- therapy as the baseline of management. *Otolaryngol Head Neck Surg* 1990;103(suppl):876-9.
- 17 Williams JW, Simel DL, Roberts L, Samsa GP. Clinical evaluation of sinusitis—making the diagnosis by history and physical examination. *Ann Intern Med* 1992;117:705-10.
 - 18 Druce HM. Diagnosis of sinusitis in adults: history, physical examination, nasal cytology, echo, and rhinoscope. *J Allergy Clin Immunol* 1992;90:436-41.
 - 19 Wilson NW, Jalowayski AA, Hamburger RN. A comparison of nasal cytology with sinus x rays for the diagnosis of sinusitis. *American Journal of Rhinology* 1988;2:55-9.
 - 20 Gill FF, Neiburger JB. The role of nasal cytology in the diagnosis of chronic sinusitis. *American Journal of Rhinology* 1989;3:13-5.
 - 21 Jannert M, Andreasson L, Holmer N-G, Lorinc P. Ultrasonic examination of the paranasal sinuses. *Acta Otolaryngol* 1982;389(suppl):1-51.
 - 22 Pfeiderer AG, Drake-Lee AB, Lowe D. Ultrasound of the sinuses: a worthwhile procedure? A comparison of ultrasound and radiography in predicting the findings of proof puncture of the maxillary sinuses. *Clin Otolaryngol* 1984;9:335-9.
 - 23 Spector SL, Lotan A, English G, Philpot I. Comparison between transillumination and the roentgenogram in diagnosis of paranasal sinus disease. *J Allergy Clin Immunol* 1981;67:22-6.
 - 24 Royal College of Radiologists Working Party. *Making the best use of a department of clinical radiology: guidelines for doctors*. London: RCR, 1993.
 - 25 Zinreich SJ. Paranasal sinus imaging. *Otolaryngol Head Neck Surg* 1990;103(suppl):863-9.
 - 26 Druce HM. Emerging techniques in the diagnosis of sinusitis. *Ann Allergy* 1991;66:132-6.
 - 27 Evans FO Jr, Syndor JB, Moore WE, Moore GR, Manwaring JL, Brill AH, et al. Sinusitis of the maxillary antrum. *N Engl J Med* 1975;293:735-9.
 - 28 Axelsson A, Grebelius N, Chidekel N, Jensen C. The correlation between the radiological examination and the irrigation findings in maxillary sinusitis. *Acta Otolaryngol* 1970;69:302-6.
 - 29 Kovatch AL, Wald E, Ledesma-Medina J, Chiponis DM, Bedingfield B. Maxillary sinus radiographs in children with non-respiratory complaints. *Pediatrics* 1984;73:306-8.
 - 30 Shankar L, Evans KL, Hawke M, Stammberger H. *An atlas of imaging of the paranasal sinuses*. London: Martin Dunitz, 1994. (£75.)
 - 31 Zinreich J. Imaging of inflammatory sinus disease. *Otolaryngol Clin North Am* 1993;26:535-47.
 - 32 Kennedy DW, Zinreich SJ, Rosenbaum AE, Johns ME. Functional endoscopic sinus surgery: theory and diagnostic evaluation. *Arch Otolaryngol Head Neck Surg* 1985;111:576-82.
 - 33 Havas TE, Motbey JA, Gullane PJ. Prevalence of incidental abnormalities on computerised scans of the paranasal sinuses. *Arch Otolaryngol Head Neck Surg* 1988;114:856-9.
 - 34 Shapiro MD, Som PM, MRI of the paranasal sinuses and nasal cavity. *Radiol Clin North Am* 1989;27:447-75.
 - 35 Zinreich SJ, Kennedy DW, Kumar AJ, Rosenbaum AE, Arrington JA, Johns ME. MR imaging of the normal nasal cycle: comparison with sinus pathology. *J Comput Assist Tomogr* 1988;12:1014-9.
 - 36 Som PM, Shapiro MD, Biller HF, Sasali C, Lawson W. Sinonasal tumors and inflammatory tissues: differentiation with MR imaging. *Radiology* 1988;167:803-8.
 - 37 Zinreich SJ, Kennedy DW, Malat J, Curtin HD, Epstein JI, Huff LC, et al. Fungal sinusitis: diagnosis with CT and MR imaging. *Radiology* 1988;169:439-44.
 - 38 Casiano RR. Azithromycin and amoxycillin in the treatment of acute maxillary sinusitis. *Am J Med* 1991;91(suppl 3A):27-30S.
 - 39 Camacho AE, Cobo R, Otte J, Spector SL, Lerner CJ, Garrison NA, et al. Clinical comparison of cefuroxime axetil and amoxycillin/clavulanate in the treatment of patients with acute bacterial maxillary sinusitis. *Am J Med* 1992;93:271-6.
 - 40 Qvarnberg Y, Kantola O, Salo J, Toivanen M, Valtanen H, Vuori E. Influence of topical steroid treatment on maxillary sinusitis. *Rhinology* 1992;30:103-12.
 - 41 Wilson R, Sykes DA, Chan KL, Cole PJ, Mackay IS. Effect of head position on the efficacy of topical treatment of chronic mucopurulent rhinosinusitis. *Thorax* 1987;42:631-2.
 - 42 Bergone-Berezin E, Berthelot G, Kafe H, Dournovo P. Influence of a fluidifying agent (bromhexine) on the penetration of antibiotics into respiratory secretions. *Int J Clin Pharmacol Res* 1985;5:341-4.
 - 43 Mabry RL. Uses and misuses of intranasal corticosteroids and cromolyn. *American Journal of Rhinology* 1991;5:121-4.
 - 44 Stammberger H. Endoscopic endonasal surgery—concepts in treatment of recurring rhinosinusitis—part I. Anatomic and pathophysiologic considerations. *Otolaryngol Head Neck Surg* 1986;94:143-7.
 - 45 Lund VJ. Inferior meatal antrostomy. Fundamental considerations of design and function. *J Laryngol Otol Suppl* 1988;15:1-18.
 - 46 Messerklinger W. *Endoscopy of the nose*. Baltimore, MD: Urban and Schwarzenberg, 1978.
 - 47 Stammberger H. Endoscopic endonasal surgery—concepts in treatment of recurring rhinosinusitis—part II. Surgical technique. *Otolaryngol Head Neck Surg* 1986;94:147-56.
 - 48 Huerter JV Jr. Functional endoscopic sinus surgery and allergy. *Otolaryngol Clin North Am* 1992;25:2311-8.
 - 49 Kennedy DW. Surgical update. *Otolaryngol Head Neck Surg* 1990;103(suppl):884-6.
 - 50 Lanza DC, Kennedy DW. Current concepts in the surgical management of chronic and recurrent acute sinusitis. *J Allergy Clin Immunol* 1992;90:505-10.
 - 51 Wigand ME. *Endoscopic sinus surgery of the paranasal sinuses and anterior skull base*. New York: Thieme, 1990:101-12.
 - 52 Stankiewicz JA. Complications of endoscopic intranasal ethmoidectomy. *Laryngoscope* 1987;97:1270-3.
 - 53 Gamble RC. Acute inflammation of the orbit in children. *Arch Ophthalmol* 1933;10:483-97.
 - 54 Patt BS, Manning SC. Blindness resulting from orbital complications of sinusitis. *Otolaryngol Head Neck Surg* 1991;104:789-95.
 - 55 Stammberger H. *Functional endoscopic sinus surgery*. Philadelphia: Decker, 1991:398-427.
 - 56 Schwietz LA, Gourley DS. Allergic fungal sinusitis. *Allergy Proc* 1992;13:3-6.
 - 57 Lin PT, Bukachevsky R, Blake M. Management of odontogenic sinusitis with persistent oro-antral fistula. *Ear Nose Throat* 1991;70:488-90.
 - 58 Muntz HR, Lusk RP. Bacteriology of the ethmoid bullae in children with chronic sinusitis. *Arch Otolaryngol Head Neck Surg* 1991;117:179-81.
 - 59 Wald ER, Milmo G, Bowen AD, Ledesma-Medina J, Salamon N, Bluestone C. Acute maxillary sinusitis in children. *N Engl J Med* 1981;304:749-54.
 - 60 McMahon JT. Paranasal sinusitis—geriatric considerations. *Otolaryngol Clin North Am* 1990;23:1169-77.
 - 61 Kulber DA, Santora TA, Shabot MM, Hiatt JR. Early diagnosis and treatment of sinusitis in the critically ill trauma patient. *Am Surg* 1991;57:775-9.
 - 62 Cho SY, Choi HY. Opportunistic fungal infection among cancer patients: a ten-year autopsy study. *Am J Clin Pathol* 1979;72:617-21.
 - 63 Kavanagh K, Hughes WT, Parham DM, Chanin LR. Fungal sinusitis in immunocompromised children with neoplasms. *Ann Otol Rhinol Laryngol* 1991;100:331-6.
 - 64 Godofsky EW, Zinreich J, Armstrong M, Leslie JM, Weikel CS. Sinusitis in HIV-infected patients: a clinical and radiographic review. *Am J Med* 1992;93:1163-70.
 - 65 Grant A, von Schoenberg M, Grant HR, Miller RF. Paranasal sinus disease in HIV antibody positive patients. *Genitourin Med* 1993;69:208-12.

Use of personal medical records for research purposes

Nicholas Wald, Malcolm Law, Tom Meade, George Miller, Eva Alberman, John Dickinson

The established practice of doctors using medical records for research purposes is threatened by the recent proposed guidelines from the Department of Health, the BMA, and the European Commission. The European Commission has proposed that explicit consent should be obtained from each patient before his or her medical records can be used; the proposals from the Department of Health and the BMA would require all research that needs access to personal medical records to be submitted to an ethics committee. We believe that these proposals would seriously impair an entire category of research and suggest therefore that another set of guidelines, proposed by a Royal College of Physicians' working group, should be used to modify the proposals. The guidelines of the working group encourage the use of medical records for research and ensure that such use can be made in a confidential manner without causing harm.

The use of medical records for research purposes is a longstanding practice by doctors of virtually all specialties. The value of such a practice has been

immense. It is now under threat from proposed guidelines issued by the Department of Health,¹ from a draft bill governing use and disclosure of personal health information produced by the BMA's Multi-disciplinary Professional Working Group,² and a draft data protection directive (SYN 287) from the European Commission. Safeguards to protect the confidentiality of financial and other personal details from unauthorised access by public authorities are being uncritically extended to cover medical records held by doctors.^{1,2} An entire category of research, which can identify, for example, the side effects of drugs, the effects of toxic substances in the environment, or the safety of medical procedures, would be seriously impaired.

Background

The use of medical records for research purposes has usually taken two forms: systematic record review and what might be termed "record linkage." Systematic record review is commonplace, carried out, for example, on a consecutive series of patients with

Wolfson Institute of Preventive Medicine, Medical College of St Bartholomew's Hospital, London EC1M 6BQ
 Nicholas Wald, professor
 Malcolm Law, reader
 Tom Meade, professor
 George Miller, senior clinical scientist
 Eva Alberman, professor emeritus
 John Dickinson, professor emeritus

Correspondence to: Professor Wald.

BMJ 1994;309:1422-4

the same diagnosis to identify the prevalence of characteristic clinical features, response to treatment, or factors influencing prognosis. Record linkage entails collating medical information from separate sources on individual patients identified by name and date of birth to seek, for example, an association between a drug and a disease. Probably every hazard that we know of has required access to medical records, often with the details of the exposure kept in one place and the details of outcome in another, requiring a formal link between the two. The associations between taking oestrogens in pregnancy and cancer,³ ionising radiation and leukaemia,^{4*} and use of oral contraceptives and venous thrombosis⁵ were all documented in this way. Recently, the risk of limb reduction defects associated with chorionic villus sampling in early pregnancy was identified through linking records.⁶ Such work can also provide reassuring information on the safety of medical procedures—for example, confirmation that amniocentesis does not cause clubfoot.⁷ The comparison of the results of blood tests from pregnant women with and without specified congenitally malformed fetuses has led to the development of antenatal screening tests.^{8*} For these purposes the personal identification of records is essential for collation, and the systematic review of medical records is impractical without sight of the name of the person to whom they relate.

The importance of personal medical records for research cannot be overestimated. Their use forms a regular part of medical practice, often leading to important discoveries. Such research often arises because an alert doctor with a hunch contacts colleagues. Examining different sets of records that relate to the same patients may clarify the position. Often no discovery results from the enquiry, but occasionally an important finding arises. Such activity is regularly carried out by clinicians, pathologists, epidemiologists, and anyone directly involved in preventing or treating disease who seeks to improve health or the quality of medical practice and is undertaken in confidence on the understanding that the patient will not be contacted. There is, therefore, no possibility of harm, and much opportunity for good.

Proposed guidelines on use of personal records

The European Commission has proposed in its draft directive that explicit patient consent should be obtained before each record can be used, a rule so stringent that this kind of research would probably stop altogether. Even the longitudinal survey carried out by the Office of Population Censuses and Surveys could be under threat from such legislation. Often tens of thousands of records have to be examined to look for clues, and it would be impractical and sometimes impossible to approach everyone. Not uncommonly, the individuals are unavailable or dead. Even if it were practical to approach each individual before a possible association were investigated, this may cause unnecessary anxiety as in most cases the research does not confirm a link between an exposure and disease.

Other guidelines, notably those recently proposed by the Department of Health¹ and the BMA,² are less draconian but are none the less unnecessarily restrictive. They require all applications for support for research using systematic record review or record linkage to be approved by an ethics committee. As in most cases such research may amount to little more than two or three doctors communicating about their patients, prior submission to an ethics committee would introduce an unreasonable barrier to what would otherwise be normal professional interchange. In many cases such exchanges would not even be contemplated if the doctors had to submit a formal application for permission to proceed, particularly when the

hunch on which the proposed work is based is tenuous. This would be disastrous, because many important findings have arisen from initially fragile ideas. Indeed, we go further in saying that provided no one is harmed a positive professional duty exists to encourage such activity because doctors have an obligation to extend knowledge and improve medical practice by examination of their collective experience.

Threat to research

Two factors explain the threat to record based research. Firstly, the examination of medical information for research purposes by doctors has unwittingly been included in an all embracing legislation regulating the transfer of personal, financial, social, and criminal details. Secondly, the term "confidential" has been interpreted in an extreme and rigid manner. In practice, degrees of confidentiality exist. At the most restrictive level information given by a patient to a doctor can be divulged to no one else. This is so restrictive as to render the communication useless in all but the most exceptional cases. A doctor can rarely be fully effective acting as a sole agent; usually the information must be shared with colleagues for the patient to benefit—for example, when requesting special tests or arranging treatment. The exchange of information among colleagues can also lead to knowledge that may benefit other patients. In practice, the duty of confidentiality is interpreted as applying not only to the doctor directly involved in the care of the patient but also to those with whom he or she judges the information may be shared; there is, in effect, a professional duty of collective confidentiality. Provided that collective confidentiality is practised no harm will come to the patient and no reasonable objection can be made as it is only through a breach of confidentiality that any harm could arise.

Once the sense of sharing personal medical information among doctors—subject to a strict duty of collective confidentiality—is accepted, it becomes irrelevant whether the activity is for research, teaching, or care. The only relevant issue is to ensure that the collective confidentiality is secure and that no breach occurs that could in any way adversely affect the individuals concerned.

A working group of the Royal College of Physicians has published a report¹⁰ that sets out guidelines that encourage the use of medical records for research and ensure that this be done in a confidential manner without causing harm. The guidelines state:

Research involving access to medical records, registers, or existing biological samples only, *without direct patient involvement*, is not considered to require individual patient consent or independent ethical approval *provided that*:

- i) explicit consent to access a person's records is obtained either from the official custodian of the records or from the patient's clinician: the decision to access personal medical information should not be left to the sole discretion of the investigator.
- ii) the recipient of the information is a senior professional person (eg a consultant medical practitioner or a principal in general practice) who may be disciplined by his or her professional body over any breach of confidentiality.
- iii) confidentiality is assured through exercising professional ethical codes of conduct.
- iv) anonymity is assured in any report or publication.

The proposals from the BMA and the Department of Health are open for discussion. We believe that they should be modified in line with the guidelines proposed by the Royal College of Physicians' report. This would permit a safe and well established type of medical research and would safeguard confidentiality. It would well serve the interests of patients and the public.

- 1 Department of Health. *Consultation document: confidentiality, use and disclosure of personal health information*. London: DoH, 1994.
- 2 Beales D. Draft bill aims at improving confidentiality. *BMJ* 1994;309:360.
- 3 Beral V, Colwell L. Randomised trial of high doses of stilboestrol and ethisterone in pregnancy: long term follow up of mothers. *BMJ* 1980;281: 1098-101.
- 4 Court Brown WM, Doll R. *Leukaemia and aplastic anaemia in patients irradiated for ankylosing spondylitis*. London: HMSO, 1957.
- 4a Court Brown WM, Doll R. Mortality from cancer and other causes after radiotherapy for ankylosing spondylitis. *BMJ* 1965;iii:1327-32.
- 5 Vessey MP, Doll R. Investigation of relation between use of oral contraceptives and thromboembolic disease. *BMJ* 1968;ii:199-205.
- 6 Firth HV, Boyd PA, Chamberlain PF, MacKenzie IZ, Morriss-Kay GM, Huson SM. Analysis of limb reduction defects in babies exposed to chorionic villus sampling. *Lancet* 1994;343:1069-71.
- 7 Wald NJ, Terzian E, Vickers PA, Weatherall JAC. Congenital talipes and hip malformation in relation to amniocentesis: a case control study. *Lancet* 1983;ii:246-9.
- 8 Wald NJ, Brock DJH, Bonnar J. Prenatal diagnosis of spina bifida and anencephaly by maternal serum alpha-fetoprotein measurement. *Lancet* 1974;ii:765-7.
- 9 Cuckle HS, Wald NJ, Lindenbaum RH. Maternal serum alpha-fetoprotein measurement: a screening test for Down syndrome. *Lancet* 1984;ii: 926-9.
- 10 Working Group to the Royal College of Physicians Committee on Ethical Issues in Medicine. Independent ethical review of studies involving personal medical records. *J R Coll Physicians Lond* 1994;28:439-43.

(Accepted 15 November 1994)

The World Health Organisation

WHO in crisis

Fiona Godlee

This is the first in a series examining the role of the World Health Organisation, its current problems, and its future prospects

Media attention has been focused on the leadership of the World Health Organisation, rather than on the real factors that limit WHO's effectiveness. These factors relate to the organisation's structure and also to its current priorities, methods, and management. This article examines the objectives and strategy of WHO in view of financial constraints and donor countries' demands; WHO's stated goal of integrated primary health care; staff morale; and the growing dislocation between the regions and headquarters.

The World Health Organisation has an image problem. People know that it exists, and most people know that it eradicated smallpox, but few have a clear idea what it does. Of those I have spoken to, some think it is a sort of world medical association, others see it only as a source of standard technical medical reports, yet others as just another faceless United Nations body where overpaid bureaucrats carve out their careers. Some politicians and doctors in Britain see it as meddling in public health matters that need not concern it when it should be concentrating its efforts on the developing world. Doctors in the developing world respect the WHO for its technical advice and support but criticise the waste of money on salaries and bureaucracy. Its slogan "Health for All by the Year 2000" has entered the international vocabulary, but few people, apart from diehard enthusiasts in the organisation, believe the target can be realised or understand how WHO intends to achieve it.

The media woke up to WHO last year when political and financial scandal seemed set to erupt over the re-election of its director general, Dr Hiroshi Nakajima. The outcome of an external audit fell short of media hopes; it found financial mismanagement and misuse of the organisation's funds but they cleared the director general of any involvement.¹ Amid the reportage of seedy dealings and the repetition of mainly unsubstantiated stories, the real factors that limit WHO's effectiveness received little attention.

It is these factors that I will be exploring in the next few weeks. They relate mainly to the structure of the organisation but also to its current priorities, methods, and management. In order to understand its problems, I have spoken to staff at WHO, former staff, diplomats, civil servants, politicians, and doctors. I have interviewed the director general and attended the annual meeting in Geneva of WHO's governing body, the World Health Assembly. I have also visited two of

the regional offices, in Delhi and Copenhagen, and interviewed five of the six regional directors. In this article I will summarise the main criticisms of WHO, first describing its objective and strategy.

Objective and strategy

WHO's objective, as laid down when the organisation was founded in 1948, is "the attainment by all people of the highest possible level of health," where health is defined as complete physical, mental, and social wellbeing and not just the absence of disease and infirmity.² WHO's strategy is to act through member states, advising their governments on technical matters, financing the training of local health professionals, and trying to influence health policy decisions.

WHO does not, except with rare exceptions, intervene directly in health care provision or disease prevention—a strategy designed to avoid charges of imperialism and ensure that developments are sustainable in the long term. But this strategy presents the organisation with important problems. Not only is it a major source of misunderstanding (WHO is frequently criticised for its lack of activity "in the field," to which staff reply wearily that "that is not the WHO's role") but it means that WHO has no direct powers to improve people's health. Its success relies entirely on the receptiveness and effectiveness of national governments and the fidelity with which other agencies like Unicef translate its principles into action.

Financial constraints and donors' demands

WHO's activities are seen by many as disparate and uncoordinated. They range over the whole gamut of health issues, from major threats to life such as AIDS and tuberculosis to lesser threats like oral disease. WHO remains committed to what it calls the "full menu" approach and aims to encompass all aspects of health care. Critics say, however, that there is little logic to how resources are allocated and that diseases of the developed world take up a disproportionate amount of WHO's time and money.³ Donors would like to see WHO focus its attention on a smaller number of essential programmes mainly in the developing world, and they are calling for WHO to set itself clearer priorities in keeping with its limited resources.⁴

WHO is suffering the same financial straits as the rest of the United Nations. Unpaid contributions, largely from the former Soviet Union but also from the

British Medical Journal,
London WC1H 9JR
Fiona Godlee, assistant editor

Correspondence to:
Department of Ambulatory
Care and Prevention,
Harvard Medical School,
126 Brookline Avenue,
Boston, MA 02215, USA

BMJ 1994;309:1424-8