Vol 1 Issue. 1 ■ November 2012

The Physician

Journal of The British Association of Physicians of Indian Origin

In this Edition ...

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UK/TRAXADV/1942012 Date of preparation: July 2012.

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Vol. 1 Issue 1 ■ November 2012

The Physician

Journal of The British Association of Physicians of Indian Origin

PUBLISHED BY:
BAPIO Publications Ltd.
178 Ampthill Road
Bedford, UK
MK42 9PU

MARKETING & ADVERTISING
Pharma Publications
Unit J413, The Biscuit Factory
TOWER BRIDGE BUSINESS COMPLEX
100 CLEMENTS ROAD, LONDON SE16 4DG
Tel: +44 0207 237 2036
Fax: +0014802475316

The Physician – ISSN – 1987 – 6329 is published quarterly by BAPIO Publications Ltd. In association with Pharma Publications. **Volume 1 - Issue 1 (November 2012) BAPIO**

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Message from the Editor in Chief

Ramesh Mehta MD, FRCP, FRCPCH, FHEA, DCH

Dr Mehta is a Consultant Paediatrician at Bedford Hospital, UK; Emeritus Professor of Paediatrics, Kigezi International School of Medicine, Cambridge and Principal Regional Examiner, South Asia, Royal College of Paediatrics and Child Health. He is a Fellow of the Higher Education Academy. He has been a member of the standards setting group in paediatrics & neonatology, General Medical Council and a Reviewer for the Health Care Commission. Dr Mehta is founder president of the British Association of Physicians of Indian Origin (BAPIO) and Secretary General of the Global Association of Physicians of Indian Origin (GAPIO).

The launch of The Physician is another accolade for the British Association of Physicians of Indian Origin (BAPIO) in its quest to provide a high-quality continuous education platform.

BAPIO is committed to the vision "Empowering doctors and dentists of Indian heritage to be the beacons of leadership and professional excellence". There is a vast pool of talent and skill amongst the doctors of Indian origin who are regarded as the backbone of the NHS. We hope The Physician will be a vehicle to inspire and encourage research amongst members, as well as provide them with opportunities for career progression.

Good medical practice leading to improved patient care is central to the success of the NHS. Quality improvement comes from everyone understanding and implementing evidence-based medicine. This publication will endeavour to promote this concept while providing up-to-date information to the medical fraternity on scientific, social and political aspects of medicine.

I am indeed grateful to a number of colleagues, eminent in their own fields, for associating with this venture and for their willingness to contribute to its success. I welcome Dr Parag Singhal for shouldering the editorial responsibilities, and Mr Buddhdev Pandya MBE as the Managing Director of BAPIO Publications.

The launch of The Physician marks a new chapter in the history of BAPIO, and adds to the efforts to promote professional excellence, in turn leading to better patient care. ■

Dr Ramesh Mehta

Editor's Note

Parag Singhal MD, MPhil, FRCP.

Dr Parag Singhal is a Consultant Endocrinologist at Weston General Hospital, WSM and Divisional Director for Emergency Care. He is MRCP (PACES) examiner and Honorary Senior Lecturer, Bristol University. Dr Singhal has written papers in prestigious scientific journals and is a referee for diabetes journals. Dr Singhal is chair of BAPIO's South West division.

It is a real privilege to have been invited to support Dr Ramesh Mehta and be associated with the experts in this exciting venture. Our National Health Service is the envy of the world as it provides quality healthcare to all, free at the point of need. As a voluntary organisation, BAPIO is committed to assist the NHS in providing the best patient care.

The publication is intended to address clinical and academic aspects of medicine, as well as NHS policy issues. Continuing medical education and training has remained a central pillar for BAPIO, not exclusive to its members but encompassing the wider medical fraternity. Therefore it is vital to provide a platform to disseminate knowledge to support good medical practice and assist in many areas of regulatory issues like revalidation. The Physician will act to promote academic endeavour and innovation in the NHS. We are committed to publishing a very high-quality journal.

I am extremely thankful to all the authors who have contributed high-quality articles, covering such topics as the challenges facing the NHS and its future, patient safety, and research articles. In the current austere NHS, it is even more important to focus on innovation, cost-effectiveness, value and establishing a culture of goodwill between NHS trusts and commissioners.

The Physician will promote the concept of sound clinical medicine, which assumes greater relevance when high-quality care needs to be provided within limited resources.

It is an honour for me to welcome Editorial Board members who have helped us in reviewing the articles and giving constructive feedback.

We are pleased to have with us Mark Barker of Pharma Publications. He has several years of experience in medical publication and will help us in sustaining the quality. ■

Dr Parag Singhal

And Finally

BAPIO has been publishing a magazine for the past few years, but there has always been a need to publish a medical journal that brings added value to the healthcare sector. This journal will focus on contributing to academic, research and clinical activities. I am indeed privileged to be invited to be the Managing Director of BAPIO Publications Ltd.

We have a very high-calibre editorial board to support the publication. It reflects academic, clinical and professional excellence. I firmly believe The Physician will meet our aspirations.

The Physician will be launched at BAPIO's Annual Conference 2012 and will be circulated to our members as well as to the NHS trusts, Deaneries and other relevant authorities and groups.

In our bid to outsource some of the functions, we have Pharma Publications as our partner. They have extensive experience and a track record of quality publications. We are extremely grateful to Mr Mark Barker, the Director of Pharma Publications, who has taken the lead in the production process, including the crucial responsibilities of proofreading and designing.

I thank all those who have contributed to the successful launch of the first issue of The Physician. ■

Buddhdev Pandya MBE, Managing Director

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Editorial Advisory Board

Preventing Avoidable Harm and Promoting Patient Safety: The Doctors' Dilemma

Sukhmeet S. Panesar and Rajan Madhok

The last decade has seen considerable interest in patient safety globally, and specifically in the NHS in England. The landmark report in 1999 – To Err is Human [1] portrayed medical error as key public health challenge given that health care itself was the eighth leading cause of death; and this was followed soon after by two other seminal reports– Crossing the Quality Chasm [2] and Organisation with a Memory [3] which provided roadmaps for addressing the problems and how to minimise avoidable harm. As a result of concerted efforts since then considerable progress has been made in understanding the frequency of patient safety incidents, how these vary by care settings, the reasons underpinning the failures of care and most importantly in the development of interventions aiming to enhance the safety of care.

Despite these developments over the last decade however, significant concerns remain about the effectiveness of the approaches to minimise avoidable harm and promote patient safety in the light of continuing high profile failures, the most notable being the Mid Staffordshire Hospital incident recently. This begs two questions: Why are patients still suffering avoidable harm including deaths? And are we paying lip-service to the zeitgeist of patient-centeredness and safer care? The evidence provided by witnesses at the Francis Inquiry into failings at Mid-Staffordshire NHS Foundation Trust provide a chilling and compelling account of disinterest in high-quality patient care – ''…one of the junior doctors told me that I needed to get my mum out of there as if she stayed in the Hospital much longer, we were going to lose her….he said that he was sorry about the way she had been treated…'' [4]

It will be interesting to see what the final report of the Inquiry, when it does get published, will have to say about not just Mid Staffs but also about the way in which the NHS has dealt with the issue of patient safety. Rather than indulge in speculation about the content of the final report, we would argue that the fundamental solution ultimately will lie with the clinicians; policymakers, funders, commissioners and providers can only help (or hinder, sadly) but unless the clinicians actively engage with the agenda by providing leadership and adopting best practice, we will remain in this quagmire. This is, however, easier said than done. The last few years have seen increasing erosion of 'power' and 'authority' away from the doctors and in any case the culture of the NHS, which still embodies the 'Who did it' rather than 'Why did it happen' spirit does not give confidence to the clinicians that when they raise concerns that they will be taken seriously. Those who muster the courage to whistle blow and alert others to situations of unsafe care are penalised; the 6th Report of the House of Commons Health Select Committee stated that 'The NHS remains largely unsupportive of whistle blowing, with many staff fearful about the consequences of going outside official channels to bring unsafe care to light.' [5] How can we ensure that patient safety is in the DNA of the organisation when the mechanisms to promote this are fraught with danger; doctors who have cited poor unsafe care which has resulted in avoidable mortality have been prevented from returning to work.[6] The NHS is not a learning organisation despite its rhetoric.

Doctors therefore face a dilemma: on the one hand, all good (which is the majority) doctors recognise the need to minimise avoidable harm and are taking appropriate actions, and on the other hand, there are considerable barriers in their way. However, doing nothing is not an option. Our patients deserve better and for the sake of our professional pride we must rise to the challenge. In any case, leadership is not about criticising or becoming disengaged, rather it is about making progress in the face of adversity. The recent NHS reforms do provide some opportunities. Commissioning will be a key driving force for the provision of high quality health services and one way of ensuring this will be to inter-twine hard measures of safety into the fabric of the commissioning process. Measures such as complication rates, complaints, compliments, readmission rates, outcomes, mortality and morbidity data along with procedure specific data and patient experience questionnaires should be up for scrutiny in the commissioning process [7]. Quality improvement measures such as clinical dashboards, [8] specialty scorecards [9] and system ratings [10] are all important tools that need to be disseminated wider in daily practice. The introduction of revalidation for doctors offers another way to force the pace – proper revalidation cannot be delivered out with the overall clinical governance context.

Of necessity organisations will have to ensure appropriate systems and procedures to enable doctors to revalidate.

The next few years will be testing times for all in the UK as the economic pressure continues and as the NHS changes start to embed. Indian doctors in the NHS can be a powerful resource for the good during these times, not just because of the large numbers but also because of their strong commitment to the NHS. We hope that BAPIO with its mission of promoting professional excellence will support them in their quest to minimise avoidable harm and promote patient safety everywhere. [11] ■

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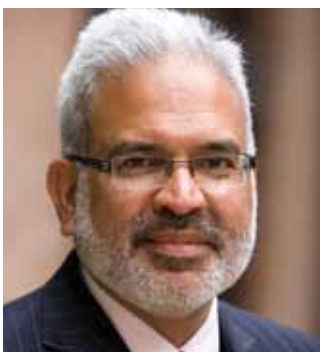
Sukhmeet S. Panesar
NIHR Academic Clinical Fellow in Public Health, Imperial College London, UK

Rajan Madhok
Formerly Medical Director, NHS Manchester, UK; GMC Council Member, UK; and Adjunct Professor, INCLEN, India

Address for correspondence:
Professor Rajan Madhok
e-mail: rajan.madhok@btinternet.com



UK-India Health Partnership to Benefit Both Countries

Mala Rao and Bhupinder Sandhu

The current sweeping healthcare reforms in the UK and India present many challenges, but may also offer physicians of Indian origin from both countries a unique opportunity to join forces with other healthcare professionals and strengthen the health collaboration for the benefit of all. Through shared learning and experience of 'what works' and contributing to innovation, they can make a real difference to improving healthcare and reducing inequalities in both countries.

In India, the liberalisation of the economy and the consequent growth in prosperity over the past few decades has enhanced her status to that of a global power and there is an evident rise in national pride and confidence. But this image masks a huge rise in socioeconomic and health inequalities, which are being addressed by Government. The Report of the Steering Committee on Health for the 12th Five Year Plan (2012-2017) published in February 2012 [1] by the Planning Commission of India highlighted that the Government's 'foremost commitment was towards evolving Universal Access to Essential Health Care and Medicines, so that disparities in access to health care, particularly those faced by the disadvantaged and underserved segments of the population would be corrected'. This is a welcome commitment in a country where more than 80% of healthcare expenditure is paid out of pocket. An increase in public health expenditure from less than 1% of GDP to 2.5% of GDP is planned by 2017, and priority is being given to the strengthening of primary care, which is recognised as an essential means to achieving affordable universal access to healthcare.

What can British Physicians of Indian Origin (BPIOs) who have experience of working in the National Health Service (NHS) contribute to and gain from improving healthcare in India in the light of these current plans? A recently published comparative study of the health systems of 14 developed countries by Ingleby et al. [2] drew several conclusions about the NHS, including: that it outperformed other high income countries on many measures, despite spending much less than most of them; it enjoyed the highest levels of public confidence and satisfaction of all the countries studied; and that the positive assessment may be associated with care which is more accessible and better organised through higher levels of investment over past years. These high scores are also likely to be attributable, at least in part, to the high quality of primary care which has been the centrepiece of the NHS since it began. Indeed, most NHS care, including preventive care and the management of chronic disease, as well as first-contact acute care, is delivered in a community setting to a good standard with universal coverage by primary care practitioners. Many of the primary care practitioners are BPIOs who have considerable experience and potential therefore to share their learning with Indian physicians and support India's strategy to strengthen its primary care.

The NHS, on the other hand, is currently facing severe financial challenges. The Government is requiring an unprecedented level of efficiency improvements and is introducing radical reforms with several key features including the opening up of the market with the aim of creating a greater diversity of healthcare providers and using competition with the hope of driving up efficiency. In addition, the commissioning of care is being handed to GP consortia, with the intention that commissioning is to be clinician-led.

In India, the healthcare landscape is one of public and private sector organisations co-existing with one another, and increasingly, working together as a result of innovative public-private partnership initiatives intended to address both public sector inefficiencies and private sector behaviours motivated by profit rather than ethics. Clinical leadership in the provision, management and commissioning of healthcare is de rigeur, and is offered as an explanation for the ability of Indian doctors, especially in the most admired institutions, to 'do more for less', and demonstrate high levels of innovation and entrepreneurship. The BPIO working in the NHS can learn much from the experience of these Indian doctors. There is thus significant scope for mutual learning about what works, and perhaps more importantly, what doesn't work, in terms of healthcare commissioning, driving efficiency through competition, and private sector involvement, as well as providing ethical clinical leadership in innovative service provision and teaching and research.

Worldwide, it is estimated that there are 1.2 million doctors of Indian origin serving in a vast number of countries. India alone has 800,000 doctors. In the UK, the NHS has a higher representation of ethnic minority doctors in its medical workforce than in the general population. It employs over 40,000

BPIOs. It is estimated that there may be around 15,000 BPIOs in training who are interested in opportunities to work in India.

The UK Global Health Strategy 2008-2013 [3] highlighted India among the priority countries for collaboration. It aimed to promote the best in British healthcare, to make an effective contribution to health in other countries and to utilise learning through partnerships to improve healthcare in the NHS. The potential for BPIOs, with their understanding of the language, culture and social conditions in the UK as well as India, puts them in a unique position to lead these partnerships and help strengthen the UK's health partnerships with India. The newly-launched Physician provides a timely opportunity for BPIOs to catalyse debate and discussion on these issues by sharing of information and dissemination of research evidence among all healthcare professionals committed to improving healthcare in India and the UK. ■

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Professor Mala Rao

Mala Rao is Professor of International Health, University of East London
Head of Public Health Workforce and Capacity, Department of Health in England

Professor Bhupinder Sandhu MD MBBS FRCP FRCPCH DSc(Hons)

Dept. Of Paediatric
Gastroenterology and Nutrition
Bristol Royal Hospital for Children

Revalidation - Raising the Bar Higher

Joydeep Grover

I have often wondered if the parents of the children having heart operations at Bristol in the early 1990s ever doubted the standard of care that their loved ones would receive. Most likely they did not; instead implicit trust was placed in individuals and the system; trust that would be betrayed.

While it would be simplistic to ascribe medical mishaps to individual factors, a collection of such failings and poor governance sets the stage for such events to recur.[1] Good medical practice (GMP)[2] goes beyond keeping skills up to date, and includes attributes that were traditionally overlooked but are equally crucial to effective medical care. The principle that all practising doctors should maintain high standards throughout their career is not in dispute, but is revalidation in the proposed form the right solution?

Come the 3rd of December 2012, revalidation will be necessary to maintain a licence to practise medicine in the UK. The GMC expects to revalidate licensed doctors by March 2016. For the nearly 250,000 doctors in the UK, the outlined framework of revalidation consists of four main identified domains: appraisal of skills, patient safety, communication and maintaining trust. These broad terms encompass a whole gamut of medical practice, and while this makes revalidation relevant, it also makes it very difficult to achieve in an objective manner.

The core method proposed for achieving successful revalidation is a series of annual appraisals that look at the four domains. GMC states that annual appraisals will be evaluated at a local level through a Responsible Officer, who would then be able to recommend revalidation of the doctor every five years.

The scope of the required annual appraisal is large. Each of the four domains is divided into three subdomains, each of which in turn has a number of attributes that need to be assessed. These total up to a total of 59 (fifty-nine) examples of principles and values linking in to GMP. This changes the concept of appraisal completely from being a formative assessment focusing on reflection and areas for improvement, to being a definitive report card, a completely different beast.

It would require huge time and effort to compile the requisite data. The Academy of Royal Medical Colleges, in their statement on the impact of revalidation, report that fewer than 50% of doctors expect to absorb revalidation in the current NHS time, with most expecting that revalidation-related activities will take away valuable time currently allocated to service development, improvement and governance.[3] They also report significant concerns about lack of support from employers, confusing information and lack of clarity on goalposts. And this is before taking into account that 25% of all doctors report not even having an appraisal in the last year! Assuming the appraisals of the nearly 50,000 doctors to be revalidated every year are in order, allocating 15 minutes of the RO's time per doctor would require 12,500 hours of work every year just from the ROs. This would require huge support from the employers who will have to fund this activity. There is as yet no cost estimate of the process, either from the Department of Health, or indeed the GMC, but the costs involved are likely to be substantial and implemented when there is significant pressure on the NHS to cut costs.

The impact of revalidation on speciality doctors and those who work less than full-time will be even greater. The rate of appraisal for speciality doctors is only 50%, and this group of doctors has long felt undervalued and unappreciated by their employers. With limited time allocated for activities outside of service provision, this group of doctors will find it especially difficult to achieve successful appraisal as their job plans do not provide adequate opportunity to address the four domains linked to GMP. A disproportionate number of speciality doctors belong to the BEM background and are International Medical Graduates, a group that has particularly felt hard done by both employers and regulators. There are genuine concerns that revalidation will perpetuate inequalities that this group has battled with over many years. The burden of appraisal and revalidation on doctors in less than full-time work will be proportionally larger as well, and may well be unachievable as they will have to provide a similar burden of proof for successful revalidation, while having disproportionately less allocated time to do so in.

Most Responsible Officers will also be line managers for the concerned doctors. This raises concerns both about conflict of interest and lack of transparency. Lack of objective criteria for both appraisal and revalidation have the potential to make unfavourable outcomes contentious. The fear is that revalidation may be used as a tool by the employers for disciplining or weeding out doctors and circumventing employment law. Failure to engage with revalidation will automatically lead to Fitness to Practice proceedings and this is never good news for the doctor involved, their employer, patients or even the GMC. Although the GMC expects 'most' doctors to be able to maintain their licence to practise, remedial measures

for the ones who are not able to meet these criteria are conspicuous by their absence. The expectation is that remedial action will happen at a local level, funded by employers, but no assessment has been published about the costs involved with such an exercise or of the impact that this will inevitably have on service delivery. There is a valid concern about adverse outcomes for International Medical Graduates who have often found themselves at the receiving end of disproportionately higher rates of complaints, disputes with employers, and subject of FTP proceedings at the GMC with a higher rate of adverse outcomes.

On the flip side, as the vast majority of doctors are expected to have no problems during revalidation, the effectiveness of the whole exercise is brought into question. Is revalidation going to end up merely being a rubber stamp, an extensive and expensive charade that will fail to fulfil the purpose that it is designed for? Would it have been successful in identifying Harold Shipman, the GP who had glowing testimonials from his patients and colleagues? Will it be able to prevent another Bristol heart scandal, where the medical directors ignored whistle-blowers and continued to support failing colleagues and a faltering system?

Doctors are the first to admit that revalidation is both essential and long overdue, but there remain many unaddressed valid concerns on the structure and implementation of this important change. It is essential that the GMC and employers gain the confidence of doctors in the initial phase of revalidation. Clear guidelines, transparent working and visible representation of minority groups will go a long way in gaining widespread trust of the doctors and making revalidation a positive process. Clarity in its implementation will also gain public confidence in both the GMC and doctors, which has steadily eroded over recent years. The alternative scenario of doctors who remain sceptical of their employers and the GMCs intent, and consequently fail to engage with revalidation, will be a huge opportunity wasted, perhaps for a generation. At this time, when the NHS is going through financial and political turmoil, the need for public support cannot be overstated. If we continue to let our patients down - Mid Staffordshire is a recent case in point 5 - the damage to the reputation of both the NHS and doctors may well be irretrievable. The stakes for the future of medical practice in the UK could not be higher. ■

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Dr Joydeep Grover
Consultant in Emergency Medicine, Frenchay Hospital, Bristol
Member of Executive Committee, British Association of Physicians of Indian Origin (BAPIO)

Implications of the NHS Bill

Terence Stephenson

The NHS Bill is now the NHS Act, ushering in huge potential changes in medical services across England and with potential knock-on effects across the UK, despite the diverging healthcare systems in the four nations.

The publication entitled Never Again by Nicholas Timmins, a senior fellow at the Institute for Government and the King's Fund, asserts why the then health secretary believed that never again – or at least not for the foreseeable future – will the NHS need to undergo another big structural change. By placing the reforms within primary legislation, the bar has been raised. Traditionally, newly-elected governments rarely spend valuable parliamentary time undoing the legislation of the previous administration. They want to push on with their own reforming, and hopefully vote-winning, measures rather than look back to the past. Whilst at present the Labour Party is committed to repealing the NHS Act, it is more likely that if elected, they will run with those new structures which work and leave those which don't to simply wither from lack of resources.

Although the exact numbers are constantly changing, the NHS Commissioning Board will devolve approximately £80bn of public money to over 200 Clinical Commissioning Groups, each buying health services for populations from as small as 70,000 to as large as 1 million people. General practitioners have been given a huge role in determining whether this will work on the ground. It is envisaged that all NHS Trusts (there are over 150 acute trusts and over 50 mental health trusts in England) will achieve Foundation Status by 2014 and their performance will be judged by Monitor (finances) and CQC (quality of care) with the disappearance of Strategic Health Authorities. Local Authority social care and education will sit down with NHS health to hammer out local priorities in Health & Wellbeing Boards, in theory held to account by local HealthWatch 'consumer representatives'. Locally, public health doctors will sit within the Local Authority whereas Public Health (England) will have the wider remit of nationwide issues, eg pandemic readiness. The potential roles of Clinical Senates and Clinical Networks are still under discussion.

The £20bn savings in the NHS have been described as cuts, but in fact under the last Comprehensive Spending Review the NHS was given a 'flat' settlement of around £110bn. ie no uplift with inflation. Therefore, the £20bn represents 'efficiency savings' necessary to pay for new, expensive treatments, to cover inflation and to deal with the secular drift to an older population requiring more medical care. The irony is that as medical and scientific ingenuity develop new treatments and technologies, financial costs and public expectations may also rise. Whereas vaccines, for example, may save both lives and costs, by preventing disease and reducing the demand on primary and secondary care, it is doubtful whether the same could be said of MRI scanning.

Approximately 40% of the NHS budget is spent on the salaries of over 1 million employees. One way to make 'efficiency savings' in the NHS is, paradoxically, to reduce access to care. For example, if operating lists for hip replacements are reduced and waiting times are allowed to rise, the NHS expenditure may go down (assuming fewer staff are employed). However, social care costs may rise if these patients need more assistance in the community to fulfill their daily activities. This is a danger of the 'silos' of government departments when the desire to protect one budget has unforeseen consequences on another part of the welfare state.

However, there are other pressures which suggest government, and beyond April 2013, the new NHS Commissioning Board will find it difficult to balance the books by a reduction in services. The final Francis Inquiry report into Mid-Staffs has now been delayed until early 2013, after which the Secretary of State will have to respond formally to Robert Francis' recommendations. Whilst the nursing and medical professions are likely to be in the firing line along with the regulators (eg CQC, GMC, NMC), the Secretary of State has already pledged to make long-term conditions and those suffering from dementia two of his four big priorities for the remainder of this parliament. This would suggest that Francis' recommendations in regard to these two groups will not be ignored lightly. The challenge becomes greater by the day. By 2030 there will be 2.6 million UK citizens aged over 85, instead of the current 1.1 million, and it is predicted the number of people suffering from dementia will have doubled to 1.4 million.

It may be that the direction of travel will be to enhance care in the community, "the best care as close to home as possible", but costs will not be kept down unless this is accompanied by a further reduction in secondary care beds. The last two decades have seen a reduction by one-third of inpatient capacity in the UK, highlighted recently in the RCP report Hospitals on the edge? The time for action, with ever shorter lengths of stay and a tendency to re-admissions ('revolving door medicine'). Over those two decades, numbers of admissions have increased by one third. The RCS and Age UK have also drawn attention in their recent report Access all Ages to implicit rationing of surgery on the basis of age, and there will be pressure to treat on the basis of clinical need and objective risk/benefit, ie on 'biological age' rather than 'chronological age'.

The new structures brought into play by the NHS Act were designed partly to encourage a bigger role for the private sector in providing healthcare. Historically, less than 10% of healthcare in the UK has been provided by the private sector, mostly outside the NHS with the patient paying directly or via an insurance scheme. An expansion in private healthcare provision is not, however, necessarily synonymous with an expansion in this 'fee for service' type of private health industry. It can also take the form of care which is free to the patient at the point of delivery, with the taxpayer reimbursing the private sector for the care which the private company provided.

So much for the Act. Most of the medical profession seem to be of the view that these organisational changes, of which this is the twentieth in as many years, do not go to the heart of the problems of the 2012 NHS. Most doctors think that what we urgently need is service re-design. Reports over the last couple of years from the RCPCH, RCOG and RCP have all flagged up the difficulty of maintaining high quality, acute services across over 200 sites in the UK. Whilst there is an undeniable need for 24/7 hospitals in

remote and rural areas, many of our hospitals are, for historical reasons, within 30 minutes' drive of another hospital. Does London really need 40 acute hospitals?

In medicine, there is often a relationship between quality of outcome and volume of caseload. There needs to be more of a public debate about treatment as close to home as possible vis a vis care which delivers world-class results. The designation of fewer, larger trauma centres; eight acute stroke centres for London instead of 32; and seven safe and sustainable paediatric cardiac surgery sites for England instead of 11 illustrate the benefits which can accrue. Highly technical, high-risk specialities need to be co-located with sufficient critical mass to ensure 24/7 cover and optimal training of tomorrow's specialists. Doctors recognise these are not easy issues for MP's, elected by and accountable to a local community who will not relish a reduction in services locally unless we as doctors articulate the benefits. Talking about hospital closures is a distraction – most sites will still offer local outpatient clinics and ambulatory care for part or all of the day. However, that does not mean every site needs to have inpatient beds and the full panoply of intensive care and all acute services 24/7. Of course, to make these changes work well, we will need prompt and well-trained retrieval and transfer services, and local health care services must be able to perform initial resuscitation and stabilisation of any unexpected cases on site.

Facing up to these competing challenges of economic austerity, more expensive care, organisational change and service re-design, I believe the medical royal colleges have much to offer. The colleges speak for the great majority of the UK's 200,000 licensed doctors on behalf of safe, high quality care for patients and the public. They are charities, not trade unions, and their members carry a wealth of experience and professional expertise. They are well-placed to provide expert clinical advice in dealing with these 21st century challenges. Indeed the Academy of Medical Royal Colleges is working with the NHS Confederation and National Voices on a project to identify the principles and good practice which should underpin the changes required by service redesign.

What will the NHS look like 10 years from now? The optimist in me says that if we can finally overcome the IT nightmare that was NPFIT and deliver a joined up patient e-record, things could be much better. Like the 'cloud' for my laptop, tablet and smartphone, it would be wonderful if every time I had a consultation, anywhere in the UK, with any doctor, nurse or pharmacist, that my basic medical history was available with my current medications. General Practice has had such systems for 30 years. Why do hospitals still lag behind and could this information be available beyond my own GP? Could I not carry my own information on a smart card?

Tele-medicine may also enable better care initiated by the patient at home. Already pilot studies have shown that diabetic patients can upload their daily blood sugar results by telephone or internet and receive advice on management. Near patient monitoring for coagulation studies and blood pressure could allow similar innovations, avoiding the need for attendance at health services.

Looking specifically at the future for doctors, in ten years revalidation should be bedded in and, hopefully, working to improve standards. It has been a long time coming, but being able to reassure the public that their doctors are fit to practice has to be the right thing. In ten years we should also be seeing the fruits of whatever emerges from the current hugely significant "Shape of Training" review of postgraduate medical education now underway.

The pessimist in me worries that by 2030 the UK is predicted to have 11 million obese adults. Already, one-third of school-age children are

overweight or obese. If nothing is done to avert this trend, the demands on the NHS for management of type 2 diabetes, hypertension and heart disease could swamp the service. In addition to these well-recognised associations with being overweight, obesity is now also recognised as a major risk factor for cancer. The Academy of Medical Royal Colleges will publish a report early in 2013 setting out the views of the medical profession on this hugely important public health issue.

Many challenges lie ahead for those of us who work in the NHS. But the NHS remains the envy of many countries because it provides care on the basis of need, not the ability to pay. Other countries spend a larger percentage of GDP on health but often the difference is largely accounted for by transactional costs - the bureaucracy required so that the healthcare provider can ensure that the patient's insurer is billed for every last needle and plaster used during the patient's care. Analysis by the Commonwealth Fund in the United States shows that the NHS provides unparalleled value for money. Since there is not likely to be more money in the near future, that is something to be proud of. ■

Professor Terence Stephenson

BSc BM BCh DM FRCP FRCPC

Professor Terence Stephenson BSc BM BCh DM FRCP FRCPC Nuffield Professor of Child Health, Institute of Child Health, University College London, Chair, Academy of Medical Royal Colleges.

Revalidation: The Need of the Day

Niall Dickson

The vast majority of doctors are good doctors – they have the skills and experience to deliver first-class care, and the range of interventions at their disposal is wider than it has ever been. But just as their capacity to do good has never been greater, the risks associated with medical care are also greater than ever. Revalidation is a response to those risks and opportunities. It is recognition of the critical role doctors play, and recognition too that safety and quality should be the organising principle in healthcare.

Doctors remain the most trusted profession in the UK. Among 15 Ipsos Mori polls of public trust over the last ten years, doctors have consistently been at the top . This is clearly reassuring. Yet it is clear that trust is much more likely to be questioned. The days when patients assumed that all doctors were universally good have gone.

It is ironic then that many patients believe there is already a system in place for making sure that doctors are competent and up to date. They know airline pilots and other key professionals in safety-critical industries are regularly checked and assume doctors must be the same.

Of course no such system exists, and only when revalidation becomes a reality will every doctor with a licence to practise become part of such a scheme.

If it works, revalidation has the potential to underpin the trust the public has in doctors, reinforcing it and providing patients with further assurance that the doctor treating them is competent and up to date.

Over time we believe it also has the potential to help identify problems in some doctors' practice earlier than is now the case. Giving practitioners the opportunity to collect information about the care and treatment they provide, including feedback from patients and colleagues, will provide them and their appraiser with an overview of their practice. Equally important is that all doctors will become part of a governed system, which is not only concerned with the standard of their practice, but is also required to make sure that every doctor is able to access the data needed to evaluate that practice.

For most doctors, perhaps the greatest potential benefit is in the opportunity it will provide for self-reflection - the chance to review their own practice and identify areas for development and improvement. As more comparative data becomes available it will also enable individual practitioners and teams to benchmark the outcomes of their practice against others, something we know is a major driver for improvement. All this must be good for both patients and doctors.

Nevertheless, revalidation is not a panacea. It will not solve all problems nor is it likely to produce instant results. We are not planning to shut down our fitness to practise operation, and no-one is suggesting that the system will be perfect. There will be glitches and we need to learn from them. Given the scale of what is involved - a programme covering 230,000 doctors and hundreds of organisations - it would be surprising if there were not lessons to be learnt for everyone involved.

The one thing we can say with some confidence at this stage is that even before it gets underway, revalidation has prompted a major strengthening of appraisal schemes and the vital systems which govern clinical processes. The evidence from countless inquiries has demonstrated that good clinical governance is a prerequisite for safe, effective healthcare. To that extent, revalidation has already made its mark.

There have been some concerns that we will require all doctors to revalidate immediately - that is not our intention. The idea is to roll out the process over the next few years. But our message to doctors is that while we do not expect every practitioner to be ready to revalidate now, everyone should be getting ready.

For most licensed doctors, being ready for their first revalidation means they need to have had one annual appraisal, with our core guidance Good Medical Practice as its focus, and that they have collected the various pieces of supporting information. They should also have had objective feedback from patients and colleagues.

Our ability to deliver revalidation, which will safeguard patients and help doctors improve the care they provide, relies on us being able to maintain the trust and confidence of everyone involved. This includes the patients we are seeking to safeguard, and the doctors we approve for revalidation. This requires us to be, and to be seen to be, fair, open and transparent in everything we do.

We have engaged extensively with those who have an interest in our work across the UK. From this we know there are concerns that revalidation may have an unfair or disproportionate effect on particular groups of doctors, including locums, doctors working overseas, doctors working part-time and doctors who take career breaks.

On this, first it is worth noting that revalidation has the potential to drive more consistency and fairness in evaluating a doctor's practice. The process should help to ensure that all doctors receive an annual appraisal and the support they need to reflect on their work.

We are working with others to put in place safeguards that will help make sure that the process is fair. We know that some doctors are concerned that some elements of revalidation have the potential to be 'unfair'. I want to address each of these concerns and set out what we are doing, in partnership with others, to respond.

First, some doctors are concerned that access to appraisals and supporting information may be harder for particular groups of doctors, such as locums (in primary and secondary care). We have seen that by making a doctor's revalidation dependent on them receiving a regular appraisal, revalidation is helping to drive up rates of appraisal and improve access for all doctors. NHS employers have also produced supplementary guidance aimed at reminding employers of their responsibilities towards locum doctors, and we have said publicly that we will not penalise doctors if their employers or responsible officers fail to prepare for revalidation or put in place ineffective systems of appraisal.

Secondly, we need to ensure flexibility for doctors who find revalidation challenging because they are absent from work due to ill health, periods of time overseas, or career breaks to care for family. To ensure flexibility, we will have the power to vary a doctor's revalidation date in response to individual circumstances. Responsible officers will also have the ability to defer their recommendation if the doctor has not been able to gather all the supporting information by the time a recommendation is due.

Deferral does not signal anything negative - it is a neutral act - and in those circumstances the doctor would continue to hold their licence. We have also made it clear that we will not penalise doctors if they have been unable to engage with revalidation because of ill health.

Thirdly, doctors have, perhaps understandably, expressed some concern about bias in feedback that they may receive from patients. GMC patient and colleague questionnaires have been subject to detailed research by the Peninsula Medical School, which has enabled us to identify particular limitations. As with any questionnaire of this kind it is important to take into account any bias when interpreting and providing feedback. We have made this clear in the instructions that accompany our questionnaires and in more detailed guidance to help appraisers interpret and handle the results. Remember too that the questionnaires are just one piece of information that feeds into the appraisal process - useful though they will be as a development tool, it would be a mistake to place too much weight on them. In any event, the evidence is that patient feedback on all types of doctor and from every background is overwhelmingly positive.

And finally, a key fairness challenge will be to make sure the recommendations from responsible officers are consistent. To tackle this, we have drawn up clear guidance on how to assess evidence and make recommendations. Responsible officers will themselves be subject to revalidation like all other licensed doctors, and will receive regular appraisals to check and review their recommendations. It is also worth noting here that designated bodies (which employ responsible officers) are subject to the 2010 Equality Act.

We believe these safeguards should ensure that revalidation is delivered fairly, openly and transparently. But we will need to evaluate its impact to make sure it is working fairly and to learn how it can be improved. As a result we will be conducting a programme of evaluation, supported by commissioned research, to assess its impact, including the impact on different groups of doctors.

In tandem with this, there will be a separate quality assurance programme. We will collect and analyse data about the recommendations that responsible officers are making, to ensure they are consistent and fair.

Revalidation will not be perfect and there are bound to be glitches in a programme of this size, but with goodwill on all sides, the medical profession and the UK health system will have created an assurance system that can be developed and improved over the years.

Revalidation is about underpinning the trust patients have in their doctor. Once it is fully implemented, patients should have confidence that the doctor who treats them will have demonstrated on an ongoing basis that they are competent and fit to practise. This is good for patients and for the profession. ■

Nial Dickson

Niall Dickson joined the General Medical Council as Chief Executive and Registrar in January 2010. He leads the Senior Management Team, which is responsible for the day to day running of the GMC. Niall is a member of the Department of Health's End of Life Care Implementation Advisory Board and former member of the Cabinet Office Honours Committee (Health). In 2008, he chaired a cross-party commission on accountability in health for the Local Government Association (LGA). He is a trustee of the Leeds Castle Foundation. His honorary awards include being a Fellow of the Royal College of Physicians and as Fellow of the Royal College of General Practitioners.

Challenges for the National Health Service

Raj Kathane

The theme of the BAPIO conference this year is very timely and appropriate. UK's most beloved institution, the NHS is very much at the crossroads. This article highlights some of the challenges that the NHS faces over the next several years.

It is important to note that delivery of health services in all the nations around the world has been going through a sea change balancing, on the one hand, the new technologies and on the other, the struggle to keep costs down and keep services affordable. The economic down turn which started in 2008 and shows no signs of abating, certainly not in the western countries, has made it imperative for policy makers to re-think again and again, this delicate balancing act.

During the boom years from 1997 to 2005, the NHS had seen phenomenal injection of cash, giving rise to much-needed investment in new hospitals, manpower, wages, hi-tech equipments, IT systems and so on. However, with stark reality staring in the face, the current Prime Minister had to announce that there was little prospect of any significant new funding coming to NHS until about 2020.

So what are the challenges?

Capacity v. Demand:

Because of the noble founding principles of NHS ('...free at the point of delivery…..') it was inevitable that the population would have high expectation about their demands to be met, what ever the demands. Over the years this has been seen in such extreme phenomena as calls for GP home visit for really trivial complaints, calls for ambulance services for completely inappropriate reasons etc. It is imperative for NHS to be able to provide appropriate level of service for appropriate priority. This stretches the NHS's capacity to deliver in the face of growing demand.

Another factor that stretches the Capacity is the size of the population and demographics. Since the inception of NHS in 1948, the population of UK has grown from approximately 47 million to the current figure of just over 62 million [1]. At the same time, life-expectancy has increased significantly from around 65 in 1950, to about 80 in 2010 [2]. The increasing age of the population puts even more demand on the NHS services as the number of illnesses / conditions (such as cancers, coronary heart disease, dementia, fractures etc) that need to be treated, needs more bed-days because of longer healing time. Apart from such 'natural and expected increase' in age-related conditions, there are other trends which stretch demand: exponential increase in alcohol intake in the teen-age population has been much publicized in the recent past, but a more recent report identifies that long term, heavy drinking among the 'baby-boomers' generation is putting a far bigger burden on the health service. Alcohol-related in-patient admissions among 55 to74 year olds cost NHS £825 million in 2011; among the 16-24 year olds, that figure was about £64 million. This cost is driven up by nearly 8 times more admissions in the older age group, compared to the younger. [3, 4, 5, 6]

Burden of chronic diseases: Just taking one example of diabetes, recent estimates [7] are that in the UK, 3.8 million people have type II diabetes and 7 million are at risk of developing it. Type-II diabetes is occurring at earlier age. Type-I diabetes is occurring with greater frequency. There is an epidemic of obesity—this is a world-wide phenomena. It is expected that 25% of the world's population will be obese; this will add 1 billion extra obese people.

When Aneurin Bevan founded NHS on the 5th of July 1948, the implication was that the NHS was meant to be for the citizen of the UK. Back then, UK certainly was the island nation, travel from the mainland Europe was not as easy as it is now and the immigration—both for pleasure and for work—not a big factor as it is now. Lack of these factors then made it easier for NHS to deliver. During the 80s and 90s immigration from non-EU countries increased, and as the word got around that it was possible to get free treatment in the NHS, many took advantage. Similarly, with the EU expanding during the early years of this century, we saw a similar phenomenon of immigration from the Eastern Europe. It is possible that some of these factors are under control now, however, unlike many other western countries, in UK, there is no requirement, at the point of requesting medical help, to show or confirm the citizenship or otherwise any medical insurance, if one is not a UK citizen or resident.

Integration of Health and Social Care: As the demands for services to the elderly and people with mental illness increase, it is inevitable that there should be greater integration between Health and the Social Care.

Technology: Advances in medicine and technology are happening at ever increasing pace and at exponential rate. New technology is expensive as are new drugs. These advances increase life span and whilst this is generally desirable, it also increases demand as mentioned above.

Social Networking: Increasingly, the phenomena of technology-based social networking (not the old fashioned, 'go and meet my friends') is going to play greater role in human interaction and therefore will influence the delivery of health services.

Competition:

The dictum of market-forces and assumption that competition drives down prices has been relentlessly applied in the NHS. The usefulness of this approach has been limited but nevertheless has created another tension between different care giving systems and has created much instability. This reduces staff morale significantly.

PFI:

Another variation of the above was the development of the Private Finance Initiative (PFI). In the opinion of many analysts, this approach has been wasteful of public purse.

Size and Budget of NHS: NHS is the world's 4th largest employer. It employs 1.7 million people [8]; of these about half are clinically qualified, there are 39,000 GPs, about 411,000 nurses, 104,000 medical and dental staff employed in the hospitals and community health services and about 18,500 ambulance staff. Only Chinese army, the Indian Railways and Wal-Mart supermarket chain employ more people directly. In 1948, at inception,

the NHS budget was £437 million (£9 billion in today's money). By 2011/2012, the budget has grown to £106 billion. Surprisingly, no accurate figures are available about how much of this is spent on staff salaries. The figures vary wildly from 38% to 55% to 70%. If, as is widely believed, nearly 2/3rd of the budget is spent on salaries, it is self-evident that to keep the Health Service affordable, there needs to be significant trimming of all these costs.

At a time when most of the countries in EU are going through severe austerity and therefore cuts in services and salaries, UK, being affected by the same strong and adverse financial winds, policy makers will be seriously considering how to make NHS leaner and to provide more value-for-money. The Government has declared that NHS must find savings of £20 billion by the end of this parliament in 2015. The following are main options:

a. Make staffs work for longer: the pension age for public service workers has recently been increased from 65 to 68. This has seen the first industrial action (July 2012) in 40 years by doctors (although it was poorly supported).

b. Reduce the numbers of higher salaried posts: A workforce survey of the Royal College of Physicians suggests that the number of 'sub-consultant' posts has quadrupled in the past 4 years.

c. Redundancies and reduce or freeze salaries: On 15 July, a consortium of 19 NHS Foundation Trusts in the South West of England, who employ some 60,000 staff (about half of them medics) declared that they were to introduce pay cuts of up to 5%, an end to overtime for nights, week ends and bank holidays, reduced holiday leave, forcing staff to work longer shifts and slashing sick pay rates. It is called the 'South West Pay, Terms and Conditions Consortium' [9]

Policy Exchange, a powerful and influential Conservative think-tank has suggested [10] that national pay bargaining for public sector workers should be scrapped in favour of locally negotiated pay linked to performance and automatic annual pay increases and progression points should be also be ditched. It suggests that incentives should be used to boost productivity. .The previous secretary of Education had lent a strong support to such an initiative to be applied to teaching profession.

What should the NHS and the country do?

Reducing Administrative Wastage:

NHS desperately needs a settled period in which the staff can get on with the job of assessment and treatment of patients without having to constantly worry about the major changes in the structure of NHS. It is widely believed that the current change from the PCT to Clinical Commissioning Groups (CCG) is untimely, unnecessary and wasteful and that the need for this change had never been convincingly demonstrated. Even if this change were to bring about some savings to the NHS, did it justify the huge amount of money that is being spent to bring about the change not to speak of the disruption to the well-established care-delivery systems and administrative structures as well as the adverse effect it had on the morale of the staff as they started moving around from Trust to Trust looking for better job security in the face of the perceived insecurity?

Prevention:

'Prevention is better than cure' says the old adage. This has never been truer than in the current age. NHS was been set up to treat illness and not as a Health or Wellness regime. Over the past few decades, the emphasis has been shifting: there have been campaigns for smoking cessation, vaccinations for children, reduction of alcohol intake and binge drinking, intake of fruits, vegetables and fibre for prevention of colon cancer, winter flu jabs for children and the vulnerable elderly just to name a few; however could even more be done for prevention? It is heartening to note that the Government intends to winter flu vaccine to all children by 2014. Although this is likely to cost £100 million, the projection is that it will prevent 11,000 fewer hospitalizations and possibly 2000 deaths, the combined cost of which would be vastly more. National Survey on Diet and Nutrition suggests [11] that over the past 25 years, British eating habits have not changed significantly. Only 30% of adults and 10% of children eat the recommended amounts of fruits and vegetables. These figures are even lower in people in receipts of social security benefits. In fact the recommended amounts of '5-a-day' are only recommended minimum: the true advisable figures are nearer to 8-a-day. Should the government give fruits-and-vegetable vouchers / coupons to the people on benefits to increase their consumption, at the risk of being branded as a nanny state? And what about discount vouchers for fitness / wellness clubs (to positively encourage fitness and exercise-taking) for population, dependent on good level of monitoring for attendance?

Treatments at home:

Hospitals are expensive and can often lead to HAI (Hospital Acquired Infections) especially in the vulnerable, elderly population. The NHS will have to find increasingly innovative ways of treating people at home and reducing the hospital stays. More and more procedures will be performed by minimally invasive and key-hole surgery. [See: C f WI predictions under Manpower Issues below].

Tele-medicine:

Technology, which creates new problems (see above), could also come to the rescue. Could NHS employ the services of doctors and other personnel / professionals who work in the Health Service but stationed outside the UK? Take for example the advances in digital revolution. Imaging (old fashioned x-rays for you!) is now digitised and these can be viewed and commented upon by experts several thousand miles away. There are already examples of this happening, for ex., the Post Graduate Institute (PGI) in Chandigarh, India are offering radiological services to UK hospitals.

Another aspect of the tele-medicine is how new technologies can and will be used to deliver health service. Following are some examples: NFC (Near Field Communications) technology will be used to monitor patients' vital signs and obtain live health data by phone, using NFC sensors, while the patient is at home. Automated computer systems already send reminders to patients to attend their out-patient appointments—could these be set up to send regular reminders to selected patients to take their medicines? Such selected patients are those with dementia, mental illness and those on complex regime of multiple medications. There is good deal of evidence that taking medications in a timely fashion reduces the incidence of relapses and deterioration.

Outsourcing:

I understand that it is a common practice in the USA for clinicians to do dictation using the digital equipments, the dictation is then sent to countries like India or Malaysia for typing and the finished document is sent back to USA in time for the start of the next day, to be checked by the clinician, signed off and posted. As the wages paid to the typists in the out-sourced countries are a mere fraction of those paid to the country of origin (in our case, UK), this saves on salaries; but will create another problem of unemployment in UK.

Charging for certain non-essential treatments such as removal of tattoos, or failed appointments (DNA) by the patients, if done wilfully or neglectfully. Proving this will be problematic and administration of this may turn out to be more costly in the long run. It will also mean that in return, to be fair to the patients, hospitals should not cancel scheduled operations and other procedures.

Trusts run by private organisations and Trust mergers / take-overs: Monitor's Chief Operating Officer has predicted that by 2015 many Foundation Trusts would be financially weaker. When a Trust runs in financial difficulties with big debts, it is thought that some times they could be run more profitably by private organisations. Hinchinbrook hospital in Huntingdon is one such example. Following from its success, the South London Healthcare Trust, which runs hospitals in Woolwich, Orpington and Sidcup, which had reported a deficit of £65 million in 2011/12, became the first to be put in to administration by the Health Secretary with an administrator being appointed who has formally asked all interested parties—NHS and private—to show expression of interest to run the services [12].

Medical tourism: Already, there are examples of patients from the western countries going to places like India, Singapore and Malaysia on a package of medical treatment (such as cataract removal or hip replacement) combined with recuperation and tourism to popular places. This often turns out to be quite cheap, certainly at a fraction of a cost of doing the same procedure privately in the UK, and there is the feel-good factor of exotic holiday and good weather. The down side of this is that in the event of complications arising after the event and after return to UK, it will be the NHS that will be expected to deal with the problem.

Learning from India: There are examples in India where procedures are performed very cost-effectively, for ex., a hospital in Bangalore performs many heart operations in rapid succession or in tandem or in parallel and Aravind eye Hospital System in several locations in India claim to perform eye surgery very cheaply and effectively, mostly for the poor people. Such models of care, often derided in the west as 'sausage-factory model' may offer very effective models to emulate and should not be discounted.

Expanding to other countries: Undoubtedly, UK offers one of the best medical care in the world with exceedingly high quality. The Care Quality Commission (CQC) in UK is an extra-ordinary development to ensure highest quality of medical care. UK is therefore uniquely placed to offer to the other countries, where health service is not so well developed, examples of good practice and high quality at the same time earning some capital for own use.

Manpower Issues: Until 1995, there was a general agreement that UK was training far fewer a number of doctors than was required for servicing the NHS, therefore the Government in 1997 decided to open up more medical schools and increase the number of places in the existing schools; and to allow immigration of qualified doctors from other countries to fill the gap in the interim. This picture has changed rapidly: in 12 short years: CfWI (Centre for Workforce Intelligence), an influential body has estimated [13] that if the NHS continues to recruit and train hospital doctors at the rate it is doing now, by 2020, there will be a 60% over-supply of doctors eligible to become Consultants, thus leading to very considerable frustration in the trainees who would have a natural expectation to become Consultants as

career progression.

Perhaps, as a result of this, the UK Universities are planning to reduce the number of medical places from current 4000 to 1000. This will open up the possibility of private medical schools operating in UK, as it happens in countries like India.

What lies at the distant horizon and beyond?

Targeted and tailor-made medicines:

For many years, pharmaceutical industry has said that the days are near when drugs will be formulated to suit an individual patient's unique needs, taking in to account their DNA and genetic structure so as to eliminate side-effects. Similarly, that drug delivery systems will evolve to target individual tissues (such as a cancerous growth) rather than the current 'scatter-gun' approach. What lies ahead with the relatively new nanotechnology and nano-machines? Leicester University is already performing 'computed autopsy' which does away with traditional 'surgical cutting autopsy': could future systems be perfected, along the same lines, to make automated diagnoses?

High Technology:

Although, advances in technology are expensive, paradoxically, high-technology can also come to the rescue. This year's Nobel Prizes in Physics and Medicine are most significant: the prize in Physics [Haroche and Wineland—"…on measuring and manipulation of individual quantum systems without destroying them…"[14]] showed that it will soon be possible to construct unimaginably powerful quantum computers, which are expected to hit shop-floors around 2020 or earlier. The famous futurologist, Ray Kurtzweil has been predicting [15] that singularity between humans and machines is likely to happen sometime around 2025. This is the state when the processing power of a computer will be equal to that of the human brain and 'machine intelligence out-paces the biological brain'. Computers will therefore be able to write programs for themselves and also evolve to make themselves better. This means computers will be able to design and run system—including hospital systems that may not need human input. Diagnosis and treatment could be automated…… and much more.

The Prize in Medicine [Gurdon and Yamanaka) "… for the discovery that mature cells can be reprogrammed to become pluripotent…." [16]] means that some time in not too distant future, damaged organs will be repaired or replaced by patient's own tissue, with no need for transplant or recourse to immuno-suppressant drugs. There will be no need to hook up a patient with failing kidneys to dialysis machines 3 times a week or for diabetic patients to take medicines for the condition because the necessary cells will be regenerated by reprogramming the ordinary mature cells through the stem cells pathway.

The combination of the above two (and such other) developments creates a possible picture that doctors as we know them now, may not be needed. All the 'algorithm-based' specialities and branches of medicine could be replaced by intelligent machines. Skill-based 'hands-on' specialities (such as surgery) will have progressively reducing dependence on humans and may eventually vanish. There was the famous case, in 2005 of the Italian surgeon performing a surgery on his patient in Italy, using a computer and a robot, as he guided the robot while being in an operating theatre in New York. Tele-surgery and Robotic Surgery it seems, is already here, just Google it!

Who knows what the Science and Art of Medicine will look like in 2030—it is just about 15 short years away! ■

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Dr Raj Kathane
Dr Raj Kathane MD, FRCPsych is a Retired Consultant Child and Adolescent Psychiatrist and Past President of BAPIO

Radial Artery Versus Saphenous Vein As Conduits In Coronary Artery Surgery: Comparison Of Intermediate To Long-Term Outcomes

Rajdeep S. Bilkhu, Anne S. Ewing, Vipin Zamvar

Abstract

BACKGROUND AND AIMS

The radial artery has become an increasingly popular arterial conduit in coronary artery bypass graft surgery (CABG), however little data exists with regard to comparison of quality of life in patients undergoing CABG with radial artery grafts and those with conventional saphenous vein grafts. The aims of this study were therefore to identify any difference in long term quality of life in surviving patients between those undergoing CABG with radial artery grafts and those with saphenous vein grafts.

METHODS

Standardised questionnaires (SF-36 and Euroqol EQ5D) were sent to assess quality of life in 130 patients who had undergone CABG with venous grafts (Group A) and 130 patients who had undergone CABG with radial artery grafts (Group B). Information was also gathered to determine any angina recurrence following CABG in the patients included in the study. In addition, information on any major adverse cardiac events (MACE) occurring post-CABG was collected.

RESULTS

70 responses were received from Group A and 82 from Group B. The mean follow up time was 6 years in both groups. On analysis there was no statistically significant difference between both groups with regard to quality of life (based on SF-36 and EQ5D scores), angina recurrence or MACE.

CONCLUSION

Our study identified no additional benefit in using radial artery grafts over saphenous vein grafts with regard to quality of life, MACE or angina recurrence in the medium term.

Introduction

The advantages of arterial endothelium have resulted in the use of arterial conduits in coronary artery bypass graft surgery (CABG), and this has become an increasingly popular alternative to saphenous vein grafts (SVGs). This is largely due to low rates of recurrent atherosclerosis in arterial grafts, which consequently results in lower incidence of recurrence of symptoms of myocardial ischaemia.[1, 2]

The left internal mammary artery (LIMA) is considered the "gold standard" conduit in myocardial revascularisation due to excellent long term patency.[1-3] The poor long term results seen with SVGs, and promising results seen with LIMA has led to the search for additional arterial conduits for CABG.[4]

The radial artery (RA) is being used more commonly as a conduit for CABG. Studies have demonstrated superior patency rates in patients receiving RA grafts over SVGs. [3,5] It is well known that vasoactive substances produced by arterial endothelium are protective and so are likely to have a role in the excellent patency rates of arterial conduits seen in those such as the RA.[6, 7]

Despite this, there is some angiographic data in early post-operative patients suggesting poor RA graft patency. This may be related to the spasmogenic nature of the radial artery.[8] Indeed; it was noted soon after Carpentier et al first proposed the use of radial arteries for CABG in 1973 that spasm and occlusion occurred in these grafts.[9] This led to the RA being abandoned before being introduced again in 1992 by Acar et al.[9, 10]

The benefits of the radial artery in the longer term should therefore be ascertained to determine its suitability as a potential alternative to venous grafting. In particular, the benefits on patients' quality of life should be identified to help in determining the suitability of the radial artery as a conduit for CABG.

We therefore selected a sample of surviving patients in the period 2001-2002 who underwent CABG and received RA grafts. We analysed their perceived health related quality of life (QOL) and any major adverse cardiac events (MACE) occurring post-CABG and compared this to data obtained from patients who had received SVGs at CABG in the same period. Data was also gathered relating to angina recurrence and further cardiac procedures performed after CABG such as percutaneous coronary intervention (PCI).

Based on available data, it was hypothesised that those receiving RA grafts would report a higher quality of life, less angina, and fewer MACE than those receiving SVGs.

Methods

Ethical approval was obtained from the Lothian Research Ethics Committee.

Between January 2001 and December 2002,[11,12] patients underwent primary isolated first time CABG at the Royal Infirmary of Edinburgh. Of these patients 1073 had 3-vessel disease. Patients were divided into three groups depending on the conduits used for surgery. Group A consisted of patients who received a LIMA graft and one or two SVGs. Group B consisted of patients who received a LIMA graft, and a RA graft with or without additional SVGs, as required. All other patients, who received only veins, bilateral mammary artery grafts, or other conduits were put into group C and excluded from the study.

Group A consisted of 591 patients, and Group B consisted of 194 patients. Patients who died in hospital were excluded from both groups. Data was obtained from the Registry Office to exclude

patients who died after discharge from hospital.

Of the surviving patients, the first 130 in chronological order of operation date from each group were selected for the purpose of this study.

Patients in both groups were sent questionnaires to assess QOL. Standardised questionnaires, the EuroQol EQ5D and the SF-36 Health Survey were used. [11, 12] To assess for the presence of exertional chest pain, the shortened ROSE angina questionnaire was used.[13, 14]

In addition, a separate questionnaire was written to collect data on patients' current medication, MACE occurring post-CABG and any strokes, angina recurrence, follow up percutaneous coronary intervention (PCI) or CABG and any pain from the conduit harvest sites or from the sternal wound. It was assumed those reporting higher health related QOL scores in the EQ5D and SF-36 questionnaires would be less physically and mentally restricted by their ischaemic heart disease and would have had a good outcome from their CABG. Similarly with angina recurrence and MACE, lower reported rates of these would suggest a more positive outcome overall and a higher QOL.

Patients were asked to complete and return the questionnaires in the prepaid envelope provided. Those who did not reply were sent reminders after 3 weeks to maximise the number of responses. The replies received were then entered onto a spreadsheet and quality of life scores calculated.

Results

STATISTICAL ANALYSIS

Data collected from questionnaires was stored on a spreadsheet and analysed using SPSS v13.0 for Windows.[15] Continuous variables were expressed as the mean ± standard deviation and analysed using the student's t-test. Categorical variables were analysed using the chi-square test or Fisher's exact test, as appropriate. A p value of <0.05 was considered statistically significant.

130 questionnaires were sent to each group. In group A, 46 reminders were sent and a total of 70 responses were received. In group B, 58 reminders were sent, and a total of 82 responses were received. Patients who did not respond were excluded from the study.

Questionnaires were received from 152 patients. The calculated scores and totals for the domains assessed in group A (n=70) and group B (n=82) were then compared. The patient characteristics are shown in Table 1.

Results and comparison of the assessed domains is shown in Table 2.

Table 1: Characteristics of both patient groups at time of surgery

	Group A, n=70	Group B, n=82	P
Mean Age	67.5	61.4	p<0.01
Mean Weight	77.7	83.9	p=0.01
Mean Parsonnet	4.11	2.7	NS
Mean EuroSCORE	3	2.18	NS
% with Hypertension	61.4	54.9	NS
% with Diabetes	11.1	21.9	NS
% with Normal Left Venticular Function	68.6	70.7	NS
% with Impaired Left Ventricular Function	31.4	29.3	NS
Total number of patients on Statin (%)	58 (82.86%)	70 (85.36%)	NS
Total number reporting MI following CABG (%)	3 (4.29%)	3 (3.66%)	NS
Total number reporting Stroke following CABG (%)	2 (2.86%)	3 (3.66%)	NS
Total number reporting Recurrent Angina (%)	8 (11.43%)	15 (18.29%)	NS
Total number undergoing PCI following CABG (%)	12 (17.14%)	13 (15.85%)	NS
Total undergoing further CABG operation (%)	0	0	NS
Total number reporting pain in chest wound (%)	9 (12.86%)	13 (15.85%)	NS
Mean EQ5D Score (%)	0.7994	0.7522	NS
Mean EQ-VAS Score (%)	72.95	72.87	NS
Total number with ROSE Exertional Chest Pain (%)	17 (24.28%)	21 (25.61%)	NS
SF-36 Physical Component Summary Score (%)	41.6	43	NS
SF-36 Mental Component Summary Score (%)	52.6	54.1	NS

MI = Myocardial infarction; CABG = Coronary artery bypass graft; PCI = Percutaneous coronary intervention; EQ5D = Euroqol 5D Questionnaire; EQ-VAS = Euroqol visual analogue scale; SF-36 = Short form 36 questionnaire

MEAN FOLLOW-UP

The mean follow-up in Group A was 78 months, and in Group B, 72 months.

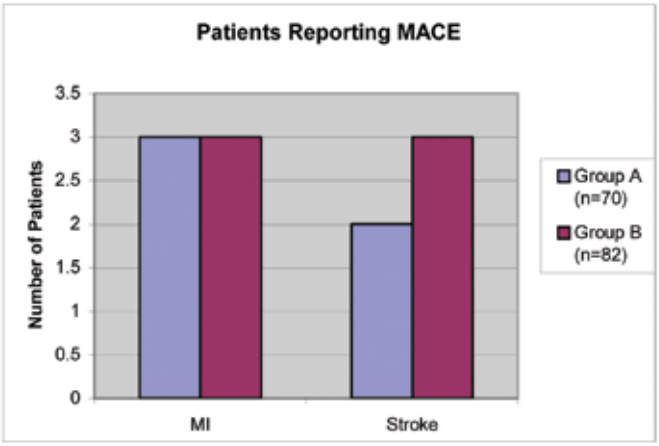
AGE and OPERATIVE RISK

Patients who received vein grafts, i.e. group A, were on average older than group B patients who received radial artery grafts, as shown in Table 1.

MAJOR ADVERSE CARDIAC EVENTS (MACE) & STROKE

As shown in table 2, most patients in both groups were taking statin medication at the time of completing the questionnaire (83% and 85% in group A and B respectively). With regard to MACE, 3 patients in each group had suffered an MI (p=0.84) where as 2 people suffered a stroke in group A and 3 in group B (p=0.79) (See Figure 1). No patients in either group underwent a further CABG operation.

Figure 1: Total number of patients suffering MACE



PERCUTANEOUS CORONARY INTERVENTION (PCI)

12 (17.1%) in group A and 13 (15.8%) in group B had undergone PCI following their CABG operation (see Figure 2). However, there was no statistical significant difference (p=0.8). PCI was performed at a mean of 59 months after CABG in Group A, and 60 months in Group B.

Figure 2: Percentage of patients undergoing PCI

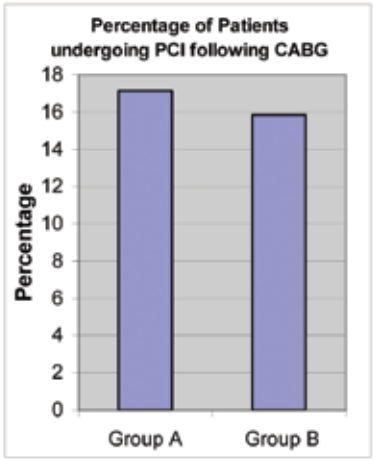


Figure 3: Percentage with ROSE Chest Pain

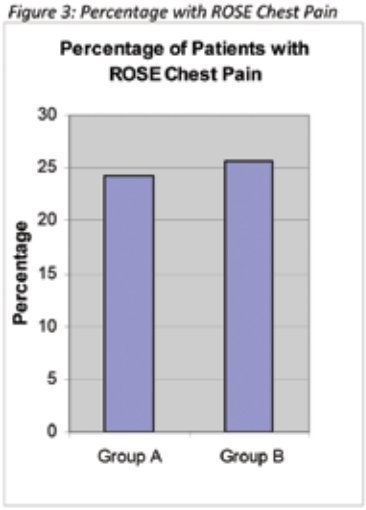
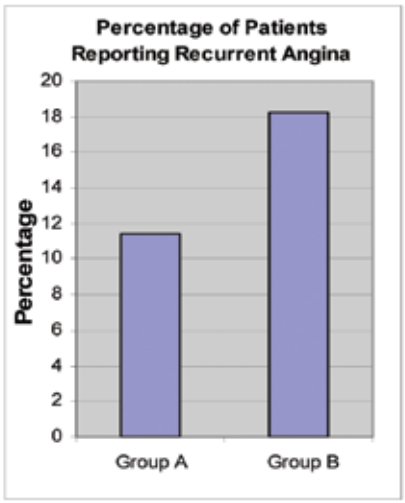


Figure 4: Percentage with Angina Recurrence



ANGINA RECURRENCE and CHEST PAIN

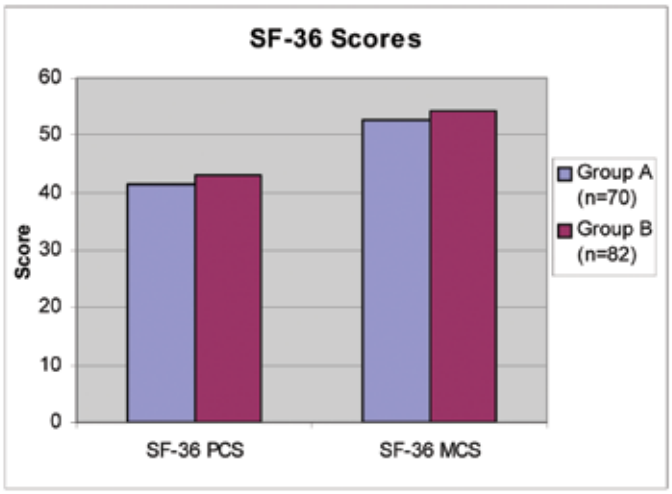
In group A, a total of 8 patients (11.4%) reported recurrent angina where as 15 (18.3%) in group B had experienced angina following CABG (p=0.23). ROSE scores showed similar numbers of patients in both groups experienced exertional chest pain following CABG.[13] (See Figures 3&4)

9 from group A and 13 from group B (p=0.18) complained of pain in the sternal wound. When reviewing comments made by patients, it was noted that most who experienced this described discomfort or an itch as opposed to pain per se. Some patients complained of reduced sensation on the left side of the chest, correlating with the use of LIMA. A number of patients, particularly in group B, complained of itching and discomfort in the conduit harvest sites.

QUALITY OF LIFE

Health related QOL was assessed by administration of Euroqol EQ5D and SF-36 Health Survey.[11, 12] After recoding, scores were calculated. The Euroqol EQ5D provided an overall score based on 5 separate health related questions, where as the SF-36 provided scores for a number of 'health components' based on the questions answered, which were then collated to give a physical component summary (PCS) score and a mental component summary (MCS) score. Group A patients had a mean EQ5D score of 0.7994 where as the mean for group B patients was 0.7522 (p=0.26).

Figure 5: SF-36 Component Scores



The mean SF-36 PCS score for group A was 41.6, whereas in group B a mean score of 43 was reported (p=0.54). MCS scores for both groups were similar; 52.6 and 54.1 for groups A and B respectively (p=0.36). Both groups scored consistently higher in the mental component score. (See Figure 5).

As part of the EuroQol questionnaire, patients were asked to score their own health out of a total of 100 (the Euroqol Visual Analogue Scale or EQ-VAS). The mean scores (detailed in Table 2 as Mean EQ-VAS Score) for groups A and B were, again, similar.

Results showed no statistically significant difference between group A and group B in relation to MACE, PCI procedures performed after CABG, angina recurrence or QOL. A statistically significant difference was noted with regard to patient age at the time of operation (p<0.01).

Discussion

Despite the increasingly popular use of the RA as a conduit for CABG, this study has shown no statistically significant difference in the long term with regard to health related QOL, angina recurrence or major adverse

cardiac events between those undergoing CABG with SVGs and those receiving RA grafts.

The results obtained are contrary to what we believed, as it was anticipated those undergoing CABG with RA grafts would report lower rates of angina recurrence, lower rates of MACE and a higher QOL. The results are somewhat contradictory to the popular conception that RA grafts are superior to venous grafts.[10, 18, 19]

Promising data from Shah et al demonstrated patency rates of RA grafts to be as high as 96% after 5 years, in a sample of 209 post-CABG patients. Certainly, others have confirmed similar findings.[20] This has led to some considering the RA a second choice conduit after the "gold standard" LIMA.[21,22]

In our study, all patients received left internal mammary artery (LIMA) to left anterior descending (LAD) grafts. Based on strong evidence from numerous studies, the LIMA has been shown to have particularly high patency rates.[23-25] The LAD artery is the most important of the three coronary arteries, and grafting this with the LIMA is responsible for the majority of the beneficial effect of CABG operation. In our study we compared the RA versus SVG applied to the second and third most important coronary arteries. The possible additional benefit of using RA grafts was studied and showed no difference in QOL or angina recurrence. Although no specific studies have been conducted into QOL in this context, many have looked at angiographic data in patients who had received RA grafts and compared this to those who have undergone CABG with SVGs. Calafiore et al identified improvement in long term angiographic outcomes in patients receiving RA grafts as compared to those receiving SVGs and showed that vein graft patency was worse (91.7%) than radial graft patency (99%) suggesting a greater incidence of angina recurrence in those receiving SVGs.[5]

Our study is unique in that the comparison of health related QOL in patients receiving venous and arterial grafts is not well documented. Studies have looked at the effects on QOL post CABG and have demonstrated supremacy against medical treatment of coronary artery disease.[26] Despite this there has been no specific study assessing QOL and comparing this in those who have undergone bypass with venous or arterial grafts.

As mentioned, the QOL scores in both patient groups were similar. The difference between SF-36 health scores of both groups was not statistically significant, similarly with EQ-5D scores. Even with numerous studies demonstrating superiority of the RA over SVGs in terms of patency rates, this it appears did not translate to a higher patient perceived health related QOL in the RA group of our study.

The similarity in results may be accounted for by use of LIMA, in that the use of this "gold standard" conduit may have had such a dominant influence on outcome in the studied patients due to its excellent long term patency, resulting in both groups experiencing similar results and therefore reporting similar QOL and to some extent, angina recurrence. As well as this, the length of follow up in the study may have had a role to play. In our study, the average follow up was 6 years and so an even longer follow up may have identified a more significant difference in QOL and in angina recurrence.

With regard to the age of the patients studied, the mean age of group B was significantly less than that of group A. As patients in group A were older, it is likely that many of these patients suffer co-morbidities, such as musculoskeletal or respiratory disease and most likely this would produce a lower QOL score. As patients in group B were younger, this would not seem to account for the similarity in QOL scores observed as one would expect these to be higher than group A scores. This may suggest those in group B are more limited from their cardiovascular disease. However,

as the number of those reporting angina recurrences and other MACE is similar, it would not seem appropriate to draw the conclusion that quality of life is lower than what one would expect in this group.

A limitation of the study is the relatively small sample size and that despite showing a marginal difference between both groups, this possible difference did not reach statistical significance to allow us to draw fully valid conclusions. A further, larger follow up study would be a suitable means of assessing any possible difference in QOL, angina recurrence and MACE. In addition, matching patients, particularly in terms of age may help to provide a more accurate assessment of quality of life between both groups as the impact of illness and disease is highly likely to have an influence on the quality of life of a patient at different ages in life.

CONCLUSION

In summary, our results show that the use of the RA as a conduit for CABG does not confer any additional benefit over SVGs in the intermediate-to-long term with regard to QOL, angina recurrence or MACE. ■

Acknowledgements

Funding for this study was received from the Royal Medical Society, Edinburgh.

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Rajdeep S. Bilkhu, Anne S. Ewing, Vipin Zamvar
Department of Cardiac Surgery,
Royal Infirmary of Edinburgh

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Early Results of ERAS (Enhanced Recovery After Surgery) Protocol in Orthopaedic Surgery

Jaydeep Shah, Keshav Singhal

Abstract

The concept of fast track (Enhanced Recovery After Surgery, ERAS) was introduced to colorectal surgery in Denmark by Kehlet in 1999 which improved the quality of the care and reduced the length of hospital stay following major colorectal surgery. The same principles of ERAS have been applied to the orthopaedic surgery particularly the hip and knee replacement surgery and fracture neck of femur surgery. It is a relatively new approach in orthopaedics to the preoperative, intraoperative and postoperative care of the patients undergoing surgery.

We have compared the length of inpatient stay, day of mobilisation, postoperative blood transfusion and adverse outcome for the patients undergoing hip or knee replacement by a single surgeon (KS) between ERAS and NON ERAS patients.

A total of 138 patients underwent hip or knee replacement, hip resurfacing arthroplasty or oxford unicompartmental arthroplasty between July 2011 and June 2012 with ERAS protocol.

In the Non ERAS group, 140 patients underwent hip or knee arthroplasty, resurfacing or oxford unicompartmental knee replacement in the previous year (July 2010 to June 2011) by the same surgeon.

Average hospital in patient stay for the ERAS patients was 4.12 days with 73.10% of the patients having an inpatient hospital stay of less than or equal to 5 days. The average hospital in patient stay for the NON ERAS patients was 8.34 days with only 24.08% of the patients being discharged in less than or equal to 5 days. Our study shows that the implementation of the ERAS protocol in hip and knee replacement surgery is associated with improved patient experience, faster recovery and shorter hospital in patient stay with no increase in complication.

Introduction:

Total hip and knee replacement are the commonest, most successful and cost effective orthopaedic surgical interventions. They provide reliable pain relief and marked improvement in the function of the patients suffering from Osteoarthritis or inflammatory arthritis of the hip or knee. [10]

Typically a patient undergoing hip or knee replacement is admitted day before the planned surgery. Traditionally after the surgery, patient stays in the bed overnight with PCA (Patient controlled analgesia), drain from the operative site and an attempt is made to mobilise out of bed on 1st postoperative day. The average length of stay for a hip or knee replacement is between 5.4 days to 9.1 days for hip replacement, and between 5.3 to 8.1 days for the knee replacement. [7]

With the Changing times and scrutiny of expenditure along with limitations/cuts on the public spending, more emphasis is put on the efficient use of available resources. At the same time the expectations of the public is increasing with increasing litigations. Reducing the hospital stay should reduce patient morbidity, free up much needed hospital beds and increase the capacity of the hospital.

The concept of fast track (Enhanced Recovery After Surgery, ERAS) was introduced to colorectal surgery in Denmark by Kehlet in 1999 which improved the quality of the care and reduced the length of hospital stay following major colorectal surgery.[1]The same principles of ERAS have been applied to the orthopaedic surgery particularly the hip and knee replacement surgery and fracture neck of femur surgery.

This is a relatively new approach in orthopaedics to the preoperative, intraoperative and postoperative care of the patients undergoing surgery. It is a multi modality, evidence based approach to improving the quality of patient care after major surgery, with a selected number of individual interventions which, when implemented together, demonstrate a greater impact on the outcomes then when implemented as individual interventions. It is a multidisciplinary approach involving surgeons, anaesthetists, nurses, physiotherapists, dieticians and occupational therapists. [3]

ERAS is a part of Wales assembly government's 1000 lives Plus campaign. Its aim is to improve the quality of care provided to the patients who undergo major surgery. By improving the quality in care, and reducing the harm it is also assumed that the hospital stay will become more efficient, thereby allowing hospital services to realise the benefits of the programme, through savings in bed days. It has already been shown to benefit patients undergoing colorectal, urological, gynaecological and orthopaedic surgery.[3]

The basic principles of the ERAS include:

1. Ensuring the patient is in the best possible condition for surgery
2. Ensuring the patient has the best possible management during and after his/her operation.
3. Ensuring the patient experiences the best possible rehabilitation, enabling early recovery and discharge from hospital, allowing them to return to their normal activities quicker. [3]

The main aspect of ERAS programme in orthopaedic surgery are , day of surgery admission (DOSA), Carbohydrate loading, Anaesthetic management, local infiltration analgesia, avoiding surgical site drain, regular postoperative analgesia and minimising the risk of postoperative nausea and vomiting, early mobilisation.

Day of surgery admission (DOSA) has a benefit of reducing the potential for surgical site infection and reducing the post operative complications. This will also help patients spending less time in the hospital and ultimately provide improved capacity within secondary care. [3]

Carbohydrate loading 12 hours and 2-4 hours prior to surgery has also been shown to reduce patient anxiety, reduce preoperative thirst, hunger, and postoperative insulin resistance. It promotes a more anabolic state leading to less post operative nitrogen and protein losses as well as better maintained lean body mass and muscle strength. Nygreet found improvement in insulin resistance with patients given carbohydrate loading and Melis demonstrated it preserved immune function post operatively. [3, 6]

Anaesthetic management: The aim is to deliver safe and effective sedation and analgesia to the patient which does not hinder early mobilisation.

For patients receiving general anaesthesia, the protocol is as under.

a. Premed analgesia pregabalin 150 mg one hour preop (reduce dose to 75 mg if patient aged over 75 years, has renal impairment or low BMI): [27,28,30]
b. Minimise/avoid opiates. Use short acting anaesthetics.
c. Intraoperatively patient receives,
d. 1 gm IV paracetamol,
e. a non steroidal anti-inflammatory,
f. 15-20 mg/kg Tranexamic acid iv bolus prior to tourniquet.[3,25]
g. Dexamethasone 8 mg [28,29,30]
h. 20mmol Magnesium Sulphate infusion during surgery (started prior to tourniquet) and to titrate rate to heart rate and blood pressure. [26]
i. 1-2 litres of iv fluid
j. Intra/postoperative local infiltration analgesia by the surgeon. [22, 23, 24]. In our institution, we use 30 mls of 5% chirocaine with 1 ml adrelaline diluted with 70 mls of normal saline.

For patients receiving spinal anaesthesia,

a. Premed as above
b. Spinal analgesia aiming at unilateral block wherever possible, and to use minimum dose of anaesthetic to reduce urinary retention and delay in motor function.

Local infiltration analgesia: it gives good post operative pain control without limiting the mobilisation with evidence showing a decreased use of patient controlled analgesia (PCA) up to 24 hours postoperatively. [22, 23, 24]

Avoiding the drains: Drains can affect patient's ability to mobilise easily and can, therefore, raise a psychological barrier to patient's active participation in their rehabilitation. Surgical drains have not been shown to reduce complications and can actually cause problems such as infection. Some believe that there may be occasional clinical indication for using drains. [3]

Regular postoperative analgesia: Suggested analgesia post operatively is regular paracetamol and a non steroidal anti inflammatory agent (depending on patient medical history) administered regularly, despite patient appearing pain free. Additional analgesia for the break through pain in the form of tramadol can be given. Pain is often a barrier for early mobilisation. The aim is for the patients to be reporting a pain score of less than 2 on movements.

Minimising the risk of post operative nausea and vomiting (PONV): PONV can be more stressful than pain and can come in the way of early mobilisation. Appropriate regular anti emetic should be prescribed routinely so is to be given at the first indication of symptoms. In our department, we have a low threshold of using ondansetron for prevention/ treatment of PONV.

Early enteral nutrition and optimal fluid management: (3, 6) Early oral or enteral feeding is associated with an improved clinical outcome and it has been shown to be safe and well tolerated. It is dependent on using appropriate anaesthesia and analgesia, nausea and vomiting prophylaxis and optimal fluid balance.

Suboptimal fluid balance can impair the wound healing, affect tissue oxygenation, leading to prolonged hospitalisation. The best way to limit postoperative intravenous fluid administration is to stop intravenous infusion and early return to oral or enteral fluid therapy.

Early mobilisation: Early mobilisation maintains the muscle mass, promotes muscle strength and reduces the respiratory complication. It also helps prevent development of deep vein thrombosis. The aim is to mobilise the patient out of bed on the day of surgery. At 2-3 hours postoperative time on return to the ward, the patients are encouraged to sit in the bed. If they feel better, they are encouraged to stand with Zimmer frame with the help of physiotherapist and nurse. Once they feel confident, they can walk to the toilet on the same day of operation. This gives confidence, sense of well being to the patient and motivation for mobilisation from the next day onwards.

Evidence for ERAS protocols in surgery is available from colorectal resections:

ERAS protocols have been shown to be associated with faster recovery and reduced length of stay in hospital compared with traditional colorectal resections. ERAS protocols were associated with 2.45 days shorter primary hospital stay and 2.46 days shorter total hospital stay. Morbidity was lower in the ERAS group. [6]

Materials and method:

ERAS programme was introduced as a structured protocol in the department of orthopaedics in Princess of Wales Hospital, ABM University health board, in July 2011. This comprised of

1. Pre operative education and assessment of all the patients, due to undergo hip and knee replacement, in the preadmission clinic lead by the consultant orthopaedic surgeon (KS) and consultant anaesthetist along with the arthroplasty nurse practitioner, physiotherapist, occupational therapist, and arthroplasty ward nurse 6 wks before the planned surgery. The patients are given information booklet for the new approach, what it involves and "what to expect".
2. Minimal perioperative starving with preoperative carbohydrate loading at 12 and 2-3 hours before the surgery. All the patients are given 2 sachets of "preload" (a neutral tasting carbohydrate loading drink) on the day of preassessment; each sachet contains 50 grams of carbohydrate preload powder to be mixed with 400 mls of water and to be drunk over 15 minutes.
3. No routine use of the drains.
4. Routine thromboprophylaxis with an oral anticoagulant agent.
5. Multimodal analgesia
6. Local anaesthetic infiltration intraoperatively: (Solution made of 30 mls of 0.5% Bupivacaine, 70 mls of saline and 1 mls of 1:1000 adrenaline)
7. Regular oral non narcotic analgesia and anti emetic with minimal use of the morphinoid drugs.
8. Structured early- on the day of surgery- postoperative weight bearing mobilisation programme.
9. Early oral feeding
10. Early discharge on day 3-4 postoperative whenever possible.
11. All the discharged patients are contacted over telephone at 48 hours post discharge by an arthroplasty nurse practitioner about their general condition and whether they have any concerns.

We have compared the length of inpatient stay, day of mobilisation, postoperative blood transfusion and adverse outcome for the patients undergoing hip or knee replacement by a single surgeon (KS) over a period of two years. All the patients were given a diary to fill the questionnaire during their stay and they were collected on the day of discharge. The diary asked the patient about the severity of pain, nausea, vomiting, day of weight bearing mobilisation, overall satisfaction. The pain has been graded from 0 to 3, with 0 as no pain and 3 as severe pain.

The data has been collected prospectively for the ERAS Patients, from July 2011 to June 2012. We compared the results with the patients who underwent hip or knee arthroplasty in a preceding year, (NON ERAS) from July 2010 to June 2011 retrospectively.

Results

In the ERAS group, a total 138 patients underwent hip or knee replacement, hip resurfacing arthroplasty or oxford unicompartmental arthroplasty from July 2011 to June 2012 performed by single surgeon (KS). 49 patients underwent total knee replacement, 44 total hip replacements while 31 underwent hip resurfacing. 2 patients underwent Oxford Unicompartmental knee replacement and 3 underwent revision hip replacement. 9 patients underwent simultaneous bilateral knee replacement.

In the Non ERAS group, 140 patients underwent hip or knee arthroplasty, resurfacing or oxford unicompartmental knee replacement in the previous year by the same surgeon (KS). 63 patients underwent knee replacement, 41 hip replacement, 35 hip resurfacing and one patient underwent oxford unicompartmental knee replacement.

Average hospital in patient stay for the ERAS patients was 4.12 days with 45.5% of the patients having stayed less than or equal to 3 days. 73.10% of the patients had inpatient hospital stay of less than or equal to 5 days. Average stay for TKR (total knee replacement) patients was 4.08 days, while bilateral TKR patients had an average stay of 4.8 days. The average hospital inpatient stay for THR patients was 5.4 days. The patients who underwent resurfacing had an average hospital inpatient stay of 3.7 days.

In the non ERAS group, the average stay of patients was 8.34 days with only 7.75% of the patients being discharged in less than or equal to 3 days, and 24.08% of the patients being discharged in less than or equal to 5 days. Average hospital inpatient stay for the patients who underwent TKR was 7.9 days without ERAS protocol, while the patients who underwent hip replacement had an average hospital inpatient stay of 8.36 days. The patients who underwent hip resurfacing without ERAS protocol had an average hospital inpatient stay of 6.17 days.

None of the patient under ERAS protocol was prescribed PCA (Patient controlled Analgesia-Morphine) routinely. They were prescribed regular paracetamol along with anti inflammatory (where it is not contraindicated) along with pregabalin. 55.6% of the patients felt that they had adequate pain relief postoperatively, while 44.4% needed top up pain relief in terms of morphine. 78% of the patients in ERAS protocol had not experienced nausea or vomiting postoperatively, while 14 % suffered only nausea and 4% had vomiting. 4% of the patients did not comment on their diary. The nausea, vomiting and pain scores are not available for the NON ERAS group of patients.

42 patients out of 98 who completed the diary walked on the day of surgery to the toilet full weight bearing, while none of the patients walked on the day of surgery in the NON ERAS group.

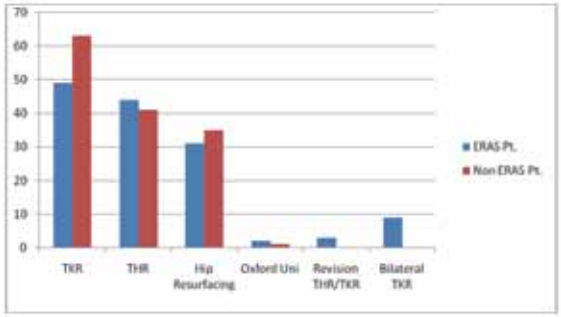
None of the patients on the ERAS protocol required postoperative blood transfusion, while 14 out of 140 patients required blood transfusion

Age range of the Patients:

Age	ERAS Group	NON ERAS Group
<60 years	38	43
61-80 years	85	79
>80 years	15	18

Type of Surgery	ERAS Group	NON ERAS Group
TKR	49	63
THR	44	41
Hip Resurfacing	31	35
Oxford Unicompartmental Knee replacement	2	1
Bilateral TKR	9	0
Revision TKR/THR	3	0
TOTAL	138	140

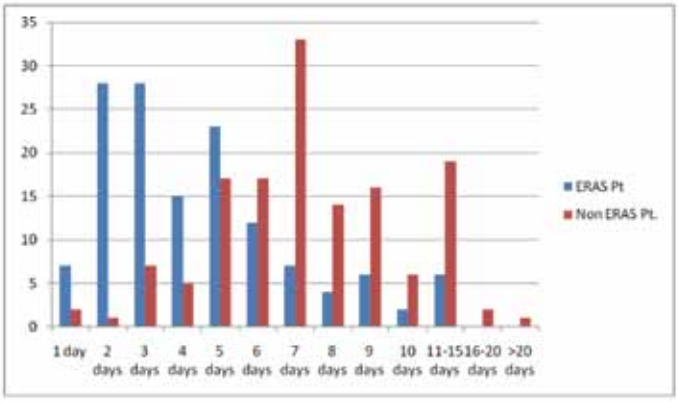
Types of surgery: Chart 1



Average hospital inpatient stay:

	ERAS Group	NON ERAS Group
Average stay for all patients	4.12 days	7.75 days
</= 3 days stay	45.5%	7.75%
</= 5 days stay	73.10%	24.08%
TKR	4.08 days	7.9 days
Bilateral TKR	4.8 days	-
THR	5.4 days	8.36 days
Hip Resurfacing	3.7 days	6.17 days

Hospital in patient stay: chart 2.



after the elective joint replacement surgery in NON ERAS group.

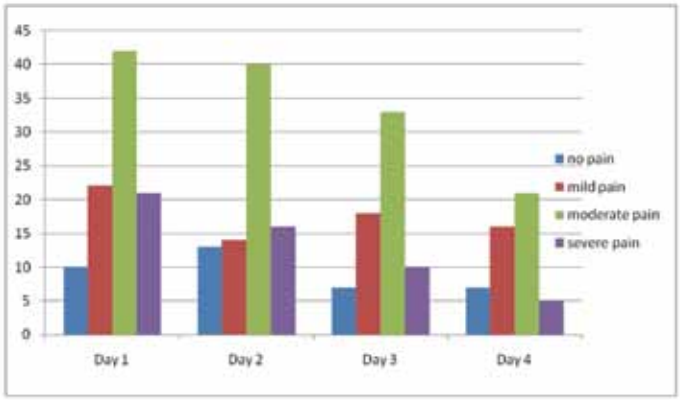
All the patients (100%) were very satisfied with the overall management starting from the day of preassessment clinic.

2 patients on the ERAS protocol developed DVT –both TKR- one occlusive below knee DVT and one non occlusive below knee DVT. 3 patients developed below knee DVT in a NON ERAS group of patients, and one developed PE. 2 patients on the ERAS protocol developed wound problems, one with wound oozing and second patient had haematoma. Both settled down with conservative management. 5 of the NON ERAS group had wound oozing problem, which also settled with conservative management. There was no incidence of postoperative wound infection in both the groups. 2 of the ERAS group patient dislocated their hips (after primary THR) following fall. One patient's hip became stable after closed manipulation and abduction bracing for 6 weeks, while the second patient required revision surgery to augment the cup orientation. One patient on the ERAS protocol developed aspiration pneumonia following general anaesthetic for which he was treated in the intensive care for 3 days. He recovered completely.

Discussion and conclusion:

The comparison data shows significant decrease in the hospital in patient stay for the patients in the ERAS protocol as compared with the standard NON ERAS group of patients. The pain was better controlled and nearly 50% of the patients who have completed diary have mobilised full weight bearing postoperatively on the day of surgery. Earlier mobilisation on the day of surgery makes the impact of surgery psychologically less

Severity of postoperative pain: Chart 3



Complications:

	ERAS Group	NON ERAS Group
DVT	2	3
Pulmonary Embolism	0	1
Wound Problems (oozing/haematoma)	2	5
Infection	0	0
Hip Dislocation	2	0
Anaesthetic Problems (Aspiration Pneumonia)	1	0
Postoperative blood Transfusion	0	14

stressful and also imparts the sense of well being. Having walked on the wday of surgery gives a confidence boost to the patients and they are more likely to be out of bed mobilising for next few days making early recovery, avoiding complication of bed rest and likely to go home earlier.

On average the patients undergoing hip resurfacing are much younger than the patients undergoing standard hip or knee replacement surgery and they have fewer or no associated medical co morbidity. This accounts for the faster recovery and shorter hospital stay for the patient after the surgery, which is evident on both, ERAS and NON ERAS, groups of patients. The overall patient experience of undergoing a major surgery was satisfactory with no increased risk of complications.

The current evidence and our study shows that the implementation of the ERAS protocol in hip and knee replacement surgery is associated with improved patient experience, faster recovery and shorter hospital in patient stay with no increase in complication. This will also result in reduced risk of hospital acquired infection, increasing patient's confidence in the organisation.

Shorter hospital stay will free up much needed hospital beds, including ITU/HDU, where applicable, with a potential to treat more patients with the same resources leading to increased capacity for the trust and longer term tariff benefits. ■

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Jaydeep Shah
MBBS, M.S (Tr and Ortho), MRCSEd, FRCSEd (Tr and Ortho).-Associate Specialist, Trauma and Orthopaedics, Princess of Wales Hospital, Bridgend

Keshav Singhal
MBBS, M.S (Tr and Ortho), MCh (Ortho), FRCS.- Consultant Orthopaedic Surgeon, Princess of Wales Hospital, Bridgend.

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Contact

Simon Syddall
simon.syddall@duntop.co.uk
01522 507000

Christine Newitt
christine.newitt@duntop.co.uk
01205 310250

Assessing Cardiovascular Safety in the Development of New Drugs for Type 2 Diabetes Mellitus

J. Rick Turner, Paul Strumph

Along with obesity and cardiovascular disease, type 2 diabetes mellitus (T2DM) is a global public health concern of staggering proportions.[1]

The International Diabetes Federation (IDF) recently observed that, in 2011, there were 366 million people with diabetes, a figure expected to rise to 552 million by 2030.2 Taking the United States as one example of a large Western country, the 2011 National Diabetes Fact Sheet3 stated that 25.8 million children and adults in the United States — 8.3% of the population — have diabetes, with 18.8 million being diagnosed and 7.0 million being undiagnosed. Another 79 million people have prediabetes. (It should be noted that the Fact Sheet used both fasting glucose and A1c levels to derive estimates for undiagnosed diabetes and prediabetes: these tests were chosen since they are most frequently used in clinical practice in that country.) While these numbers are of considerable magnitude, the IDF also observed that most people with diabetes live in low- and middle-income countries, and it is these countries that will see the greatest increase between now and 2030.[2]

While preventive measures such as eating an appropriate diet and engaging in regular physical activity have been shown to be effective in preventing the progression of prediabetes to diabetes in some people,[4,5] many individuals require medications to treat T2DM. As the European Medicines Agency (EMA) has noted, "Glucose control in type 2 diabetes deteriorates progressively over time, and, after failure of diet and exercise alone, needs on average a new intervention with glucose-lowering agents every 3-4 years in order to obtain/retain good control."[6] The latter part of the quote makes clear that, while there are good drugs currently on the market, there is an ongoing need for additional drugs to be developed.

This paper therefore reviews recent guidance by both the EMA and the United States (US) Food and Drug Administration (FDA) concerning the development of such drugs, and specifically the cardiovascular safety of these compounds. The authors believe that an understanding of the requirements and challenges involved in bringing all drugs to market is beneficial not only for those actively involved in life-cycle drug development but also for prescribing physicians and health professionals who dispense and administer pharmaceutical medicines to patients. Clinical research informs clinical practice and evidence-based medicine, and practising physicians can benefit from having sufficient knowledge about clinical research and drug development programmes to understand their role in placing new drugs within their treatment armamentaria and generating the evidence contained in treatment practice guidelines.[7]

Assessing Cardiovascular Safety

Since 2008, new regulatory landscapes have emerged in the US8 and the European Union (EU)6 addressing the prospective exclusion of unacceptable cardiovascular risk in the development of new antidiabetic drugs for the treatment of T2DM. These are reviewed in turn.

US Regulatory Landscape

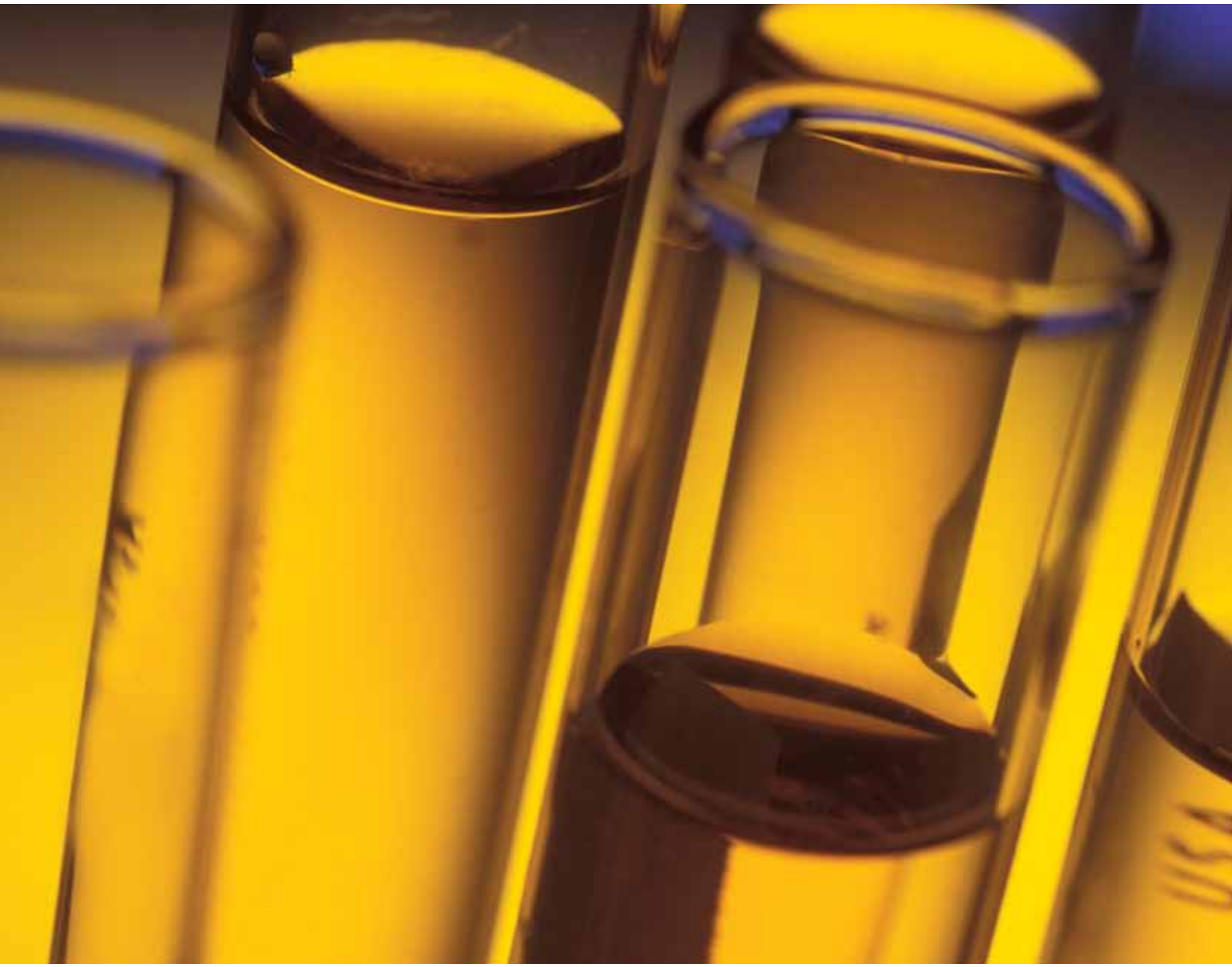
In February 2008 the FDA released a general draft guidance entitled "Diabetes mellitus: developing drugs and therapeutic biologics for treatment and prevention."[9] Its contents did not cover cardiovascular safety, but commented as follows:

A premarketing recommendation to demonstrate macrovascular risk reduction in the absence of a signal for an adverse cardiovascular effect may delay availability of many effective antidiabetic drugs for a progressive disease that often requires multiple drug therapy. A reasonable approach may be to conduct long-term cardiovascular studies post-approval in an established time frame…This approach is beyond the scope of this guidance.

In July 2008, the FDA's Endocrinologic and Metabolic Drugs Advisory Committee held a meeting related to cardiovascular safety assessment, the end result of which was a 14-2 yes/no vote that, even for antidiabetic drugs without a concerning cardiovascular safety signal during Phase II/Phase III development, there should be a requirement to conduct a long-term cardiovascular trial or to provide other equivalent evidence to rule out an unacceptable cardiovascular risk.[10] Subsequently, in December 2008, the FDA issued a guidance addressing this issue entitled "Guidance for Industry. Diabetes Mellitus: Evaluating cardiovascular risk in new antidiabetic therapies to treat type 2 diabetes" in final format.[8, 11, 12].

The guidance requires sponsors to provide compelling evidence that new agents to treat T2DM are not associated with an unacceptable increase in cardiovascular risk, operationalised as an unacceptable increase in the number of adverse clinical cardiovascular events. Clinical endpoints of interest include, but are not limited to, non-fatal myocardial infarction, non-fatal stroke, and cardiovascular mortality (events which comprise the Major Adverse Cardiovascular Events [MACE] composite endpoint), acute coronary syndrome, and urgent revascularisation procedures. A composite endpoint can be advantageous in circumstances in which the number of individual events can be too low to meaningfully compare those occurring in the test drug treatment group with those occurring in the comparator treatment group. The guidance also makes clear that endpoints require independent adjudication.[13] Additional changes to development programmes going forward include the length of trials to be conducted and the nature of the subject population employed. Larger and longer late Phase II trials are called for, as are larger and longer Phase III trials that include subjects at high risk for cardiovascular events.

The approach to excluding unacceptable risk can be represented by a three-component model incorporating clinical science (clinical judgments concerning absolute and relative risks), regulatory science (benefit-risk judgments at the public health level and choice of thresholds of regulatory interest), and statistical science (determining whether or not regulatory thresholds have been breached).[14] On this occasion, the regulatory thresholds of interest are 1.8 and 1.3, which are to be



discharged sequentially: the nature of these values is explained shortly. Upon completion of a planned preapproval clinical development programme, a meta-analysis exploring the investigational drug's MACE liability is conducted by incorporating data from Phase II and Phase III trials. Risk is operationalised in terms of a relative risk ratio, with the number of MACE composite endpoint events in the drug treatment group as the numerator and the number of such events in the control group as the denominator. This calculation yields the risk ratio point estimate. Two-sided 95% confidence intervals (CIs) are then placed around this point estimate. Attention falls on the upper CI limit, with a value of 1.8 or greater attracting regulatory concern (see Turner[15] for a more detailed explanation of this statistical approach). Three scenarios are described in the guidance:

- If the upper limit of the CI is equal to or greater than 1.8, the drug would be deemed to have an unacceptable risk. In this case, "an additional single, large safety trial should be conducted that alone, or added to other trials, would be able to satisfy this upper bound before NDA/BLA submission."[8]
- If the upper bound is equal to or greater than 1.3 and also less than 1.8, and the overall risk-benefit analysis presented at submission supports marketing approval, "a postmarketing trial generally will be necessary to definitively show that the upper bound of the two-sided 95 percent confidence interval for the estimated risk ratio is less than 1.3."[8]

Having discharged the 1.8 value at the time of marketing application, the 1.3 value is then to be discharged in a second step. The postmarketing trial referred to in the previous bullet is a large-scale cardiovascular outcomes safety trial focusing on MACE outcomes: this trial will be discussed in the next section.

It should be noted that, while unlikely in practical terms, it is possible that the 1.3 value (and hence also the 1.8 value) could be discharged by the meta-analysis of premarketing data. The guidance addresses such a scenario as follows:

- If the upper limit is less than 1.3 and the overall risk-benefit analysis presented at submission supports marketing approval, "a postmarketing cardiovascular trial generally may not be necessary."[8]

A review by Joffe et al.[16] provides a more detailed review of the guidance's content and consequences, and is recommended to readers. As these authors noted, "The new approach to developing medications for the treatment of type 2 diabetes will lead to evaluation in patients more representative of those who will use these therapies, if approved, and will help healthcare providers make informed decisions when choosing a medication within the growing treatment armamentarium for type 2 diabetes." Their comment further emphasises the benefits to prescribing physicians of a good knowledge of how new drugs for T2DM are developed and approved.

EU Regulatory Landscape

The EMA draft guideline makes it clear that two approaches prospectively excluding unacceptable cardiovascular risk are conceivable. The first is a meta-analytic approach, similar in spirit to the one discussed in the FDA guidance. With regard to the second, the guidance comments as follows:

As an alternate approach or when there is suspicion of an adverse CV signal (from the database), a specific long-term controlled outcome study with at least 18-24 months follow-up (depending on the characteristic of a drug and baseline risk of the studied population) would be expected as part of the clinical development program of new glucose lowering agents at the time of submission of the MAA.[6]

With two notable exceptions, the approaches in the FDA and EMA documents are comparable. These salient difference are: **1** there are no explicit thresholds of regulatory concern corresponding to the values of 1.8 and 1.3 as presented in the FDA document with regard to a meta-analysis of data from Phase II and Phase III trials; and **2** the EMA wishes to be fully satisfied at the time of granting marketing approval that there are no cardiovascular safety liabilities. This contrasts with the FDA's approach of sponsors satisfying a regulatory threshold of 1.8 at the time of granting marketing approval, and subsequently using postmarketing data to satisfy the 1.3 threshold.

Large-scale Cardiovascular Outcomes Trials

The literature provides various examples of studies underway. In a recent editorial published in Diabetes & Vascular Disease Research, Gore and McGuire[17] listed 14 Phase III and Phase IV cardiovascular outcomes trials addressing the cardiovascular safety and efficacy of drugs for T2DM. Examples include the dipeptidyl peptidase 4 (DPP-4) inhibitors alogliptin, linagliptin, saxagliptin, and sitagliptin; the incretin glucagon-like peptide

1 (GLP-1) receptor agonists dulaglutide, exenatide long-acting release, liraglutide, and lixisenatide; and the sodium glucose co-transporter 2 (SGLT2) inhibitors canagliflozin and empagliflozin. As an instructive example, consider the trial being conducted with saxagliptin.

The Saxagliptin Assessment of Vascular Outcomes Recorded in Patients with Diabetes Mellitus-Thrombolysis in Myocardial Infarction 53 (SAVOR-TIMI 53) trial is currently underway not only to determine that saxagliptin is not associated with an unacceptable increase in cardiovascular risk, but that it also reduces cardiovascular risk in patients with T2DM.[18]

At the end of the preapproval clinical development programme a meta-analysis was conducted using pooled data from the Phase II and Phase III trials, which included a total of eight studies involving 3356 subjects who received saxagliptin at various doses and 1251 subjects who received a control treatment (placebo, metformin, up-titrated glyburide, or a thiazolidinedione). The MACE composite endpoint employed included death, myocardial infarction, stroke, and cardiac ischemic events. The relative risk analysis (conducted as a Cox proportional hazard ratio on adjudicated events) was 0.43 (95% CI, 0.23-0.80). Of note is that the upper CI limit, 0.80, is not only below 1.8 and also 1.3, but it is also below unity (represented here as 0.00). This result indicates that there were fewer cardiovascular events in the saxagliptin treatment group than the control treatment group, hence implying not only acceptable cardiovascular safety but also an actual cardiovascular benefit.[19] The authors noted the limitations of such an analysis, and stated that "The hypothesis of CV protection with saxagliptin will be tested prospectively in a large randomized clinical outcome trial evaluating saxagliptin compared with standard of care in patients with type 2 diabetes at increased risk for CV events."[19] From both clinical and marketing perspectives, being able to demonstrate cardiovascular benefit is a very powerful advantage. The SAVOR-TIMI 53 trial is therefore statistically powered to be large enough to be able to determine whether saxagliptin can indeed reduce the risk of cardiovascular events: it intends to enroll 16,500 subjects.

While acceptable safety of one drug in a class should not generally be regarded as 'evidence' that subsequent drugs in that class will also be acceptably safe, it is of interest here that meta-analyses conducted for other DPP-4 inhibitors have also not detected a cardiovascular safety signal. Cardiovascular outcomes studies are ongoing for alogliptin, linagliptin, and sitagliptin. In conjunction with SAVOR-TIMI 53, these trials will provide a very large amount of clinical outcome data for this class of drug that will address questions of both cardiovascular safety and cardiovascular benefit.

Concluding Comments

The increasing global prevalence of T2DM requires continued development of new antidiabetic drugs. One aspect of such development is the prospective this topic with the intent of providing prescribing physicians, and all allied health professionals, with a fundamental understanding of the methodology required to provide compelling evidence of the cardiovascular safety of new antidiabetic drugs for the treatment of this disease. ■

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J. Rick Turner, PhD

J.Rick Turner, PhD, is Senior Director, Clinical Communications, Quintiles. He is a clinical triallist, author, and editor who has published 130 peer-reviewed papers and articles in professional journals, and published 14 books. He has testified before two US Food and Drug Administration Advisory Committees with regard to the cardiovascular safety of antidiabetic drugs for Type 2 Diabetes Mellitus.

Email: rick.turner@quintiles.com

Paul Strumph, MD

Paul Strumph, MD, is Vice President, Therapeutic Strategy Lead, Cardiovascular and Metabolic Therapeutic Delivery Unit, Quintiles, and the Head of their Diabetes Center of Excellence. He is a Diplomate in Internal Medicine, Pediatrics, Adult Endocrinology, Diabetes and Metabolism, and Pediatric Endocrinology. He is an author of more than a dozen articles in scientific journals and magazines, including Nature, Clinical Pediatrics, the Journal of Clinical Endocrinology and Metabolism, and Diabetes Care.

Email: paul.strumph@quintiles.com

First choice for cost-effective CMA management

Dr Joanne Walsh explains how using Nutramigen as the first-line formula for cow's milk allergy is supported by expert guidelines,[1] and can reduce costs by up to £1,300 per patient in the first year of management in primary care.[2]

Nutramigen LIPIL*
First for cow's milk allergy

Cow's milk allergy (CMA) affects 2–7.5% of infants,[3] making it a major paediatric health problem in the UK. Recent NICE guidelines on food allergy in children provide a valuable guide for diagnosis in primary care.[4] To diagnose and manage CMA in formula-fed infants, a hypoallergenic formula is needed. Expert bodies have established the following guidance for choosing an appropriate formula:

- Extensively hydrolysed formula (eHF), such as Nutramigen, is effective in >90% of infants with CMA and should be used as the first-line hypoallergenic formula in the majority of cases[1]
- Amino acid-based formula (AAF), such as Nutramigen AA and Neocate® LCP, should be reserved for severe CMA, multiple allergies, or when eHF is ineffective[1,3]
- Soya formula is not recommended in infants under 6 months,[5] and a substantial proportion of infants with CMA are also allergic to soya[6]

With the pressing need to review prescribing costs, GPs are looking for ways to save money while optimising quality of care for patients. A new study has demonstrated that by using Nutramigen first-line, GPs can align practice to expert recommendations while reducing costs by up to 41% (£1,300) per CMA patient in the first year of management.[2] Nutramigen is the leading hypoallergenic formula in the UK, supported by over 70 years of experience in managing CMA and over 70 clinical studies.

Using Nutramigen first-line can reduce costs by 41% per CMA patient in the first year[2]

Taylor *et al.* compared healthcare resource use and associated costs in infants with CMA who presented with similar symptoms.[2] In all, 150 infants were initially prescribed Nutramigen (eHF), in line with the expert guidelines, and 145 were initially prescribed Neocate (AAF).[2]

Study results

- **No significant difference in clinical outcomes**
  - Nutramigen (eHF) is as effective as Neocate (AAF) in newly diagnosed infants with CMA[2]
  - Both groups achieved symptom resolution by 5 weeks[2]
- **Nutramigen is cost effective vs Neocate**
  - Prescribing Nutramigen first-line reduced NHS costs by £1,300 per patient over the first 12 months of management, compared to Neocate[2]

Reduce NHS costs by £1,300 per CMA patient in the first year of management with Nutramigen (2008/9 prices)[2]

	Total NHS costs in first 12 months		
	Nutramigen	Neocate	
Per infant	£1,853	£3,161	Save over £1,300
For 12 patients	£22,236	£37,932	Save over £15,000

Current prices per 400g tin: Nutramigen LIPIL – £10.11; Neocate LCP – £26.22 (MIMS, April 2012)

Nutramigen has proven efficacy for the management of CMA. In addition, the new comparative study demonstrates that Nutramigen is cost effective compared to Neocate in this patient group.[2] Using Nutramigen as the first-line formula for the majority of infants with CMA matches expert guidelines,[1] reduces costs by 41% in the first year of management and can potentially save money when compared to using Neocate.[2]

Dr Joanne Walsh BSc MBChB DFFP MSc is a Norwich GP with an interest in allergy.

First line for CMA

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Guidelines recommend extensively hydrolysed formula (eHF) as first choice for the management of cow's milk allergy.[1] Nutramigen LIPIL® eHF gives equivalent clinical outcomes when compared to a standard amino acid-based formula, with both formulas resolving symptoms of newly-diagnosed infants in under 5 weeks.[1,2] What's more, Nutramigen LIPIL® is 58% less expensive than the amino acid-based formula[3] and, when used first line, is associated with fewer GP visits over the first 12 months of treatment.[3]

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IMPORTANT NOTICE: *Breastfeeding is best for babies. The decision to discontinue breastfeeding may be difficult to reverse and the introduction of partial bottle-feeding may reduce breast milk supply. The financial benefits of breastfeeding should be considered before bottle-feeding is initiated. Failure to follow preparation instructions carefully may be harmful to a baby's health. Parents should always be advised by an independent healthcare professional regarding infant feeding. Products of Mead Johnson must be used under medical supervision. EU 11.564.*

† The 5 weeks figure is an average value for Nutramigen LIPIL® and amino acid-based formula

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A Review of Travel-associated Diarrhoeal Illnesses

Barry Dyer MB, BS

Introduction

Travellers' diarrhoea is the most common travel-related illness. It usually occurs within the first week away from home, and affects between 10 and 60 per cent of all those who go abroad.[1] Travellers are especially likely to become ill at high-risk destinations such as low-income nations in Latin America, Africa, Asia and the Middle East.

Signs and Symptoms

Traveller's diarrhoea (TD) is defined as the passage of at least three loose or watery stools in 24 hours. This can be accompanied by abdominal cramps, nausea and fever. Vomiting may occur less commonly, and bloodstained stools or mucous are unusual. Symptoms are frequently self-limiting but may persist long after return.[2]

Aetiology

Travellers' diarrhoea can be caused by a multitude of organisms: viruses, bacteria and parasites. Most travel-associated diarrhoea is caused by bacterial contamination including ETEC (enterotoxigenic E. coli), Salmonella, Shigella and Campylobacter species. Norovirus is often implicated in large-scale outbreaks on board vessels and in destinations that would otherwise be deemed low-risk.[3]

Viruses, such as rotavirus and clacivirus, and parasites such as protozoa (Cryptosporidium, Giardia or Entameba histolytica) are other common causes. Cyclospora particularly impacts travellers visiting Nepal.[4]

Although reported frequently in international media, cholera is an infrequent cause of travellers' diarrhoea [5] as most tourist destinations do not experience cholera outbreaks. However, those who travel to visit friends and relatives ("VFR") and international aid workers remain at risk.

Investigation

Investigations should be reserved for prolonged diarrhoeal episodes or when stools are bloodstained. This is initially directed at stool culture for microscopy to examine ova, cysts or parasites and to establish sensitivities of any cultured organisms.

Treatment

Most cases of travellers' diarrhoea will resolve spontaneously within a day or two. Guidance is directed at replacing fluids lost by continuously sipping clear fluids such as water, soft drinks or weak tea. Patients should be directed to avoid dairy products, alcohol and coffee as these can compound symptoms and worsen dehydration.

The priority in treating acute diarrhoea is the prevention or reversal of fluid and electrolyte depletion. The extremes of age are particularly susceptible to dehydration. Parents should be advised to seek medical advice early if children are affected.

Oral rehydration preparations are widely available in some countries, but availability does vary. For example, Mexico does not permit the sale of oral rehydration salts, only pre-mixed oral rehydration solution. It is imperative to ensure that any water used to reconstitute oral rehydration salts is safe for human consumption.

Occasionally dehydration will require intravenous fluids, especially if there has been significant vomiting or extreme diarrhoea. Travellers should seek treatment with reputable medical facilities that provide quality pharmaceutical goods and adhere to international standards of hygiene.

Medications

Two main types of medications are used to treat travellers' diarrhoea.
Drugs to slow the diarrhoea

Antimotility drugs

Loperamide

For self-treatment in adults, the recommended initial dose is 4mg after a loose stool, followed by 2mg after each unformed stool. The dose should not exceed 8mg in a 24-hour period. It should not be used if there is a high fever or blood in the stool, or in young children. Patients should be advised to seek medical attention if no better in 48 hours.

Loperamide can be used in conjunction with antibiotic treatment.

Antispasmodics

Hyoscine Butylbromide and others are occasionally of value in symptomatic relief, but should not be used for primary treatment.

Antibiotics

Initial empiric treatment of TD is with an antibiotic known to be active against the most prevalent enteropathogens in the region of travel, and include:

Ciprofloxacin

- 500mg bd for three days. (Single dose therapy can be used.) Cannot be given to children.

Azithromycin

- Adults: 1000mg as a single dose. Safe for children – dosage 10mg/kg per day for three days.

Rifaximin

- 200mg tds for three days. Should not be used if the patient has a fever or blood in the stool as it is ineffective against invasive causes of TD. UK prescribing guidelines do not permit administration in children.

For travel to locations with a high risk of TD, it may be advisable to prescribe a standby treatment course of antibiotics for the traveller to carry with them.[6]

Prevention

All travellers should be advised to be careful in their selection of food and water. The following guidelines can be given to travellers to developing countries:

Selecting Safe Food

- Always wash your hands with soap before eating, or use a hand sanitising gel/lotion.
- Select food that is thoroughly cooked while fresh and served very hot, since heat usually kills bacteria.
- Avoid undercooked or raw meat, fish or shellfish, even if they are the local delicacy. These are potentially a major source of infection.
- Avoid food sold by street vendors and establishments that don't have access to safe water for washing produce and utensils.
- Only eat raw fruit you have peeled yourself (oranges, bananas, mangos, avocados, etc).
- Avoid salad and raw vegetables in restaurants. Only eat raw vegetables if they were washed well with safe water.
- Avoid food that has been left unrefrigerated for more than two to four hours, especially if it was kept warm. Food that has been prepared hours (or days!) ago is more likely to be contaminated than freshly cooked food.
- Only drink pasteurised cow, sheep or goat milk. Avoid dairy products (such as ice cream, butter and cheese) if you do not know if they have been made from pasteurised milk.

Avoiding Contaminated Water

Where there is a risk that the tap water may be contaminated:

- Bottled water and drinks are normally safe, especially carbonated drinks. Look for an intact seal.
- The outside of cans or bottles may be contaminated, especially if they were stored in ice. Clean and dry bottles and cans before drinking from them or pouring the liquid into a glass.
- Remember that ice may have been made from contaminated water, or contaminated afterwards through handling, and therefore may not be safe.
- Use safe water for brushing teeth and for washing raw vegetables and salad.
- Don't drink the water from open wells or rivers.

If bottled water is not available, the following alternative means of sterilisation can be used:

- Boiling water is a reliable method for making it safe to drink. Bring water to a full boil for one minute and allow it to cool to room temperature (longer if at altitude).
- Disinfectants
- Iodine is very effective: Four drops of two per cent tincture of iodine should be added to each litre of water and left for 15 minutes. Avoid using iodine for prolonged periods (longer than six weeks).
- Sterotabs and Puritabs: These are chlorine-based and are less effective against some infectious agents, including amoebic cysts.
- In an emergency, use household bleach: use two to four drops per litre of clear water and leave for 15 minutes. This is safe and effective but will leave water tasting of chlorine.
  (Disinfecting can be ineffective if the water is visibly cloudy.)

Portable Water Filters

There are several types of water filters. Each provides various degrees of protection against microbes:

- Reverse-osmosis filters provide protection against viruses, bacteria and parasites. They are expensive and large, and the small pores of these filters are easily blocked by muddy or cloudy water.
- Microstrainer filters can remove bacteria and parasites from drinking water, but they do not remove viruses. To remove viruses, travellers using microstrainer filters should also disinfect the water with iodine or chlorine after filtration.
- Filters with iodine-impregnated resins are most effective against bacteria. The iodine in these filters can also kill some viruses, but the contact time does not allow the killing of parasites such as Cyptosporidium and, in cold water, Giardia. It is important to maintain and replace the cartridges as specified by the manufacturer's instructions.

Vaccination

There are vaccines available for some faecal-orally transmitted organisms such as Salmonella typhi, hepatitis A, and Vibrio cholerae. Vaccinated travellers may still develop diarrhoea caused by other organisms.

The Medicines and Healthcare products Regulatory Agency advised that the availability of some typhoid-containing vaccines became limited in early October 2012 following a recall of Sanofi-manufactured vaccines.[7,8] Seek MHRA recommendations in the event of vaccine shortages.

The oral B-subunit cholera vaccine Dukoral® gives good protection against cholera and halves the risk of developing traveller's diarrhoea caused by ETEC (enterotoxigenic E. coli). It is available in an increasing number of countries, including Canada and the UK, among other European nations.[9] However, travellers who use this vaccine should also carry self-treatment remedies in the event that they develop diarrhoea that is not caused by ETEC.[10]

Summary

An ounce of prevention is worth a pound of cure, and all travellers should be educated in the selection of safe food and water. Travellers to high-risk destinations or with high-risk itineraries should consider pre-departure vaccination against typhoid and hepatitis A. In addition, carrying a course of rehydration preparation, antimotility agent, and treatment antibiotics is advisable. ■

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Dr Barry Dyer MB, BS

Manager, Medical Information & Analysis. International SOS Assistance (UK) Ltd, Chiswick Park, Building 4, 566 Chiswick High Road, London, England W4 5YA, United Kingdom

Barry graduated from King's College School of Medicine and Dentistry in 1998 and worked in the NHS for seven years, primarily in emergency medicine and anaesthetics. He joined International SOS in 2005 and supported government organisations and international travellers in accessing healthcare around the world. He is currently studying for an MSc in Health Informatics at the University of Edinburgh.

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REFER TO FULL SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) BEFORE PRESCRIBING.
Presentation: Film-coated tablet containing rifaximin 200 mg. **Uses:** Xifaxanta is indicated for the treatment of travellers' diarrhoea that is not associated with fever, bloody diarrhoea, eight or more unformed stools in the previous 24 h, occult blood or leucocytes in the stool. **Dosage and administration:** Adults over 18 years of age: 200 mg every 8 hours for three days (total 9 doses). Rifaximin must not be used for more than 3 days even if symptoms continue and a second course of treatment must not be taken. Not recommended in children under 18 years of age **Contraindications:** Hypersensitivity to the active substance, to any rifamycin (e.g. rifampicin or rifabutin) or to any of the excipients. **Warnings and precautions for use:** Not recommended for the treatment of travellers' diarrhoea caused by invasive enteric pathogens. If symptoms worsen, treatment with rifaximin should be interrupted. If symptoms have not resolved after 3 days of treatment, or recur shortly afterwards, a second course is not recommended. The potential association of rifaximin treatment with *Clostridium difficile* associated diarrhoea and pseudomembranous colitis cannot be ruled out. **Interactions:** Due to the negligible gastrointestinal absorption of orally administered rifaximin (less than 1%), the systemic drug interaction potential is low. Rifaximin should not be administered concomitantly with other rifamycins and the tablets should not be administered for at least two hours after the administration of charcoal. **Pregnancy and lactation:** Rifaximin is not recommended during pregnancy and in women of childbearing potential not using contraception. The benefits of rifaximin treatment should be assessed against the need to continue breastfeeding **Undesirable effects:** Common effects reported in clinical trials are dizziness, headache, abdominal pain, constipation, defecation urgency, diarrhoea, flatulence, bloating, distension, nausea, vomiting, rectal tenesmus and pyrexia. Other effects that have been reported are candidiasis, herpes simplex infections, clostridial infections, palpitations, increased blood pressure, liver function test abnormalities, blood disorders (e.g. thrombocytopenia) and anaphylactic reactions, (e.g. angioedemas, hypersensitivity and skin reactions). **Licensing and legal category:** Legal category: POM. **Cost:** Basic NHS price £15.15 (9 tablets). **MA number:** PL 20011/0021. **For further information contact:** Norgine Pharmaceuticals Limited, Norgine House, Moorhall Road, Harefield, Middlesex, UB9 6NS. 01895 826606. E-mail: medinfo@norgine.com. **Date of preparation/revision:** XIF/2960/JUN/12.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Medical Information at Norgine Pharmaceuticals Ltd on 01895 826606.

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NORGINE

XIF/3114/OCT/12. Date of preparation: October 2012.

Perennial Rhinitis

Glenis Scadding

Rhinitis - Definition and Classifications

Rhinitis means nasal inflammation, and sufferers have two or more of the symptoms of running, itching, sneezing and blocking. It has traditionally been classified as seasonal or perennial, or both.

Most people are familiar with seasonal allergic rhinitis, or hay fever, as it is known in the UK. In this the symptoms occur when seasonal pollens enter the nose of people who are allergic to them - grass pollen is the commonest, and the problem is seen in the summer.

Perennial rhinitis occurs throughout the year. It is sometimes allergic in nature and is then caused by allergens which are present all year, such as pets, house dust mites, moulds and occupational allergens.

The ARIA (Allergic Rhinitis and its Impact on Asthma) classification of rhinitis uses a different approach: symptoms are either intermittent (less than four days a week ,or less than four weeks at a time), or persistent, in which case they exceed four days at a time for over four weeks. Persistent does not equate to perennial since perennial sufferers are not always troubled to that extent; similarly seasonal allergic rhinitis is not necessarily intermittent , but can be persistent, particularly at the height of the season.

The ARIA classification also introduced a system for assessing AR severity based on the impairment of four health-related quality of life (HRQL) items: sleep, daily activities/sport and leisure, work or school performance, and troublesome symptoms. According to the ARIA workshop group, AR is mild when there is no impairment of any of these items, while it is moderate/severe when one or more of these items are impaired [1].

Thus perennial rhinitis can be intermittent or persistent, and mild or moderate to severe.

Prevalence and Co-morbidities

Rhinitis is common: Allergic rhinitis affects 10-30% of the adult population. Approximately 80% of individuals diagnosed as having AR develop symptoms before the age of 20. Older children have a higher prevalence of AR than younger ones, with a peak occurring in children aged 13-14. While boys are more likely than girls to have AR, this tendency switches in puberty so that equal numbers of adults are affected. A postal survey within the UK in 1991 reported the prevalence of all forms of rhinitis (excluding infectious) as 24%, with 30% seasonal, 13% perennial and 57% mixed. However, a more recent study puts the total nearer 30% of the population.

Symptoms of allergic rhinitis (rhinorrhea, nasal congestion, itch and sneezing) impair the performance of daily activities, and reduce sleep quality, cognitive function, school and work attendance, and productivity.

Severity, more than the persistence of symptoms, is the factor most affecting quality of life and school performance. Rhinitis generates an important socioeconomic burden. AR is also closely linked to other inflammatory diseases affecting the respiratory mucous membranes, such as asthma, rhinosinusitis, otitis media with effusion, and allergic conjunctivitis.

An association between asthma and allergic rhinitis is noted in epidemiological, experimental, functional and clinical studies, including evidence of significant improvement in outcomes when the upper airway is appropriately treated. Around one-third of rhinitis patients also have asthma – but those who have not yet developed asthma have a risk of so doing some three times higher than non-rhinitics. This is true for both allergic and non-allergic rhinitis. The mean time between the development of asthma in rhinitics is two years, allowing a window of opportunity for possible prevention of progression.

Most asthma patients also suffer from rhinitis, whether atopic or non-atopic. Atopy is the abnormal tendency to develop specific IgE in response to innocuous and ubiquitous environment allergens. Atopic diseases include allergic rhinoconjunctivitis, asthma, atopic dermatitis and food allergies, and these run in families. Atopy has been linked to multiple genetic loci, including those on chromosomes 2, 5, 6, 7, 11, 13, 16 and 20. Development of atopic disease occurs in 13% with no family history, 29% if one parent or sibling was atopic, 50% if both parents were atopic and 72% if they shared the same atopic manifestation. Other risk factors for allergic rhinitis include being non-Caucasian, firstborn, or of high socioeconomic status, environmental pollution, birth during a pollen season, late entry into daycare, heavy maternal smoking, indoor allergen exposure, serum IgE level >100 IU/mL before age six, the presence of positive skin-prick tests, and early introduction of foods or formula. Multiple studies have also found that early environmental exposure to various infectious agents such as mycobacteria, hepatitis A, Toxoplasma gondii and lipopolysaccharide (found in Gram negative bacteria), protects against development of atopy.

Most asthma exacerbations (80% in children and over 60% in adults) are related to upper respiratory viral infections – primarily due to rhinoviruses. Allergic children suffer more from colds, which tend to last longer and to be more complicated. In both mite-induced and pollen-induced rhinitis minimal persistent inflammation (MPI), a low-grade inflammatory infiltration in the mucosa unaccompanied by obvious symptoms, has been demonstrated with weak and persistent expression of intercellular adhesion molecule-1 (ICAM-1), the major receptor for human rhinoviruses. This over-expression in asymptomatic allergic subjects is important since synergy occurs between allergic and infective inflammation. The combination of a rhinoviral cold in a sensitised asthmatic child exposed to relevant allergen gives a nearly 20-fold risk of hospitalisation for asthma. Therefore perennial rhinitis demands accurate diagnosis and effective treatment.

Diagnosis

Rhinitis is often undiagnosed, misdiagnosed and / or mistreated. The patient's history is most important. In seasonal rhinitis the nasal symptoms are usually obvious, with immediate sneezing, itching and running related to mast cell degranulation in relation to allergen exposure (early phase response).

Conjunctivitis and itchy eyes accompany nasal symptoms in 70%, aiding the differential diagnosis from the common cold.

In perennial rhinitis the predominant symptom is often a blocked nose; especially when the problem is persistent, rhinorrhoea can be predominantly posterior, and the relationship to allergen hidden. This is because the late phase response to allergen predominates and involves inflammation with eosinophils, a cardinal feature (Figure 1). Conjunctivitis is less likely (under 50%). Inflammation may extend beyond the nasal cavity to involve the sinus linings, when it is known as rhinosinusitis. Symptoms can include nasal blockage, rhinorrhoea, facial pain, headache and reduced sense of smell.

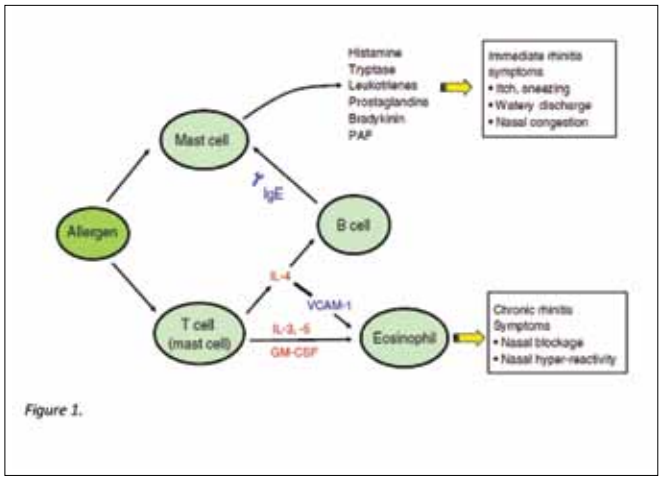

Figure 1.

The allergic response with an early phase related to immediate mast cell degranulation upon allergen exposure and IgE cross-linking by allergen and a late phase, often seen with chronic or very high-dose allergen exposure, where inflammation predominates. Symptoms are rapid and obvious in the early phase, but chronic obstruction, hyper-reactivity and reduced olfaction characterise the late phase

From Stephen Durham, Imperial College, London, with thanks.

If a history of exacerbation and remission in response to possible allergens (pets, house dust mite, moulds, work) is not sought and corresponding skin-prick or blood IgE tests not arranged, then the allergic nature of the problem can be missed. Even among those with negative skin-prick tests there is a population of subjects with local allergic rhinitis who respond to nasal allergen challenge. Conversely positive skin-prick tests to allergens such as house dust mites can be found in asymptomatic people (sensitisation without clinical disease), thus a history of reaction upon exposure and improvement on avoidance is needed.

The differential diagnosis of perennial rhinitis is wide, and includes serious diseases such as Wegener's granulomatosis in adults and reduced immunity in children (primary ciliary dyskinesia, cystic fibrosis). All subjects need careful nasal, full ENT, and chest examinations. Those with unusual symptoms such as bleeding, unilateral discharge, nasal collapse or septal perforation and/or systemic illness need full systematic review and screening blood tests. Those with non-allergic disease can be subdivided into inflammatory and non-inflammatory forms by nasal smears. In non-allergic eosinophilic rhinitis, aspirin sensitivity should be considered, especially if nasal polyps and asthma are present.

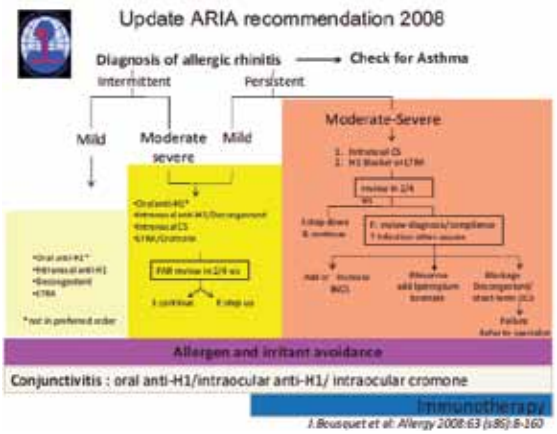

Figure 2.

Rhinitis treatment, adapted from ARIA 2008 update.

Treatment

For allergic rhinitis the ARIA document suggests basic underlying treatment with allergen and pollutant avoidance, plus consideration of nasal douching with saline. Sprays such as Sterimar are a convenient aid to concordance with this recommendation, and can be used even in small children when symptoms are troublesome or after exposure to allergens or pollutants. Saline douching is also effective in chronic rhinosinusitis.

Antihistamines are useful for mild intermittent symptoms; more

Table A4. Grades of recommendation for various interventions

	Seasonal allergic rhinitis (SAR)		Perennial allergic rhinitis (PAR)	
Intervention	Adults	Children	Adults	Childre
Oral anti-H1	A	A	A	A
Intranasal anti-H1	A	A	A	A
Intranasal CS	A	A	A	A
Intranasal chromone	A	A	A	A
Subcutaneous SIT	A	A	A	A
Sublingual/nasal SIT	A	A	A	A
Anti-leukotriene	A	A	–	–
Allergen avoidance (ex: Nasal Douching)			D	D

CS, corticosteroid; SIT, specific immunotherapy.

severe disease requires pharmacotherapy, with intranasal corticosteroids the treatment of choice, being demonstrably more effective than antihistamines or montelukast in meta-analyses of clinical trials. Modern molecules such as mometasone furoate, fluticasone propionate and furoate have proved safe in use over a year in children. Combinations of therapy are used when one fails: recent trials of a spray containing fluticasone propionate plus azelastine show better efficacy than either alone.

Some 20% of AR sufferers remain uncontrolled by guideline-directed pharmacotherapy – these should be referred to a specialist for consideration for immunotherapy where there is a clear allergen driver of symptoms. Nasal allergen challenge may be needed to ascertain the relationship of perennial rhinitis to allergen exposure before embarking on expensive allergen-specific treatment. Immunotherapy is now available by both subcutaneous and sublingual routes, the latter being safer and more applicable to children, sadly with restricted availability of allergens as yet, since alteration of disease progression is a necessary outcome imposed by European regulatory authorities. Perennial allergens such as house dust mite and cat are at present in clinical trials.

In summary, perennial rhinitis involves a spectrum of disease from mild, intermittent forms which are likely to relate to occasional allergen exposure and can be treated by allergen identification and avoidance, backed up by saline douching; to severe, persistent disease which needs accurate diagnosis and specific treatment, but where saline douching may still play a role in therapy. ■

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Dr. Glenis Scadding
Consultant Allergist & Rhinologist, RNTNE Hospital, London.

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Resurgence of Vitamin D Deficiency Rickets

M Zulf Mughal

Introduction

Rickets is a disorder of the growing child arising from disorders that result in impaired apoptosis of hypertrophic cells and mineralization of the growth plate. Rickets arising from deficiency of vitamin D remains an important health problem in many developing and developed countries. In this article I shall discuss factors that lead to vitamin D deficiency rickets. Diagnosis, treatment and prevention of vitamin D deficiency rickets will also be discussed.

What Is Rickets?

Rickets is a disease of the growing child in which there is failure of mineralization the growth plate and osteoid matrix. The orderly differentiation of the growth plate is regulated by a number of growth and transcription factors. Cartilage cells in the 'resting zone' of the growth plate, adjacent to the epiphysis, mature into chondrocytes. These chondrocytes become organized into columns, aligning themselves along the longitudinal axis and undergo hypertrophy. The terminally differentiated hypertrophic chondrocytes, undergo vascular invasion, apoptosis and mineralization. The scaffold left behind by apoptotic chondrocytes is turned into to primary spongiosa by invading osteoclasts. Low serum phosphate is responsible for the reduced apoptosis of hypertrophic chondrocytes and development of rachitic changes [1,2]. In vitamin D deficiency low serum phosphate concentration arises from elevated serum parathyroid hormone (PTH) levels, which in-turn causes in renal phosphate wastage from proximal renal tubules. The accumulation of hypertrophic chondrocytes in the growth plate, secondary to hypophosphatemia gives rise to clinical signs of rickets, such as the hypertrophy of the costochondral junctions and swelling of ends of long bones. It also results in the radiological signs of widening of metaphyses

Sources & Metabolism Of Vitamain D

Vitamin D exists in two forms: vitamin D3 (cholecalciferol) and vitamin D2 (ergocalciferol). In humans over 90% of vitamin D comes from the photo conversion of 7-dehydrocholesterol in the skin to cholecalciferol by solar ultraviolet radiation (UVB; 290-320 nm). Vitamin D3 is derived from natural dietary sources such as oily fish, eggs & liver and fortified foods makes a small contribution to body sores of vitamin D. Ergocalciferol or vitamin D2 is derived from plant and fungal sources, or produced commercially by irradiation of yeasts. The two forms undergo identical metabolism and will be referred to as vitamin D when it is not necessary to distinguish between them. Vitamin D is metabolized to 25-hydroxyvitamin D 25(OH)D by a number of cytochrome P450 (CYP) enzymes. A rare case of rickets due to CYP2R1 mutation suggests that this might be an important CYP enzyme responsible for synthesis of 25(OH)D [3,4]. Serum 25(OH)D is the major circulating form of vitamin D and it's serum concentration is used to determine an individual's vitamin D status. Circulating 25(OH)D is hydroxylated by the 1 hydroxylase enzyme (CYP27B1) in the kidney to 1,25 dihydroxyvitamin D (1,25(OH)2D), the biologically active metabolite of vitamin D. The activity of, CYP27B1 is stimulated by PTH and low serum concentration of calcium and phosphate. It's activity is inhibited by the fibroblast growth factor 23 (FGF23), a hormone that is produced by osteocytes which plays an important role in phosphate homeostasis (see below). 1,25 dihydroxyvitamin D acts on its nuclear receptor, the vitamin D receptor (VDR) in intestinal cells to promote gastrointestinal absorption calcium & phosphorus. 1,25(OH)2D is also important for calcium homeostasis. When dietary calcium intake or serum ionised calcium concentration is low, 1,25(OH)2D interacts with the VDR in osteoblasts to induce the expression of the plasma membrane protein receptor activator of NF-□B ligand (RANKL). The RANKL binds to RANK on preosteoclasts causing them to mature to osteoclasts, which in turn cause bone resorption, releasing calcium & phosphorous into the circulation. Both 25(OH)D and 1,25(OH)2D are catabolized by 24-hydroxylase (CYP24A1) to inactive metabolites, 24,25-dihydroxyvitamin D and calcitroic acid respectively.

Vitamain D Deficiency Rickets

Vitamin D deficiency remains an important cause of rickets in many parts of the world [5]. In spite of abundance sunshine, vitamin D deficiency rickets in not uncommon in Middle Eastern countries [6, 7,8, 9 10]. There appears to be resurgence among children of ethnic minorities living in Europe and North America [11, 12, 13]. It is a disorder of the growing child and is therefore manifests during infancy (usually < 18 months of age) and during the adolescent growth spurt. Detailed discussion of factors responsible for vitamin D deficiency rickets is beyond the scope of this review but include:

a) Residence at latitudes where the sun is too low in the sky during winter months, for example among < 1yr old infants in Northern territories of Canada [13].

b) Atmospheric pollution, which limits UVB reaching the ground level [14].

c) Wearing of clothing which cover most of the skin surface area & because of voluntary sunshine avoidance for religious and cultural reasons [15,16].

d) Maternal vitamin D status during pregnancy. Vitamin D deficiency in pregnant women increases the risk for rickets in their offspring. [17].

e) Skin pigmentation; melanin absorbs ultraviolet B radiation thus diminishing cutaneous vitamin D synthesis [18].

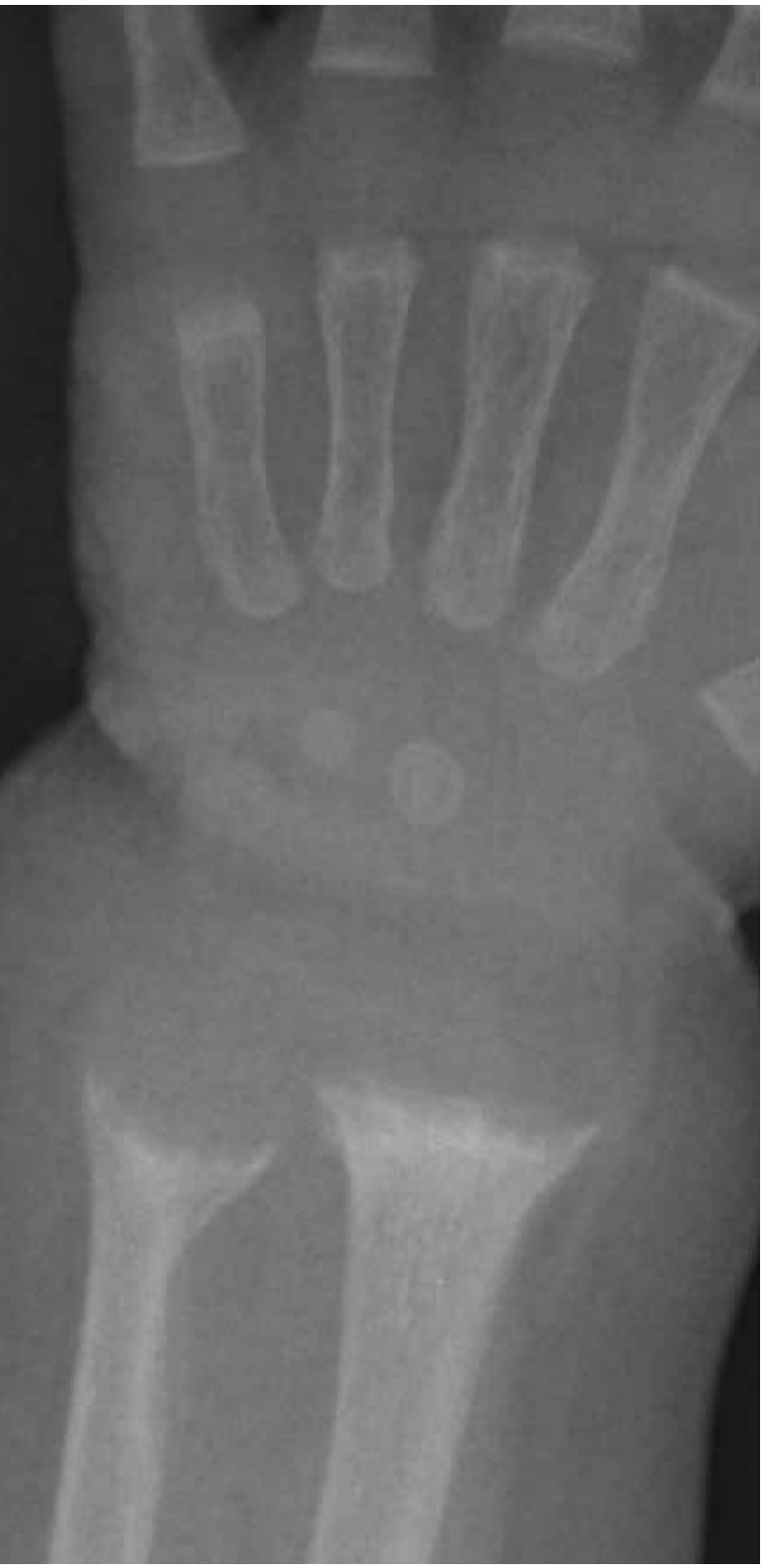
f) Rachitogenic role of vegetarian diets [19].

g) Low calcium diet, which induces secondary hyperparathyroidism. High serum PTH leads to increased synthesis of 1,25(OH)2D, which is known to degrade 25(OH)D to inactive 24,25(OH)2D, thereby depleting body stores of vitamin D [20,21].

h) Prolonged and exclusive breast feeding without vitamin D supplements [22]; human milk contains only about a 40 i.u (1 µg) per liter.

i) Genetic and ethnic differences in vitamin D metabolism [23,24].

Clinical features vary with the severity and the age of onset of rickets. Florid skeletal deformities are more common in infancy. Infants with rickets usually develop deformities of their weight bearing limbs. A crawling child develops deformities in the forearms, whereas a walking toddler develops



bow legs (genu varum) or knocks knees (genu valgum). Other features of rickets include growth retardation, frontal bossing of the skull, swelling of wrists, knees, and ankles. 'Rachitic rosary' arises due to expansion of the costo chondral junctions, and an inward diaphragmatic pull of soft rib cage gives rise to Harrison's sulcus (groove). Dentition may be delayed and development of tooth enamel impaired. Irritability, considered to be secondary to bone pain, is a common feature in rachitic infants. Muscle weakness associated with vitamin D deficiency leads to hypotonia and delay of the motor development.

Adolescents with rickets usually present with vague symptoms such as aches and pains in lower limbs, which are precipitated by walking or playing games. They also complain of muscle weakness and the proximal myopathy may cause difficulty in climbing stairs. Frequently musculoskeletal symptoms in these youngsters are attributed to 'growing pains' and are inappropriately treated with analgesics. Florid signs of rickets are rare in adolescents. Deformities such as bowlegs and knock knees may develop with long standing vitamin D deficiency. Pelvic deformities that develop during adolescence can later lead to obstructed labor.

Most children with vitamin D deficiency rickets have serum 25(OH)D concentrations <10 ng/ml, and usually < 5 ng/ml. However, serum 25(OH) D concentrations may not be markedly reduced in overtly rachitic children who have low dietary calcium intake. In a study from Connecticut, USA, 50% of infants with clinical, biochemical and radiological signs of rickets had serum 25(OH)D concentrations >20 ng/ml [25]. In the early stages of vitamin D deficiency, serum calcium concentration is low with a normal serum phosphate concentration. Hypocalcemia leads to secondary hyperparathyroidism, which in turn results in an increase in serum 1,25(OH)2D concentration, normalization of serum calcium concentration and a decrease in serum phosphate concentration. At this stage serum 25(OH)D concentration is low and the concentration of 1,25(OH)2D is normal or high. This biochemical state is maintained at the expense of the resorptive action of PTH on bone. Long standing vitamin D deficiency eventually leads to recurrence of hypocalcaemia. Serum alkaline phosphatase activity is raised above the upper limits of normal for the age.

Radiological signs are seen at rapidly growing ends of long bones, for example at the distal rather than the proximal end of the femur. The earliest radiological sign of rickets is the loss of the crisp line, produced by the zone of provisional calcification at the interface of the epiphyseal growth plate and metaphyses of long bones, is lost. This zone becomes frayed or 'brush like', and in more advanced stages of rickets it becomes concave or "cup shaped". The metaphyseal area also becomes wider than normal [Figure 1]. These metaphyseal changes tend to be more marked in toddlers rather than in adolescents with rickets. Radiological features of secondary hyperparthyrodism include generalized osteopaenia, subperiosteal bone resorption and periosteal reaction along diaphyes.

Treatment & Prevention

There are numerous regimens for treatment of vitamin D rickets [26], however, it is fairly straightforward and involves administration of vitamin D2 or D3 in therapeutic doses (1500 6000 i.u./daily) until there is normalization of biochemistry. Usually treatment is necessary for 2 to 3 months; it important to provide calcium supplements in those with inadequate dietary calcium intake. Some advocate use of a single-day large oral dose of vitamin D or 'Stoss therapy', particularly in those with poor compliance [27] However, such regimens can be associated with increased risk of hypercalcemia [28]. Improvement in clinical symptoms, such as aches and pains occur within 2 weeks, and in toddlers, the disappearance of swelling of the distal ends of long bones (metaphyses) occurs usually by 6 months. In this group, full correction of bowed legs or knock-knees can take up to 2 years, but the adolescents are usually left with residual skeletal deformities that require surgical correction.

Vitamin D supplementation has been shown to be safe and effective way of reducing vitamin D deficiency rickets in vulnerable infants [29]. A nationwide program of providing free vitamin D drops (400 i.u. daily) to newborns and infants reduced the prevalence of rickets from 6% in 1998 to 0.1% in 2008 in children less than 3 years of age [30]. ■

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Dr M Zulf Mughal

Consultant in Paediatric Bone Disorders &
Honorary Senior Lecturer in Child Health
Royal Manchester Children's Hospital
Central Manchester University Hospitals NHS Foundation Trust
Oxford Road
Manchester
M13 9WL

Practical Pain Management in Older People

BalMukund Bhala, Neeraj Bhala,

Introduction

Pain relief, whether acute, chronic or related to surgery, is an issue throughout the world. However, as a result of a changing population demographic in countries like the UK, the proportion of older patients is increasing, which poses unique challenges when considering analgesia. We have a potential aging 'time bomb' and we need to prepare our services to meet the needs of this older age group ensuring their dignity and their well-being not compromised. Hence, five years ago the British Pain Society worked with the British Geriatrics Society & the Royal College of Physicians, reviewed the evidence and produced national guidance to help all practitioners in assessing pain in older people with a simple algorithm in October 2007[1] (Appendix 1). The purpose was to provide professionals with a set of practical skills to assess pain as the first step towards its effective management.

To put the effects of pain in the elderly in perspective, national UK statistics have indicated that pain or discomfort was reported by about half of those over 65 years old, and 56% of men and 65% of women aged 75 years and over. Higher prevalence estimates are obtained from samples of institutionalised older people, where 45–83% of patients report at least one current pain problem.

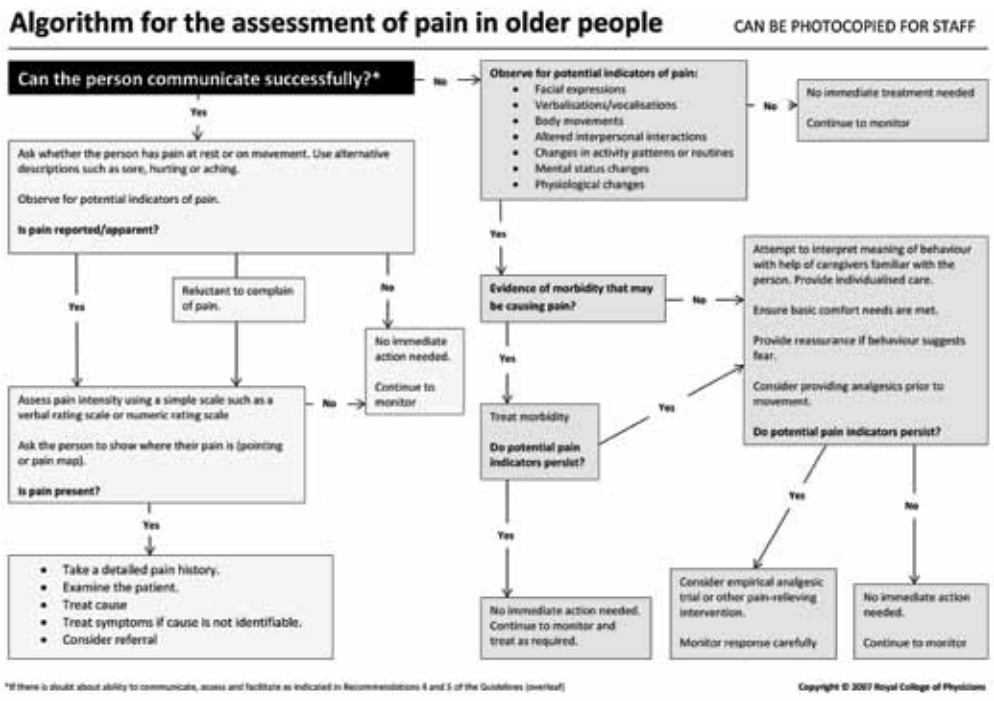
Pain Assessment

Compared to young adults some of the challenges are cognitive impairment, communication, language and cultural barriers. Box 1 in that report lists the key components like: direct enquiry, observations of signs, description (sensory, affective & its impact), measurement & cause of pain. Their table 1 & 2 describe the observational changes associated with pain & various scales for assessing pain.

Assessment of pain may be carried out by normal methods and conventional numerical or graphical methods work well. However, impairment of higher intellectual functions may mean that observational techniques may also be needed.

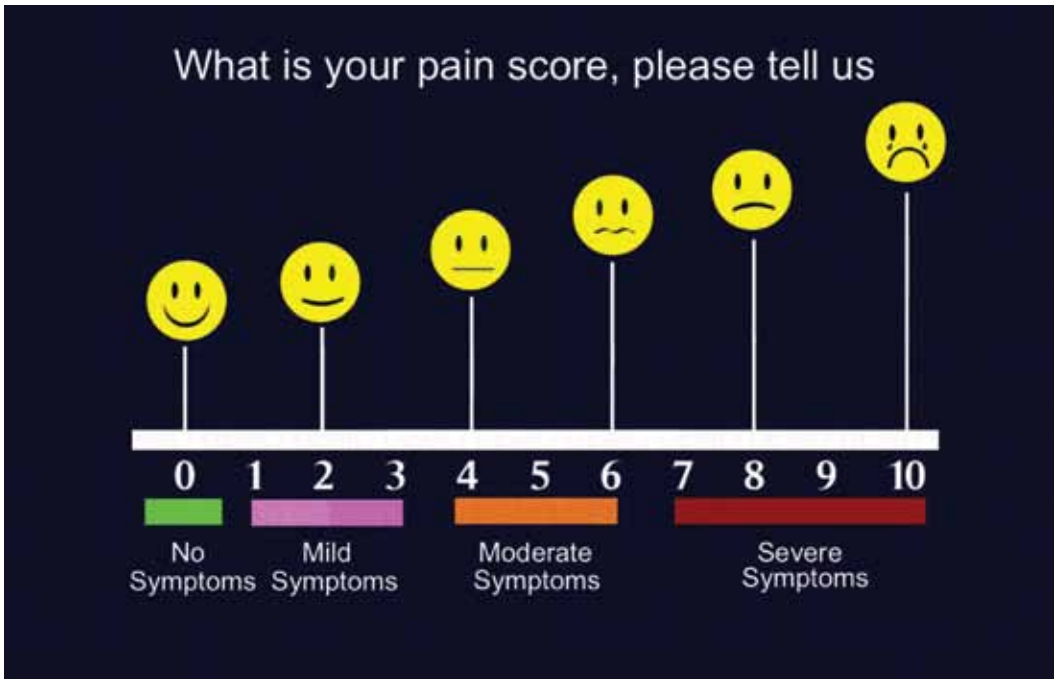
Key components of an assessment of pain include direct enquiry about the presence of pain and observation for signs of pain, especially in older people with cognitive / communication impairment. Description of pain should include the sensory dimension, the affective dimension (e.g. fear, anxiety or depression) and impact on the patient. Measurement of pain should ideally use standardised scales in a format that is accessible to the individual. Of course the aim of history, examination and investigation is to establish the cause of pain, in order to effect treatment (Box 1).

Observational changes associated with pain can also be more marked (or subtle) in the elderly, including autonomic changes, facial expressions and body movements. Aggressive verbalisations / vocalisations and altered interpersonal interactions can sometime be the presenting complaint of those with pain, especially if there is preceding cognitive impairment. Changes in activity patterns and mental status changes can sometimes also occur (Table 1).



Our experience at NELTC

We at NELTC have standardised the process along the entire surgical care pathway (from pre-assessment, through admission on the wards, theatre & recovery to discharge home and follow up) with a Coloured Visual Analogue Scale (Appendix 2). Pain maps are sometimes used to get more details on localisation as in some patients with chronic pain (Appendix 3). Our numeric rating scale from 0 to 10 is used in those patients, with some difficulties, who are able to use verbal descriptor 0 to 5 scale by converting it to 0 to 10 while recording it



(Appendix 4). We found this standardisation to be very helpful in doing our routine recording of pain scores by our nurses on the wards, and also in the Pain & Sickness Audit carried out by us based on their records. This audit showed us excellent pain & sickness scores, with a high patient satisfaction rate, compared to world literature & was presented at various conferences in Birmingham (BAPIO), Wembley (BAOIA), Tel Aviv (ISA), Mumbai (ISA) & Granada (WSPC) and well received by the audience [2]. We followed the recommendations of the National Guidelines which are summarised (Appendix 5) along with the algorithm (Appendix 1).

Management of Acute Postoperative Pain

Three years ago European Society of Regional Anaesthesia and Pain Therapy produced general recommendations and principles for successful pain management postoperatively[3]. Effective pain management is a very important part of modern surgical practice. The goals are to: improve quality of life, rapid recovery & early discharge with minimum morbidity. Listening to and believing in patient is the first step. Use of one scale within a hospital ensures that everyone in the team 'speaks the same language' of intensity of pain, from pre-assessments, wards, recovery to discharge time. This also helps in adjusting drugs for better pain management[4].

Informed consent ensures detailed discussion about pain and its treatment. To keep realistic expectations of care patient participation is important and they need to know about 'pain relief', not a 'pain free status'. In addition to verbal information wall posters in the clinics / wards and patient leaflets are useful.

As the mechanism of pain is multi-factorial these days multimodal analgesia is recommended for a balanced combination of analgesics, co-analgesics & local anaesthetic (LA) blocks or infiltrations. Surgeons routinely use local anaesthetics before or after (preferably both), with or without other form of anaesthesia to improve pain control. Using LA before incision means patient's analgesic requirements & side-effects are reduced, especially in those older patients with multiple co-morbidities.

The elderly present special problems in the provision of analgesia. As a general rule, the elderly report pain less frequently and require smaller doses of analgesic drugs to achieve adequate pain relief. Many patients are anxious, which may be associated with increased pain postoperatively.

Commonest drugs in use are Paracetamol, NSAIDs, Gabapentin / Pregabalin, Codeine, Tramadol, Oxycodone, Morphine in various combinations, through a step by step approach depending on the severity of pain & patient's tolerance / intolerance of drugs. Drug dose for each drug prescribed needs to be tailored to patient requirements especially taking their age and age-related metabolic changes in consideration. Coxib or NSAIDs are used with caution in older people usually with proton pump inhibitor and routinely monitored for drug interactions, gastrointestinal, renal & cardiovascular side effects.

NSAIDs (e.g. diclofenac, ibuprofen and naproxen are amongst the most widely used medications globally for analgesia, particularly in patients with rheumatological conditions, but they can have serious side effects. Upper gastrointestinal disorders ranging from heartburn and dyspepsia are more common to peptic ulceration and gastrointestinal bleeding. Care should also be taken in patients with compromised hepatic or renal function. These drugs can also cause raised blood pressure, as well as leading to heart failure and myocardial infarction in high-risk patients, first detected in studies of selective cyclo-oxygenase inhibitors.

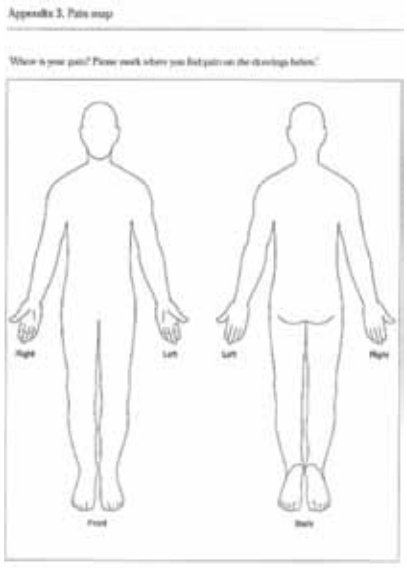
Self-medication with opioids is not always wise in elderly patients and thus the role of patient-controlled analgesia may be limited. The elderly may be particularly sensitive to opioids and side effects such as confusion, sedation and respiratory depression assume greater importance. Because of changes in hepatic and renal function lower doses of opioids are needed and the expected length of action may be longer.

Only one analgesic drug should be used at a time in the elderly. In general about half the normal adult dose, even less in very old, should be given at first, especially if the drug is being given intravenously. Small doses should be given regularly to anticipate pain where appropriate.

When analgesic drugs are given they may not be absorbed as well or metabolised as efficiently. In practical terms, doses of drugs such as NSAIDs and opioids in the elderly should be reduced because of a decrease in liver metabolism. In addition, since the metabolites of drugs such as morphine and pethidine are excreted by the kidneys, any decrease in renal function may lead to accumulation with repeated doses. The elderly are more likely to be receiving more than one drug for underlying medical conditions and the possibility of drug interaction is also greater.

Spinal anaesthetic (LA + opioid) is now generally more popular than Epidural, and LA infiltrations are becoming more common than Nerve Blocks. For intra-articular LA infiltrations some adrenaline, NSAID & opioids maybe indicated for better results than LA alone. Some of these drugs also help in reducing the incidence of the pain becoming chronic (beyond 3 months after surgery).

Nerve blocks are a most effective way of giving postoperative pain



relief. Intercostal nerve block can aid pulmonary function after chest or upper abdominal surgery and pain below the waist can be abolished by epidural blockade aiding the return of gastrointestinal function after surgery. However, blocks spread more widely in the elderly and there may be compromise of respiratory function due to intercostal paralysis. In addition, a greater sympathetic block may occur with a consequent fall in blood pressure. With care, local anaesthetic blocks can be very useful in the elderly and give excellent pain relief whilst permitting mobilisation and rehabilitation by physiotherapists.

Non-pharmacological treatments like cold therapy with iced water bag on the joints seem to help reducing the swelling as well as pain. Fewer analgesic drugs are required, as we move towards enhanced recovery from surgery.

We have regular meetings of Anaesthetists Group and Pain Group to continue to update and improve with latest evidence and mutual agreements. Daily multi-disciplinary ward rounds headed by an anaesthetist (with overall responsibility) have been valuable for some of the improvements in quality of life, reduced morbidity, rapid enhanced recovery and early discharges. Older patients in particular may need more time commitments and mutual co-operation from all staff in a multi-disciplinary set up.

Management of Chronic Pain

Professor Schofield and colleagues produced a paper reviewing the main recommendations within the guidelines by the BPS & BGS[4].

Any pain beyond three months by definition is chronic. Prevalence of any pain in older persons is 0 to 93% by various estimates carried out, according to this joint report. Current pain ranged from 20-46% in the community & 28-73% in residential care. Chronic pain prevalence ranged from 25-76% in community & 83-93% in residential care. Women have a higher prevalence than men.

The three most common sites of pain in older people were: back, lower limb and other joints. This shows that millions of people live with chronic pain as if it is 'expected to be part of ageing' that they are 'learning to live with'.

In addition to the drugs for acute pain these patients might need the following, initially in lowest doses: Tricyclic antidepressants, anti-epileptics, gabapentin / pregabalin, with prophylactic anti-emetics and laxatives.

Interventional therapies showing benefits in well selected cases by Pain Clinicians include facet joint radiofrequency lesioning and intra-articular corticosteroids or hyaluronic acid injections. In acute herpes zoster & post-herpetic neuralgia LA infiltration or nerve block with LA & corticosteroids is effective. In trigeminal neuralgia in older people percutaneous procedures are preferred over microvascular decompression.

Psychological approaches like cognitive behaviour therapy (CBT) has some role and maybe relaxation, meditation, mindfulness etc.

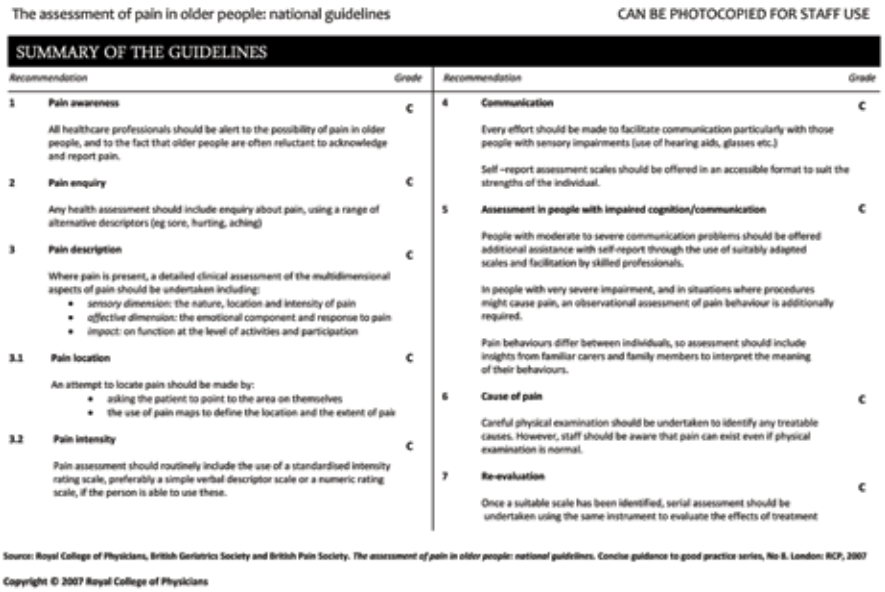
Ethical & Legal Aspects of Pain management

While assessing & managing pain in older people some important aspects of ethics and law need to be kept at the back of our minds [5 & 6]

Firstly, it is now important that the consent is as informed as possible, with patients having rights to refuse. Consent in various situations and in different age groups, from cradle to grave, is discussed. [7 & 8] On the basis of the Data Protection Act 1998, Confidentiality is considered along with express consent. Risk Management includes statutes such as the Medical Acts, NHS Acts and the Health & Safety at Work Act.

It is suggested that we use Complaints Management from local resolutions to legal proceedings and ADR, in the light of Lord Woolf's Reforms. Importance of good quality (Medical / Anaesthetic / ICU / Pain / Clinic / Hospice / Hospital) records is stressed in medical defence of any unfortunate incidents [9 & 10]. From Bolam to Bolitho is the consideration on Clinical Negligence. Here the importance of practising within the issued guidelines from public authorities, like NICE, GMC, Royal Colleges or Boards, WHO, UN and international evidence based medical (EBM) practice, is stressed. Over 40 years of practice and experiences from the USA, Canada, Europe, Balkans, Australia, New Zealand and India help us do a global comparison but we still need to tune into national guidelines, especially those drawn up by experts like BPS,BGS, RCP.

If we visit a virtual courtroom to study civil, military and criminal cases and the law governing those Medical Witnesses and Medical Experts we will see various types and grounds of Discrimination including the latest developments in this highly prevalent, but preventable, area of Employment Law. An LLM project on 'Race Laws in the NHS', and experience in the BMA Medical Ethics Committee are briefly mentioned.



The assessment of pain in older people: national guidelines — CAN BE PHOTOCOPIED FOR STAFF USE

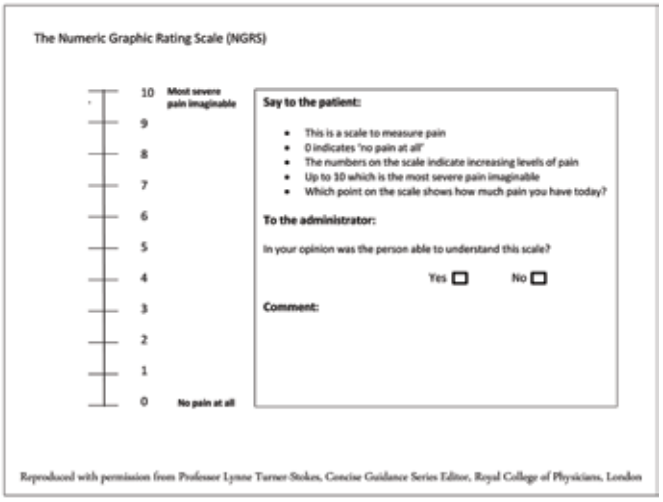
SUMMARY OF THE GUIDELINES

Recommendation		Grade
1	**Pain awareness** All healthcare professionals should be alert to the possibility of pain in older people, and to the fact that older people are often reluctant to acknowledge and report pain.	C
2	**Pain enquiry** Any health assessment should include enquiry about pain, using a range of alternative descriptors (eg sore, hurting, aching)	C
3	**Pain description** Where pain is present, a detailed clinical assessment of the multidimensional aspects of pain should be undertaken including: • *sensory dimension*: the nature, location and intensity of pain • *affective dimension*: the emotional component and response to pain • *impact*: on function at the level of activities and participation	C
3.1	**Pain location** An attempt to locate pain should be made by: • asking the patient to point to the area on themselves • the use of pain maps to define the location and the extent of pain	C
3.2	**Pain intensity** Pain assessment should routinely include the use of a standardised intensity rating scale, preferably a simple verbal descriptor scale or a numeric rating scale, if the person is able to use these.	C
4	**Communication** Every effort should be made to facilitate communication particularly with those people with sensory impairments (use of hearing aids, glasses etc.) Self –report assessment scales should be offered in an accessible format to suit the strengths of the individual.	C
5	**Assessment in people with impaired cognition/communication** People with moderate to severe communication problems should be offered additional assistance with self-report through the use of suitably adapted scales and facilitation by skilled professionals. In people with very severe impairment, and in situations where procedures might cause pain, an observational assessment of pain behaviour is additionally required. Pain behaviours differ between individuals, so assessment should include insights from familiar carers and family members to interpret the meaning of their behaviours.	C
6	**Cause of pain** Careful physical examination should be undertaken to identify any treatable causes. However, staff should be aware that pain can exist even if physical examination is normal.	C
7	**Re-evaluation** Once a suitable scale has been identified, serial assessment should be undertaken using the same instrument to evaluate the effects of treatment	C

Source: Royal College of Physicians, British Geriatrics Society and British Pain Society. *The assessment of pain in older people: national guidelines. Concise guidance to good practice series, No 8.* London: RCP, 2007

Appendix 4. Examples of pain scales

4A Numeric rating scale



4B Verbal descriptor rating scale (5 points)

A very significant shift in English Law, due to a European introduction (from October 2000) of the Human Rights Act 1998, is highlighted [11, 12 & 13]. With this knowledge we then try to predict the likely impact on the Pain Practice with all its sub-specialties. We will certainly be looking forward to any suggestions for tackling information overload while continuing to practice evidence-based, safe pain management, anaesthesia and critical care for our older patients! Let the Medical Law continue to evolve in the West and be lead by Ethics from the East, based on Bhagavad-Gita [14].

Recommendations & Conclusion

Based on our recent experience & developments locally we recommend that the following steps will help us move in the right direction for better pain management in older people:

- Institutions to have Strategic Pain Groups for those interested in the topic with a commitment for updates & continuous improvement leading to creating local champions everywhere.
- To standardise Pain Scales with Pain Maps for better assessing pain localization & pain intensity.
- On surgical side, to give more emphasis on acute pain management including safe use of LA in almost all patients & utilizing the skills of Anaesthetist colleagues.
- On Medical side, to use balanced analgesic combinations mainly, seeking expert advice from Pain Clinics in chronic or acute on chronic pains or from Psychologists in selected cases.
- Not to forget the Ethical & Legal issues in pain practice while using our National Guidelines.

In conclusion, 'Sarve Bhavantu sukhinah, Sarve santu niramayaah' meaning let everybody be happy, free of pain & suffering. Let's aspire to make the world of older people free of pain so we can all look forward to a long & happy retirement too!. ■

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Dr BalMukund Bhala

TD, RAMC (V) MD (Anaesthesiology), FFARCSI, MBA (OUBS), LLM in Medical Law (UNN) Care UK Consultant Anaesthetist & Chair, Anaesthetists Group & Pain Group, North East London NHS Treatment Centre, near KGH, Ilford, Essex IG3 8YY. Member of Pain in Older Adults Special Interest Group of British Pain Society.

Dr Neeraj Bhala

MBChB, MRCP, MSc(Epi.), DLSHTM, FRSPH Specialist Registrar in Gastroenterology and General Medicine
Queen Elizabeth Hospital, University Hospitals Birmingham NHS Trust, B15 2TH. MRC Health of the Public Fellow
Clinical Trial Service Unit, University of Oxford, OX3 7LF.

Making Sense of the Pension Rules

Apart from the shared experience of long hours whilst training, the one thing that GPs in partnerships, single-handed, locums, salaried and NHS consultants have in common is membership of that national treasure, the NHS Pension Scheme.

What is the impact of the new rules on pension contributions to BAPIO members?

At the outset we should say that the effect is not straightforward and every reader will have a different outcome, so you should seek professional guidance. However, we set out below some pointers for your consideration.

Rule 1: The Maximum Annual Allowance

The basic rule is that the maximum pension saving in a year on which you receive tax relief is £50,000 and if you, or your employer, in total contribute more than this then you may pay a tax charge on the amount over the annual allowance. This includes both the NHS Pension Scheme and any other schemes which you may contribute to.

Whether you have to pay a tax charge depends on whether you have unused annual allowances in the previous three years, for which HMRC have also set the limit as being £50,000. A separate calculation would be needed for each year along the lines of that set out below.

However for members of the NHS Pension Scheme, and other lifetime average or final salary schemes, this is made far more difficult because the savings figure is deemed as being the growth in your pension entitlement from one year to another, rather than the contributions you have actually made after adjustments have been made for inflation.

Each year to 31st March is treated as a Pension Input Period (PIP).

The determining factors in deciding the size of your pension scheme entitlement, and hence whether you may be exceeding your Annual Allowance of £50,000, are your salary, which of course also determines the level of your employee and employer contributions, but more importantly the level of your pension along with the length of your membership of the scheme. Dynamisation of lifetime profits is also a major determinant for GPs.

The higher your salary/profit share, and greater your length of membership, the greater the likelihood of your exceeding the Annual Allowance. Added years payments will further increase the value of your pension entitlement, and hence the year-on-year increase in pension entitlement. The biggest game-changer in this is of course when you get promotions or significantly increased pensionable profits.

The amount of tax that you will pay, if you are liable, is the increase in value of benefits over the PIP less the annual allowance, less any unused allowance from the previous three years, and will be payable at your top rate of tax. If this excess takes you into a higher tax bracket then you will pay the higher rate on part of it.

If, for example, we take a doctor with an annual salary or pensionable profit of £120,000 for the year to 31 March 2011 and 20 years' service, and then consider the situation if the pensionable income increased to £130,000 in the year to 31 March 2012, we would have the following calculation:

	£	£
Pension Entitlement at end of year (21/80 x 130,000)	34,120	
Pension Entitlement at start of year (20/80 x £120,000) plus inflation at say 2.5%	30,750	
Increase in Annual Pension	3,375	
Value of Increase in Pension 16 x 3,375		54,000
Cash sum at end of year (3 x £33,468)	102,360	
Cash sum at start of year after inflation (3 x £30,750)	92,250	
Increase in Value of Lump Sum		10,110
Increase in Value of Pension		64,110
Annual Allowance		50,000
Amount in Excess of £50,000		14,110
Tax due at 40% - payable on 31 January 2013		5,644

Rule 2: The Lifetime Allowance Charge

There is now a limit on the value of retirement benefits that can be drawn from any approved pension scheme, including the NHS Pension Scheme. From 1 April the lifetime allowance is £1.5m.

(Between 2009 and March 2012 the Lifetime Allowance was £1.8m, and for those with benefit entitlements worth more than £1.5m there have been a series of elections that would have provided either enhanced, primary or fixed protection against additional charges to tax. These are beyond the scope of this article as they are not now available).

The value of your pension entitlement for these purposes is calculated as being 20 times the value of your pension entitlement plus the tax free lump sum payable on retirement. If your entitlement is in excess of the £1.5m (or more if you claimed protection), then should the excess be paid to you as a lump sum, tax would be payable as a one-off 55% recovery charge. If the chargeable excess is paid in the form of a pension, then 25% of the payment otherwise payable would be paid as penalty tax, with the remainder being subject to income tax in the usual way.

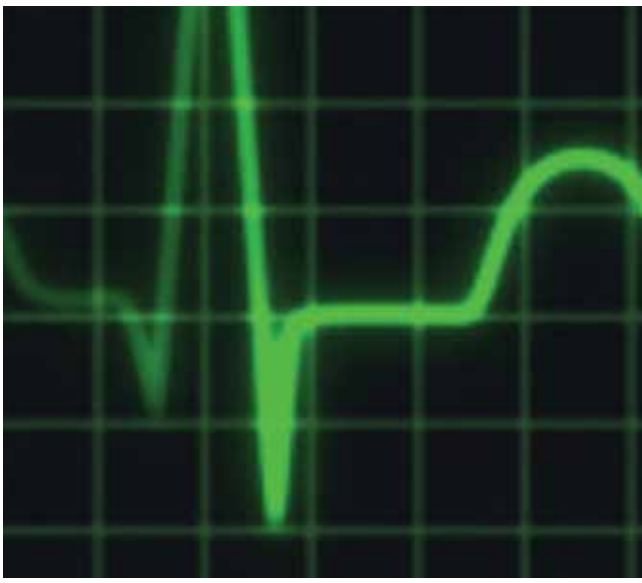
	£	Value of Benefits £
Annual Payment Entitlement before excess	75,000	1,500,000
Tax Free Lump Sum (3 times annual payment)		225,000
Total Value		1,725,000
Lifetime Allowance		1,500,000
Excess		225,000
Penalty Tax 25% - Payable by NHS Pension Scheme		56,250
Increase in Value of Pension		
Annual Deduction 1/20th	2,812	
Taxable Pension Payable	72,188	

The reduced pension is payable for the whole of your life, and subsequent pension increases will only be applied to the pension after allowing for the lifetime allowance deduction. So in this example, if you had a pension of £75,000 and did not have protection then inflationary increases would be based on £72,188.

For those who have already retired from the NHS Pension Scheme but are still contributing to other schemes, the value of the NHS Scheme also has to be added to your other scheme for the calculation of your lifetime allowance. For these purposes the valuation is 25 times the annual NHS pension you are drawing.

You will need therefore to obtain an annual valuation from the NHS Pension Scheme in order that you can properly complete your tax return.

There is no substitute for informed professional advice, and you should ensure that you seek advice from a suitably qualified advisor with experience in this field. ■



David Belbin FCA DChA (david.belbin@cbhc.uk.com) is a member of the ICAEW Healthcare Group and is the current chairman of the Charter-Group Healthcare Group and leads CBHC LLP's Specialist Health services team.

Philip Redhead FCCA (philip.redhead@cbhc.uk.com) is a partner in CBHC's specialist healthcare team and has been working with healthcare professionals for many years.

Neil Manning FCII (neil.manning@cbhc.uk.com) is the partner who heads up our Wealth Management team providing solutions to our clients as they seek to manage their wealth through a portfolio of assets and provide protection in the event of unforeseen circumstances.

The Physician Speaks with Sukdhip Sidhu of Arjun Products About The Latest in Nutritional Supplements

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Q5 – What are the benefits of prescribing ARJUN products?

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- The quality of the product is assured and consistent from batch to batch with full QC testing of all raw materials and finished goods, and Certificates of Analysis available. Equivalent products sourced from manufacturers of unlicensed medicines will vary between suppliers and from batch to batch.

Q6 - Are these products available over the counter?

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Q7 - How do I prescribe the ARJUN products?

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Q8 - Will the pharmacy be able to get the products to fulfil the prescription?

Our products are readily accessible for pharmacists as they are distributed under reduced wholesale distribution agreements via AAH and Alliance Healthcare. As such, all pharmacies in the UK will have access to the ARJUN Product range and the items are delivered free of charge. ■

Sukdhip Sidhu, MRPharms

Sid attended Liverpool School of Pharmacy qualifying as a Pharmacist in 2004. He has worked in community pharmacy, secondary care and industry and is currently Head of Product Development in the ARJUN Products division of United Drug plc

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Pitfalls of Public Private Partnership

"To succeed, public-private partnerships in health care need strong regulators."

Dr Amar Jesani Editor, Indian Journal of Medical Ethics, Mumbai

Recently, it came to light that over 16,000 hysterectomies, most of them deemed unnecessary, had been conducted on women from below poverty line (BPL) families in private hospitals in Bihar. Not long before that, private hospitals in Chhattisgarh had come under scrutiny for the same reason. The operations were allegedly conducted to fleece insurance funds available under the government's Rashtriya Swasthya Bima Yojna (RSBY).

The epidemic of unnecessary hysterectomies had already hit many sections of urban women. With public money easily available under the RSBY, it has now made inroads into rural and remote areas as well. What's more, such hysterectomies may only be the tip of the iceberg — there are rampant irregularities in the provision of healthcare by the private sector, using public money. It brings into focus serious flaws in the government policy of providing money to the private sector instead of investing it to strengthen and expand public health services.

To begin with, government regulators do not seem up to the task of unearthing such scams and taking action against the perpetrators. According to the reports on Chhattisgarh, the director of health services, under public pressure, appointed a fact-finding team and suspended doctors involved in 22 known cases, although thousands were reported. In Bihar, the chief minister has ordered an inquiry into the matter. Directorates of health services, used to running government facilities, are ill-equipped to regulate the quality and ethical standards of private hospitals and doctors working there. Schemes like the RSBY were launched without building regulatory capacities.

> "In any country where the private sector has been provided funds or land, tax holidays, subsidies and other largesse to help it dispense health-care to those who can-not afford it, government funds have been fleeced in the absence of strin-gent regulations and community monitoring."

Ever since the government launched the National Rural Health Mission (NRHM) and public-private partnerships for the delivery of healthcare, activists in the task forces and working groups of the NRHM and the Planning Commission have argued that the government first needed to put in place strong regulatory agencies that would oversee registration, medical standards, patient protection and rights. They also urged for community monitoring of private healthcare. Policymakers tackled the process upside down, pumping money into the private healthcare sector without strengthening public services, and without setting up a transparent and accountable governance system.

Yet, the practice of partnering with the private sector to deliver public healthcare services is several decades old. In any country where the private sector has been provided funds or land, tax holidays, subsidies and other largesse to help it dispense healthcare to those who cannot afford it, government funds have been fleeced in the absence of stringent regulations and community monitoring. In our country, most of the states do not have effective laws for the registration of private hospitals; neither do they have periodic medical and financial audits by independent regulators. Doctors' and hospitals' associations have grown so strong that any attempt to impose regulations has been countered by threats and strikes.

Despite the noise made by the politicians and by bureaucrats of health directorates about taking action against the doctors and hospitals, very little is expected in terms of bringing the culprits to book. While it may seem easy to crack down on those who claimed insurance money without doing the surgeries, it is more difficult to prove fraud where allegations of unnecessary surgery are involved. Unless the regulator has the power to take full medical and financial audits, and has protocols for the treatment of various ailments covered under the insurance scheme, reports submitted by investigators will turn out to be ambiguous. Instead of making a case for a robust regulatory regime, such reports would only lead to a few cosmetic punishments that would be forgotten soon.

The unnecessary hysterectomies also point to the neglect of reproductive health and reproductive rights in our public and private health services. Much has been said about the unethical conduct of doctors who generated a "supplier-induced-demand" — women agreed to get rid of a uterus that was giving them "trouble" after the doctors scared them with talk of the potential development of cancer and other diseases. Supply side regulations to prevent irrational and unnecessary medical care ought to be combined with provisions to cater to the reproductive needs of women in rural areas. For that, primary care in rural areas and urban slums must be equipped to look after the reproductive health for women. This should be combined with changes in social traditions and greater awareness about reproductive health problems. In the present set-up of primary healthcare, reproductive health is neglected. Yet when women travel to private hospitals for care, their bodies are deprived of a vital organ, causing long-term damage to their physical and hormonal systems. ■

Published in the Indian Express 10 Sept 2012

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Enough to Make You Blush: A Case of REM Sleep-Related Painful Erections Presenting with Flushing

Jessica Megan Triay, Parag Singhal

Introduction

The syndrome of Sleep-Related Painful Erections is recognised to cause significant distress, affect relationships, and lead to excessive daytime somnolence due to poor sleep quality. Polysomnography is the cornerstone of diagnosis. Treatment, although difficult, can greatly improve wellbeing. Due to the sensitive nature of symptoms, it is under-reported by patients, who can present to a variety of different specialities, however, the condition is frequently under-recognised by clinicians.

Case History

A 70-year-old man sought a diagnosis to explain troublesome symptoms of flushing within the endocrine service. Six months earlier he had become troubled by nocturnal waking associated with erythema, the intense sensation of heat originating around the genitalia and forceful, painful erections. These events took up to 20 minutes to settle and he often experienced up to four discrete episodes every night, leading to considerable sleep loss and genital soreness. Problems never occurred during the day, when erectile function was normal. On questioning, he recognised the development of symptoms over a seven-month period, initially with waking due to painless erections and then the later development of the uncomfortable symptoms. He never experienced respiratory distress, wheeze or bowel disturbance, and his weight was stable. Symptom severity and frequency had remained constant over several months, and although distressing, there were no psychological concerns. Simvastatin 40mg, Bisoprolol 1.25mg and Aspirin 75mg had been commenced after earlier investigation identified a mitral valve prolapse with regurgitation and coronary artery disease. Bedside examination was consistent with mitral valve regurgitation but was otherwise normal, and no penile abnormalities were detected.

He was admitted for observation and investigation and remained asymptomatic during the day. During the night, however, he was assessed following flushing, painful priapism and palpitations. His hands, feet and groin were flushed, although physical examination and electrocardiogram were unchanged. The problems settled completely over 20 minutes.

Investigations showed an initially marginally elevated urinary noradrenaline (675nmol/24hrs) that normalised on two subsequent tests despite persistent symptoms. Notably, gonadotrophins and testosterone were normal (LH 4.1 IU/L, FSH 11.4 IU/L, testosterone 10.4 nmol/L), as was urinary 5-HIAA (1.6 mmol/mol Crt). The rest of his urine and blood testing were unremarkable. Cardiac autonomic studies showed some evidence of cardiovascular functional neuropathy, with absent rebound tachycardia on Valsalva manoeuvre and fall in blood pressure on standing (140/70mmHg to 125/75mmHg). It was felt that this may have been a function of age [1] or the low dose of Bisoprolol. A 24-hour electrocardiogram was normal, and computed tomography scan of the chest and abdomen revealed only gallstones.

Polysomnography (sleep studies) showed marked fragmentation during rapid eye movement (REM) sleep, with frequent arousals from REM when the patient reported sensations of heat in the genital area. Sleep efficiency and other aspects of the polysomnography were within normal limits of his age. Recordings of penile tumescence, a marker of penile swelling, were not undertaken, however the polysomnography features were consistent with a diagnosis of REM Sleep-Related Painful Erections. This is also known as Nocturnal Penile Tumescence.

The gentleman received counselling and coping strategies for his symptoms, and commenced Clonazepam 500 micrograms for four nights weekly to help reduce the frequency of the episodes and help with improved sleep quality. Clonazepam can be further titrated to a maximum of 1.5mg on four nights weekly and using the step-wise approach helps to ascertain the lowest required dose, while intermittent use reduces the possibility of drug tolerance evolving. He has since been discharged from follow-up with improved control of his symptoms.

Discussion

This case highlights the importance of wider awareness of a condition which is likely to be under-reported and under-recognised [2]. Sleep-Related Painful Erections were first reported in 1971 [3], followed by a handful of case reports and small case series that form the basis of our clinical knowledge [2, 4, 5]. It is defined by the International Classification of Sleep Disorders [6] as a Rapid Eye Movement (REM) sleep parasomnia with painful erections. Before the diagnosis is made, it is important to exclude psychological disturbances, such as depression, or penile abnormalities that can cause erectile pain, including Peyronie's disease and phimosis. The majority of those affected are men over the age of 40 years, and symptoms typically progress gradually. No predisposing factors have been identified and there is no reported female equivalent of the disease. Men continue to have normal, painless erections in the awake-state and generally have normal sexual function. Polysomnography is recommended for diagnosis and shows patterns of awakening during sleep-related penile tumescence, a measure of penile vascular engorgement, attributed to pain.

The true cause of the condition is unclear. REM sleep is the commonest period for normal sleep-related erections [7], and therefore does not provide a clue to the aetiology of the condition. There is mounting evidence for the presence of autonomic nervous system involvement, although identifying whether reduced vagal response or increased beta-adrenergic activity is the culprit behind the erectile dysfunction is unclear. In a case series by Ferini-Strambi et al. [8], REM sleep in men with the condition was associated with a reduction in resting heart rate, suggesting a reduced cardiac vagal tone, however, there was also a greater cardiac response rate to spontaneous movements, indicating possible beta-adrenergic hyperactivity during sleep. These participants had no alternative explanations for autonomic dysfunction, such as diabetes, polyneuropathy, or a cardiovascular history, and all were non-smokers. Another key finding suggesting that autonomic dysfunction may play a role is the evidence for Propranolol providing some relief of symptoms, although these only seem to be of value on a short-term basis [2, 4], and there is no long-term data to suggest progressive autonomic dysfunction.

A second possibility for the development of these symptoms is central neurotransmission disturbance, as suggested by some case reports [9, 10], and the finding that rats have spinal pacemakers controlling sexual function [11] and stimulation of the anterior hypothalamus causing non-contact erections.

Interestingly, our case had one measurement of mildly elevated urinary noradrenaline, although this normalised on subsequent testing, and cardiovascular testing demonstrated loss of rebound tachycardia, suggesting some autonomic dysfunction. Introduction of low-dose beta-blockade in our patient was for cardioprotection and did not impact on his symptoms. Treatment was undertaken with clonazepam, however, baclofen and clozapine can also be used, although randomised, blinded, placebo-controlled clinical trials are lacking. ■

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Dr Jessica Megan Triay
Specialist Registrar in Endocrinology, Bristol Royal Infirmary, Marlborough Street, Bristol, BS1 3NU]

Dr Parag Singhal
Consultant in Endocrinology, Weston General Hospital, Grange Road, Uphill, Weston-super-Mare

News In Brief

How can the NHS do more for less?

The health service must get back to basics if hospitals are to have a chance of meeting the productivity challenge

The key to modern-day success in public services seems to be doing more for less. Countless policy pronouncements and political speeches make it clear that, if only we could find ways of working smarter, applying "lean" thinking, and being "transformational", our concerns about funding constraints, rising demand and gloomy economic predictions would magically disappear. Our report, Can NHS hospitals do more with less?, highlighted the critical role of the following: leadership, management and staff engagement; technology adoption; hospital operational processes; staff productivity; and the external policy environment.

What is needed is relentless attention to the detail of basic administrative and management practice, including the purchasing of supplies, organisation of back-office functions, and assessment of the performance of every department, ward and consultant against national and international benchmarks.

To do more for less, the NHS needs to get back to basics. ■

Judith Smith is head of policy at the Nuffield Trust and is co-chairing the trust's event How can hospitals do more with less? Implementing best practice for efficiency on Wednesday.

Patients with rare conditions face postcode lottery

Research shows that patients with rare conditions have less chance of accessing 'orphan' medication if they live in England

- Seriously ill patients with life-threatening rare diseases are being denied vital drugs because of a postcode lottery across the NHS that campaigners say is frustrating and unfair.
- New research reveals that patients with a rare condition have much less chance of accessing "orphan" medication if they live in England rather than Scotland or Wales. "Orphan" drugs treat patients with a condition affecting fewer than five in 10,000 people. ■

Doctors to be given 'fit to practise' tests

Annual assessments and five-yearly competency checks will start from December, the health secretary announces

Doctors will be given annual assessments and full five-yearly checks to ensure they are still competent and fit to practise starting from December, the health secretary, Jeremy Hunt, will announce today in a surprise move that puts an end to more than a decade of negotiation. ■

Efficiency savings

The Nicholson challenge to achieve £20bn of efficiency savings is not going to be met.

The King's Fund's quarterly monitoring report published in September said finance directors from a range of organisations were on track to achieve their planned cost improvements for this year, but many already see little chance of the overall target being hit.

Monitor's review of foundation trust plans for 2012-13 predicts savings will exceed 4% for each of the next two years, but that is not going to do the job. In this first 18 months of the challenge, trusts have been stripping out the easily identifiable inefficiencies and benefiting from the pay freeze. But the freeze cannot go on much longer and further savings will be much harder to deliver. ■

Our social environment encourages obesity

We can't begin to treat obesity when the food and drink industry has so much invested in it

Public health is clearly at odds with the vested interests of the food and drink industry, whose profits are fuelled by the obesity and alcohol epidemics. The impact of my targeting Simon with health promotion, or prescribing drugs to modify his fat metabolism, pales to nothing in the face of ubiquitous and malign social promotions.

The government's protracted emphasis on personal responsibility deflects attention from these broader determinants of health. Rather than regulating to create an environment in which individual prevention and treatment could be effective, the government actively seeks the food industry's advice in partnership arrangements. Capitalism has replaced public health advisers with corporate moguls. Tax bad food, subsidise good food, and I'll have a fighting chance to make every contact count. But without social change, when I next see Simon he will probably be contributing to the diabetic epidemic, and still thinking I'm a nag. ■

Sign of Strength

The government was forced to introduce a "pause" in April 2011 to allow a two-month listening exercise over the radical plans to overhaul the NHS, after a chorus of protests and claims that the policy was in chaos. Two months later, David Cameron would admit that he had made mistakes on the NHS as he agreed to make "substantive" changes to the legislation following recommendations by a panel of experts. The prime minister sought to cast the rethink as a "sign of strength

Increase in breastfeeding could save NHS £40m a year, according to report

Research finds that breastfeeding for longer reduces rate of cancer, respiratory illness, ear infections and bowel diseases

If half the women who currently do not breastfeed were to do so for up to 18 months, there would be 865 fewer cases of breast cancer, says Unicef. Photograph: Justin Paget/Corbis The NHS could save at least £40m a year if more women were given help to breastfeed for longer, according to a new report.Research by Unicef UK for the first time calculates the cost to the health service of the UK's poor record on breastfeeding. Research has shown that breastfeeding lowers women's risk of breast cancer and protects babies against infections. ■

Quarter of bowel cancer patients diagnosed after emergency hospital trip

About a quarter of bowel cancer patients in England are only diagnosed with the disease after an emergency admission to hospital, according to research published on Monday. This equates to about 8,000 out of 31,000 patients admitted in a 12-month period.

These patients are less likely to have surgery than those whose first admission was not an emergency case, according to the report, which looked at bowel cancer records and hospital data.

The finding about diagnosis upon emergency admission is in keeping with research by the National Cancer Intelligence Network about bowel cancer, which is diagnosed in about 31,000 people each year in England and Wales. It is the second most common cause of cancer death. ■

When it's more dangerous to go to the hospital at weekends

Hospitals aren't able to provide a consultant-delivered service 24/7, so centres of excellence and better outreach are needed

Dr Foster Intelligence, which is half-owned by the NHS, has published data suggesting that patients admitted as emergencies to NHS hospitals at the weekend incurred higher mortality rates than patients admitted during weekdays. This was particularly evident in patients with vascular disease. Patients admitted with painful or ruptured abdominal aortic aneurysms, where there is a ballooning (dilatation) of the main artery of the abdomen, had a 10% increase in mortality at the weekends, while those with emergency atherosclerotic conditions – a threatened limb because of a sudden loss of blood supply leading to gangrene, ulceration and/or pain at rest – had an 8% increase in mortality.

There is now compelling evidence that centres of excellence for vascular surgery with a critical mass of consultants and greater access to imaging technologies 24/7 offer better outcomes to patients (ie lower mortality rates) than smaller hospitals delivering vascular surgery with fewer consultants and limited access to diagnostic imaging on Saturdays and Sundays. This is because the centres of excellence enable each emergency patient to be seen and treated by consultants every day of the week. ■

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Vitamin D deficiency or insufficiency in children over 12 years 1 capsule daily depending on the severity of the disease and the patient's response to treatment. Should only be given under medical supervision.

Fultium-D_3 should not be used by children under 12 years.

The capsules should be swallowed whole (not chewed) with water.

Contraindications: Hypersensitivity to vitamin D or any of the excipients in the product; peanut or soya allergy; hypervitaminosis D; nephroithiasis; diseases or conditions resulting in hypercalcaemia and / or hypercalciuria; severe renal impairment.

Warnings and Precautions: Vitamin D should be used with caution in patients with impairment of renal function or sarcoidosis and the effect on calcium and phosphate levels should be monitored. In patients with severe renal insufficiency, vitamin D in the form of colecalciferol is not metabolised normally and other forms of vitamin D should be used. Close monitoring of calcium levels should be carried out under medical supervision. Caution is required in patients receiving treatment for cardiovascular disease. Consider vitamin D supplementation from other sources. Contains arachis oil (peanut oil).

Interactions: Concomitant treatment with phenytoin, barbiturates and glucocorticoids can decrease the effect of vitamin D.

Interactions have also been seen with digitalis and other glycosides, ion exchange resins, laxatives such as paraffin and cytotoxic agents.

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