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Drug eluting stents for patients with diabetes

The role of coronary revascularisation versus medical treatment needs clarification

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In general, drug eluting stents have improved outcomes after percutaneous coronary intervention (PCI).[1] However, more deaths were reported in patients with diabetes who received drug eluting stents than in those who received bare metal stents.[2] For several years, coronary artery bypass grafting has been the main method of coronary revascularisation in patients with diabetes and multivessel disease because of better survival and lower need for repeat revascularisation than with stenting.[3] Complex coronary anatomy, diffuse and extensive disease, presence of comorbidities, and problematic vascular access as well as accentuated inflammation, and oxidative stress may account for these poorer outcomes in patients with diabetes.

However, a network meta-analysis recently reported that drug eluting stents were safe and prevented target vessel revascularisation in patients with and without diabetes who were given dual antiplatelet treatment for more than six months.[4] In a linked research paper, Bangalore and colleagues explored the relative differences in outcomes for various commercially available drug eluting stents (impregnated with sirolimus, paclitaxel, everolimus, and zotarolimus).[5]

This mixed treatment comparative meta-analysis of 42 trials with 10 714 patients with diabetes found that everolimus eluting stents provided the lowest rate of target vessel revascularisation. Compared with bare metal stents, the number needed to treat to prevent a revascularisation procedure was 13.4. Importantly, drug eluting stents, especially everolimus eluting stents, did not increase stent thromboses, including late events. Indeed, the two year risk of stent thrombosis for everolimus eluting stents was about a third to half of that after implantation of a drug eluting stent in general.[6] These findings are a reasonable guide for clinicians in choosing a stent for their patients with diabetes undergoing PCI. However, the US Food and Drug Administration recently approved the second generation zotarolimus eluting stent as the only limus eluting stent for use in patients with diabetes.

Whether the clinical efficacy of bioresorbable everolimus eluting stents is superior for patients with diabetes remains unclear

The reasons for the better outcome associated with everolimus eluting stents in the current study are not clear. In vitro studies found that everolimus was two to three times less potent than sirolimus.[7] Although sirolimus, everolimus, and zotarolimus have similar efficacy in preventing the proliferation of human coronary smooth muscle,[7 8] the amount of drug delivered on the stent is lower for everolimus and zotarolimus, and drug release kinetics also differ between stents (table). In addition, Bangalore and colleagues selected studies that evaluated devices with durable polymer to carry the drug, but the thickness of the polymer varied between studies and devices (thinner for everolimus eluting stents and zotarolimus eluting stents; table). Some authors have suggested that the polymer induces inflammation and stent thrombosis.[9] Its composition and thickness may have a positive effect on outcomes, as might the thickness of struts on the stents and the nature of the stent's base material. These drug and stent factors may account, at least in part, for the variation in outcomes.

Although the number of coronary stenting procedures fell from 399 558 in 2004 to 322 024 in 2009 in the United States (a 19% decline),[10] the burden of older patients with diabetes is expected to increase dramatically worldwide. Evidence of the efficacy of second and third generation drug eluting stents is beginning to affect the fundamental considerations that underpin the choice between surgical and percutaneous coronary revascularisation for patients with diabetes. The current study reports better outcomes with everolimus eluting stents, but whether the clinical efficacy of bioresorbable everolimus eluting stents is superior for patients with diabetes remains unclear.[11] What the current study did not investigate is the rate of late repeat revascularisation procedures.[12] The FREEDOM (Future REvascularization Evaluation in patients with Diabetes mellitus: Optimal management of Multivessel disease) study, which is currently investigating outcomes after sirolimus or paclitaxel eluting stents and bypass surgery in 1900 patients with diabetes, will provide further evidence.[13]

The cost effectiveness of using drug eluting stents for patients with diabetes also requires further evaluation. A recent cost effectiveness analysis found that, over three years, the cost of preventing one target vessel revascularisation procedure was $6379 (£4036; €5083). This included the cost of the drug eluting stent and the incremental cost of treating a patient who has received such a stent (eg for clopidogrel for at least a year).[14] A major drawback is that PCI in the non-acute setting, even with drug eluting stents, has not been shown to be superior to optimal medical treatment.[15] Optimal medical treatment will probably remain the core treatment for patients with diabetes.

Competing interests: K-HM was previously a member of an ad hoc medical advisory board of Boston Scientific, which provides comments on emerging technology but does not assist in the development of products.

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Characteristics of various drug eluting stents

Stent name	Drug (concentration, µg/cm2)	Polymer	Polymer thickness (µm)	Release kinetics (28 days)	Platform*	Design	Strut thickness (µm)
Cypher	Sirolimus (140)	Polyethelyne co-vinyl acetate and poly-n-butyl methacrylate	12.6	80%	SS 316L	Closed cell	140
Taxus Express	Paclitaxel (100)	Poly(styrene-b-isobutylene-b-styrene)	16.0	‹10%	SS 316L	Open cell	132
Endeavor	Zotarolimus (100)	Phosphorylcholine	5.3	95%†	MP35N CoCr	Hybrid	91
Xience V	Everolimus (100)	Polyvinylidene fluoride co-hexafluoropropylene and poly-n-butyl methacrylate	7.6	80%	L605 CoCr	Hybrid	81

*SS=stainless steel; CoCr=cobalt-chromium; †At 14 days.

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Setting objectives for the NHS Commissioning Board

The draft mandate must be rewritten if it is to be fit for purpose

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One of the principal aims of England's Health and Social Care Act 2012 is to distance politicians from the day to day management of the NHS. This aim is being pursued by the creation of the NHS Commissioning Board, which will take responsibility for allocating resources to clinical commissioning groups and commissioning some services directly. Government critics have described the board as "the greatest quango in the sky" because of its major role in the new system, overseeing how £80bn (€100bn; $126bn) of public money is spent and employing 3500 staff drawn mainly from the Department of Health and the NHS.[1] The board will work under a mandate from the secretary of state for health, setting out his objectives and priorities for the NHS. The government published the draft mandate in July 2012 and is now consulting on it and seeking views on how it can be strengthened.[2]

The government intends that the mandate should establish clear and transparent expectations of the NHS and form the basis on which the commissioning board is held to account. It will be a document that sets ambitions for improving outcomes over a period of years. To ensure that it has impact in the long term, ministers have made it clear that the mandate should rarely be changed between annual reviews and that most objectives should roll forward until they have been achieved.[2] It is, therefore, particularly important that the first mandate is well designed because the framework that it establishes will probably be in place for some time.

The draft mandate focuses initially on outcomes contained in the NHS Outcomes Framework, which identified 60 indicators across five domains.[3] In addition, it proposes several other objectives that encompass putting patients first, the broader role of the NHS, effective commissioning, and financing the NHS. A supporting technical annex describes the data sources that will be used to assess progress in delivering the objectives.

If the mandate is to serve a useful purpose, then the lessons of previous attempts to strengthen the accountability and performance of public services should be heeded.[4] The most important are the need to identify a small number of objectives and priorities, express these clearly and in a way that can be measured, and ensure that the goals are both stretching and realistic within a specified timescale. The objectives and priorities that are chosen must also reflect the main areas of health and care that ministers are trying to improve and that resonate with the views of patients, the public, and staff.

On most of these counts the draft mandate falls far short of what is needed. Its main weaknesses are the large number of objectives it contains—22 in total—and the general and vague language in which many of these objectives are expressed. For example, the stated aim of objective 11 is to "develop a collaborative programme of action . . . to further the ambition that healthcare professionals throughout the NHS should take all appropriate opportunities to support people to improve their health." It will be well nigh impossible to measure the achievement of an objective phrased in such vague terms.

The current draft is entirely focused on listing specific and general objectives with no sense of how the experience of patients will be changed for the better

Some objectives, mainly those that relate to outcomes, are set out in a way that can be measured, but progress will be assessed using one aggregate indicator for each of the five domains. Although this may seem to be sensible and simple, in reality it requires a complex series of calculations that are incomprehensible to most people working in or served by the NHS, as illustrated by the lengthy and detailed technical papers that describe how this will be done.[5] As a consequence, it will be near impossible for the board and NHS commissioners to determine what they can do to support the achievement of these objectives.

Other objectives bear all the hallmarks of priorities identified by policy leads in the Department of Health and other government departments who are anxious to ensure that their areas of responsibility are not left out. For example, objective 16 effectively amounts to a shopping list of high level aspirations in relation to other public services, whose provenance can be clearly traced to various parts of Whitehall. The mandate risks becoming devalued both in concept and in practice before it has got off the ground because when everything is a priority then nothing really is.

Another weakness is the transactional rather than transformative tone of the draft mandate. If the mandate is to live up to the ambitions of its architects, not only must it be capable of holding the commissioning board to account for its performance but it must also inspire NHS leaders and staff to redouble their efforts to bring about improvements in health and care. The current draft fails to do this by being entirely focused on listing specific and general objectives and omitting to convey any sense of how the experience of patients and those caring for them will be changed for the better as a result.

In our view, government ministers and officials should go back to the drawing board and heed the old adage that less is often more. The number of objectives in the mandate should be cut drastically and objectives should be included only if they fulfil the SMART criteria (specific, measurable, achievable, realistic, and time limited) often used in the setting of key performance indicators. More emphasis should be placed on situating the final list of objectives in the context of a clear and compelling vision for the future of health and social care that demonstrates the link between delivery of objectives and the transformational changes in models of care that are urgently needed.[6]

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bmj.com
- Clinical review: Substance misuse: alcohol, tobacco, inhalants, and other drugs (*BMJ* 2005;330:777)
- Editorial: Tackling alcohol misuse in the UK (*BMJ* 2008;336:455)

Teaching postgraduates about managing drug and alcohol misuse

Report from UK medical royal colleges outlines the key competencies

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A working group of the UK medical royal colleges reported recently on the core competencies needed by all postgraduate specialist trainees regarding substance misuse.[1] This follows other recent reports, including those from individual royal colleges, parliament, and other stakeholders, that highlight the need to change the system by which we recognise and manage drug and alcohol misuse. Such changes were implemented in the undergraduate curriculum after the International Centre for Drug Policy produced guidance on teaching about substance misuse in 2007.[2] However, such skills are not yet part of the core competencies of postgraduate medical training in the United Kingdom.

The increasing use of illicit drugs and the hazardous consumption of alcohol provide a growing challenge for the NHS. In 2009-10, more than one million hospital admissions in England were alcohol related,[3] at a cost of almost £3bn (€3.8bn; $4.7bn).[4] It is estimated that in England alone, 25% of the adult population (7.6 million people) drink hazardous amounts of alcohol and almost half of them show signs of alcohol related ill health.[4] In addition, around 9% of adults questioned as part of the British crime survey 2010-11 admitted to illicit drug use at least once in the past year.[5] As numbers of cases increase so too do costs and workloads.

Of specific concern, clinicians often miss opportunities to identify and provide effective interventions for people with harmful drinking and drug use. Only about 6% of people with alcohol dependency in England receive appropriate treatment, perhaps because clinicians fail to ask patients about their drug and alcohol use in routine consultations.[6]

The royal colleges working group's core competencies for all postgraduate trainees have been grouped into the three domains common to most postgraduate curriculums—knowledge, skills, and attitudes and behaviour (summarised in the box).[1]

As with any new intervention in medical training, setting out the core competencies is just the starting point. The way in which the competencies are taken up and integrated into the existing curriculums, teaching programmes, and assessment programmes of the specialty training schools will be key to the success of the endeavour. The report's aim of introducing these competencies across all specialty schools highlights not only the importance of the problem of substance misuse, but also that it is a problem within all healthcare disciplines, from child health and paediatrics through to the care of older adults. The report also serves as a reminder to all royal colleges that attitudes to dealing with drug and alcohol misuse need to change throughout the medical profession. Improving the detection and treatment of this increasingly common condition is the responsibility of all doctors, and any potential conflicts between personal attitudes and professional duties must be tackled. These competencies would not be complete if they did not cover the prevalence of alcohol and drug misuse among doctors, sources of help for doctors with alcohol and drug problems, and the obligation to act if a colleague's drinking or drug use threatens patient care.

Only about 6% of people with alcohol dependency in England receive appropriate treatment, perhaps because clinicians fail to ask patients about their drug and alcohol use in routine consultations

The report is rightly ambitious in deciding that competencies should be implemented across all specialties, each with their very different curriculums, training requirements, assessment tools, and teaching arrangements. Although all the royal colleges have adopted modern educational approaches that include supervised training and e-portfolio resources, methods of teaching and the emphasis given to face to face teaching vary. The report does not mention how the core competencies will be delivered or assessed. A multifaceted approach will be needed—probably a combination of face to face teaching, simulated patients, and instruction on conducting motivational interviewing and "brief intervention" techniques.[7 8] In addition, it will be important for doctors to know that a multidisciplinary approach (psychology, clinical pharmacology, and specialist nurse input) should be used. A robust system of assessment that will drive the desired change in behaviour (implementation of the competencies and change in practice) rather than just confirm that the information has been delivered will be necessary. The report does not mention how such extra multifaceted teaching and assessment should be financed. Inconsistency could undermine the quality of the training for these complex skills, however.

The working group's core competencies for all postgraduate trainees

Knowledge
- Effects, common presentations, and potential for harm of alcohol and other drugs
- Addictive potential of alcohol and other drugs, including prescribed and over the counter drugs
- Range of interventions, treatments, and prognoses for use of alcohol and other drugs
- Effects of alcohol and other drugs on the unborn child, children, and families
- Recommended limits on alcohol intake

Skills
- Become competent in assessing the use of alcohol and other drugs, including history taking and the use of validated tools
- Recognise the wide range of acute and long term presentations associated with the use of alcohol and other drugs (such as trauma, depression, and hypertension)
- Provide brief advice on the use of alcohol and other drugs
- Provide management or referral when appropriate

Attitudes and behaviour
- Work in a supportive, empathic, and non-judgmental manner without collusion
- Be confident and comfortable discussing the use of alcohol and drugs with patients
- Act appropriately on any worries about own or colleagues' use of alcohol or drugs

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A national programme of expanded surveillance is urgently needed so that the burden of these diseases in the US can be accurately determined

Fighting neglected tropical diseases in the southern United States

Poverty and lack of awareness need to be tackled

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The neglected tropical diseases are a group of chronic parasitic and related infections such as hookworm, schistosomiasis, lymphatic filariasis, Chagas disease, and leishmaniasis that often affect the "bottom billion" in Africa, Asia, and Latin America.[1] Extreme poverty, defined by the World Bank as average daily consumption of $1.25 (£0.8; €1.0) or less, is the main social factor associated with a high prevalence of these diseases.[1] The World Health Organization, the World Bank, and professionals have advocated strongly for global programmes to deliver packages of essential drugs to treat the tropical diseases with the highest prevalence while simultaneously developing new or improved drugs and vaccines.[2] Diseases such as Chagas disease, cysticercosis, leishmaniasis, and dengue are listed in the 17 tropical diseases being targeted by WHO for control or elimination in low and middle income countries.[3 4] That these diseases affect literally millions of Americans living in poverty,[8] with prevalence rates of selected tropical diseases in some areas of the US comparable to rates in low and middle income countries, is less well known.[9]

Roughly 15% of Americans (46 million people) currently live below the US poverty line.[10] Most are concentrated in the American South, especially the Gulf coast, Mississippi delta, and south Texas.[8] About five years ago we began to estimate the burden of neglected tropical diseases among those classified as poor in the American South and elsewhere in the US (then roughly 12% of Americans—36.5 million people).[8] Most of these diseases are not reportable illnesses in the US and few surveillance data were available. However, an initial analysis suggested a substantial but largely hidden burden of disease in the US.[8]

Recently, poor Americans have been getting poorer.[10] A recent study from the National Poverty Center estimated that 1.46 million US families, with 2.8 million children, each live on less than $2 a day.[11] An analysis of US census data from 2010 indicates that the income of 20 million Americans is below one half of the US poverty level.[10]

PETER TURNLEY/CORBIS

Diseases of extreme poverty in the US's back yard

Texas has the second largest population of all the US states and possibly the largest number of Americans living below the poverty line, with one in five Texans living in poverty.[12] Tropical diseases such as Chagas disease and cysticercosis are widespread in Texas.[12] Poor housing conditions and homelessness promote exposure to selected vector borne tropical diseases, such as dengue and murine typhus.[12] On the basis of previous experience, the current outbreak of West Nile virus infection in Texas will probably affect homeless people and those living in poverty disproportionately.[13]

Exactly how and why poverty is inextricably linked to neglected tropical diseases is still unclear. In low and middle income countries, these diseases cause or perpetuate poverty because of their negative impact on child development, productivity of workers, and maternal health.[1] In Texas and the greater American South, a combination of socioeconomic factors linked to poverty probably play a part.[14] As suggested in a recent *New York Times* opinion piece, these factors include dilapidated housing without adequate insect screens or air conditioning, poor sanitation and plumbing, and absent or inconsistent rubbish collection and street drainage.[14] Such elements, together with a warm and humid climate, create ideal conditions for the spread of these diseases. Although immigration undoubtedly accounts for some imported cases of tropical disease in North America, conditions of poverty and climate also promote their transmission within US borders.[8 12 13] Mother to child transmission of neglected diseases such as congenital cytomegalovirus, syphilis, and toxoplasmosis also occurs disproportionately among the poor and disenfranchised in the US,[8] and recently the first well documented case of congenital Chagas disease was reported.[15]

In 2011, a new National School of Tropical Medicine (NSTM) was established at the Texas Medical Center in Houston. The NSTM was partly inspired by the Liverpool School of Tropical Medicine and the London School of Hygiene and Tropical Medicine, with their ongoing commitment to studying translational medicine relevant to the world's poor. But Houston has tropical diseases in its backyard. Accordingly, a new tropical medicine clinic has been created at the NSTM.

What needs to be done to deal with the problem of tropical diseases among America's poor? Firstly, a programme of expanded surveillance is urgently needed so that the burden of these diseases in the US can be accurately determined.[8 14] More work is needed to help understand what contributes to disease transmission and how it links with poverty. This will require collaborative working with federal, state, and local public health agencies, as well as regional universities. In addition, training is needed. The NSTM now offers a Diploma in Tropical Medicine. Finally, new drugs, diagnostics, and vaccines must be developed.[8 14]

Regional efforts alone will not be enough. National awareness must increase if tropical diseases, which represent one of the most glaring examples of health disparity in the US today, are to be tackled properly. A bill known as the Neglected Infections of Impoverished Americans Act (HR 528) was recently introduced to Congress to raise awareness of this problem in the US.

Competing interests: PJH is the president and director of a product development partnership (PDP) that develops and tests vaccines for neglected tropical diseases; these vaccines are supported by the Bill and Melinda Gates Foundation, Southwest Electric Energy Medical Research Institute, Carlos Slim Institute of Health, Texas Children's Hospital, US National Institutes of Health, Dutch Ministry of Foreign Affairs, Brazilian Ministry of Health, Blavatnik Charitable Foundation, Gary Michelson, Mr and Mrs Mort Hyman, and Howard Harpster; the Sabin Vaccine Institute headquartered in Washington, DC also accepts funds for its vaccine advocacy programs from multinational drug companies, but not for its PDP.
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