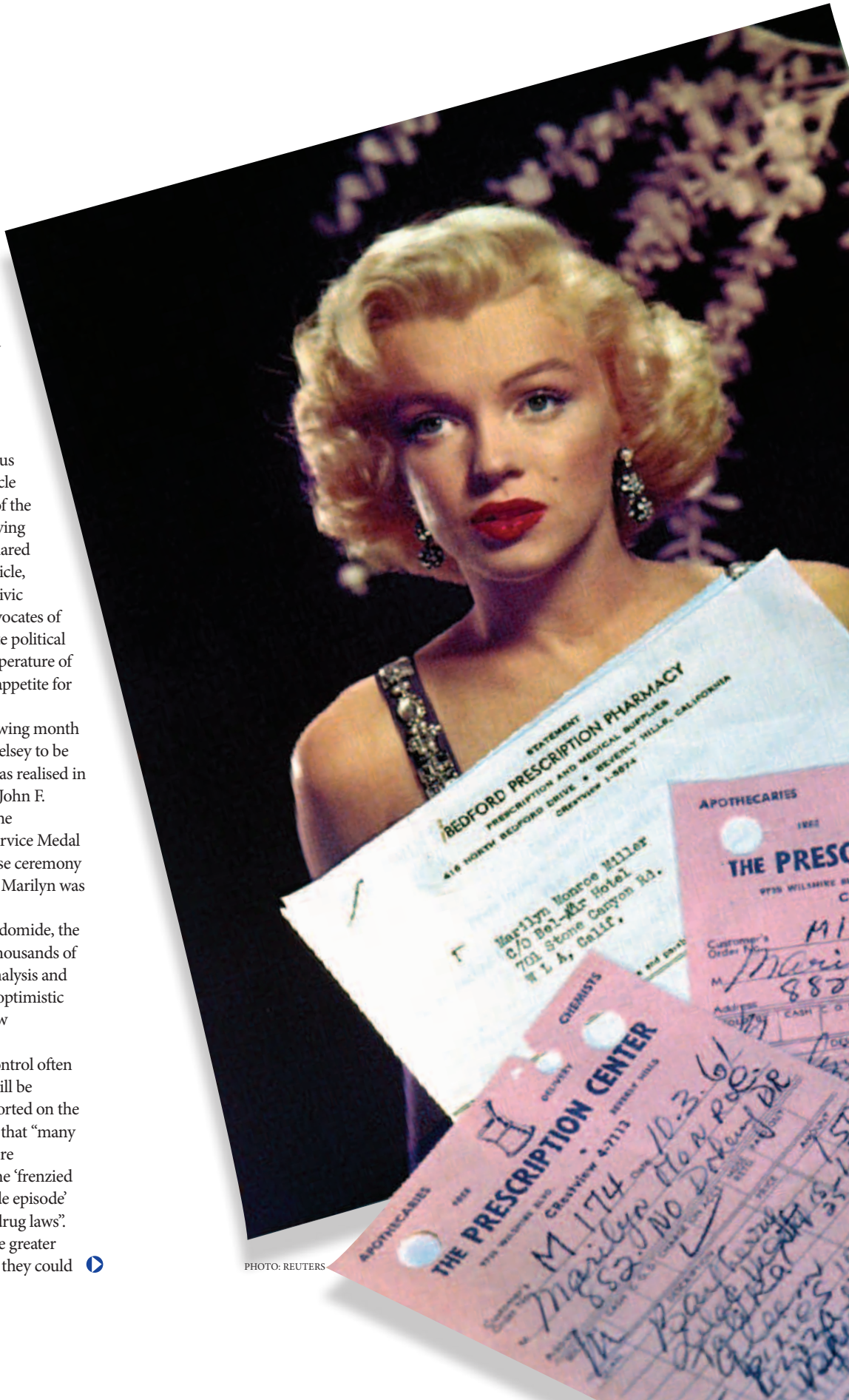


PHOTO: REUTERS

"There is something absurdly crass about linking Marilyn's, albeit manufactured, beauty with the monstrosity of thalidomide's effects"

foresee in the forthcoming legislation.

The only one of these concerned scientists to be named in the piece was Louis Lasagna who offered "a way out". He is quoted as calling for "academicians and industrial scientists...to serve in advisory capacities to help draft sensible provisions to safeguard the American people".

Thalidomide "too valuable"

Perhaps Lasagna had himself in mind for this role, together with his "industrial scientist" colleagues at Merrell, for he went on to argue that "thalidomide is too valuable a drug to lose. It is the safest sedative yet discovered; it will not kill animals or humans even in heavy overdoses". That Lasagna should still be rooting for thalidomide in August 1962, when reports of several thousand birth defects in Europe had already been received, is difficult to understand and perhaps betrays either a lack of judgement or a too cosy relationship with his industrial sponsors.

He went on to defend his position by linking the thalidomide tragedy with the other headline of the hour—Monroe's premature death. Osmundsen reports: "Lasagna observed that, if Marilyn Monroe's physician had been able to prescribe thalidomide instead of barbiturates, the movie star might be alive today".

Lasagna's claim is undoubtedly true, for in overdose thalidomide is a much safer drug than the Nembutal taken by Marilyn. But Lasagna failed to appreciate, or perhaps just failed to acknowledge, the likely outcome if thalidomide had been available on prescription (or even over-the-counter, as Merrell had wished) in 1960s America. The United States at the time was a much more medicated population than the UK or Germany, with a considerably larger population than both countries combined. The numbers of thalidomide-associated birth defects would likely have been proportionately greater in the US than elsewhere and would certainly have run into the tens of thousands.

What if...?

Yes, Marilyn may have been saved, she may have completed *Something's Got to Give*, her final doomed movie, and, who knows, even gone on to live long enough to receive her honorary Oscar one day, but the associated

PHOTO: DR P. MARAZZI/SCIENCE PHOTO LIBRARY

costs would have been enormous. Marilyn would not have been the only victim of barbiturate poisoning saved by the availability of a "safer" alternative. In New York City alone, between 1957-63 there were over 1,100 deaths due to barbiturate overdose. But those were not the lives Lasagna chose to balance against the use of thalidomide. It was Marilyn's, the screen goddess, whose death at the age of 36 had made the front page of every newspaper and magazine in America only three weeks before.

The symbolism of his statement was powerful, and the counterfactual it presented was tempting. What if thalidomide had been prescribed instead of Nembutal, would Marilyn still be smiling her perfect inviting smile in Technicolor; would the fantasy still be alive? There is something absurdly crass about linking Marilyn's, albeit manufactured, beauty with the monstrosity of thalidomide's effects and Lasagna's use of this imagery seems insensitive and misplaced.

Lasagna was, however, right when he predicted that thalidomide was "too valuable a drug to lose" but not, as he thought, because it was a useful sedative. In 1998, the FDA approved the drug for the treatment of erythema nodosum leprosum, a severe and debilitating complication of leprosy. Although thalidomide offered some benefit to patients with this condition it still possessed its teratogenic effects and the FDA took the unprecedented step of tightly controlling the drug's marketing and insisting on a robust patient education programme, the maintenance of a patient registry and even mandatory pregnancy testing for sexually active women of childbearing age.

At the age of 80, Frances Kelsey, still working for the FDA, served on their Working Group to develop and implement uniform standards of safety for clinical studies using thalidomide. Her experience with the drug was, understandably, seen as a great advantage. While she was acutely aware of the potential benefits that thalidomide may offer certain patient groups, Kelsey remained

PHOTO: OMIKRON/SCIENCE PHOTO LIBRARY

Above: child with thalidomide-associated birth defects. Below: Frances Kelsey receiving award from President Kennedy.

PHOTO: NATIONAL LIBRARY OF MEDICINE/SCIENCE PHOTO LIBRARY

cautious. "We need to take precautions," she said, "because people forget very soon".

Perhaps when we recall her meeting with Louis Lasagna, some 37 years earlier, and the position he maintained afterwards we might be forced to conclude that some fail to learn in the first place.

Dr Allan Gaw is a clinical researcher and writer in Glasgow

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The right response

Dr Ian Reeves and Gráinne Byrne of the Scottish Public Services Ombudsman discuss why patients complain and how an effective response can often prevent complaints from escalating

"DELAY, deny and defend" is how the NHS approach to complaints handling was described in a recent report. An independent government-commissioned inquiry led by Labour MP Ann Clwyd also highlighted "deep dissatisfaction" with a system (in England) in which people often did not bother to complain about poor care because the process was either too confusing or they feared for their future care or that of a loved one.

Complaints are usually reviewed negatively by the recipient, both at an individual and organisational level. Criticism is hard to take and the subsequent response is often ineffective as noted in the Francis report into deaths at Mid Staffs hospital.

The report stated: "A complaints system that does not respond flexibly, promptly and effectively to the justifiable concerns of complainants not only allows unacceptable practice to persist, it aggravates the grievance and suffering of the patient and those associated with the complaint, and undermines the public's trust in the service."

Better complaints handling

Given these reports, it seems that complaints handling could and should be high on organisations' agendas. The Scottish Government's detailed guidance on the NHS complaints handling procedure is outlined in the document *Can I Help You?* It emphasises the importance of learning from complaints, which is also a key focus of the work of the Scottish Public Services Ombudsman's (SPSO) Complaints Standards Authority (CSA), which strives to improve complaints handling across the public sector. The SPSO is the final stage for complaints about public services in Scotland. (Similar organisations exist in England, Wales and NI).

Another crucial focus of the CSA is ensuring that complaints are handled effectively and, if possible, resolved at the first point of contact. The CSA provides advice and guidance for all complaints, not just those that reach the SPSO, including how to make an apology more meaningful and specific.

Apologies offered in response to a complaint need to show that the reason for the complaint has been understood, and that action will be taken to prevent a recurrence. It is also appropriate to acknowledge that the complainant is 'right' and their complaint is justified.

The CSA offers training courses on complaint handling which involve analysing the aspects of a complaint, and how to investigate and respond. This is applicable to all those involved in complaint handling, such as practice managers. With NHS Education for Scotland, the CSA has also developed e-learning modules to support frontline staff and complaints handlers.

SPSO investigations

The SPSO will only investigate complaints after the local organisation has concluded their response, and if the complainant remains dissatisfied.

A significant proportion of problems from the complaint process arise from delays in dealing with complaints. Dissatisfaction with the content of the complaint response usually arises where the organisation decides to "defend" the service provided, rather than offer an apology. It is also more likely if the apology is ineffective.

Errors in the complaint response, such as getting names/dates/clinical details wrong undermine the confidence of the recipient in the complaint process, so diligent fact-checking and proofreading are essential.

After a dissatisfied complainant refers the complaint to the SPSO it is handled by an SPSO complaints reviewer who requests the relevant notes and, where appropriate, seeks clinical advice from a relevant independent professional. In the case of GP complaints, this is usually a GP working in Scotland who is familiar with current standards of GP care.

The outcome of the SPSO process is communicated to the complainant and the relevant service in the form of a letter to both parties. Some investigations are laid before parliament as an investigation report if there is a specific public interest.

The SPSO may make recommendations to provide redress for the complainant, and to ask the service to make changes to ensure any system errors are corrected. Individuals involved are usually asked to reflect on the complaint and SPSO findings as part of their annual appraisal.

Summary

- Complaints should be valued by organisations and individuals, not feared.
- The SPSO process is not punitive but provides an independent evaluation of the complaint process.
- Following CSA guidance and training can help turn complaints into a positive experience.
- Following complaint handling advice from organisations such as the CSA and SPSO will help ensure complaints are resolved satisfactorily while also improving the quality of the organisation's services.

Links:

- The SPSO: **www.spso.org.uk**
- The Complaints Standards Authority **www.valuingcomplaints.org.uk**
- Twitter: **@SPSO_ombudsman**

Dr Ian Reeves is a professional adviser to the SPSO and Gráinne Byrne is an SPSO communications officer

Is it a stroke?

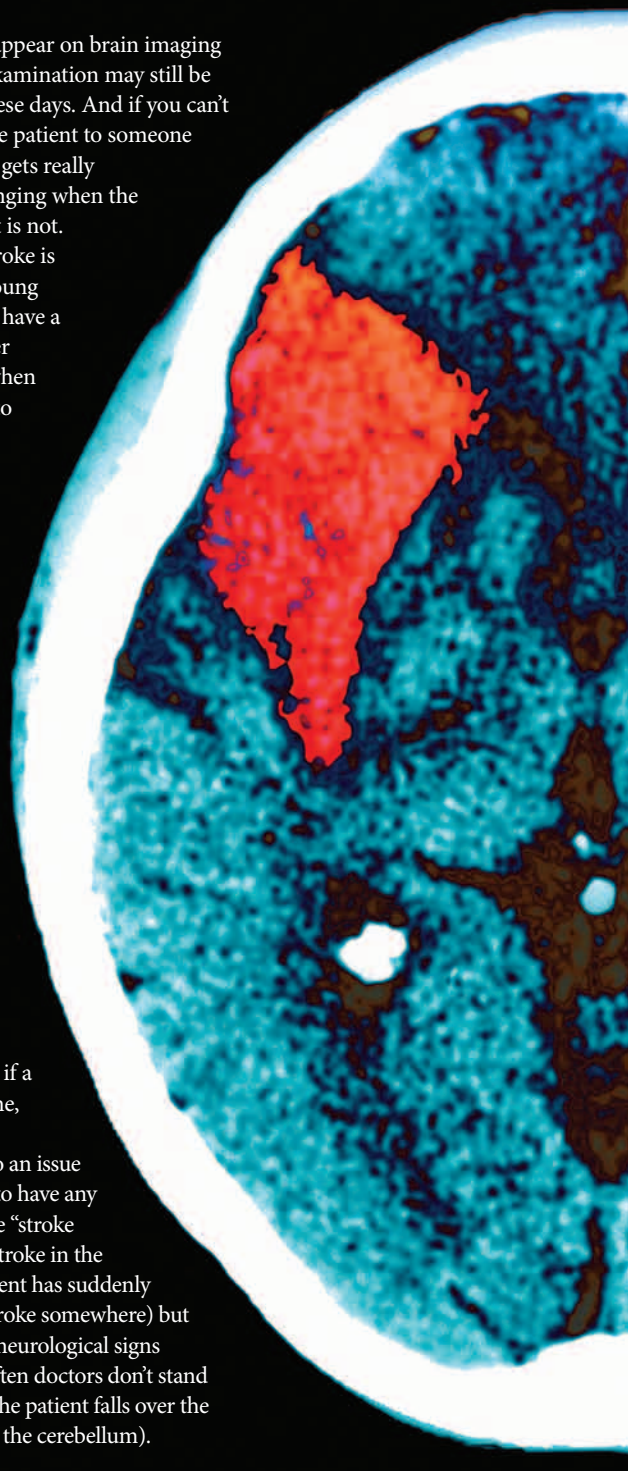


PHOTO: ZEPHYR/SCIENCE PHOTO LIBRARY

Professor Charles Warlow discusses some common pitfalls in the early diagnosis of stroke

DIAGNOSING a stroke should be easy – very easy. After all, sudden onset of a focal neurological deficit can hardly be anything else. By sudden, I do mean sudden. The onset occurs at a recognisable moment in time and, if asked, the patient can generally recall what they were doing when it happened. And by focal I mean not a general perturbation of brain function (like feeling faint or woozy in the head, or losing consciousness) but some manifestation of a focal lesion in the brain like weakness or numbness down the whole or part of one side of the body, losing vision to one side, difficulty thinking of words, difficulty in finding one's way about, double vision or serious imbalance.

In stroke, after the sudden onset, the focal deficit may worsen, the patient may lapse into coma, and about one third die. But the rest improve over days, weeks and months and many recover completely. If the patient survives but does not improve, something else may be going on, perhaps a brain tumour (unlikely to have been missed on CT scan, but it does happen) or something very obscure (in which case call an obscure specialist, i.e. a neurologist).

When the diagnosis is tricky and liable to be missed

If anything, stroke is over-diagnosed these days, particularly in clinics devoted to stroke and particularly now that doctors fear the sins of omission far more than the sins of commission. What can be so wrong in unnecessarily prescribing a statin even if the patient only has migraine, against failing to start secondary stroke prevention in someone with a mild stroke or transient ischaemic attack who goes on to have a stroke and then sues the doctor for negligence? Quite a lot in my view, but that is another subject.

The usual culprits in over-diagnosis (or misdiagnosis) are:

- migraine aura
- functional problem (i.e. symptoms without disease) which is not confined to young people or even to people who are overtly depressed or anxious
- a space-occupying lesion such as a tumour or subdural haematoma
- occasionally hypoglycaemia
- multiple sclerosis
- possibly focal epilepsy.

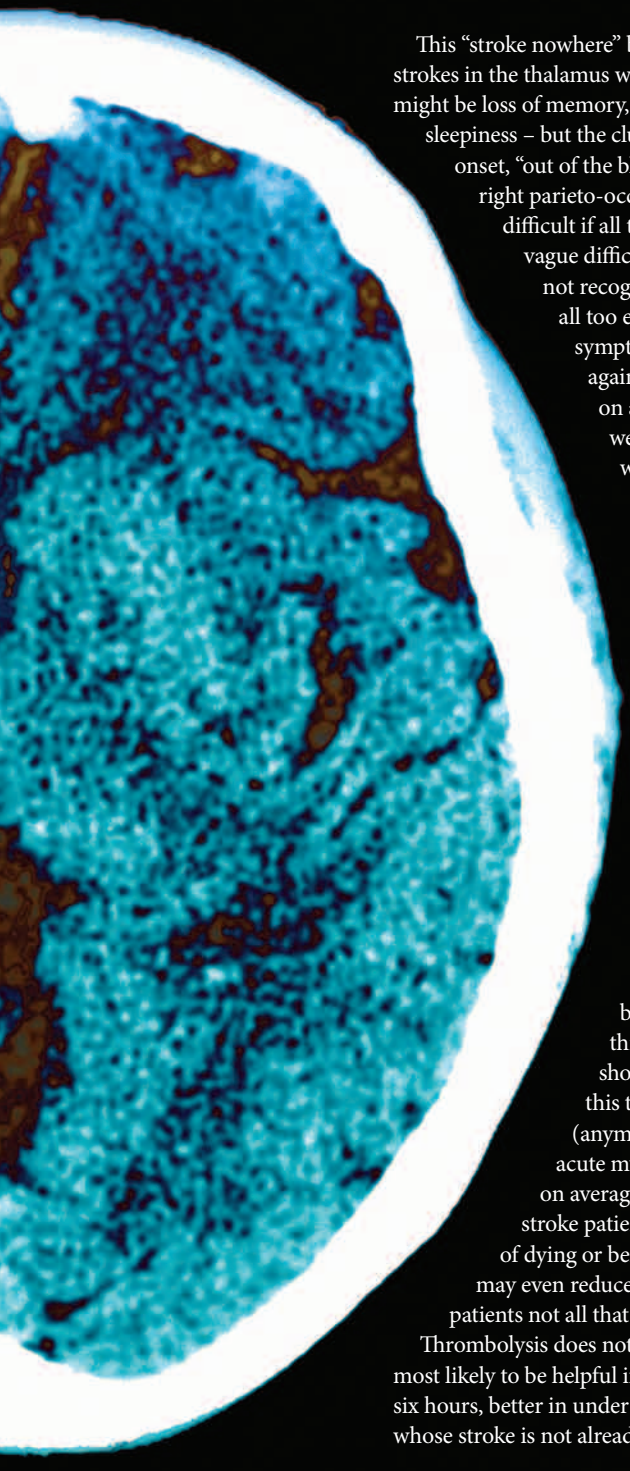
Even a peripheral nerve lesion can confuse some people. Some diagnoses will appear on brain imaging but not all. The history and examination may still be all one has to rely on, even these days. And if you can't manage that yourself, refer the patient to someone who can – after all neurology gets really interesting and indeed challenging when the scan is normal but the patient is not.

Missing the diagnosis of stroke is particularly problematic in young people who are so unlikely to have a stroke compared with an older person. But it happens and, when it does, any stroke is not due to atheroma but more likely to:

- Dissection of the neck arteries: ask directly about indirect trauma like a car crash, being grabbed round the neck etc. This is a fruitful area for litigation not against the doctor but whoever was responsible for the trauma
- Embolism from the heart: check the heart and rhythm
- Haemorrhage due to an intracranial vascular malformation.

Sometimes stroke even happens inexplicably out of the blue and no cause is ever found (although the oral contraceptive is often blamed if a woman is taking it which some, but not all, are).

Missing the diagnosis is also an issue if the patient does not appear to have any focal symptoms. So beware the "stroke somewhere, stroke nowhere, stroke in the cerebellum" scenario. The patient has suddenly become unwell or disabled (stroke somewhere) but there do not appear to be any neurological signs (stroke nowhere). However, often doctors don't stand the patient up; if they do and the patient falls over the diagnosis is obvious (stroke in the cerebellum).



This "stroke nowhere" business also applies to strokes in the thalamus where the only symptom might be loss of memory, perhaps along with some sleepiness – but the clue as ever is the sudden onset, "out of the blue". Sometimes stroke in the right parieto-occipital region can be very difficult if all the patient complains of is vague difficulty with their vision, maybe not recognising places and people. It is all too easy to brush off the symptoms as psychological, but again the clue is that they came on all of a sudden – one day they were there, the day before they were not.

Early diagnosis: delays can matter

Not so long ago it really didn't matter too much if the diagnosis of stroke was delayed for hours or even a day or two. It didn't even matter if the diagnosis was completely missed, provided the patient recovered, because until the 1980s there was no intervention that would reduce the risk of another stroke.

Now it does matter because intravenous thrombolysis is, or at least should be, available. Although this treatment is no panacea (anymore than thrombolysis for acute myocardial infarction), it does on average across a population of stroke patients reduce somewhat the risk of dying or being left dependent, and it may even reduce the level of dependency of patients not all that affected in the first place. Thrombolysis does not work for everyone, but is most likely to be helpful if the patient is treated within six hours, better in under three hours, and in someone whose stroke is not already getting better.

Of course thrombolysis is contraindicated if the stroke is due to haemorrhage, so everyone needs a CT brain scan first. Upsetting as it may be for the neurologists who prefer the comfort of their outpatient clinic to the hurly burly of an acute ward, stroke patients are now blue light medical emergencies. Recently qualified doctors know this; older ones may not be so aware. In their day stroke was 'untreatable'.

"No history available"

What nonsense – there is always some history from someone if one bothers to look for it. But how often does one see these three weasel words written in medical notes! Apart from the patient, has anyone else been asked what happened – paramedics, friends, relatives, bystanders, police? This issue is important for inebriated patients who are found unconscious where a cut on the head might be due to falling as a result of a stroke rather than alcohol. The presence of focal neurological signs should be one clue to do a scan, but of course rather than a stroke one might find a subdural haematoma which is certainly useful to know about.

A sound history is also important for anyone who is otherwise unable to give their own history, particularly if they are dysphasic. Dysphasia can be misinterpreted for psychosis if you are not careful to listen to how the patient is speaking. Are their words wrong, jumbled up, rather than just slurred?

Conclusions

- Take a decent history and not just from the patient. Was the onset sudden? Exactly when did it all start? What exactly seems to be wrong?
- Make an attempt at the neurological examination. It does sometimes matter a lot, e.g. radial nerve palsy vs stroke.
- If in doubt ask for help, and fast if there has been an apparently sudden onset of focal neurological symptoms in the previous few hours.
- And again ask for help if the patient keeps coming back with the same problem and you have not got a sensible diagnosis, even if the brain scan is normal.

■ *Charles Warlow is Emeritus Professor of Medical Neurology at the University of Edinburgh*

A friend in need

Do the same rules for doctors treating family and friends apply to dentists? Maybe not to the same degree, says MDDUS dental adviser Doug Hamilton, *but he urges caution*

MY medical colleagues often express amazement that dentists routinely treat their family and friends. This is primarily because the GMC takes a very restrictive view of this practice, advising registrants to avoid "providing medical care to anyone with whom you have a close personal relationship".

Obviously, this rule is not invoked in emergencies and I suspect that in other circumstances, such as where a doctor works in a remote setting, common sense is allowed to prevail. However, there's plenty of anecdotal evidence that doctors take the GMC guidance very seriously and will generally arrange for relatives to be seen by another practitioner.

Other than to provide stringent guidance in relation to drug prescribing, the GDC has not imposed such restrictions. This is perhaps unsurprising since the practice of dentistry does not involve intimate examinations or life and death decisions. However, advice sought from MDDUS does indicate that a less formal dentist-patient relationship does present its own hazards.

Just a friendly handshake

Firstly, there is the issue of consent. Ordinarily, before treatment can commence patients will be advised of factors such as the risks, benefits and alternatives. However, familiarity with a patient can make adherence to standard procedure seem unnecessary and even a little awkward.

One particularly tricky aspect of consenting close acquaintances is the issue of money, with dentists often feeling obligated to discount fees or "just charge the lab bill" as a gesture of goodwill. While this act of generosity is usually appreciated it often remains undocumented, an aberration which can unfortunately lead to problems. To paraphrase Mario Puzo, "friendship and money are like oil and water" – it's not unknown for even the most generous price reduction to be subsequently challenged or even misrepresented as a tacit admission of substandard treatment. If there is no record of what was agreed and on what basis, the practitioner is left in a vulnerable position.

Clinical considerations

Over-eagerness to help our friends may not only result in poor consenting, but may also skew our clinical judgement. It is quite understandable that, when treating those close to us, we may adopt practices that would not be routinely countenanced. A restorative plan, which would normally be regarded as over-ambitious, might just be attempted. A posterior resin might be claimed as NHS amalgam (in Scotland) to improve aesthetics and reduce the patient charges.

Usually, treatment will proceed as planned and any such aberrations will have no relevance. Even when problems do arise, good friends or immediate family members will generally accept the outcome and be appreciative of our efforts.

However, it's not hard to imagine circumstances where, for example, a more distant or estranged relative takes a less indulgent view. Equally, former auxiliary staff who may have left the practice in less than amicable circumstances may feel disposed to second-guess any treatment offered to them gratis, particularly if it was of the exotic variety. These patients, who may have been quite happy to benefit from your kindness when all was going well, can prove to be especially ungrateful if the finished treatment does not meet expectations. If the investigation of a subsequent complaint reveals inadequate consenting or questionable treatment planning, the fact that these faults were a product of kindness will get little sympathy.

By the book

Possibly the best means of pre-empting such problems and avoiding causing offence is to apply the correct rules uniformly. Written treatment plans and cost estimates are expressly required in most cases for both NHS and private patients. If the practice policy is to provide everyone (except, perhaps, your mother) with this document prior to treatment of any complexity then no-one, not even your best mate, should feel affronted. Equally, no-one can subsequently attempt to take advantage of your good nature by "misremembering" the agreed charges.

Regardless of an appointment's informality, records must include all of the usual observations, such as examination results and details of the treatment provided. Where there are any doubts, don't feel abashed about requiring a signature on the consenting document. After all, this is the standard practice policy. Finally, don't be tempted to consent your friend or discuss treatment in the course of exchanging personal e-mails. The GDC have taken the view that all clinical information must be included in the patient records.

A convenient prescription

If the provision of dentistry to family and friends is fraught with its own unique pitfalls, then the decision as to whether you should also write them a prescription is a real high-wire act. It is in relation to this particular facet of dentistry that the GDC has published *Guidance on Prescribing Medicines* which offers the following explicit guidance:

"If you prescribe medicines for someone with whom you have a close personal relationship you may not be able to remain objective and you could overlook serious problems, encourage addiction, or interfere with treatment provided by other healthcare professionals. Other than in emergencies, you should not prescribe medicines for anyone with whom you have a close personal relationship."

Any departure from this guidance (most probably where prescription medicine forms an integral part of a planned course of treatment) should be completely logical, safe and well-documented.

> "Other than in emergencies, you should not prescribe medicines for anyone with whom you have a close personal relationship"

Quite understandably, the GDC have created an exception to allow for prescribing in dental emergencies. What, however, if the condition was serious, but of non-dental origin? Normally, the dentist's involvement would be limited to recommending urgent consultation with a doctor or a trip to A&E. However, when the patient in question is a relative, there may be a temptation to intervene personally. Obviously, it would be impossible to prescribe for most medical conditions using an NHS script. However, there is no restriction on the choice of drugs that can be prescribed by a dentist on a private basis. Beware – even if the condition is common and its treatments and their hazards are scrupulously researched, this is not carte-blanche to prescribe at will.

The GDC's new *Standards* and *Scope of Practice* require that registrants only carry out treatments for which they are "appropriately trained… and indemnified".

In support of this position, the GDC cite the example of a dentist who prescribed one week's supply of diabetic medication for his mother who lived abroad and whose supply was running short. The Investigating Committee noted with sympathy the surrounding circumstances but still issued the dentist with a warning.

Bearing this example in mind, one must fear for the poor dentist who succumbs to pressure from a life-long golf partner and gives a penicillin script for a "sore throat". While such an action might seem inconsequential, it would in all likelihood, breach the requirement that registrants should prescribe for identified dental needs and that registrants should prescribe within their competence. It also contravenes the restriction on prescription to close friends outside emergency situations. A full house if ever there was one!

There may be an assumption that such minor transgressions would only come to light in the event of some catastrophic complication. Admittedly, such an outcome is pretty unlikely. However, it only takes an unfortunate drug interaction or a report from a professional colleague to spark off many months of regret and worry.

So, reflect very carefully before departing from your normal prescribing, treatment planning or claiming practices. Dentists who stretch the rules for friends will usually do so out of compassion and not for personal gain. However, previous instances have shown that, where these actions conflict with GDC standards, NHS regulations or accepted clinical practice, such mitigating arguments are of limited value.

■ ***Doug Hamilton is a dental adviser at MDDUS***

CASE studies

These studies are based on actual cases from MDDUS files and are published in *Summons* to highlight common pitfalls and encourage proactive risk management and best practice. Details have been changed to maintain confidentiality

DIAGNOSIS: HAEMATURIA NOTED

BACKGROUND: A 48-year-old patient – Mr P – attends his local surgery with a two-day history of urinary tract symptoms: frequency and urgency. His GP – Dr K – examines the patient and finds: "No palpable bladder, apyrexial, urine cloudy with mucous. Test positive for blood, protein, leucocytes." The GP also notes that Mr P has had a history of bladder outflow problems in childhood for which he had surgery.

Dr K diagnoses urinary tract infection (UTI) and prescribes the antibiotic trimethoprim. Urine culture later confirms the infection. Two days later Mr P phones the surgery and speaks to Dr K reporting an improvement in symptoms but that he feels intermittent blockage and that his urine is still cloudy. Dr K makes a routine non-urgent referral for Mr P to a urology outpatient clinic.

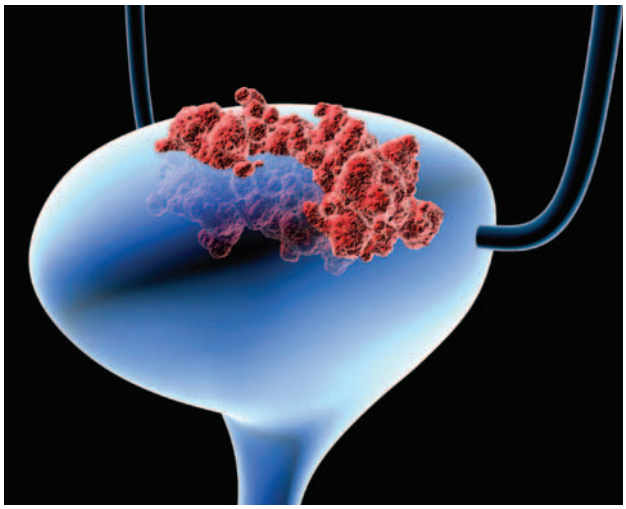
Two months later Mr P is seen at the outpatient clinic. He again complains of persistent frequency and urgency. A staff grade physician measures flow rate and performs an ultrasound scan to assess bladder emptying. This reveals no abnormality and no further investigations are undertaken.

A week later the patient requests an emergency appointment at the surgery and sees a different GP. He has blood in his urine but the GP notes that the patient was only just recently assessed and given an all-clear. Mr P is prescribed more antibiotics and told to present a urine sample in 10 days.

Later that week Mr P makes another appointment at the surgery and sees Dr K. The GP notes that the patient is passing urine 20-30 times per day and with significant difficulty. He is also passing blood. Dr K makes an urgent referral under the two-week cancer rule and records in the referral letter that the patient has both white and red blood cells present in his urine.

Four days later Mr P is seen at the urology clinic. An SpR arranges for an ultrasound and cystoscopy to investigate the cause of the patient's recurrent UTI. The tests reveal a bladder cancer invading muscle. A CT scan shows that Mr P already has metastatic disease. A transurethral resection is carried out and chemotherapy organised with an oncologist. The patient fails to respond to treatment and dies three months later.

Six months later a letter arrives from solicitors acting on behalf of Mr P's family alleging clinical negligence against Dr K for not referring the patient for urgent investigation after the initial consultation. This would have allowed diagnosis and treatment of the carcinoma before it metastasised.



ANALYSIS/OUTCOME: Dr K contacts MDDUS and expert opinions are commissioned from both a primary care physician and a consultant urologist.

In the letter of claim it's alleged that Mr P had complained of frank haematuria with clotting but this is not reflected in Dr K's notes – and it is on the basis of the recorded observations that the GP made a non-urgent referral in the initial consultation. The diagnosis of UTI was confirmed by culture and the GP's judgment was further supported by the fact no abnormality was noted when Mr P was eventually seen in the outpatient clinic. The primary care expert offers the opinion that a competent GP acting with reasonable care would have managed the patient in a similar way to Dr K.

The urologist is of the same opinion that Mr P's symptoms at the initial consultation with Dr K were consistent with UTI. However, he is critical of the attending physician at the first outpatient consultation. In his opinion standard practice with symptoms of urgency would have warranted a cystoscopy to rule out bladder pathology.

In the question of possible causation the urologist states that even had the tumour being diagnosed in an urgent referral after the first consultation it is likely there was already metastatic disease present. MDDUS solicitors offer a denial of liability and rebuttal of causation. No further action is pursued by the family.

KEY POINTS

- Clear and comprehensive records are key in defending negligence claims.
- More than one positive test result for haematuria merits further investigation.
- Recurrent urinary tract infection is a red flag, especially in men.

INFORMED CONSENT/TREATMENT:
TOOTH BEYOND SAVING

BACKGROUND: Mr J attends his regular dentist – Mr D – with pain in a lower left molar. Mr D examines the tooth and finds it badly infected. He advises the patient that the tooth needs to be extracted but this procedure cannot be done until the infection clears. He prescribes Mr J antibiotics and advises him to return in a few days.

Two days later Mr J phones the dental surgery complaining of severe pain. Mr D is away so he attends another dentist – Mr S. The dentist examines the tooth and advises immediate extraction despite the previous advice from Mr D. No discussion is recorded in the notes of potential alternatives to extraction such as root treatment and there is also no record of any investigations such as radiographs or vitality testing to assess the state of the tooth.

Mr S administers a local anaesthetic and tells the patient to sit in the waiting room. Only a few minutes pass before Mr J is called back to the dental chair. The patient tells the dentist that his lip and tongue have not yet gone numb and that he can still feel pain in the tooth. Mr S says "It will be okay" and proceeds with the extraction.

Mr J finds the extraction painful and when he cries out Mr S (it is later alleged)

tells him to "Shush". The dentist applies "considerable force" and the tooth fractures. He proceeds then to remove fragments of bone and tooth from the tooth socket. Mr J is given a pad to bite on to stop the bleeding and discharged.

A few months later Mr S receives notification from solicitors that the patient is pursuing a claim of clinical negligence.

ANALYSIS/OUTCOME: In the letter of claim it is alleged that Mr S failed to carry out an adequate investigation of the tooth in order to determine the necessity for extraction and there was no discussion of alternative treatments. Thus, consent was not informed. The patient is claiming for personal injury and damages and for the costs of dental work to replace the missing molar.

Mr S contacts MDDUS and all correspondence and dental records in the case are dispatched to a GDP expert who produces a report. The fact that no radiographs of the tooth were taken by either dentist makes it impossible for the expert to comment on the state of the molar prior to extraction but this does not mean the decision to extract was flawed. Had Mr S, on examination, judged that no other treatments were viable to save the tooth then the patient's consent to extraction would be informed by that clinical judgement. But the dentist's notes from the consultation consist of a single line: "LL6 Ext LA".

MDDUS advisers and solicitors consider the full evidence and although the expert report is supportive of Mr S they conclude the defence is vulnerable due to the dentist's lack of adequate treatment notes. It is agreed best to settle the case out of court.

KEY POINTS

- Ensure full treatment options and risks are discussed with patients and record these discussions in the notes.
- Consent can be withdrawn at any point during treatment – so do not ignore signs of patient distress.
- A bad experience in the dental chair increases the risk of a complaint or claim.

DISCLOSURE:
CALL RECORDINGS

BACKGROUND: Mrs L has been in regular telephone contact with her general practice over the past few weeks regarding numerous issues including availability of appointments and repeat prescriptions. There has been some disagreement over the exact nature of what has been discussed and Mrs L has now requested copies of the recordings of her calls with the practice.

The practice is unsure how best to respond to the request. GP, Dr F, is concerned about the privacy of the receptionist who features in the phone calls and is worried about what Mrs L might do with the recording, such as posting it online. He seeks advice from MDDUS.

ANALYSIS/OUTCOME: Under the Data Protection Act (DPA), individuals have a right to access their personal data – including that contained in electronic recordings – in an intelligible form by making a subject access request.

Dr F is therefore advised to provide Mrs L with a copy of the recordings. For ease, the practice could offer her a transcript of the calls or invite her to listen to the calls at the practice, but she has the right to ask for a copy of the audio recording. The DPA stipulates that this can be provided for a maximum subject access request fee of £10 plus any photocopying costs.

In terms of the privacy concerns, the DPA has a provision to protect third parties who could be identified from the information being requested. If the request for disclosure cannot be met without identifying a third party then, unless that third party consents, it is not necessary to comply. In this case, however, the identity of the receptionist is already known to Mrs L so there would be no breach of confidentiality in that regard and this would not be grounds to refuse the request.

Dr F is also advised that Mrs L has the right to use the recording as she wishes, which may include making it available publicly, i.e. online.

KEY POINTS

- Patients have the right to access personal data held about them by practices, including audio recordings.
- Concern over how the patient might use the data is not reason enough to refuse a subject access request.

From the archives:
Only a misadventure

DOCTORS will always make mistakes – it's only human to do so. But when do they constitute medical negligence? The landmark court case in England that helped established the criteria for assessing negligence was *Bolam v Friern Hospital Management*.

In 1954 a salesman named John Hector Bolam was admitted to Friern Hospital suffering from persistent depression. There he was advised by a consultant to undergo electro-convulsive therapy (ECT). Bolam signed a consent form but was not warned of the small risk of fracture in the treatment. Later in one of the treatment courses he sustained dislocation of both hips and fractures of the pelvis.

The use of relaxant drugs would have excluded the fracture risk but these were not administered nor were manual restraints used, though nurses were in attendance throughout the treatment. Among professionals skilled in ECT there were two bodies of opinion on fracture risk. One favoured the routine use of relaxant drugs or manual restraints; the other considered the use of such drugs was attended by mortality risks and manual restraints in some cases increased the risk of fracture.

Bolam sued the hospital for negligence in the administration of the treatment and for not warning him of the risk of fracture. The case centred on the question of professional skill. In summing up, the presiding judge directed the jury:

"...a doctor is not guilty of negligence, if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art. The test is the standard of the ordinary skilled man exercising and professing to have that special skill..."

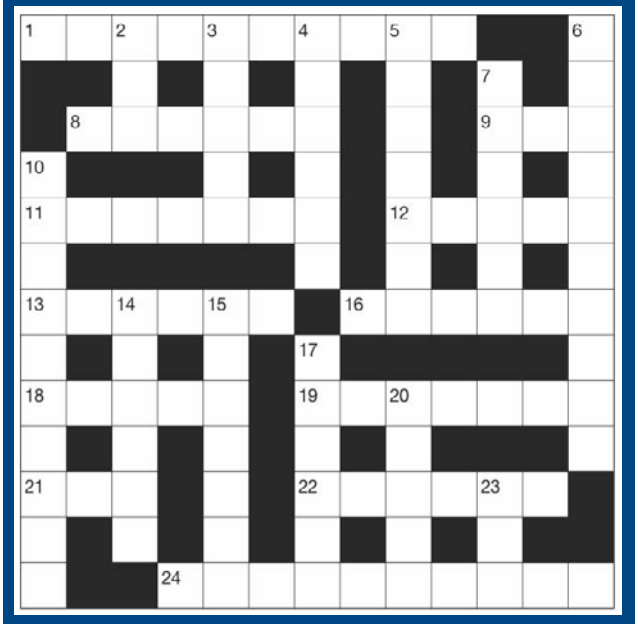
The judgment was handed down in favour of the hospital and principles established in an earlier Scottish case (*Hunter v Hanley*) were cited in support. There was a visionary undertone in the judge's direction to the jury when he quoted an earlier judgement by Lord Denning:

"...we should be doing a disservice to the community at large if we were to impose liability on hospitals and doctors for everything that happens to go wrong. Doctors would be led to think more of their own safety than the good of their patients...We must insist on due care for the patient at every point, but we must not condemn as negligence that which is only a misadventure."

Legal precedent has moved on since then with further case law but the historic importance of Bolam remains undisputed.

Adapted from MDDUS history - A Century of Care

Crossword



ACROSS
1. Ciprofloxacin, for instance (10)
8. Central parts of cells (6)
9. Ireland (abbr.) (3)
11. Executioner (7)
12. Ballroom dance (5)
13. Bear-like (6)
16. Marilyn (6)
18. Prefix, nose (5)
19. Physician, pharma researcher and pasta dish? (7)
21. Information privacy legislation (3)
22. Reveal the presence of (6)
24. In which Salmond wants yes vote (10)

DOWN
2. Synthetic rubber material (abbr.) (3)
3. Famous medico-legal case (5)
4. Position correctly (6)
5. Fire (7)
6. One-sided (10)
7. Involuntary oscillatory movement of muscle (6)
10. Shambolic Happy Mondays vocalist (5-5)
14. Of 20 (6)
15. Newborn infant (7)
17. Alternative forms of same gene (6)
20. Backbone (5)
23. Rare and fatal brain disease (abbr.) (3)

See answers online at www.mddus.com.
Go to the Notice Board page under News and Events.

Object obscura:
Thumb sucking guards

THESE thumb guards dating from the early twentieth century could be mistaken for medieval instruments of torture. Most particularly the 1906 Babe Mitts – a metal sock fitted over a baby's fist and tied around the wrist.

IMAGE COURTESY OF BDA MUSEUM

Vignette: GP and political activist Baroness Edith Clara Summerskill (1901 - 1980)

PHOTO: SCIENCE PHOTO LIBRARY

"TIMES were different then" and it took vision and the determination of a few people to change them. Political activity, female equality with men and the desire to improve healthcare were the lifelong driving forces of Dr Edith Summerskill.

One of Edith's early memories was of being driven by a coachman in a horse-drawn victoria with her father William Summerskill to visit his patients in north London. What she saw then of illness, hardship and inequality for women inspired her career. Her father had supported women's suffrage and also instilled socialist ideas in her.

Edith was the youngest of three children and was educated at Eltham Hill grammar school. She finished school the year WW1 ended and continued her education at King's College, University of London. Summerskill studied medicine at Charing Cross Hospital (MRCP, LRCP 1924) where she met and in 1925 married Edward Jeffrey Samuel, retaining her maiden name. They worked together as general practitioners until the end of WW2 but Edith always combined medicine with politics. Working married women were quite rare in the 1930s and Summerskill became an early member of the Married Women's Association.

It was a time when effective medicines were few but her father had shown her the importance of a good bedside manner and allowing time for the patient to speak. Those drugs that were available were not always given, notably anaesthetics were often denied to mothers at childbirth. This unnecessary suffering inspired Edith to write her first book *Babies without Tears*.

Only by political action could health and female equality be achieved. Summerskill had joined the Socialist Medical Association in the early thirties, and a publicly funded and administered healthcare service was one of its aims. In 1934 she won a by-election to Middlesex county council and represented the working-class Green Lanes division of Tottenham until 1941.

Her first attempt to be selected as an MP failed because of opposition to her support for birth control but in 1938 she was elected as MP for West Fulham. She was delighted when Clement Atlee made her parliamentary secretary at the Ministry of Food. She might have preferred health but in fact she made a great contribution to health by reform of the dairy industry to ensure that supplies of milk were free from tuberculosis bacilli (Clean Milk Act 1949).

Food shortages and rationing continued for many years after the war so she had a great responsibility for the welfare of the British population. During this period Edith was a member of the Fabian Society. She was appointed to the Privy Council in 1949.

In 1950, for a brief period before the fall of the Atlee government, she held ministerial office for Social and National Insurance. Then, when Labour lost power, she served as a minister in the Shadow cabinet until 1959. Of course, she had political enemies in her own party, notably Bevan who she thought had unjustly claimed the NHS as his creation.

Her concern for women was not confined to Britain. She supported the republican side in the Spanish Civil War through the National Women's Appeal for Food for Spain, and visited refugee camps for women and children. In 1944 she was invited to Australia and New Zealand, a journey that took her round the world. She was often the only woman among politicians and diplomats but easily held her own. Everywhere she fearlessly addressed issues of female equality.

A decade later she became Labour party chairman. Boundary changes abolished her constituency, so from 1955 she was elected MP for Warrington. In 1961 she was made a life peer and continued her career in the House of Lords as Baroness Summerskill of Kenwood. The 1964 Married Women's Property Act, introduced as a private member's bill, was energetically and successfully campaigned for by her. Among other campaigns she supported were reform of the law on homosexuality, legalisation of abortion and opposition to boxing which was supported by evidence that it caused brain damage.

She became one of a select group when she was awarded Order of the Companions of Honour (CH) in 1966. The award of political honours had come under question and Summerskill was invited to apply her intelligence and probity by serving on the House of Commons Political Honours Scrutiny Committee.

She had two children: Michael and Shirley, who followed her mother as a doctor and politician. Over the years Edith had written to her daughter and frankly discussed issues such as female sexuality and education. In 1957 she published a book of a selection, entitled *Letters to my daughter*.

Edith Summerskill died at home in Highgate, London, on 4 February 1980 in her 79th year.

■ ***Julia Merrick is a freelance writer and editor in Edinburgh***

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