

Controversies in management

Should doctors perform an elective caesarean section on request?

Rates of caesarean section are rising, and mothers' requests for elective caesarean section in an uncomplicated pregnancy are not uncommon. Performing a caesarean section when it is not clinically indicated has traditionally been considered inappropriate, but views may be changing. Sara Paterson-Brown and Olubusola Amu and colleagues debate the issue

Yes, as long as the woman is fully informed

Sara Paterson-Brown

Queen Charlotte's
and Chelsea
Hospital, London
W6 0XG

Sara
Paterson-Brown,
consultant in
obstetrics and
gynaecology

s.paterson-brown@
rpms.ac.uk

BMJ 1998;317:462-5

Surgery is performed by doctors when they believe it is clinically justified and in accordance with accepted medical practice. In obstetrics an elective caesarean section in an uncomplicated pregnancy has traditionally been considered inappropriate, and any request for such a procedure has been refused.¹ However, the view that this procedure is clinically unjustifiable has been challenged,² and over the past decade or so prophylactic caesarean section has been gaining credence.³⁻⁴ The balance of benefit versus harm between caesarean section and vaginal delivery is crucial to this debate; although the evidence is incomplete, it challenges the dogma that vaginal delivery is almost always better.

Evidence of risks

The strongest argument against caesarean section relates to maternal complications. However, evidence supporting this for elective operations under regional blockade with antibiotic cover and thromboprophylaxis is poor. Data on mortality from caesarean section relate to procedures performed for medical or obstetric reasons, often emergencies and often under general anaesthesia.⁵⁻⁶ These are not comparable to the elective procedure, which most practising obstetricians consider safe. Recent evidence of maternal morbidity after caesarean section and normal and instrumental vaginal delivery challenges some deep rooted obstetric and midwifery teachings: normal vaginal deliveries can cause damage to the pelvic floor,⁷ and instrumental vaginal deliveries are associated with slower recovery⁸ and greater pelvic floor damage and incontinence⁹ than normal delivery and caesarean section. Previous caesarean section does compromise future obstetric performance,¹⁰⁻¹¹ but evidence is limited and, with reduced family size, this has probably become less important in decision making.

Evidence on intrapartum fetal safety reveals that a baby weighing >1500 g at birth has a risk of death of 1 in 1500 in the United Kingdom.¹² The risk of permanent brain damage due to labour is difficult to quantify: 1 in 1750 labours results in hypoxic ischaemic encephalopathy,¹³ from which many babies recover, whereas intrapartum events account for about 10% of all babies with cerebral palsy,¹⁴ although recent work suggests this might be an underestimate.¹⁵ In addition to these risks, as gestation progresses beyond the due date and spontaneous labour is awaited, unexpected intrauterine death occurs in about 1 in 600 pregnancies.¹⁶ Elective caesarean section cannot guarantee normality, but it avoids the above problems by virtue of avoiding labour and prolonged pregnancy. Short term complications to the neonate of transient tachypnoea and respiratory distress syndrome are reduced by delaying elective caesarean section until 39 weeks of pregnancy have been completed.¹⁷

Changing views

Armed with this information, and exposed to the risks of both vaginal delivery and caesarean section in everyday practice, 31% of London female obstetricians with an uncomplicated singleton pregnancy at term would choose an elective caesarean section for themselves.¹⁸ This group is clearly unrepresentative of women as a whole, and we do not know what proportion of British women would make the same choice. In Italy, however, where women's choice of mode of delivery must, by law, be respected, 4% of lay women choose an elective caesarean section.¹⁹ Even though it is probably only a small minority of women who would opt for elective caesarean section, contributing little to the overall rise in caesarean section rates, there is no doubt that women's choice has a big impact on decisions about caesarean section in

obstetric situations that are not completely straightforward.^{20 21} Vaginal delivery of a fetus in breech presentation is becoming a rare obstetric art, and half of pregnant women who have already had a caesarean section choose to have another.^{22 23} What we do not know is what has changed the views of both the women and their obstetricians about the balance of benefit to harm in these situations to the extent that the risk of trial of vaginal delivery is considered too high.

We are at a turning point in obstetric thinking, brought about not only by the advances that have made caesarean section safe and the evidence that vaginal delivery can be associated with substantial morbidity but also by the attitudes of our society, which reflect intolerance to risk. We encourage "family planning" and pre-pregnancy counselling, we routinely perform antenatal screening, and we offer prenatal diagnosis—all of which are "unnatural" and promote a concept of the "designer baby." Can we do all this and then refuse a woman a safe mode of delivery (caesarean section) that removes the gambles associated with labour and which she personally finds unacceptable?

Conclusions

The reports *Health Committee Maternity Services* and *Changing Childbirth* suggested that women should have a pivotal role in their obstetric care,^{24 25} yet some are now being criticised for the choices they are making. These choices should not be discredited simply because they are not the ones that were expected. We should respect a woman's view and choice if it is fully informed, if she expresses a logical reason for wanting a caesarean section, and if she can demonstrate an understanding of the implications of the procedure. We should not be dictating to women what they should think, nor should we be judgmental of their values if they happen to differ from our own.

This does not mean that obstetricians should become technicians at the mercy of women's choice, but that they should be partners in the process of decision making. There is no room for complacency with such incomplete evidence, and further research is needed; but on the basis of the available evidence the concept of a prophylactic caesarean section being outrageous has been shattered by the fact that almost a third of female obstetricians would choose it for them-

selves.¹⁸ Prophylactic caesarean section can no longer be considered clinically unjustifiable, and it now forms part of accepted medical practice.

- Hall M. When a woman asks for a caesarean section. *BMJ* 1987;294:201-2.
- Feldman GB, Freiman JA. Prophylactic cesarean section at term? *N Engl J Med* 1985;312:1264-7.
- What is the right number of caesarean sections?[editorial]. *Lancet* 1997;349:815.
- Drife J. Maternity services: the Audit Commission reports. *BMJ* 1997;314:844.
- Lifford RJ, Van Coeverden deGroot HA, Moore PJ, Gingham P. The relative risks of caesarean section (intrapartum and elective) and vaginal delivery: a detailed analysis to exclude the effects of medical disorders and other acute preexisting physiological disturbances. *Br J Obstet Gynaecol* 1990;97:883-92.
- Report on confidential enquiries into maternal deaths in the UK 1991-3. London: HMSO, 1996.
- Sultan AH, Kamm MA, Hudson CN, Thomas JM, Bartram CI. Sphincter disruption during vaginal deliveries. *N Engl J Med* 1993;329:1905-11.
- Glazener CMA, Abdalla M, Stroud P, Naji S, Templeton A, Russell IT. Postnatal maternal morbidity: extent, causes, prevention and treatment. *Br J Obstet Gynaecol* 1995;102:282-7.
- MacArthur C, Bick DE, Keighley MRB. Faecal incontinence after childbirth. *Br J Obstet Gynaecol* 1997;104:46-50.
- Hemminki E, Merilainen J. Long-term effects of cesarean sections: ectopic pregnancies and placental problems. *Am J Obstet Gynecol* 1996;174:1569-74.
- Greene R, Gardeil F, Turner MJ. Long-term effects of cesarean sections. *Am J Obstet Gynecol* 1996;176:254-5.
- Confidential enquiry into stillbirths and deaths in infancy 4th annual report. London: Maternal and Child Health Research Consortium, 1997.
- Adamson SJ, Louisa MA, Badawi N, Burton PR, Pemberton PJ, Stanley F. Predictors of neonatal encephalopathy in full term infants. *BMJ* 1995;311:598-602.
- Nelson KB, Ellenberg JH. Antecedents of cerebral palsy: multivariate analysis of risk. *N Engl J Med* 1986;315:81-6.
- Grether JK, Nelson KB. Maternal infection and cerebral palsy in infants of normal birth weight. *JAMA* 1997;278:207-11.
- Hilder L, Costeloe K, Thilaganathan B. Prolonged pregnancy: evaluating gestation specific risks of fetal and infant mortality. *Br J Obstet Gynaecol* 1998;105:169-73.
- Morrison JJ, Rennie JM, Milton PJ. Neonatal respiratory morbidity and mode of delivery at term: influence of timing of elective caesarean section. *Br J Obstet Gynaecol* 1995;102:101-6.
- Al-Mufti R, McCarthy A, Fisk NM. Survey of obstetricians' personal preference and discretionary practice. *Eur J Obstet Gynecol Reprod Biol* 1997;73:1-4.
- Tranquilli AL, Garzetti GG. A new ethical and clinical dilemma in obstetric practice: caesarean section "on maternal request." *Am J Obstet Gynecol* 1997;177:245-6.
- Lescale KB, Inglis SR, Eddleman KA, Peeper EQ, Chervenak FA, McCullough LB. Conflicts between physicians and patients in nonelective cesarean delivery: incidence and the adequacy of informed consent. *Am J Perinatol* 1996;13:171-6.
- Mould TAJ, Chong S, Spencer JAD, Gallivan S. Women's involvement with the decision preceding their caesarean section and their degree of satisfaction. *Br J Obstet Gynaecol* 1996;103:1074-7.
- Lau TK, Wong SH, Li CY. A study of patients' acceptance towards vaginal birth after caesarean section. *Aust NZ J Obstet Gynaecol* 1996;36:155-8.
- McMahon MJ, Luther ER, Bowes WA, Olshan AF. Comparison of a trial of labour with an elective second cesarean section. *N Engl J Med* 1996;335:689-95.
- Health committee maternity services. London: HMSO, 1992.
- Expert Maternity Group. *Changing childbirth*. London: HMSO, 1993.

Maternal choice alone should not determine method of delivery

Olubusola Amu, Sasha Rajendran, Ibrahim I Bolaji

The Cumberland report, in response to the select committee report of 1992 (the Winterton report), advocated a shift of maternity services to a more woman centred approach to provide a service that is appropriate and acceptable to the individual and is effective and efficient.¹ The report recommended that women should be provided with adequate information to enable them to participate in decisions about their care and to help them make informed choices.

The knowledge of the right to choose, however, has led to increasing exercise of positive and negative

rights. Many units, including ours, are now experiencing the phenomena of maternal requests for elective caesarean section (positive right) and cases of women refusing a medically indicated intervention (negative right). The latter are powerful rights and can be abrogated only under the most extreme circumstances. The result is the ethical conflict between patients' rights to autonomous decision and carers' right to autonomy in operating in accord with accepted medical practice.²

Caesarean section remains an important area of controversy as the rate of this operation has risen

Department of
Obstetrics and
Gynaecology,
Leicester General
Hospital, Leicester
LE5 4PW
Olubusola Amu,
specialist registrar
Sasha Rajendran,
senior house officer
continued over

Department of
Obstetrics and
Gynaecology,
Grimsby Hospital,
Grimsby
DN33 2BA

Ibrahim I Bolaji,
*consultant
obstetrician and
gynaecologist*

Correspondence to:
Dr Bolaji
general@grimhosp.
demon.co.uk

dramatically worldwide.³ Breech presentation, prematurity, increased use of electronic fetal monitoring, and the fear of litigation have been implicated,^{4 5} and obstetricians have been largely blamed for the rising trend without consideration that women's preference may play a part (caesarean section on maternal request).

Reasons for preferences

Some women who have had a difficult instrumental vaginal delivery or an emergency caesarean section after a long and painful labour would not contemplate further attempts at vaginal delivery. Vaginal delivery after a previous caesarean section is not considered at all by some women because of concerns about fetal brain damage during labour and the ability to schedule delivery in advance with elective delivery. Requests are now being made for elective caesarean section to protect the pelvic floor from obstetric trauma and its sequelae.^{6 7} A survey of female obstetricians by Al Mufti et al showed that 31% would prefer to give birth by elective caesarean section rather than vaginal delivery, and 80% of these doctors indicated fear of perineal damage as their main reason.⁸ Anecdotal evidence also suggests that delayed onset of childbearing by professional women may be associated with increased demands for caesarean section.

Conversely, some women choose vaginal delivery despite doctors' recommending caesarean section, and, occasionally, court orders have had to be sought to effect delivery of the fetus by caesarean section.⁹ Some women believe that vaginal birth results in healthier children, some associate caesarean section with reproductive abnormality, and others make their choice largely because of fear of major surgery.

Women's requests for a particular mode of delivery for fear of the consequences of the other method are not necessarily rational.

Risks and benefits

Forceps delivery has been shown to be the single independent factor associated with trauma to the anal sphincter, and most women who sustain anal sphincteric damage do so in their first pregnancy.¹⁰ Maternal age has not been shown to have any bearing on the vaginal delivery rate, even after a caesarean section.¹¹ Most developmental delays are unrelated to the method of delivery, so a policy of elective caesarean sections would not necessarily prevent long term disability. An elective caesarean section does, however, avert the need for episiotomies, prolonged and painful labours, and difficult instrumental deliveries. Trauma to the pelvic floor and to the urethral and anal sphincters, associated with long term predisposition to genital prolapse and urinary and anal incontinence, would also be avoided.¹²

Caesarean sections are not without complications and consequences. Maternal risks in the short term include haemorrhage, infection, ileus, pulmonary embolism, and Mendelson's syndrome. The prevalence of hysterectomy due to haemorrhage after caesarean section is 10 times that after vaginal delivery, and the risk of maternal death is increased up to 16-fold.¹² Long term morbidity—including formation of adhesions, intestinal obstruction, bladder injury, and uterine

rupture—is often underestimated during subsequent pregnancy. There is evidence suggesting decreased fecundity, increased risk of ectopic pregnancy, placenta praevia, and worse infant outcome in subsequent pregnancies, although the effect on non-reproductive health is unclear and contradictory.¹³ Feelings of inadequacy, guilt, and failure in not completing a natural process may affect bonding between mother and infant, particularly if the operation was conducted under general anaesthetic.

No proper data exist about the risks and benefits of elective caesarean section versus labour in uncomplicated pregnancies, looking at multiple medical outcomes as well as psychological, social, and economic implications. Obstetricians do not always know best; no doctor can say whether a mother or fetus will be damaged in labour; and current surveillance tests are not always reliable indicators of poor outcome. Despite these uncertainties, it is the responsibility of the healthcare professional to impart information to women and their partners that is accurate and readily understandable.

Conclusions

We strongly support patients' right to autonomy, and we believe that choice is a fundamental human right, and there are few justifiable constraints on women's choice. Choice, however, needs to be informed. Ultimately, competent women are free to decline medical advice and treatment for rational or irrational reasons, or for no reason, even if, as a consequence, they or their fetus suffer death or injury. The law is clear that the unborn child has no independent status and that a mentally competent expectant mother's wishes must take precedence.¹⁴ Unfortunately, the law does not distinguish between the rights of a mentally competent but foolish (unwise) pregnant woman and other adults. Therefore, if caesarean section is the preferred mode of delivery by the mother, her choice, however foolish or irrational, must be respected.

Healthcare providers must be aware of the importance and consequences of decisions about mode of delivery, as neither method is devoid of risks. Accepting maternal choice as the sole determinant of the method of delivery is probably doing pregnant women a disservice and may constitute a lack of responsibility. The trend for increasing use of caesarean section, coupled with a greater emphasis on patients' autonomy in medical decision making, has clearly progressed too far for a return to paternalistic directions to women on how they should give birth.¹⁵ Women with particular needs or views about treatment should be offered adequate information about alternative options.

Conflicts between maternal and fetal interests are potentially complex, ethically and emotionally, and difficult to resolve. Our view is that doctors, midwives, and childbirth educators must give full and honest advice based on the available information; they may persuade but never coerce. Active participation by patients should be encouraged to arrive at a safe and logical informed decision about method of delivery, with carers recommending what they perceive to be the best course of action in keeping with the available evidence.

- 1 Department of Health. *Changing childbirth: the report of the Expert Maternity Group*. London: HMSO, 1993.
- 2 Pinkerton JV, Finnerty LL. Resolving the clinical and ethical dilemma involved in fetal-maternal conflicts. *Am J Obstet Gynecol* 1996;175:289-95.
- 3 Bolaji II, Meehan FP. Post caesarean delivery. *Eur J Gynaecol Obstet Reprod Biol* 1993;51:181-92.
- 4 Meehan FP, Raffle NM, Bolaji II. Delivery following previous caesarean section. In: Studd J, ed. *Progress in obstetrics and gynaecology*. Vol 10. London: Churchill Livingstone, 1993:213-28.
- 5 Savage W, Francome C. British caesarean section rates: have we reached a plateau? *Br J Obstet Gynaecol* 1993;100:493-6.
- 6 Sultan AH, Kamm MA, Hudson CN, Thomas JM, Bartram CI. Anal sphincter disruption during vaginal delivery. *N Engl J Med* 1993;329:1905-11.
- 7 Sultan AH, Kamm MA, Hudson CN, Bartram CI. Third degree obstetric anal sphincter tears: risk factors and outcome of primary repair. *BMJ* 1994;308:887-91.
- 8 Al-Mufti R, McCarthy A, Fisk NM. Obstetricians' personal choice and mode of delivery. *Lancet* 1996;347:544.
- 9 Dolan B, Parker C, Bowley S, Whitfield A, Bastian H, Conroy C. Caesarean section: a treatment for mental disorder? *BMJ* 1997;314:1183-7.
- 10 Snooks SJ, Swash M, Mathers SE, Henry MM. Effect of vaginal delivery on the pelvic floor: a 5-year follow up. *Br J Surg* 1990;77:1358-60.
- 11 Weinstein D, Benschushan A, Tanos V, Zilberstein R, Rojansky N. Predictive score for vaginal birth after caesarean section. *Am J Obstet Gynecol* 1996;174:192-8.
- 12 Sultan AH, Stanton SL. Preserving the pelvic floor and perineum during childbirth—elective caesarean section? *Br J Obstet Gynaecol* 1996;103:731-4.
- 13 Hemminki E, Merilainen J. Long-term effects of caesarean section: ectopic pregnancies and placental problems. *Am J Obstet Gynaecol* 1996;174:1569-74.
- 14 NHS Executive. *Consent to treatment; summary of legal rulings*. Wetherby: Department of Health, 1997. (Executive letter EL(97)32.)
- 15 What is the right number of caesarean sections? [editorial]. *Lancet* 1997;349:815.

Getting research findings into practice

Closing the gap between research and practice: an overview of systematic reviews of interventions to promote the implementation of research findings

Lisa A Bero, Roberto Grilli, Jeremy M Grimshaw, Emma Harvey, Andrew D Oxman, Mary Ann Thomson on behalf of the Cochrane Effective Practice and Organisation of Care Review Group

Despite the considerable amount of money spent on clinical research relatively little attention has been paid to ensuring that the findings of research are implemented in routine clinical practice.¹ There are many different types of intervention that can be used to promote behavioural change among healthcare professionals and the implementation of research findings. Disentangling the effects of intervention from the influence of contextual factors is difficult when interpreting the results of individual trials of behavioural change.² Nevertheless, systematic reviews of rigorous studies provide the best evidence of the effectiveness of different strategies for promoting behavioural change.^{3,4} In this paper we examine systematic reviews of different strategies for the dissemination and implementation of research findings to identify evidence of the effectiveness of different strategies and to assess the quality of the systematic reviews.

Identification and inclusion of systematic reviews

We searched Medline records dating from 1966 to June 1995 using a strategy developed in collaboration with the NHS Centre for Reviews and Dissemination. The search identified 1139 references. No reviews from the Cochrane Effective Practice and Organisation of Care Review Group⁴ had been published during this time. In addition, we searched the *Database of Abstracts of Research Effectiveness* (DARE) (www.york.ac.uk/inst/crd) but did not identify any other review meeting the inclusion criteria.

We searched for any review of interventions to improve professional performance that reported explicit selection criteria and in which the main outcomes considered were changes in performance or outcome. Reviews that did not report explicit selection

Summary points

Systematic reviews of rigorous studies provide the best evidence on the effectiveness of different strategies to promote the implementation of research findings

Passive dissemination of information is generally ineffective

It seems necessary to use specific strategies to encourage implementation of research based recommendations and to ensure changes in practice

Further research on the relative effectiveness and efficiency of different strategies is required

criteria, systematic reviews focusing on the methodological quality of published studies, published bibliographies, bibliographic databases, and registers of projects on dissemination activities were excluded from our review. If systematic reviews had been updated we considered only the most recently published review. For example, the *Effective Health Care* bulletin on implementing clinical guidelines superseded the earlier review by Grimshaw and Russell.^{5,6}

Two reviewers independently assessed the quality of the reviews and extracted data on the focus, inclusion criteria, main results, and conclusions of each review. A previously validated checklist (including nine criteria scored as done, partially done, or not done) was used to assess quality.^{7,8} Reviews also gave a summary score (out of seven) based on the scientific quality of the review. Major disagreements between reviewers were resolved by discussion and consensus.

This is the seventh in a series of eight articles analysing the gap between research and practice

Institute for Health Policy Studies, University of California at San Francisco, 1388 Sutter Street, 11th floor, San Francisco, CA 94109, USA

Lisa A Bero, associate professor Unit of Clinical Policy Analysis, Laboratory of Clinical Epidemiology, Istituto di Ricerche Farmacologiche Mario Negri, Via Eritrea 62, 20157 Milan, Italy
Roberto Grilli, head

continued over

BMJ 1998;317:465-8



Additional data can be found on our website

Health Services
Research Unit,
Department of
Public Health,
Aberdeen
AB25 2ZD
Jeremy M
Grimshaw,
programme director

Mary Ann
Thomson,
senior research fellow

Department of
Health Sciences
and Clinical
Evaluation,
University of York,
York YO1 5DD
Emma Harvey,
research fellow

Health Services
Research Unit,
National Institute of
Public Health, PO
Box 4404 Torshov,
N-0462 Oslo,
Norway

Andrew D Oxman,
director

Correspondence to:
Dr Grimshaw
j.m.grimshaw@
abdn.ac.uk

Series editors:
Andrew Haines and
Anna Donald

Results and assessment of systematic reviews

We identified 18 reviews that met the inclusion criteria. They were categorised as focusing on broad strategies (such as the dissemination and implementation of guidelines^{5 6 9-11}), continuing medical education,^{12 13} particular strategies (such as audit and feedback,^{14 15} computerised decision support systems,^{16 17} or multifaceted interventions¹⁸), particular target groups (for example, nurses¹⁹ or primary healthcare professionals²⁰), and particular problem areas or types of behaviour (for example, diagnostic testing,¹⁵ prescribing,²¹ or aspects of preventive care^{15 22-25}). Most primary studies were included in more than one review, and some reviewers published more than one review. No systematic reviews published before 1988 were identified. None of the reviews explicitly addressed the cost effectiveness of different strategies for effecting changes in behaviour.

There was a lack of a common approach adopted between the reviews in how interventions and potentially confounding factors were categorised. The inclusion criteria and methods used in these reviews varied considerably. Interventions were frequently classed differently in the different systematic reviews.

Common methodological problems included the failure to adequately report criteria for selecting studies included in the review, the failure to avoid bias in the selection of studies, the failure to adequately report criteria used to assess validity, and the failure to apply criteria to assess the validity of the selected studies. Overall, 42% (68/162) of criteria were reported as having been done, 49% (80/162) as having been partially done, and 9% (14/162) as not having been done. The mean summary score was 4.13 (range 2 to 6, median 3.75, mode 3).

Encouragingly, reviews published more recently seemed to be of better quality. For studies published between 1988 and 1991 (n=6) only 20% (11/54) of criteria were scored as having been done (mean summary score 3.0); for reviews published after 1991 (n=12) 52% (56/108) of criteria were scored as having been done (mean summary score 4.7).

Five reviews attempted formal meta-analyses of the results of the studies identified.^{12 17 19 23 25} The appropriateness of meta-analysis in three of these reviews is

uncertain,^{12 17 19} and the reviews should be considered exploratory at best, given the broad focus and heterogeneity of the studies included in the reviews with respect to the types of interventions, targeted behaviours, contextual factors, and other research factors.²

A number of consistent themes were identified by the systematic reviews (box). (Further details about the systematic reviews are available on the *BMJ's* website.) Most of the reviews identified modest improvements in performance after interventions. However, the passive dissemination of information was generally ineffective in altering practices no matter how important the issue or how valid the assessment methods.^{5 9 11 13 21 26} The use of computerised decision support systems has led to improvements in the performance of doctors in terms of decisions on drug dosage, the provision of preventive care, and the general clinical management of patients, but not in diagnosis.¹⁶ Educational outreach visits have resulted in improvements in prescribing decisions in North America.^{5 13} Patient mediated interventions also seem to improve the provision of preventive care in North America (where baseline performance is often very low).¹³ Multifaceted interventions (that is, a combination of methods that includes two or more interventions such as participation in audit and a local consensus process) seem to be more effective than single interventions.^{13 18} There is insufficient evidence to assess the effectiveness of some interventions—for example the identification and recruitment of local opinion leaders (practitioners nominated by their colleagues as influential).⁵

Few reviews attempted explicitly to link their findings to theories of behavioural change. The difficulties associated with linking findings and theories are illustrated in the review by Davis et al, who found that the results of their overview supported several different theories of behavioural change.¹³

Availability and quality of primary studies

This overview also allows the opportunity to estimate the availability and quality of primary research in the areas of dissemination and implementation. Identification of published studies on behavioural change is difficult because they are poorly indexed and scattered across generalist and specialist journals. Nevertheless, two reviews provided an indication of the extent of research in this area. Oxman et al identified 102 randomised or quasirandomised controlled trials involving 160 comparisons of interventions to improve professional practice.¹¹ The *Effective Health Care* bulletin on implementing clinical guidelines identified 91 rigorous studies (including 63 randomised or quasirandomised controlled trials and 28 controlled before and after studies or time series analyses).⁵ Even though the studies included in these two reviews fulfilled the minimum inclusion criteria, some are methodologically flawed and have potentially major threats to their validity. Many studies randomised health professionals or groups of professionals (cluster randomisation) but analysed the results by patient, thus resulting in a possible overestimation of the significance of the observed effects (unit of analysis error).²⁷ Given the small to moderate size of the observed effects this could lead to false conclusions about the significance of the effectiveness of interventions in



Interventions to promote behavioural change among health professionals

Consistently effective interventions

- Educational outreach visits (for prescribing in North America)
- Reminders (manual or computerised)
- Multifaceted interventions (a combination that includes two or more of the following: audit and feedback, reminders, local consensus processes, or marketing)
- Interactive educational meetings (participation of healthcare providers in workshops that include discussion or practice)

Interventions of variable effectiveness

- Audit and feedback (or any summary of clinical performance)
- The use of local opinion leaders (practitioners identified by their colleagues as influential)
- Local consensus processes (inclusion of participating practitioners in discussions to ensure that they agree that the chosen clinical problem is important and the approach to managing the problem is appropriate)
- Patient mediated interventions (any intervention aimed at changing the performance of healthcare providers for which specific information was sought from or given to patients)

Interventions that have little or no effect

- Educational materials (distribution of recommendations for clinical care, including clinical practice guidelines, audiovisual materials, and electronic publications)
- Didactic educational meetings (such as lectures)

both meta-analyses and qualitative analyses. Few studies attempted to undertake any form of economic analysis.

Given the importance of implementing the results of sound research and the problems of generalisability across different healthcare settings, there are relatively few studies of individual interventions to effect behavioural change. The review by Oxman et al identified studies involving 12 comparisons of educational materials, 17 of conferences, four of outreach visits, six of local opinion leaders, 10 of patient mediated interventions, 33 of audit and feedback, 53 of reminders, two of marketing, eight of local consensus processes, and 15 of multifaceted interventions.¹¹ Few studies compared the relative effectiveness of different strategies; only 22 out of 91 studies reviewed in the *Effective Health Care* bulletin allowed comparisons of different strategies.⁵ A further limitation of the evidence about different types of interventions is that the research is often conducted by limited numbers of researchers in specific settings. The generalisability of these findings to other settings is uncertain, especially because of the marked differences in undergraduate and postgraduate education, the organisation of healthcare systems, potential systemic incentives and barriers to change, and societal values and cultures. Most of the studies reviewed were conducted in North America; only 14 of the 91 studies reviewed in the *Effective Health Care* bulletin had been conducted in Europe.⁵

The way forward

This overview suggests that there is an increasing amount of primary and secondary research in the areas of dissemination and implementation. It is striking how little is known about the effectiveness and cost effectiveness of interventions that aim to change the practice or delivery of health care. The reviews that we examined suggest that the passive dissemination of information (for example, publication of consensus conferences in professional journals or the mailing of educational materials) is generally ineffective and, at best, results only in small changes in practice. However, these passive approaches probably represent the most common approaches adopted by researchers, professional bodies, and healthcare organisations. The use of specific strategies to implement research based recommendations seems to be necessary to ensure that practices change, and studies suggest that more intensive efforts to alter practice are generally more successful.

At a local level greater attention needs to be given to actively coordinating dissemination and implementation to ensure that research findings are implemented. The choice of intervention should be guided by the evidence on the effectiveness of dissemination and implementation strategies, the characteristics of the message,¹⁰ the recognition of external barriers to change,¹³ and the preparedness of the clinicians to change.²⁸ Local policymakers with responsibility for professional education or quality assurance need to be aware of the results of implementation research, develop expertise in the principles of the management of change, and accept the need for local experimentation.

Given the paucity of evidence it is vital that dissemination and implementation activities should be rigorously evaluated whenever possible. Studies evaluating a single intervention provide little new information about the relative effectiveness and cost effectiveness of different interventions in different settings. Greater emphasis should be given to conducting studies that evaluate two or more interventions in a specific setting or help clarify the circumstances that are likely to modify the effectiveness of an intervention. Economic evaluations should be considered an integral component of research. Researchers should have greater awareness of the issues related to cluster randomisation, and should ensure that studies have adequate power and that they are analysed using appropriate methods.²⁹

The NHS research and development programme on evaluating methods to promote the implementation of research and development is an important initiative that will contribute to our knowledge of the dissemination of information and the implementation of research findings.³⁰ However, these research issues cut across national and cultural differences in the practice and financing of health care. Moreover, the scope of these issues is such that no one country's health services research programme can examine them in a comprehensive way. This suggests that there are potential benefits of international collaboration and cooperation in research, as long as appropriate attention is paid to cultural factors that might influence the implementation process such as the beliefs and perceptions of the public, patients, healthcare professionals, and policymakers.

The results of primary research should be systematically reviewed to identify promising implementation techniques and areas where more research is required.³ Undertaking reviews in this area is difficult because of the complexity inherent in the interventions, the variability in the methods used, and the difficulty of generalising study findings across healthcare settings. The Cochrane Effective Practices and Organisation of Care Review Group is helping to meet the need for systematic reviews of current best evidence on the effects of continuing medical education, quality assurance, and other interventions that affect professional practice. A growing number of these reviews are being published and updated in the *Cochrane Database of Systematic Reviews*.^{4 31}

This paper is based on a briefing paper prepared by the authors for the Advisory Group on the NHS research and development programme on evaluating methods to promote the implementation of research and development. We thank Nick Freemantle for his contribution to this paper.

Funding: This work was partly funded by the European Community funded Eur-Assess project. The Cochrane Effective Practice and Organisation of Care Review Group is funded by the Chief Scientist Office of the Scottish Office Home and Health Department; the NHS Welsh Office of Research and Development; the Northern Ireland Department of Health and Social Services; the research and development offices of the Anglia and Oxford, North Thames, North West, South and West, South Thames, Trent, and West Midlands regions; and by the Norwegian Research Council and Ministry of Health and Social Affairs in Norway. The Health Services Research Unit is funded by the Chief Scientist Office of the Scottish Office Home and Health Department. The views expressed are those of the authors and not necessarily the funding bodies.

Conflict of interest: None.

- 1 Eddy DM. Clinical policies and the quality of clinical practice. *N Engl J Med* 1982;307:343-7.
- 2 Grimshaw JM, Freemantle N, Langhorne P, Song F. *Complexity and systematic reviews: report to the US Congress Office of Technology Assessment*. Washington, DC: Office of Technology Assessment, 1995.
- 3 Mulrow CD. Rationale for systematic reviews. *BMJ* 1994;309:597-9.
- 4 Bero L, Grilli R, Grimshaw JM, Harvey E, Oxman AD, eds. *Effective professional practice and organisation of care module*, Cochrane Database of Systematic Reviews. *The Cochrane Library*. The Cochrane Collaboration; Issue 4. Oxford: Update Software; 1997.
- 5 Implementing clinical guidelines: can guidelines be used to improve clinical practice? *Effective Health Care* 1994; No 8.
- 6 Grimshaw JM, Russell IT. Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. *Lancet* 1993;342:1317-22.
- 7 Oxman AD, Guyatt GH. The science of reviewing research. *Ann N Y Acad Sci* 1993;703:123-31.
- 8 Oxman AD. Checklists for review articles. *BMJ* 1994;309:648-51.

- 9 Lomas J. Words without action? The production, dissemination, and impact of consensus recommendations. *Annu Rev Public Health* 1991;12:41-65.
- 10 Grilli R, Lomas J. Evaluating the message: the relationship between compliance rate and the subject of a practice guideline. *Med Care* 1994;32:202-13.
- 11 Oxman AD, Thomson MA, Davis DA, Haynes RB. No magic bullets: a systematic review of 102 trials of interventions to help health care professionals deliver services more effectively or efficiently. *Can Med Assoc J* 1995;153:1423-31.
- 12 Beaudry JS. The effectiveness of continuing medical education: a quantitative synthesis. *J Continuing Education Health Professions* 1989;9:285-307.
- 13 Davis DA, Thomson MA, Oxman AD, Haynes RB. Changing physician performance: a systematic review of the effect of continuing medical education strategies. *JAMA* 1995;274:700-5.
- 14 Mugford M, Banfield P, O'Hanlon M. Effects of feedback of information on clinical practice: a review. *BMJ* 1991;303:398-402.
- 15 Buntinx F, Winkens R, Grol R, Knotterus JA. Influencing diagnostic and preventive performance in ambulatory care by feedback and reminders: a review. *Fam Pract* 1993;10:219-28.
- 16 Johnston ME, Langton KB, Haynes RB, Mathieu A. Effects of computer-based clinical decision support systems on clinician performance and patient outcome: a critical appraisal of research. *Ann Intern Med* 1994;120:135-42.
- 17 Austin SM, Balas EA, Mitchell JA, Ewigman BG. Effect of physician reminders on preventive care: meta-analysis of randomized clinical trials. *Proceedings—the Annual Symposium on Computer Applications in Medical Care* 1994;121-4.
- 18 Wensing M, Grol R. Single and combined strategies for implementing changes in primary care: a literature review. *Int J Quality Health Care* 1994;6:115-32.
- 19 Waddell DL. The effects of continuing education on nursing practice: a meta-analysis. *J Continuing Education Nurs* 1991;22:113-8.
- 20 Yano EM, Fink A, Hirsch SH, Robbins AS, Rubenstein LV. Helping practices reach primary care goals: lessons from the literature. *Arch Intern Med* 1995;155:1146-56.
- 21 Soumerai SB, McLaughlin TJ, Avorn J. Improving drug prescribing in primary care: a critical analysis of the experimental literature. *Milbank Q* 1989;67:268-317.
- 22 Lomas J, Haynes RB. A taxonomy and critical review of tested strategies for the application of clinical practice recommendations: from "official" to "individual" clinical policy. *Am J Prev Med* 1987;4:77-94.
- 23 Gyorkos TW, Tannenbaum TN, Abrahamowicz M, Bédard L, Carsley J, Franco ED, et al. Evaluation of the effectiveness of immunization delivery methods. *Can J Public Health* 1994;85(suppl 1):14-30S.
- 24 Mandelblatt J, Kanetsky PA. Effectiveness of interventions to enhance physician screening for breast cancer. *J Fam Pract* 1995;40:162-71.
- 25 Silagy C, Lancaster T, Gray S, Fowler G. The effectiveness of training health professionals to provide smoking cessation interventions: systematic review of randomised controlled trials. *Qual Health Care* 1995;3:193-8.
- 26 Lomas J, Anderson GM, Domnick-Pierre K, Vayda E, Enkin MW, Hannah WJ. Do practice guidelines guide practice? The effect of a consensus statement on the practice of physicians. *N Engl J Med* 1989;321:1306-11.
- 27 Whiting-O'Keefe QE, Henke C, Simborg DW. Choosing the correct unit of analysis in medical care experiments. *Med Care* 1984;22:1101-14.
- 28 Grol R. Implementing guidelines in general practice care. *Qual Health Care* 1992;1:184-91.
- 29 Donner A, Birkett N, Buck C. Randomisation by cluster: sample size requirements and analysis. *Am J Epidemiol* 1981;114:906-14.
- 30 NHS Research and Development Programme. *Methods to promote the implementation of research findings in the NHS: priorities for evaluation*. Leeds: Department of Health, 1995.
- 31 Freemantle N, Grilli R, Grimshaw JM, Oxman A. Implementing the findings of medical research: the Cochrane Collaboration on effective professional practice. *Qual Health Care* 1995;4:45-7.

The articles in this series are adapted from *Getting Research Findings into Practice*, edited by Andrew Haines and Anna Donald and published by BMJ Books.

Statistics Notes

Time to event (survival) data

Douglas G Altman, J Martin Bland

In many medical studies an outcome of interest is the time to an event. Such events may be adverse, such as death or recurrence of a tumour; positive, such as conception or discharge from hospital; or neutral, such as cessation of breast feeding. It is conventional to talk about survival data and survival analysis, regardless of the nature of the event. Similar data also arise when measuring the time to complete a task, such as walking 50 metres.

The distinguishing feature of survival data is that at the end of the follow up period the event will probably not have occurred for all patients. For these patients the survival time is said to be censored, indicating that the observation period was cut off before the event occurred. We do not know when (or, indeed, whether) the patient will experience the event, only that he or she has not done so by the end of the observation period.

Correspondence to: Mr Altman
continued over

BMJ 1998;317:468-9

Censoring may also occur in other ways. Patients may be lost to follow up during the study, or they may experience a “competing” event which makes further follow up impossible. For example, patients being followed to a cardiac event may die from some other disease or in an accident.

In most survival studies patients are recruited over a period and followed up to a fixed date beyond the end of recruitment. Thus the last patients recruited will be observed for a shorter period than those recruited first and will be less likely to experience the event. An important assumption, therefore, is that patients’ survival prospects (prognosis) stay the same throughout the study (although this will not matter too much in a randomised trial). We also assume that patients lost to follow up have the same prognosis as those remaining in the study.

Table 1 shows the survival times of 44 patients in a randomised trial. Several patients in each group were still alive at the end of the study, while one was lost to follow up. In such a study we wish to compare the survival times of the two groups of patients. Statistical methods such as *t* tests cannot cope with the uncertainty in the data caused by censoring. Patients with censored data contribute valuable information and they should not be omitted from the analysis. It would also be wrong to treat the observed time (at censoring) as the survival time. We cannot tell, for example, whether the patient in the control group who was still alive at 127 months would have lived longer than the patient in the prednisolone group who died after 143 months. Rather we need recourse to a specialised set of statistical methods that have been developed for handling such data. We shall consider methods for graphical display and analysis of survival data in subsequent Statistics Notes.

Implicit in the preceding discussion is that survival should be evaluated in a cohort of patients followed forwards in time from a particular time point, such as diagnosis or randomisation, even if the cohort is identified retrospectively. An alternative, and potentially highly misleading, approach is to take a group of people experiencing the event of interest, perhaps in a certain time interval, and ascertain the elapsed time since the start of the relevant preceding time span. For example, we might take all newly diagnosed diabetics and find out when they first experienced certain symptoms. Similarly we might take birth as the start of the time period of interest for a group of individuals who have died and investigate associations between age at death and other variables.

Analyses of such data can cause serious problems. A good example is the highly dubious finding that left handed people die on average seven years younger than right handed people.² In this study those dying at old ages were survivors from a cohort born 70 or more years ago while those dying young may have been born at any time, and so on average will have been born later. Such studies make strong implicit assumptions—in essence that the prevalence of the risk factor(s), the characteristics of the population at risk, and the survival (prognosis) remain unchanged over many decades.³ These assumptions will usually be untenable and may also be untestable. Using this study design we would certainly find that people who use electric guitars or even personal computers die

much younger than those who do not. The differing longevity in relation to handedness² would have arisen if the prevalence of left handedness had increased over the past 80 years. Proper prospective studies have found no evidence of an effect of handedness on lifespan.^{4,5}

The same design was used in a study of long term survival in prostate cancer. All patients dying in a three year period who had been treated with palliative intent were “followed from death to diagnosis,”⁶ a period of up to 30 years. The authors reported that the proportion of deaths due to cancer increased with length of survival. This finding cannot be trusted because of the problems noted above, which are common to all such studies.³ Subjects with long survival times must have been diagnosed decades ago, whereas those with short survival times may include some patients diagnosed recently. The observed association could be a spurious consequence of improved treatment, earlier diagnosis, or some other change over time. The same error was seen recently in the *BMJ*.⁷

Retrospective studies can be valuable, but this design should be avoided when studying survival times. Whenever possible times to an event of interest should be studied in a definable cohort of individuals followed forwards in time.

- 1 Kirk AP, Jain S, Pocock S, Thomas HC, Sherlock S. Late results of the Royal Free Hospital prospective controlled trial of prednisolone therapy in hepatitis B surface antigen negative chronic active hepatitis. *Gut* 1980;21:78-83.
- 2 Halpern DE, Coren S. Handedness and life span. *N Engl J Med* 1991;324:998.
- 3 Abrahamsson PA, Adami HO, Taube A, Kim K, Zelen M, Kulldorff M. Re: Long-term survival and mortality in prostate cancer treated with noncurative intent. *J Urol* 1996;155:296-7.
- 4 Cerhan JR, Folsom AR, Potter JD, Prineas RJ. Handedness and mortality risk in older women. *Am J Epidemiol* 1994;140:368-74.
- 5 Aggleton JP, Bland JM, Kentridge RW, Neave NJ. Handedness and longevity: an archival study of cricketers. *BMJ* 1994;309:1681-4.
- 6 Aus G, Hugosson J, Norlén L. Long-term survival and mortality in prostate cancer treated with noncurative intent. *J Urol* 1995;154:460-5.
- 7 MacManus I. Which doctors die first? *BMJ* 1997;314:1132.

ICRF Medical Statistics Group, Centre for Statistics in Medicine, Institute of Health Sciences, Oxford OX3 7LF
Douglas G Altman, head

Department of Public Health Sciences, St George's Hospital Medical School, London SW17 0RE
J Martin Bland, professor of medical statistics

Table 1 Survival times (months) of 44 patients with chronic active hepatitis randomised to receive prednisolone or no treatment¹

Prednisolone (n=22)	Control (n=22)
2	2
6	3
12	4
54	7
56†	10
68	22
89	28
96	29
96	32
125*	37
128*	40
131*	41
140*	54
141*	61
143	63
145*	71
146	127*
148*	140*
162*	146*
168	158*
173*	167*
181*	182*

*Still alive at time of analysis.

†Lost to follow up.

Endpiece

Hopefully, the last word

Since at least the 17th century, certain adverbs in -ly have acquired the ability to qualify a predication or assertion as a whole. Such adverbs are elliptical uses of somewhat longer phrases. . . . In the 20th century there has been a swift and immoderate increase in the currency of [such] adverbs [which] include actually, basically, frankly, hopefully, regretfully, strictly, and thankfully. Suddenly, round about the end of the 1960s, and with unprecedented venom, a dunce's cap was placed on the head of anyone who used just one of them—hopefully—as a sentence adverb. . . . Conservative speakers, taken unawares by the sudden expansion of an unrecognised type of construction, have exploded with resentment that is unlikely to fade away before at least the end of the 20th century.

Robert Burchfield,
The New Fowler's Modern English Usage
(Oxford: Clarendon Press, 1996)