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MMR: Science and Fiction. Exploring the Vaccine Crisis

Richard Horton

Granta Books, £7.99, pp 220 ISBN 1 86207 764 9 www.granta.com

Rating: ★★★★

MMR and Autism: What Parents Need to Know

Michael Fitzpatrick

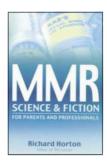
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Rating: ★★★★

The publication in 1998 of an article in the Lancet proposing a new syndrome of autistic enterocolitis should have attracted little publicity (Lancet 1998;351:637). The authors, researchers at the Royal Free Hospital, stated clearly in the article that "We did not prove an association between measles, mumps, and rubella [MMR] vaccine and the syndrome described." However, the first author surprised his colleagues by suggesting at a subsequent press conference that children should be offered the three vaccines individually with an interval of a year between each dose. This, unlike the article, was "news." The ensuing media frenzy resulted in a fall in uptake of the vaccine and led directly to the current real threat of large outbreaks of measles in the United Kingdom.

These two books, written by supporters of the vaccine, describe the MMR story and its context. Although both authors are doctors who have played a major part in events, the accounts are written from very different perspectives. Richard Horton, as editor of the *Lancet*, could be said to deserve some of the blame for the current situation. Michael Fitzpatrick, on the other hand, is a general practitioner in north London and father to a son whose autism began to manifest itself a few months after receiving the MMR vaccine.

Fitzpatrick describes how in the 1990s "popular confidence in science, medicine and government was already running low and anxieties over health issues were running high." At the same time as people were turning away from conventional medicine, the media and complementary practitioners were blaming "immune dysfunction"





for an increasing number of disorders. This was all fertile ground for the rapid growth of a scare story. The *Lancet* paper was the necessary seed.

As a result of the MMR story, many parents are once again being made to feel responsible for their child's condition—in this case, by accepting the MMR vaccine. Meanwhile, other parents are nervously watching their healthy MMR vaccinated children for signs of autism. This is an additional but little recognised consequence of the health scare that has caused immense grief and anxiety to some parents.

Richard Horton, as editor of the *Lancet*, could be said to deserve some of the blame for the current situation

Michael Fitzpatrick points out that the original "science" behind the *Lancet* paper was poor, and was recognised at the time to be so in an accompanying commentary by Robert Chen and Frank DeStefano. Richard Horton, on the other hand, makes a lot of the revelations earlier this year that one of the researchers had received funding from the then Legal Aid Board to ascertain whether the children's problems were a result of the vaccine. This, he claims, throws into question the validity of the original paper and casts doubt on the selection of the children included in the study.

However, the potential bias had already been clearly pointed out in the commentary at the time. More importantly, Chen and DeStefano had voiced concerns about the potential effect of this paper on public confidence in the vaccine and the consequences that might result. Although subsequent events have not been quite as bad as they predicted, their final statement has unfortu-

nately proved to be well founded: "This painful history was shared by the UK (among others) over pertussis in the 1970s after another similar case-series was widely publicised, and it is likely to be repeated all too easily over MMR. This would be tragic because passion would then conquer reason and the facts again in the UK."

Richard Horton proposes the setting up of an independent body-National Agency for Science and Health (NASH)-to act as a forum in which to "debate and judge conflicting evidence concerning the health effects and ethical implications" of many of the contentious issues of what is essentially public health. He is also very sympathetic to concerns about supposed conflicts of interest in this story, referring to "The Dawn of McScience," and suggests the setting up of a Council for Research Integrity. However, to concentrate on the financial conflicts so much is probably too simplistic as for most researchers this is a minor consideration. Much more important is the esteem in which they are held by their colleagues and a genuine desire to do good for their fellow man. Sometimes the former may get out of hand and a rush for publications of low quality may result, but fraud is still uncommon. As Horton so rightly points out, without any trace of irony, the peer review system is not perfect, but he does not really come up with a better option. It is debatable whether the setting up of more bodies will help significantly.

Both books offer a useful and interesting insight into the MMR vaccine story. If you had to choose only one to read which would it be? For parents it has to be Mike Fitzpatrick's. For healthcare professionals, his account is probably still the more valuable, but if you want an insight into medical publishing it has to be Richard Horton's. While we would not agree with everything either of them says, we recommend reading both.

David Elliman consultant in community child health, Islington Primary Care Trust and Great Ormond Street Hospital, London EllimD@gosh.nhs.uk

Helen Bedford *lecturer in children's health, Institute of Child Health, London*

Competing interests: DE and HB have in the past received funding from vaccine manufacturers Wyeth, Aventis Pasteur MSD, and GlaxoSmith-Kline to attend symposiums and conduct research.



US media needled over flu vaccine shortage

n outbreak of feverish media coverage has been unleashed upon the United States. "We're facing the prospect of a major epidemic," says Dr Arthur Kellermann, of the American College of Emergency Physicians, who has been interviewed about the shortage of flu vaccine for no fewer than 14 television and print stories over the past few weeks.

Fifty million doses of flu vaccine, or around half of America's expected supply, were condemned on 5 October when British regulators found bacterial contamination at the Liverpool factory where they had been produced. Newspaper articles were quick to deliver the relevant statistics: only 60 million doses would be available in the United States, for the 90 million Americans deemed to be at "high risk" from the influenza virus.

"Scene by disheartening scene, the spectacle of a severe shortage of flu vaccine is unfolding around the country," wrote Denise Grady in the *New York Times*. Two days later, the ubiquitous Dr Kellermann appeared on a PBS broadcast to point out that "without swift action, the vaccine shortage could cripple our healthcare system."

Although the papers touted the "flu crisis" of 2004, few cases of the flu were actually reported. An article published on 18 October noted "scattered cases in seven states," but for the most part the news focused on what might happen once the flu season began in earnest. In years without vaccine shortages, as many as 36 000 Americans die from the flu, with 200 000 more hospitalised—and a diminished vaccine supply would put even more people at risk.

Once the crisis had been established, coverage turned to its secondary effects. Several elderly people required hospitalisation after spending hours waiting for a flu shot, and a 79 year old woman in San Francisco collapsed in line and died. A number of towns throughout the country have set up lottery systems for distributing the vaccine to those most in need—"We are hoping the public sees this as the most fair and equitable way to do this," one official told ABC News. And a set of proposed state laws would make it illegal for doctors to give vaccines to people not at risk for complications from the illness.

A bit of a scandal transpired when the *Chicago Tribune* reported that the entire Chicago Bears football team had been offered flu shots, but team officials now claim that only two players actually received the vaccine—and both have asthmatic conditions that place them at especially high risk. Every member of the Chicago Bulls basketball team had also been vaccinated before the shortage was announced.

While the federal Centers for Disease Control joined state legislatures in urging doctors to save flu shots for high risk patients, the Capitol's own attending physician, Dr John Eisold, urged all 535 members of Congress to get vaccinated, even if they were in good health. He argued that lawmakers—who shake a lot of hands, and often meet elderly and sick people—were at particular risk of getting infected and passing on the virus. News reports have identified at least eight members of Congress under the age of 65 and in good health who have received the vaccine, including House majority leader Tom DeLay.

Both of the presidential candidates have promised to forego vaccination this year, but each has used the vaccine shortage in their media campaigns. In public speeches and radio advertisements, Senator John Kerry has accused the president of jeopardising the lives of children, pregnant women, and elderly people. Members of the Bush administration have responded by using press conferences to blame the shortage on the excessive costs of medical malpractice insurance, which they say has pushed manufacturers out of the vaccine business.

The major newspapers have indulged in a great deal of introspection and sobering analysis of what went wrong. Warnings about the nation's vaccine supply have been pointed and frequent over the past few years, as the number of suppliers has diminished. America now receives almost all of its flu vaccine from two sources, while demand has quadrupled over the past decade. In contrast, the United Kingdom relies on five different suppliers.

A certain amount of resentment towards the British has also emerged in response to this disparity. An editorial in the *Chicago Sun-Times* under the headline "Brits too quick to close flu vaccine factory" accuses the British regulators of having been "nitpicky because they could afford to be... The British will not be facing needless disease and death this winter—Americans will"

Some of the news stories have pointed out that in most years the United States ends up with too much of the flu vaccine, and millions of doses end up being destroyed. Vaccination rates tend to be well below the national goal of 90%, especially among minority groups and people over the age of 65. Until now, health officials have had to work hard to raise awareness and increase demand for the flu shots among these groups.

"Most years at this time, we're begging people to come in," said the US surgeon general Richard Carmona. He went on to call the situation "an artificial crisis," caused by an increased demand resulting from all the publicity.

Carmona's claim suggests one story that hasn't yet appeared in the popular press: could all this publicity improve vaccination rates in the coming years? More to the point: will the flu crisis of 2004 end up saving American lives?

WHAT IF WE GAVE
AMERICA THE
FLU?

Cartoon from the Milwaukee Journal-Sentinel

Daniel Engber freelance journalist, Washington DC, United States engber@lehrer.ucsf.edu

PERSONAL VIEWS

Does evidence based medicine do more good than harm?

Do we even need

evidence that

evidence based

medicine works?

dvocates of evidence based medicine (EBM) have unleashed a huge move towards asking explicit questions, critical appraisal of the literature, finding and applying the best available evidence, and a rigorous quantitative approach to medicine. But does EBM do more good than harm?

If we argue that medicine needs to be evidence based, then logically we need evidence to support EBM. I have yet to find that evidence. It would be impossible to design a randomised study evaluating the cost effectiveness of EBM that would fulfil the criteria for qualifying as "evidence," because of the contamination that occurs from one case (doctor) to the next and because the sample size would need to be

enormous. Probably the only feasible study would be to measure the costs and (subjectively experienced) usefulness of different forms of continuing education that use an EBM approach and to compare them with a regular approach.

Do we even need evidence that EBM works? Some people say that the evidence in favour of using EBM is the evidence itself. Isn't it obvious that we should be well informed before we make a medical decision? I sometimes wonder why we needed a new movement to make this point. However, what EBM teaches is a set of skills to keep us up to date with the literature—and it is up to each one of us to adapt these skills to our personal needs. The steps of EBM should be considered aids and the checklists guides to help us think critically about what we read, but at the same time we need to remain critical of the approach itself.

The hierarchy of evidence suggested by EBM may not be justified and can be misleading. For example, a systematic review of a few small, poorly conducted, open randomised controlled trials is clearly not better than one large, well done, double blind trial. The hierarchy may not apply to the problem at hand. A randomised controlled trial is not the best way to determine rare side effects of a treatment: a case control or observational study is better. Randomisation is not always ethically justifiable. We can't randomise patients with end stage lung disease to transplantation and no transplantation arms, but we can model a control arm on the basis of data collected from patients on the waiting list for a donor organ. Sometimes requiring randomisation as evidence before an intervention is ridiculous: no study would compare plaster casts with expectant management for a fracture, even though the use of plaster casts is based solely on observational data. Finally, even a randomised study done according to state of the art methods can lead to spurious ridiculous results: a randomised controlled trial showed remote retroactive prayer to be effective (*BMJ* 2001;323:1450-1).

Research into causes of illnesses and prognoses is usually best done with cohort studies—lower in the EBM hierarchy of levels of evidence but vital to our understanding of disease. Evaluating diagnostic tests is most efficiently done with a cohort study and decision model; a randomised trial of diagnostic tests is justifiable only under certain circumstances. In fact, every type of study has a place, even the case report. The case report is where it all

begins: the equivalent of the time honoured method of teaching doctors during grand rounds. Published case reports focus on the rare and unexpected, but it is precisely these unexpected observations that lead us to question our beliefs and that

can lead to new ideas and developments.

Besides the negative effect that EBM can have on how we appraise the literature, we may waste resources through inappropriate research, especially randomised controlled trials, by blindly conforming to EBM's levels of evidence. Meanwhile patients are denied potentially beneficial treatment. We should make the best decision according to the best available evidence and not withhold treatment just because we lack a randomised controlled trial and a systematic review. Value of information analysis can show whether doing more studies on a particular problem will reduce uncertainty to the extent that the research costs are justified. If they are not justified the resources would be better spent elsewhere.

We need to keep in mind that EBM reflects a particular perception of how medical decisions ought to be made. Rational, quantitative decision making may be important-but patients and doctors are human beings, and human beings are by no means always rational. The most rewarding aspects of caring for patients are neither rational nor quantitative. Focusing too much on the rational and quantitative aspects of clinical problems-an inherent danger in EBM-can have a negative influence on the doctor-patient relationship and can erode the caregiver's role in providing "care" in the fullest and most human way possible. Patients need empathy and understanding in order to express their preferences, values, and fears. Evidence is not enough: we need to communicate with our patients, listen to

their concerns, elicit their values, be involved, really care about them. We also need to integrate the evidence with patients' values and preferences. Caring for patients is a complex process: it requires evidence, critical thinking, communication, judgment, intuition, and—most of all—tender loving care.

M G Myriam Hunink professor of clinical epidemiology and radiology, Erasmus MC, Rotterdam, The Netherlands m.hunink@erasmusmc.nl

Hit parade

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SEPTEMBER

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- 3 News: Study indicates nine risk factors explain most heart attacks BMJ 2004;329:527 6368 hits
- 4 Clinical review: Recent developments in Bell's palsy
 BMJ 2004;329:553-7
 5517 hits
- 5 Editor's choice: Is it better to be smart or stupid BMJ 2004;329 (25 September) 5510 hits
- 6 Editorial: Treating hypertension with guidelines in general practice BMJ 2004;329:523-4 5189 hits
- 7 Editor's choice: Why Britons should be grateful for the NHS

 BMJ 2004;329 (4 September)

 4467 hits
- 8 Clinical review: The journey: Parkinson's disease BMJ 2004;329:611-4

BMJ 2004;329:611-4 3756 hits

9 ABC of sexual health: Gender related disorders BMJ 2004;329:615-7 3744 bits

10 This week in the BMJ: Bell's palsy responds best to immediate treatment BMJ 2004;329 (4 September)

All articles cited are full text versions unless otherwise shown

NFTI INFS

- If you want to stay in touch with the big picture and catch up on the latest science stories, then look at the news service from the Nature Publishing Group (www.nature.com/news/index.html). This is an excellent digest, and any overlap with the BMf's own science news coverage is minor. Each story gets just a few lines of description on the main page, but by clicking on some stories (some are labelled premium content and require a subscription) you get the full account. As with all good news websites, there is a rapid rotation of stories. This is a heavyweight resource about news and breakthroughs in the world of science.
- If you are interested in stroke guidelines and "consensus statements," then check out the Internet Stroke Center (www.strokecenter.org/prof/ guidelines.htm). This is a huge compilation of links to resources dealing with the many aspects of stroke. Diagnosis, imaging, acute stroke, and prevention are just some of the areas covered. A simple click will take you to the origin of the recommended document.
- If you want an answer to the question "What is medical informatics?" then point your browser at the website of Oregon Health and Science University's department of medical informatics and clinical epidemiology (www.ohsu.edu/ dmice/whatis/index.shtml). This is a text based article that has been ideally adapted to the web, but it is not overloaded with words, and hypertext links are woven liberally throughout. The page is a treasure chest of material.
- Health professionals commonly use online textbooks to find the answers to clinical queries. A fine example of such a textbook is the General Practice Notebook (www.gpnotebook.co.uk/). Defining itself as a "UK medical encyclopaedia on the world wide web," it focuses on primary care, and its home page claims to offers 26 000 pages of material. This is a useful and free resource that has wide UK and international appeal.
- Information about the choice of pathology tests and-equally important—their interpretation is of huge use to a clinical audience. So the Royal College of Pathologists of Australasia's online manual (www.rcpamanual.edu.au/ default.asp) may be a handy port of call. The menu on the left hand of the home page allows easy access to the many facets of this deep and detailed database. The manual can be downloaded to PDAs (personal digital assistants) for Palm and Pocket PC operating systems.

Harry Brown general practitioner, Leeds DrHarry@DrHarry.co.uk

We welcome suggestions for websites to be included in future Netlines. Readers should contact Harry Brown at the above email address.

Evidence from samples of one

ersonal accounts of medical ordeals make illuminating contributions to the published literature on evidence. Left undocumented, the triumphs over cancer of Susan Sontag (Illness as Metaphor) and Michael Gearin-Tosh (Living Proof), the late Alice Trillin's battles with the aftermath of treatment for lung cancer (N Engl J Med 1981;304:699), and Lenore Manderson's account of a sudden onset of brachial plexopathy (Internal Medicine Journal 2002;32:353) might have been classified as "anecdotal evidence," for which evidence based medicine has little or no place. Some doctors do, however, use evidence from single case studies, gaining understanding of medical phenomena encountered in their social and ecological contexts.

The following brief summary of an ongoing longitudinal observation study of

"Observation only"

strategy—and one

case is not too few

is a legitimate

treatment

childhood idiopathic thrombocytopenic purpura (ITP) aims to contribute to this body of literature. Although case specific by nature, certain principles pertaining to medical decision making processes are likely to be transferable. The subject of this case

study happens to be my first born child, who had the disease diagnosed just before his third birthday. Symptoms of pronounced bruising and widespread appearance of petechiae had been a part of life as he knew it. I was therefore more relieved than shocked when the diagnosis was confirmed. By definition, idiopathic meant cause unknown, and that left me most concerned.

Our consultant haematologist presented me with two treatment options: steroids to (temporarily) boost his blood platelet count or "observation only," provided that he remained in reasonable health. I chose observation and promised to visit the consultant haematologist with my child every six months-or sooner in case of emergency. The consultant had seen other children with ITP. Some "grew out of it" and some didn't but were no longer in touch with him, having grown up. I quickly turned to complementary medicine-homoeopathy and osteopathy-in the hope of finding a cure. These proved helpful in controlling the unsightly bruising. The petechiae became a thing of the past, and my son's sense of wellbeing was restored. The platelet count remained the same, however, and we continued to visit the children's hospital twice a year for seven years. Our consultant haematologist remained friendly, open, and supportive. When we moved from old to New England in 2000 he released my son with a detailed referral note.

Our new paediatrician, concerned about the ITP, referred us to a specialist. In November 2000 my child and I found ourselves in a hospital haematology department, trying to make sense of the stark options presented to us: steroids or splenectomy. "Observation only" was no longer on offer. My preference to explore naturopathic medicine failed to impress the specialist. My son and I simply decided not to go back. Our primary care physician remained supportive.

The once very active toddler who bruised incessantly has now grown into a calm and handsome teenager who spends more time on the piano than on the soccer fields. He plays basketball, and that worried our doctor, a very thoughtful man, who urged me to "do something." I sought a second opinion and was pleasantly surprised by what the second recommended specialist had to say. This specialist addressed my son directly, instantly putting him at ease. He complimented my son for looking well and

happy. When I mentioned been managing was "fine."

that we had been scared into seeking his opinion he said he was there to "unscare" us. There was no need to remove the spleen, and several less aggressive options were open to us. He recognised that the way we had

In his written notes to the primary care physician (copied to me) he wrote: "Observation only is the name we would give to the strategy that has been used all these years. It is remarkably successful. Patients with low platelet count and ITP have much less risk of bleeding than patients with low platelet counts and other disorders. We list the desirable platelet counts for different sports at our website (www.ITPkids.org)." This particular specialist was also a member of the medical advisory board of a support group founded by a patient with ITP who underwent splenectomy to no avail.

Clearly, inquisitive patients may make effective use of evidence if the evidence exists in the first place and is comprehensible. Gearin-Tosh found authoritative medical evidence discouraging but was able to navigate around it. Sontag, on the other hand, used medical evidence together with faith in her chosen practitioners. Most lay patients do not have access to information and other resources available to Sontag and Gearin-Tosh, but they trust their doctors, as Alice Trillin did at first. Trillin's experience taught her "Don't just do something, stand there," which might have helped at the very beginning. "Observation only" is a legitimate treatment strategy-and one case is not too few, especially given that, even with large samples, absence of evidence is not necessarily evidence of absence (*BMJ* 2004;328:476–7).

Astier M Almedom medical anthropologist, Tufts University, Boston, Massachusetts astier-m.almedom@tufts.edu

Learning from evidence based mistakes

A promising

treatment is just

a disappointing

the larval stage of

guess it's safe to say I'm a diehard evidence enthusiast. It's essential to get as close to the truth as you can, especially through the tangled mix of commercial and power biases that so plague health information. But if we all paid more attention to the potential adverse effects of evidence based medicine (EBM) too, maybe there would be even fewer mistakes.

My first evidence based mistake came early in my involvement with EBM. When two of the member organisations of the consumer coalition I was involved with were set against each other because of a controversy, we did the evidence based thing. We turned to the systematic review to decide what stand we should take.

The subject? Bromocriptine for lactation suppression. One of our member groups demanded that we support a call for a ban of the drug for this indication, while another objected just as vehemently to removal of access. The systematic review concluded that the drug was

effective, with no concerning adverse effects. We didn't support the call for a ban, and we were wrong. The drug, it turned out, was causing serious harm, including deaths.

It was the first of many experiences of being led down the garden path by a systematic review because of absent or weak information on adverse effects. Typically, trials are powered for effectiveness and are fairly short term. This is not much help for determining adverse effects if they aren't common and the trials aren't very large. EBM has a long way to go before this problem is solved, although people are working on it.

Jumping to conclusions too soon is another cause of evidence based mistakes. This is a big bugbear of the leading experts in EBM, of course, and gets talked about quite a bit. But the message isn't getting through. Too many systematic reviews make judgment calls far too soon. This applies especially to reviews that speak of a "promising treatment"—a pure piece of emotionally exploitive marketing terminology if ever there was one; it should have no place in science. A promising treatment, I've learnt, is generally just the larval stage of a disappointing one.

Eventually, of course, EBM is self correcting. It is science, after all. Meanwhile, it can lead people astray. In 2001, for example, I fell for this problem of believing a too early conclusion yet again. A review came out on whiplash injury, which concluded that maybe "rest makes rusty" and perhaps we should think of holding off on those neck collars. An update in 2003, though, took it back the other way: neck collars may be the way to go after all. Bad luck for people with whiplash in the care of avid EBM enthusiasts

between 2001 and 2003. At least that time the harm was only sore necks. A few times a year, though, the reversal of evidence fortunes is about something life threatening.

Change in practice led by EBM enthusiasts often does a lot of good. But sometimes it causes harm, especially when people react every time that individual trial results become available. Recently I saw some data comparing the practice of hospitals in Canada that had participated in a multicentre international trial of carotid endarterectomy (surgery for blocked arteries in the neck) with hospitals that had not participated. The data were put forward as proof that getting into the heart of EBM and participating in trials was an effective way to

implement research results.

The trial enthusiasts and the other hospitals ended up with much the same levels of intervention. However, one group had spiked precipitously up and down as positive and negative trial results were published, while the other

group of hospitals had moved slowly and steadily to the same point. It is perhaps an article of faith, more than a matter of evidence, that the people being cared for by EBM enthusiasts are always better served.

A great characteristic of the EBM movement that attracts many of us is its critical nature and constant concern with improving methods. I wish, though, that the movement would ponder more explicitly the adverse effects of EBM itself and the way it presents itself.

EBM is a challenge to those with much money and power to lose by its advance. So I suppose it is understandable that many people in the movement focus on promotion and have a tendency to get defensive. But there's an excess of certainty, too—even some arrogance and snobbery about how the ordinary folk do things, with their attention to the evidence of their own eyes and to what others they respect are doing.

This attitude can get obnoxious and is itself causing adverse effects. It limits the spread of EBM. One of the consequences of hubris is that people aren't as keenly attuned to their own mistakes as they are to the errors of others.

Over time EBM should cause fewer mistakes than other options, especially profit driven medicine. The trouble is that people get hurt by the evidence based mistakes too—sometimes badly. We should be paying more attention.

Hilda Bastian head of department, patient information and research, Institut für Qualität und Wirtschaftlichkeit in Gesundheitswesen, Cologne, Germany hilda.bastian@iqwg.de

SOUNDINGS

Of free condoms

The *Lancet* has broadcast the ultimate socialist message: "The lesson: even in the world's richest country, the right price for condoms is zero" (*Lancet* 2004;364:13).

The first step will be the erection of thousands of condom factories, financed by the Bretton Wood Sisters—the International Monetary Fund and the World Bank.

The United Nations will need to discuss how to calculate the numbers of condoms required. Applying human rights criteria, every male capable of penile erection (including those who achieve this by means of mechanical props or chemicals) is entitled to condoms.

Of the six billion world citizens there are a little less than three billion males, and perhaps one and a half to two billion of these are capable of erection.

As to the annual requirement in sheathing this penile force, the Lancet should invite global studies such as "Cultural and health determinants of the frequency of coitus according to age sets." It can be assumed that the highest requirement occurs in the third decade in life when the annual demand can reach, in certain countries (such as Hungary), a thousand pieces. In the second decade erection is frequent, but, for the lack of opportunity and courage, coitus is not. The World Health Organization might advise young people to practise condom use when masturbating. From the fourth decade onwards the frequency of erection declines. It is unlikely that any male would be capable of more than 25 000 copulations in his life.

In what proportion of the grand total of penile exertion is it appropriate—to use President Bush's words—to use a condom? What proportion of the total takes place in stable monogamous or polygamous relationships, the only situations when condom use may not be required? More research is needed.

Condom distribution will be the duty of WHO. The UN will bear the cost of production. There is only one remaining problem: disposal. Without draconic legal measures, the world will be littered with discarded condoms within a decade, and every hole, natural or artificial, will be plugged up. Recycling may be an option. To encourage men to save and surrender used condoms they will have to be paid. One way to recover costs would be to find a use for the contents.

Imre Loefler editor, Nairobi Hospital Proceedings, Kenya