Decision aids for women with a previous caesarean section

Focusing on women's preferences improves decision making

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Rates of caesarean section are a cause of concern worldwide, although the problems vary according to the setting. In many poor countries, mostly in Africa, where average rates are 2%, caesarean section is underused because of lack of facilities and trained personnel.[1] In other developing countries, such as ones in Latin America and eastern Asia, incidence is 30% of all births or higher, even though large sections of the population lack access to basic obstetric care, while in developed countries it has steadily risen to about 20–25%.[1] Despite such big differences between countries, the modifiable causes of rising caesarean section rates and what to do about them are unclear.

In this week's *BMJ*, a randomised controlled trial by Montgomery and colleagues looks at the effect of two computer based decision aids compared with usual care in pregnant women who have had a previous caesarean section.[2] One aid provided structured information about possible outcomes and their probabilities associated with different modes of delivery and left women's preferences implicit; the other was a decision analysis model that required women to define their preferences, while information about probabilities was concealed.

Importantly, one of the outcomes measured in the trial was the actual birth method, which usefully separates how choices are experienced from the option chosen. The trial found that both aids significantly improved the subjective experience of women about their choices compared with usual care. However, rates of caesarean delivery were similar in the information group, and lower in the decision analysis group compared with usual care.

Unlinking the experience of decision making from its outcome brings a refreshing perspective to the problem of overuse of caesarean section. In light of these authors' findings, it is tempting to conclude that the rise in caesarean rates is due to delivery being seen as purely a medical problem, and the solution being guidelines and recommendations. In 1985, representatives of a study group convened by the World Health Organization wrote, "there is no justification for any region to have caesarean section rates higher than 10–15%."[3] At the time, such levels were considered high but acceptable in developed countries. However, now that caesarean rates in many countries exceed 20%, the recommendation has been dramatically overtaken by events. Notably, rates continue to rise despite evidence showing that caesarean delivery may increase the risk of maternal death.[1 4 5]

Surprisingly little research exists on determinants of caesarean section, at either the aggregate or the individual level.[6 7] The few randomised trials that have been published found no effect of decision aids on caesarean section rates.[8 9] This is despite evidence in other areas of medical care showing that decision aids such as pamphlets and videos can improve people's knowledge of the options, create realistic expectations of their benefits and harms, improve decision making, and increase participation in the process.[10] Against this background, Montgomery and colleagues may have opened up a promising new avenue for research.

As the study was underpowered to measure an effect on birth method reliably, this finding requires confirmation. That information alone had no impact on rates of caesarean birth is consistent with the results of previous trials.[8 9] That decision analysis did have an effect may have two important corollaries.

Firstly, in this study women seem to have been part of the decision making process regarding mode of delivery. Previous trials of decision aids may not have shown a correlation between women's preferences for birth method and the actual birth method because women lacked this decision making power.[8]

Secondly, the result seems to confirm the psychological principle that people do not reliably make decisions involving choice under uncertainty, in the sense that, depending on how the uncertain options are presented, their choices systematically contradict their aims.[11] Reasons for this include widespread avoidance of negative outcomes (loss aversion) and difficulties in reasoning about probabilities.

Although this principle is less well recognised in medical decision making, it poses profound challenges for conventional notions of informed choice in medical care. Although a definitive answer must await further research, the present study suggests that women with a previous caesarean section make better choices about mode of delivery when the purely cognitive demands of reasoning about the probabilities of uncertain birth outcomes are separated from their preferences about the outcomes. Interestingly, the study also suggests that this improvement in decision making is possible even when women's subjective experience of the decision making process is less positive. If this hypothesis can be confirmed, it could help bridge the gap between mere knowledge about the outcomes of decisions and effective decision making.

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Community based health insurance in developing countries

Removing financial barriers is only the first step towards better access to care

P VIROT/WHO

RESEARCH, p 1309

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In this week's *BMJ*, a cluster randomised controlled trial by Ranson and colleagues describes a community based health insurance scheme run by the Self Employed Women's Association (SEWA) in Gujarat, India.[1] Community based health insurance is a valuable way to finance the delivery of health services in developing countries. By combining the risk of falling sick with resources, such insurance facilitates access to care and offers financial protection against the cost of illness. In doing so, community based health insurance aims to overcome inequities in access and socioeconomic status by reducing existing gaps between the poor and the less poor.

Research from Asia and sub-Saharan Africa shows that community based health insurance has been less effective in securing equity than expected. Poor people are less likely to enrol in such schemes,[2-4] and limited evidence shows that once enrolled their use of the services is not great enough to compensate for pre-existing inequities in access.[5-7] Therefore, the major challenge for community based health insurance is how to secure greater equity across socioeconomic groups, in terms of both enrolment and access to services.

The scheme described by Ranson and colleagues aimed to make access to health services and protection from the cost of illness more equitable among its members.[1] SEWA focused on interventions after enrolment because many poor people have already enrolled, but it is unclear whether they use the services as much as those who are less poor. The trial compared four interventions in 16 rural sub-districts: after sales service with supportive supervision, prospective reimbursement, both packages, and neither. The trial found that none of the interventions secured greater equity, measured by the ability of poorer members to enjoy a greater share of the scheme benefits.

We believe that the disappointing results of the current trial should not discourage policymakers from implementing similar schemes or be used as a reason to abandon efforts to test the impact of similar interventions aimed at increasing equity in developing countries. Our experience in sub-Saharan Africa mirrors that reported by Ranson and colleagues, and it suggests that removing financial barriers to access through enrolment in such schemes is only the first step towards better access to care and greater financial protection against the cost of illness for poor people.

Distance to services as well as social and educational deprivations have a central role in determining poor people's access to services,[8-10] including health insurance.[2 4 11 12] Future research could test whether greater equity can be achieved by targeting interventions exclusively to people most in need—the very poor. Given the limited resources usually available to community based health insurance schemes, targeted interventions may prove to be more cost effective than interventions aimed at all members, as attempted by SEWA.

The structure of the scheme itself could be another reason why the interventions implemented by SEWA did not increase equity. The SEWA scheme uses an ex-post reimbursement policy—people have to pay for care in advance and claim reimbursement afterwards. Even the increased support provided by the interventions described in the study may have been insufficient for poor people to learn "how to work the system." We realise that the structure of some schemes may require them to use ex-post reimbursement, but our experience in sub-Saharan Africa suggests that systems that do not require members to advance cash in times of illness may increase equity in access (data currently under analysis).

The success of community based health insurance in developing countries depends on discovering which interventions increase equity between very poor people and those who are less poor. In doing so, we must remember that although schemes can learn from one another's experience, each scheme is set within its own context and has its own set of challenges. Thus, while SEWA may be trying to improve equity in use of health services, many schemes still struggle to secure

equity in enrolment in the first place.[3 4 12] In any case, we should be encouraged to follow the example set by SEWA, which rather than adopting standardised "pre-packaged" solutions, first identified barriers to access[5] and then developed and tested interventions aimed at overcoming these specific barriers.

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β blockers and statins in non-cardiac surgery

Routine use to prevent perioperative cardiac complications is not evidence based

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Globally, about 100 million adults have non-cardiac surgery each year. In the United States, perioperative cardiac complications occur in 0.5-1%, so around one million patients risk cardiac complications and about a quarter will die each year.[1 2] Outcomes in Europe are similar to the US.[3] Anaesthetists have progressively changed the emphasis on **reducing perioperative** cardiovascular risk from assessing preoperative coronary artery anatomy to understanding the pathophysiology of perioperative myocardial ischaemia. Despite efforts to identify risk factors for perioperative myocardial ischaemia and potential therapeutic options in the perioperative period, the benefit of giving β blockers and statins at this time remains unclear.[2 4 5]

Since the early studies that incorrectly attributed survival benefits to perioperative treatment with β blockers,[6] rigorous meta-analysis confirmed the need for a large multicentre randomised placebo controlled trial.[5] Since then, 1520 patients have been randomised to three studies that have shown no benefit from perioperative metoprolol.[7-9]

The diabetic postoperative mortality and morbidity study from Denmark recruited 921 patients and found that metoprolol had no benefit in patients with diabetes who were β blocker naive with respect to death, myocardial infarction, unstable angina, or congestive heart failure 30 days after surgery.[7]

The perioperative β blockade study in the United Kingdom randomised 103 patients undergoing infrarenal vascular surgery and found that perioperative metoprolol did not reduce cardiovascular events at 30 days. Events included all cause mortality, myocardial infarction, unstable angina, ventricular tachycardia, and stroke.[9]

The metoprolol after vascular surgery study randomised 496 vascular surgery patients and also reported no benefit from perioperative metoprolol in reducing postoperative cardiac events at 30 days and six months.[8] These three studies of two groups of patients at moderately high risk of perioperative cardiac complications or death (patients with diabetes and patients with vascular disease), undergoing moderate and high risk surgery, provide no strong evidence that treatment with β blockers in the perioperative period confers any benefit. However, all three studies document a strong association of β blockade with an increased risk of bradycardia and hypotension that will require treatment.[7-9] The results of these studies have been summarised and coupled with a call to examine the process that led to the widespread adoption of perioperative β blockade by many practitioners.[10]

A study of 10 000 patients (POISE) is under way and plans to report early if a significant beneficial effect of β blockade is uncovered.[11] More than 8000 patients have been recruited to the trial, which started in 2002 and is scheduled to finish in July 2008, but which may not achieve the target recruitment of 10 000 patients. However, no results have been reported, suggesting that any beneficial effect of β blockers is likely to be moderate at best.[11]

Like β blockers, statins have also been advocated to reduce the risk of perioperative myocardial ischaemia. Despite studies involving nearly 800 000 patients the number of people enrolled in randomised studies is small. The non-randomised studies suggest that statins confer benefit, but the evidence remains weak.[5] The favourable results seen in cohort studies may be due to the beneficial effect of other agents taken concomitantly, rather than the effect of statins alone.

Randomised studies may prove valuable, but completing a multicentre randomised controlled trial like POISE will be challenging. To show that statins

reduce the risk of myocardial events by 25%—which is a relatively low target, as the current literature suggests perioperative rates of death or acute coronary syndromes are 30-42% lower in statin users than in patients who are not taking statins at the time of surgery—a trial of at least 6000 people would be needed.[5] For the same reduction in overall survival more than 12 000 patients would be needed.[5 12] The DECREASE IV trial plans to recruit over four years to assess the affects of a β blocker (bisoprolol) and a statin (fluvastatin), but it may face similar difficulties to those seen for the POISE trial.

The risks of myocardial events associated with sudden withdrawal of treatment are similar for β blockers and statins. However, while the safety profile of β blockers is well documented this is not so for statins, which are associated with serious liver and muscle toxicity, although these are rare in perioperative use.[5 12]

The benefits of statins in reducing myocardial ischaemic events in the general population and high risk patients are well known,[5 12] but robust evidence to confirm that these drugs are valuable in routine perioperative use has not been published. So, on the basis of the evidence currently available what should practising clinicians do? We suggest that patients already receiving β blockers or statins before surgery should continue with treatment. Only patients who need heart rate or blood pressure control, or both, in the perioperative period should start treatment with β blockers. No patient should start taking statins in the perioperative period specifically to reduce the likelihood of perioperative cardiac events.

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Diabetic ketoacidosis

Saline should be used for fluid replacement rather than Hartmann's solution

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Diabetic ketoacidosis is a life threatening condition caused by insulin deprivation or inadequate use of insulin in people with type 1 (or occasionally type 2) diabetes mellitus. Precipitants include deliberate insulin omission, intercurrent illness, surgery, trauma, alcohol, late presentation of previously undetected type 1 diabetes, and the use of drugs that alter carbohydrate metabolism.[1] People with diabetic ketoacidosis need swift intervention by specialists because of the substantial morbidity and mortality arising from the acid-base imbalance, profound fluid loss, and electrolyte disturbances.

Current guidelines written by diabetes specialists from the United States and the United Kingdom recommend initial replacement of fluids and electrolytes and intravenous insulin.[1 2] The fluid advocated in these guidelines is 0.9% saline. However, people may be treated by emergency and intensive care doctors as well as diabetes specialists, and the type of fluid used can vary.

During the first few hours of hospital admission many people with diabetic ketoacidosis are treated by emergency or intensive care doctors who commonly prefer to use Hartmann's solution (sodium lactate intravenous infusion).[3] Subsequent care is usually delivered by the diabetes team, who prefer to use 0.9% saline. The conflict arises because guidelines for fluid replacement in the acute setting are written by diabetes specialists,[1 2] whereas no widely accepted guidelines have been written by emergency or intensive care doctors for fluid replacement in diabetic ketoacidosis.

For decades, 0.9% saline has been the fluid of choice for diabetic ketoacidosis, and its use continues to be advocated in modern textbooks on diabetes.[4] Early studies on diabetic ketoacidosis in the 1970s used 0.9% saline,[5] and this approach was reinforced a decade later.[6] However, giving patients large amounts of chloride can cause a hyperchloraemic metabolic acidosis,[3 7] so administration of 0.9% saline for diabetic ketoacidosis could potentially worsen the metabolic acidosis. Thus, 0.9% saline may be the fluid of choice simply because evidence for the efficacy of other fluids is lacking. The question of which fluid replacement is optimal in patients with acute diabetic ketoacidosis is, therefore, still unanswered.

Saline 0.9% contains 150 mmol/l of sodium and chloride. Hartmann's solution contains 131 mmol/l of sodium, 111 mmol/l of chloride, 29 mmol/l of bicarbonate (as lactate), 5 mmol/l of potassium, and 2 mmol/l of calcium. The pH of 0.9% saline and Hartmann's varies according to temperature. At 25°C the pH of 0.9% saline is about 4.5 and that of Hartmann's solution is about 6.0. Although Hartmann's solution has a lower chloride concentration and higher pH, its routine use in diabetic ketoacidosis could be argued against for several reasons.

Firstly, people with diabetic ketoacidosis already have a high lactate to pyruvate ratio, and the 29 mmol/l of lactate in Hartmann's solution could potentially exacerbate this and lead to more adverse outcomes.[8] Secondly, Hartmann's solution raises plasma lactate and generates more glucose from the lactate.[9] Thirdly, giving a solution containing even 5 mmol/l potassium to a patient who may be hyperkalaemic could lead to potentially fatal cardiac arrhythmias, such as bradycardia and asystole. Fourthly, bicarbonate is not recommended for patients with pH greater than 7.0 because it could worsen the acidosis.[10] Finally, because low serum sodium at presentation is a risk factor for developing cerebral oedema, initial treatment with a relatively hypotonic fluid could be harmful.[11] Thus, Hartmann's solution does not seem to be optimal for use in diabetic ketoacidosis, and Hartmann himself strongly argued against its use after some of his insulin deprived patients died.[12]

Diabetes specialists accept that acidosis caused by large volumes of 0.9% saline is mild and transient, and it is not associated with adverse outcomes or prolonged length of stay.[1] The low base deficit in the face of a normal pH may be a cause of concern and may lead to the perception of persistent hypoperfusion. However, this is a trap for the unwary, because if a high chloride concentration is found, then the base deficit can be safely ignored.

The primary treatment in diabetic ketoacidosis is replacement with large volumes of fluid. This in itself substantially reduces blood glucose and begins to correct the acidosis. Ideally, a randomised study comparing 0.9% saline and Hartmann's would provide information about the optimum type of fluid replacement. This is unlikely to happen, though, partly because of the potential dangers of Hartmann's solution discussed above. In the absence of such a trial and in view of the large body of supporting evidence that has led to the development of the guidelines,[1 2] the fluid of choice in the initial resuscitation of people with diabetic ketoacidosis should remain 0.9% saline.

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Centralised application services for specialist training

Other countries manage

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This week marks the end of round one of the UK's scheme to fill specialty training posts that become available in August. All applicants have been offered the opportunity of at least one job interview, and those who have not been offered a job can apply for any unfilled posts in round two. For this second round, however, local deaneries will manage the process. The Medical Training Application Service (MTAS), whose premature and poorly implemented introduction was condemned by a judge for its "disastrous consequences,"[1] has been shelved.

Good riddance, chorus Britain's doctors, but the decision brings little comfort to the thousands of demoralised juniors still caught up in the uncertainties and frustrations of finding a job. While assessing the ongoing fallout of MTAS, it's salutary to be reminded that other countries have pulled off what looks from Britain like an impossible feat. In this week's journal, Tony Jefferis reports that "a central application portal with local selection . . . has been used successfully in the United States, Canada, and, in a modified form in Australia and New Zealand for at least 30 years." And these countries have successfully negotiated, or are negotiating, the transition to computerisation.[2]

What can Britain learn from their example? Jefferis found that other countries' matching schemes "are all efficient, have clear time tables, and are consistent from year to year." Candidates have time

Why the numbers didn't add up

Last year's Postgraduate Medical Education and Training Board survey indicated that there were 17 500 SHOs in educationally approved posts in the UK. Posts available for MTAS recruitment were estimated at 18 500, not including posts filled by general practitioner trainees. In total, the UK had around 23 000 posts at SHO level—so plenty to go round. But there was also an unknown number of trust grade doctors and doctors outside the UK with, or eligible for, General Medical Council registration. In total, 34 000 doctors applied, hugely in excess of the SHO population for whom the posts were intended.

Until last year, international medical graduates appointed to training posts were given permit-free training visas. Without warning, the government announced last year that this scheme was withdrawn. Doctors without right of residence could work only if no suitable UK or European Union candidates had applied for the job and the employing trust could apply for a work permit using the "resident labour market test." Meanwhile, such doctors could apply for permission to work through the highly skilled migrant programme. These doctors would be able to apply on an equal footing to UK citizens, but they would initially be granted a visa for only two years and would then need an extension. They would therefore not have a visa to cover the whole of the training programme, and the Department of Health recommended that they should not be eligible for training programmes longer than two years.

For the time being, however, these doctors have been granted equal eligibility to UK citizens and others with a right to work pending an appeal against a High Court judgment that restrictions on permit free training were lawful. Thus, these doctors were included in the first round of application to MTAS and added to the excess of applicants.

"to make informed choices and to compile their application."

Britain's year one was always going to be tough, but many things made it tougher, in ways that those responsible for its implementation should have predicted. Computer crashes and security breaches are par for the course for the United Kingdom's public sector information technology projects, few of which deliver on time, on budget, and to specification.[3] By opting for a "big bang" approach—including all training jobs, at all levels, in all geographical areas—the system was maximally stressed. An added complication was that while the senior house officer (SHO) grade is disappearing overnight, the many doctors filling such posts aren't, and nor are the service needs they have been fulfilling.

The breakneck speed with which the changes were introduced just about overwhelmed the human resources needed to process the applications. The need to build in flexibility was sacrificed to getting the scheme off the ground. Many juniors, and those who should have been advising them, did not appreciate the scale of cultural change and how qualitatively different the new selection process was going to be. Understanding—let alone "buy in"—was lacking.

The next substantial criticism of the new system was that it was a poor discriminator of applicants. (The "evidence" for this is the large numbers of "high flyers" without job offers, a claim that will have to await the end of round two for proper substantiation.) The new application form was blamed for giving precedence to free text answers about competency over evidence of clinical experience.[4] Its masking of medical school and country of training—an attempt to reduce discrimination—was seized on as a weakness rather than a strength.

The countries that Jefferis analysed do things the way Britain used to. All have application forms covering undergraduate and graduate training, honours and prizes, research and publications, and extracurricular and community activity. To help in selection, all four countries use reports and references—from medical school deans, referees, supervisors, and the like (some solicited by telephone). Programme directors rank candidates in order of preference using the application form, references, and interview. Candidates' preferences and those of the programmes are then matched centrally, "without controversy." Jefferis doesn't explore how these systems protect candidates from selectors' biases towards "people like us,"[5] which was a laudable aim of the UK's proposals.

The remaining serious criticism of MTAS was that it would leave 12 000 junior doctors jobless from August, which no amount of tweaking with computer programs or application forms would have altered. A large proportion of the "excess" applicants are thought to be doctors trained overseas—including some working in non-training grade trust posts, some doing unpaid observerships or locums as they try to get substantive appointments, and others currently overseas. Jefferis found that the countries he looked at avoided these problems—while international graduates made up an integral part of their medical workforce their applications were considered only after those of domestic graduates.

John Tookes's inquiry into the UK's specialty training scheme, Modernising Medical Careers, is looking much more widely than merely "the mechanics of the process," although it is hard to imagine this won't consume a lot of its attention, given the shortfalls of the discredited system. In its current consultation phase the inquiry wants to explore "alternative solutions, grounded in evidence." Jefferis's article shows that a scheme that combines central computerised application with local selection is not necessarily an impossible dream.

1 Eaton L. *Remedy UK loses its high court case.* http://blogs.bmj.com/category/comment/mtas/.
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3 O'Dowd A. Richard Granger resigns as chief executive of Connecting for Health. *BMJ* 2007 doi: 10.1136/bmj.39251.605475.DB.
4 Coombes R. MTAS: which way now? *BMJ* 2007 doi: 10.1136/bmj.39252.407350.68.
5 Esmail A, Everington S. Racial discrimination against doctors from ethnic minorities. *BMJ* 1993:306:691-2.