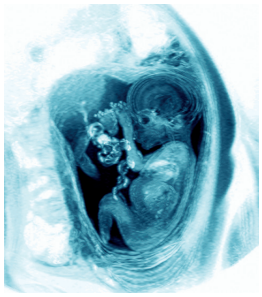
Improving outcomes in pregnancy

What are the implications of first trimester fetal growth and racial origin?



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RESEARCH pp 833, 836

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Two of the greatest challenges facing reproductive science in many developed countries are dealt with by two studies in this week's *BMJ*.[1 2] The first challenge is the need to find innovative approaches to prevent perinatal death, low birth weight, and preterm birth. The second is the challenge to our healthcare systems resulting from the attendance of large numbers of people of differing racial origins. Together, the findings from these two studies provide vital clues as to how healthcare outcomes may be improved by strategies aimed at the early stages of human life.

In the developed world, the outcome of pregnancy for both mother and child improved dramatically during the 20th century. Reproduction has never been as safe as it is today. Many of the advances that have contributed to improved outcomes have come from the application of medical discoveries in late pregnancy and during childbirth. Yet some of the major complications of pregnancy are proving remarkably difficult to prevent. Several of the major causes of perinatal mortality are not declining, including term deaths from hypoxia and infection,[3] and rates of preterm birth in most countries are either static or rising.[4] Furthermore, in multiracial communities, different racial groups often show disparities in outcomes, despite the apparent availability of high quality healthcare services for all.[5] It may be that current systems of care will be unable to improve poor outcomes until innovative approaches to prediction and prevention are discovered.

In this week's *BMJ*, Bukowski and colleagues[1] show that reduced fetal growth in the first 12 weeks of pregnancy contributes to low birth weight and early birth. Their study was based on women who had known dates of conception through assisted reproductive technology, and it paves the way for improved prediction of the outcome of pregnancy by incorporating data from the first trimester.

Recently, it has been reported that low levels of placental proteins, such as pregnancy associated plasma protein A, around the time of first trimester screening may predict subsequent fetal growth restriction.[6] Evaluation of early fetal growth patterns may add to this predictive ability. Bukowski and colleagues' findings also add a new dimension to our understanding of the early origins of adult health and disease. Low birth weight is associated with adult illnesses, including heart disease and diabetes, and much of the early evidence for this association came from midwifery records in the United Kingdom.[7] Emphasis on birth weight resulted from its ready availability in medical records, but more recent research has attempted to unravel the patterns of fetal growth rather than rely on the summary measure of birth weight.[8] The evidence that growth in the first trimester may predict subsequent pregnancy outcomes suggests that measurable events in the first trimester may play a greater role in determining our destiny than previously thought.

Also in this week's *BMJ*, Balchin and colleagues[2] show that racial origin influences the risk of perinatal mortality at different gestational ages. The study follows a previous report by this group that median gestational age at delivery is lower in South Asian and black women than in white women.[9] After 40 weeks, antepartum stillbirth rates increased at earlier gestational ages in South Asian women.[2] This finding suggests that in this racial group it might be prudent to start fetal surveillance and planned delivery at an earlier gestational age than is the current standard of practice, which was developed using data from pregnancies of white women.

The findings may also be another milestone in our journey from health care that assumes all patients are fundamentally the same to an era where a variety of individual attributes may be harnessed to maximise the effectiveness of evidence based care.[10] Furthermore, the evidence that racial origin may be important in the management of pregnancy emphasises that research should be conducted within specific communities so that tailored management protocols can be devised.

People of South Asian origin are one of the groups most at risk in the current epidemic of obesity, diabetes, and metabolic syndrome.[11] Much of this risk arises from rapid transition from traditional to Westernised lifestyles, with a mismatch between the metabolic world for which the offspring is intended and the life that actually ensues.[12] At the heart of this sequence is low birth weight, followed by accelerated postnatal growth. Research is now needed to investigate how early in gestation such growth restriction occurs, and if biometry in the first trimester can be of use in predicting predisposition to chronic disease in adulthood.

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NHS walk-in centres

Do not have a meaningful impact on the demand for general practice

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RESEARCH p 838

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NHS walk-in centres were introduced in England in 2000. They are primarily led by nurses, have long opening hours, and provide advice and treatment for minor illnesses and injuries. NHS walk-in centres are intended to improve access to primary care and to reduce pressure on other providers of health care, such as general practices.[1] A paper in this week's *BMJ* by Maheswaran and colleagues looks at whether they have achieved this second aim.[2]

Maheswaran and colleagues conducted an ecological study to determine whether proximity to a walk-in centre was associated with general practices meeting the NHS access target to offer an appointment within 48 hours. Using a series of sophisticated models, they found no evidence that walk-in centres led to shorter waits in general practice.[2] This is consistent with several earlier studies, which found no impact of walk-in centres on consultation rates at other healthcare providers.[3-5]

The underlying hypothesis is that if people go to walk-in centres then demand on general practices will drop and the wait for an appointment will be reduced. But each step in this apparently logical argument is questionable. Firstly, if walk-in centres improve the accessibility of care this may lead to extra consultations as previously unmet demand is catered for[6]; also, some people go to walk-in centres and general practice with the same problem,[7,8] so demand on practices may not be reduced. Secondly, any change in demand on general practice may not necessarily lead to changes in waiting times. Practices all have ways of accommodating changes in demand, such as offering extra appointments at the end of surgery or allowing patients to wait in an "open" surgery. Thirdly, even if walk-in centres did reduce demand in general practice, this would have a negligible effect because of the volume of people attending each type of site.

The average walk-in centre conducts about 35 000 consultations each year,[9] equivalent to the productivity of about five general practitioners. An earlier evaluation found that an average of 58 general practitioners work within 3 km of each walk-in centre,[10] which greatly dilutes any potential impact of a walk-in centre on individual practices.

The study assesses the proportion of practices that met the NHS 48 hour access target, using data from the primary care access survey. However, the validity of this measure is debatable. This survey involves primary care trusts making telephone calls to practices to inquire about the availability of appointments, and until 2006 practices were informed in advance when the inquiry would be made. Practices and primary care trusts have strong financial incentives to report that targets are met, which might explain the discrepancy between the positive findings of the survey[9] and patients' reported difficulties in making an appointment.[11] Although an independent validation study supported the reliability of the survey, this was also based on non-anonymised calls to practices.[12] My own recent research (under review), based on anonymised calls by simulated patients seeking to make an appointment, suggests that the primary care access survey substantially overestimates achievement of the access target.

What are the implications of Maheswaran and colleagues' paper for primary health care? It shows that walk-in centres are unlikely to have a meaningful impact on the demand for general practice unless they expand massively in number. This would be hard to justify given their higher cost per consultation and more limited range of services than general practice,[10] and uncertainty about whether greater provision would lead to inflation of demand and duplication of services rather than substitution.

Can walk-in centres be justified on the grounds of their other aim, to increase the accessibility of care? They offer a popular and convenient route to care for patients who value not having to make an appointment to see a nurse.[8] An alternative strategy would be to encourage more general practices to offer similar services. The widespread provision of practices, and economies generated by combining rather than duplicating facilities, mean this is likely to be a much more cost effective way to increase the accessibility of care.

Several other countries have walk-in centres, including the United States, Canada, Australia, and South Africa, but we need to be cautious in applying the findings of this study to other settings. The term walk-in centre is used to describe many types of facility, which

have different roles in different countries. But one interpretation of this study is internationally relevant. Health care is a complex system in which demand and supply are related and met through an intricate web of provider organisations. Changes in the provision of care within one element of the system, particularly introducing an entirely new type of facility such as a walk-in centre, may not have the intended effects. It is important that we fully understand the contribution of different healthcare providers and how and why they are used by different groups of patients.

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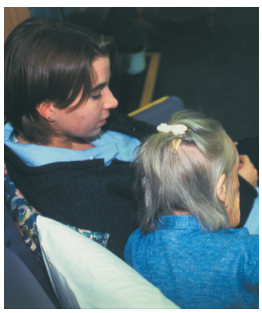
Palliative care in the community

UK programme shows promise but services also need adequate investment



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OBSERVATIONS p 830

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Primary care has a vital role in delivering palliative care.[1 2] In most developed countries more people die in hospital than at home,[3] although substantially more people would prefer to die at home.[4] Primary care professionals play a central role in optimising available care, but they often lack the processes and resources to do this effectively.[1 5]

The Gold Standards Framework for community palliative care[6] is a primary care led programme in the United Kingdom that is attracting international interest.[2] The framework enables general practitioners and community nurses to optimise practice by providing guidance through workshops and locally based facilitation on how to implement processes needed for good primary palliative care. It is supported by a plethora of practical tools, guidance documents, and examples of good practice.[7] It integrates many established aspects of primary palliative care: identifying patients systematically; naming a lead general practitioner and community nurse for each patient; coordinating multidisciplinary working through regular meetings; and planning of care with patients. Good communication, with out of hours and specialist care providers is also stressed, as is the importance of support for family carers.[6]

The framework is applicable to end of life care in general, not just cancer care, and its key elements could also be applied in any culture or healthcare setting through developing locally relevant tools and processes, so enabling the delivery of more effective and equitable end of life care in the community.

The programme has evolved rapidly and has been incorporated into UK health policy. After it was piloted in 12 practices in Yorkshire in 2001, its national implementation was sponsored by the charity Macmillan Cancer Support. More recently it has been sponsored by the National Health Service End of Life Care Programme in England and the National Lottery in Scotland. As a result, the framework has now been adopted by around 3000 practices in England, which cover a third of the population, and two thirds of practices in Scotland.

Despite limited evidence of its cost effectiveness and clinical effectiveness, it was recognised as an effective programme for palliative care by the National Institute for Health and Clinical Excellence (NICE) in 2004,[8] endorsed by the Royal College of General Practitioners in 2005, and identified in the 2006 government white paper on community services as a central aspect of future health policy in the NHS in England. The Gold Standards Framework is now firmly embedded within primary care and has raised the profile of palliative care both professionally and politically.[7]

The national evaluation of the framework has focused on 1305 practices, 73% of which completed an audit questionnaire at baseline and after 12 months in the programme. Initial results suggest that the programme led to change—most participating practices reported that they had set up registers of patients undergoing palliative care, organised regular multidisciplinary team meetings, and were more confident that they were delivering good palliative care.[9]

A qualitative study of practices that have adopted the programme found that, in general, palliative care patients were being systematically identified and that communications had improved. As a result, planning of care had improved and practitioners had more confidence in symptom control.[10] However, variations in how the programme had been implemented; differences in levels of commitment among professionals within individual practices; and the increased administrative

burden, particularly on the framework coordinator within the practice, were highlighted as drawbacks.[10] The extent to which these problems threaten the effectiveness of the programme in future practices remains to be seen.

Despite a paucity of evidence linking structured approaches in primary palliative care with outcomes, patients and carers undoubtedly value a holistic approach with care planning, good communication, and continuity of care from primary care teams.[11 12] While some practice based audits suggest that adopting the framework may enable more patients to die at home,[7] it is still uncertain how widely this aim can be realised. Improved primary care practice needs to be supported by realistic funding to make community nursing care and "night sitting" services available, and to provide access to specialist palliative care support, 24 hours a day seven days a week.[8]

As populations in developed countries become increasingly elderly, care of the dying becomes ever more important as a public health issue. Primary care can fulfil a central role in delivering effective palliative care, and the Gold Standards Framework is a model that can be built upon by applying its fundamental principles within the context of the local health service.[2] However, it must be properly resourced, especially when competition for healthcare funding is so intense. Without this, the mismatch between preference for a home death and the prospect of this occurring will persist.

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Pathological gambling in Parkinson's disease

Reducing or stopping dopamine agonists may help

FEATURES p 828

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Parkinson's disease is common. It is estimated to affect around one in 200 people in the developed world (between six and 11 people per general practice in the United Kingdom).[1] For many patients, care is shared between general practitioners, geriatricians, general physicians, and neurologists, often alongside specialist nurses. Motor symptoms and signs of Parkinson's disease are well recognised, yet the behavioural problems are less well known, particularly the recently described problems of pathological gambling and other addictive behaviours.[2-7] Pathological gambling is an impulse control disorder characterised by excessive gambling.[8] The prevalence of pathological gambling in Parkinson's disease is about 3.4%, rising to 7.2% in patients taking dopamine agonists.[6] In contrast, the lifetime prevalence of pathological gambling in the general population in the UK is 1%.[9] It can be associated with the presence of other compulsive disorders such as the compulsive use of dopaminergic drugs,[4] compulsive shopping, and hypersexuality.[6] People who develop Parkinson's disease at a younger age are reported to have a higher risk of pathological gambling.[5]

Although the pathophysiology of pathological gambling in Parkinson's disease is not well understood, it may relate to aberrant dopaminergic stimulation.[2] It is not clear which dopamine agonist precipitates the disorder, as all such agonists have been implicated.[2 3 5] Patients taking both a dopamine agonist and levodopa are at increased risk,[2] although those who take either a single dopamine agonist or levodopa can be affected.[7]

About 5.8 million people in the UK—one in 10 internet users—log on to internet gambling sites each month.[10] This is expected to rise as more households connect to the internet[11] and as the use of broadband increases. Many internet gambling companies actively lure gamblers with pop-ups to place free bets. This marketing technique is pervasive and can make it hard for vulnerable people to wean themselves off gambling.[3]

We have noted that our patients are often secretive about their gambling and may end up thousands of pounds in debt before the problem is realised. Patients and families often do not suspect drug treatment as the cause of pathological gambling and therefore do not mention it to the doctor. Better awareness of the problem among patients and carers, coupled with routine direct questioning by clinical staff about changes in behaviour and development of new compulsions and gambling, will help to identify the problem early.

Once recognised, several strategies may help. Reducing or stopping dopamine agonists may be considered, as anecdotal evidence suggests this helps improve or stop the pathological gambling behaviour.[2 3]

If this results in deterioration of the motor state, then combinations of other drugs for treating Parkinson's disease may be tried, including levodopa, apomorphine, catechol-*O*-methyltransferase inhibitors (such as entacapone), and monoamine-oxidase-B inhibitors (such as selegiline). Cognitive behaviour therapy and serotonin selective reuptake inhibitors have been tried with variable success.[12] Nalmefene (Revex), an opioid antagonist, was recently reported in a randomised controlled trial to be effective in pathological gambling.[13] However, the lack of good quality clinical trials in pathological gambling that assess the long term impact of interventions means that patients need to be closely monitored for signs of relapse, by sensitive but direct questioning to patients and their families. Advice given by clinicians to the patient and family on practical ways to avoid the temptation to gamble (such as installing firewalls against internet pop-ups for internet gamblers,[3] or tearing out the newspaper racing pages), together with support from family, friends, and carers to control finances may help resolve the problem.

Details of the UK's proposed regulations on the internet gambling industry are due to be announced shortly.[11] The current debate on regulating gambling is relevant to this group of patients. This provides an ideal opportunity to deal with the problem through appropriate legislation to protect a small, though highly vulnerable, group in our society.

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Regulation of opioid prescribing

Over-regulation compromises doctors' ability to treat pain

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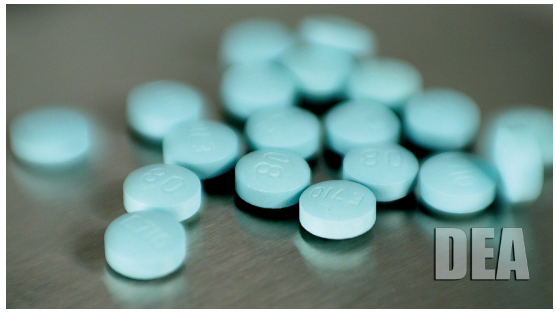
Long before the discovery of endogenous opioid systems, opium was used to produce insensibility and relieve pain. Societies began regulating opiates when the availability and use of opiate drugs reached a level that made opiate addiction a problem to society. In the United Kingdom and the United States this was at the beginning of the 20th century, with the Drug Enforcement Act in the UK (1920) and the Harrison Act in the US (1918). Before regulations, opiates were widely available in chemist shops, doctors' surgeries, and opium dens, and the choice of use was entirely up to the individual, with the risk of addiction being understood. None the less, a stigma was attached to the use of opiates, even therapeutically, but nothing like that seen after regulations made the use of opiates, other than by prescription, a criminal offence. Once these regulations were introduced, a hugely profitable illicit trade in opiates began. This, along with the increasing problems in society attributed to abuse of opiates and other drugs, inevitably compounded the stigma attached to these drugs and affected the use of opiates for relieving pain.

Pain advocacy—lobbying for (opiate) treatment of pain—is a powerful movement in the US, more so than in the UK. This is probably because early US regulations made it illegal for doctors to prescribe opiates to treat opiate addiction (addendum to the Harrison Law, 1919), whereas in the UK doctors could treat addicts with opiates in their surgeries until 1965 (Brain Committee formed in 1965, Misuse of Drugs Act 1971). Punishment for inappropriate opiate prescribing in the US could (and still does) include loss of medical licence, criminal prosecution, and imprisonment. Therefore, the prescription of opiates to relieve pain effectively ceased when these regulations were introduced.

Advocacy was needed in the US to restore the use of



DRUG ENFORCEMENT AGENCY

these invaluable drugs for the treatment of pain. Even though UK and European governing bodies have gradually adopted American style regulations (European and US laws allow only limited prescribing of opiates for addiction, with special certification),[1] pain advocacy remains a more powerful force in the US, and one that is needed to counteract American "opiophobia". Pain advocates have consistently lobbied the US regulatory authority, the Drug Enforcement Agency (DEA), in an effort to protect prescription of opiates for pain.

The level of the DEA's cooperation with pain advocates has varied over time, partly with the political winds. In 2001, the DEA signed a consensus statement, published in 2004, that outlined legitimate prescribing practices—so that practitioners might feel protected.[2 3] But then inexplicably, and without agreement from the healthcare agencies involved in producing the original consensus statement, the DEA withdrew its support, saying that the original document contained "misstatements."[4]

In 2006, the DEA was persuaded it should at least retain the provision from the 2004 consensus statement that allows the issuing of multiple prescriptions to be filled sequentially over 90 days. This is especially important for patients in rural communities, who find it difficult to reach distant clinics to pick up prescriptions. Physician and pharmacy groups argued that providing multiple prescriptions with a "do not fill until" instruction, which had been a widespread though not officially sanctioned practice, increases safety as the alternative is to prescribe greater amounts. The DEA published notice of this proposed change in September 2006, and invited comment from the public.[5] Whether or not the proposed change in DEA regulations will receive final approval remains to be seen.

We have seen a change in opiate prescribing over the past few decades. In the US, many patients with acute pain and pain during terminal illness who would have been denied opiate treatment a few decades ago are now likely to receive appropriate treatment. Others, though, still fall victim to prejudices against opiates. An emerging problem, however, is that the success of pain advocacy in restoring opiate treatment of acute and end of life pain has been used to advocate extension of opiate treatment to patients with chronic and non-terminal causes of pain. Here the benefits for patients are less clear.

Although opiates have reduced pain and improved quality of life for some patients with chronic non-terminal pain,[6] the long term use of these drugs has many problems. For example, a recently published epidemiological study from Denmark, where opiates have been liberally prescribed for chronic pain, found that pain, quality of life, and function were worse in patients with chronic pain who were treated with opiates than in a matched group not receiving opiates.[7 8] Treatment goals were not met—at least not in this population. Such large scale epidemiological studies are not feasible in the US, but trends here that affect the decisions of regulators include the documented increases in misuse of prescription drugs[9]; high profile stories about the misuse of prescription drugs, such as the proliferation on the streets of OxyContin ("hillbilly heroin")[10]; and the addiction of celebrities to pain medication.[11] At the same time, many US doctors remain fearful of prescribing when they learn of colleagues imprisoned for prescribing apparently in good faith. In fact, the authorities tend to target only those doctors who flagrantly flout the law, but the fear persists none the less.[12]

Friction between regulators and medical providers is perhaps inevitable, as they both have noble yet conflicting goals—the one to control diversion, the other to preserve treatment for pain. As drug misuse becomes a greater problem, legislators react by tightening regulations.[1 4 9] The American experience teaches that over aggressive regulations that ignore legitimate needs for opiates compromise doctors' ability to treat pain. As the pendulum has swung here between medical underuse and overuse, patients have been harmed. Now that it is becoming clear that the outcome of chronic opioid treatment is often poor, studies are urgently needed to investigate who benefits and under what conditions. The bigger question may be whether regulations have succeeded at all in controlling drug misuse, but the more immediate question for doctors in the US and elsewhere is how they should control their own prescribing so that interference by regulators does not discourage appropriate medical use of opiates.

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