high cost of stenting and high pressure balloon dilatation over conventional angioplasty in all cases. None the less, this route to successful percutaneous coronary revascularisation has been truly revolutionary.

> NEAL G UREN Visiting cardiologist

Division of Cardiovascular Medicine, Stanford University School of Medicine. Stanford, CA 94305, USA

> NICOLAS AF CHRONOS Assistant professor of medicine

Andreas Grüntzig Cardiovascular Center, Emory University Hospital, Atlanta, GA 30323,

- 1 Weintraub WS, King SB III, Douglas IS Ir, Kosinski AS. Percutaneous transluminal coronary angioplasty as a first revascularization procedure in single-, double- and triple-vessel coronary artery disease. J Am Coll Cardiol 1995;26:142-51.
- Currier JW, Faxon DP. Restenosis after percutaneous transluminal coronary angioplasty: have we been aiming at the wrong target? J Am Coll Cardiol 1995;25:516-20.
- 3 Pocock SJ, Henderson RA, Rickards AF, Hampton JR, King SB III, Hamm CW, et al. Meta-analysis of randomised trials comparing coronary angioplasty with bypass surgery. Lancet 1995;346:1184-9
- 4 Sigwart U, Puel J, Mirkovitch V, Joffre F, Kappenberger L. Intravascular stents to prevent occlusion and restenosis after transluminal angioplasty. N Engl J Med 1987;316:701-6.

- 5 Serruys PW, Strauss BH, Beatt KJ, Bertrand ME, Puel J, Rickards AF, et al. Angiographic follow-up after placement of a self-expanding coronary artery stent. N Engl J Med 1991;324:13-7.
- Serruys PW, de Jaegere P, Kiemeneii F, Macava C, Rutsch W, Hevndrickx G, et al for the Benestent Study Group. A comparison of balloon expandable stent implantation with balloon angioplasty in patients with coronary artery disease. N Engl J Med 1994;331:489-95.

 7 Fischman DL, Leon MB, Baim D, Schatz RA, Savage MP, Penn I, et al for the Stent Restenosis
- Study Investigators. A randomized comparison of coronary stent placement and balloon angioplasty in the treatment of coronary artery disease. N Engl J Med 1994;331:496-501.

 Schatz RA, Baim DS, Leon MB, Goldberg S, Hirshfeld JW, Cleman MW, et al. Clinical
- experience with Palmaz-Schatz coronary stent: initial results of a multicenter study. Circulation 1991;83:148-161
- 9 George BS, Voorhess WD, Roubin GS, Fearnot NE, Pinkerton CA, Raizner AE, et al. Multicenter investigation of coronary stenting to treat acute or threatened closure after pe cutaneous transluminal coronary angioplasty: clinical and angiographic outcomes. J Am Coll
- 10 Popma JJ, Satler LF, Pichard AD, Kent KM, Campbell A, Chuang YC, et al. Vascular complications after balloon and new device angioplasty. Circulation 1993;88:1569-78.
 11 Colombo A, Hall P, Nakamura S, Almagor Y, Maiello L, Martini G, et al. Intracoronary stenting without anticoagulation accomplished with intravascular ultrasound guidance. Circulation 1993;68:1569-78. 1995;91:1891-7.
- 12 Morice MC, Zemour G, Beneviste E, Biron Y, Bourdonnec C, Faivre R, et al. Intracoronary stenting without coumadin: one month results of a French multicenter study. Cathet Cardio-
- 13 Hall P, Nakamura S, Maiello L, Itoh A, Blengino S, Martini G, et al. A randomized comparison of combined ticlopidine and aspirin therapy versus aspirin therapy alone after successful intravascular ultrasound-guided stent implantation. Circulation 1996;93:
- 14 Nakamura S, Colombo A, Gaglione S, Almagor Y, Goldberg SL, Maiello L, et al. Intracoronary ultrasound observations during stent implantation. Circui
- 15 Serruys PW, Emanuelsson H, van der Giessen W, Lunn AC, Kiemeneii F, Macava C, et al for the Benestent-II Study Group. Heparin-coated Palmaz-Schatz stents in human coronary arteries. Early outcome of the Benestent-II pilot study. Circulation 1996;93:

Lactational amenorrhoea method for family planning

Provides high protection from pregnancy for the first six months after delivery

It has long been known that breast feeding can delay the return of fertility, but until recently the conditions under which women could rely on this phenomenon were unclear. In August 1988 an international group of scientists gathered in Bellagio, Italy, to review the scientific evidence related to the effect of breast feeding on fertility.12 In what came to be known as the "Bellagio consensus," they concluded that women who were fully or nearly fully breast feeding and amenorrhoeic had a less than 2% risk of pregnancy in the six months after delivery.

Subsequently, several groups have collected further data on risks of pregnancy among breast feeding women in relation to time after delivery and feeding patterns.3-7 Their results, including those from Ramos and colleagues reported in this week's BMJ (p 909)7 as well as other relevant research,8-10 were reviewed in December 1995 at a second Bellagio conference. This confirmed the conclusions of the original Bellagio consensus11: women who are fully or nearly fully breast feeding are at very low risk of becoming pregnant in the first six months after delivery as long as they remain amenorrhoeic indeed, the observed cumulative life table rates of pregnancy at six months were less than 2%. In studies that included the promotion of appropriate breast feeding practices, the percentage of women still amenorrhoeic and fully breast feeding at six months after delivery was higher than in control groups not receiving such support. 12 13

From the research done to date, the experts participating in the second Bellagio conference (who included two authors of the paper by Ramos et al) also concluded that whereas amenorrhoea is an absolute requirement for ensuring a low risk of pregnancy, it might be possible to relax the requirement of full or nearly full breast feeding. 4 10 14 15 It may also be possible to extend the duration of use beyond six months without jeopardising effectiveness. 10 14 15 Additional research is needed to establish the conditions under which these modifications to the Bellagio consensus could be made.

In 1989 a method of family planning for women was defined, based on the Bellagio consensus. It was called the lac-

tational amenorrhoea method, and guidelines for its use were developed.16 These guidelines include the three criteria mentioned above-amenorrhoea, full or nearly full breast feeding, and protection limited to the first six months postpartum—all of which must be met to ensure adequate protection from an unplanned pregnancy. The guidelines include the advice that women who no longer meet these three criteria, or no longer wish to use the lactational amenorrhoea method, should immediately start to use another method of family planning if they wish to avoid pregnancy.

As well as the study by Ramos et al, several other reports have been published on the lactational amenorrhoea method, 6 12-18 but experience is still limited. Additional but experience is still limited. Additional research is needed to determine its effectiveness and acceptability under field conditions, to evaluate the implications of running a programme of the lactational amenorrhoea method for services catering for mothers, and to assess the impact of reliance on lactational amenorrhoea on subsequent use of other family planning methods, especially among women who would not otherwise attempt family planning. As indicated earlier, the guidelines for use of lactational amenorrhoea promote the adoption of other methods of family planning as soon as the six month period of protection has ended,16 and it is therefore conceivable that using lactational amenorrhoea may increase subsequent use of contraception.19

> PAUL FA VAN LOOK Associate director

UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction, World Health Organisation, 1211 Geneva 27, Switzerland

- Consensus statement. Breastfeeding as a family planning method. Lancet 1988;ii:1204-5.
 Kennedy KI, Rivera R, McNeilly AS. Consensus statement on the use of breastfeeding as a family planning method. Contraception 1989;39:477-96.
 Kennedy KI, Visness CM. Contraceptive efficacy of lactational amenorrhoea. Lancet 1992;339:227-30.

BMJ VOLUME 313 12 OCTOBER 1996

- ewis PR, Brown JB, Renfree MB, Short RV. The resumption of ovulation and menstruation in a well-nourished population of women breastfeeding for an extended period of time. Fertil Steril 1991:55:529-36.
- 5 Díaz S, Aravena R, Cárdenas H, Casado ME, Miranda P, Schiappacasse V, et al. Contraefficacy of lactational amenorrhea in urban Chilean women. Contraception
- 6 Kazi A, Kennedy KI, Visness CM, Khan T. Effectiveness of the lactational amenorrhoea method in Pakistan. Fertil Steril 1995;64:717-23.
- 7 Ramos R, Kennedy KI, Visness CM. Effectiveness of the lactational amenorrhoea method in preventing pregnancy in Manila, the Philippines. BMJ 1996;313:909-12
- 8 Gray RH, Campbell OM, Apelo R, Eslami SS, Zacur H, Ramos RM, et al. Risk of ovulation during lactation. Lancet 1990;335:25-9.
- 9 Díaz S, Miranda P, Cárdenas H, Salvatierra AM, Brandeis A, Croxatto HB. Relative contributions of anovulation and luteal phase defect to the reduced pregnancy rate of breastfeeding women. Fertil Steril 1992;58:498-503.
- 10 Short RV, Lewis PR, Renfree MB, Shaw G. Contraceptive effects of extended lactational amen-
- orrhoea; beyond the Bellagio consensus. *Lancet* 1991;337:715-7.

 11 Kennedy KI, Labbok MH, Van Look PFA. Consensus statement: lactational amenorrhoea method for family planning. Int J Gynaecol Obstet 1996;54:55-7.

- 12 Pérez A, Valdés V. Santiago breastfeeding promotion program: preliminary results of an intervention study. Am J Obster Gynecol 1991;165:2039-44.
- 13 Valdes V, Perez A, Labbok M, Pugin E, Zambeano I, Catalan S. The impact of a hospital and clinic based breastfeeding promotion programme in a middle class urban environment. J. Tropical Pediatrics 1993;39:142-51.
- The contraceptive potential of breastfeeding in Bangladesh. Stud Fam Plann 1993;24:1008
- 15 Cooney KA, Nyirabukeye T, Labbok MH, Hoser PH, Ballard E. An assessment of the nine-month lactational amenorrhea method (MAMA-9) in Rwanda. Stud Fam Plann
- 16 Labbok MH, Pérez A, Valdés V, Sevilla F, Wade K, Laukaran VH, et al. The lactational amenorrhea method (LAM): a postpartum introductory family planning method with policy and program implications. Adv Contracept 1994;10:93-109.
- 17 Pérez A, Labbok M, Queenan J. Clinical study of the lactational amenorrhoea method of family planning. Lancet 1992;339:968-70.

 Wade KB, Sevilla F, Labbok MH. Integrating the lactational amenorrhea method into a family
- planning program in Ecuador. Stud Fam Plann 1994;25:162-75.
- Winikoff B, Mensch B. Rethinking postpartum family planning. Stud Fam Plann 1991;22:

Barriers to evidence based policy

Health promotion in primary care changes again

This month the policy for health promotion by Britain's general practitioners is changing again, for the third time since 1990. Decisions about health promotion will now be devolved to local general practitioners and health authorities. Effective health promotion depends on a close relation between science and policy. However, these repeated policy changes, tenuously informed as they have been by scientific evidence, illustrate some of the barriers to this relation.1

In 1990 specified health promotion activities, such as threeyearly health checks and health promotion clinics, became part of the new general practitioner contract. The contract was widely criticised for its lack of scientific basis, and it caused an exponential increase in health promotion payments to general practitioners.2 In 1993 the government abolished health promotion clinics and three yearly checks and replaced them with the health promotion banding system. This was an improvement because it clearly identified health priorities (cardiovascular disease and stroke), but it put the emphasis on paying general practitioners for collecting data rather than for intervening.1 Continued dissatisfaction with the system has led to the latest changes. What does this case history show us about the failure of policy to reflect scientific evidence? There are three main issues: the complexity of the scientific evidence, the intricacies of the policy process itself, and the influence of political priorities.

The scientific evidence for health promotion is complex. Despite a huge amount of research on the prevention of cardiovascular disease and stroke in general practice, many questions remain unanswered, particularly regarding the effectiveness and cost effectiveness of primary prevention.³ Health promotion clinics were introduced without waiting for the results of two major trials that were already under way. 4 5 Moreover, when these were published the debate that followed showed that scientific results can be given widely differing interpretations.² ⁶ Even when a scientific consensus is reached, Britain has no explicit and systematic way of incorporating it into policy. This contrasts with the United States and Canada, where independent national bodies have been set up specifically to provide summaries of the scientific evidence on health promotion.⁷

At the centre of this debate is the actual process by which policy is formulated. For health promotion in general practice, the central policy making community is dominated by the General Medical Services Committee and by the branch of the NHS Executive concerned with the general practitioner contract. Inevitably negotiations are sensitive and secret, and general practitioners' pay is a major consideration. This makes for a closed process that is dominated by contractual matters and relatively inaccessible to scientific influences.9 While there are many other

bodies that have an interest in the prevention of cardiovascular disease in primary care—including the Royal College of General Practitioners, academic departments, and organisations such as the Coronary Prevention Group and the National Forum for Coronary Heart Disease Prevention—they have no direct influence on policy. This makes for a profusion of opinions but no single authoritative voice, leading to an informal and diffuse relation between science and policy.

A further aspect of the policy process concerns the role of medical civil servants. This group performs the crucial function of translating scientific evidence into policy advice to ministers. A recent review by the Department of Health recognises that good quality scientific advice depends on the calibre and organisation of medical civil servants.10 Factors such as frequent changes in post or lack of experience in a particular field may militate against good quality advice. As staff numbers in the Department of Health are being reduced, there is an increasing danger that medical civil servants will be overstretched and will lack the necessary expertise. Furthermore, a civil servant's primary duty is to serve ministers, and advice to ministers is confidential. This secrecy means that when there are policy failures it is difficult to distinguish between poor scientific advice by civil servants or poor decision making by politicians, perhaps influenced by political imperatives. 11

Political values may give higher priority to economic or electoral issues than to health or scientific validity. Such priorities have been influential in the development of health promotion policy for general practitioners. In 1990 the inclusion of health promotion in the new contract reflected a political view that prevention was popular and cheap. 12 This view was used to legitimise changes in the health service that were unpopular with the medical profession and for which the scientific evidence was limited. The emphasis on financial incentives as the best method of influencing clinical practice was another example of ideology prevailing over evidence in the late 1980s. When the 1990 contract had to be revised urgently, this again militated against strategic evidence-based thinking, this time because of the pressing need to control expenditure.

While it would be naive to suppose that policy can be independent of political influences, some changes at the national level could increase the evidence basis of policy. Firstly, scientific evidence is easier to ignore when there is no explicit consensus: an authoritative independent body providing consensual scientific advice on health promotion could provide a way of addressing both scientific uncertainty and the vagaries of politics. Secondly, the Department of Health needs to be more open: if the scientific evidence on which policy decisions are based was made clear, the scientific community could contribute more directly to the policy

894 BMJ VOLUME 313 12 OCTOBER 1996