EXAMPLE

The event that most worries endoscopic surgeons is intraoperative vascular injury that leads to loss of a limb or death. We selected well known international reports of series of laparoscopic appendicectomies and cholecystectomies from the literature.³⁻¹⁵ None of them reported a major vascular injury with subsequent loss of a limb or death. We applied Hanley's rule of three to the data in the papers to calculate the upper limit of a 95% confidence interval for such an adverse event. The table shows the results of these calculations.

Discussion

Several conclusions can be drawn from the table. It is obvious that a small series of any procedure can say hardly anything about the safety of the technique. Even though a major vascular injury with subsequent loss of a limb or death never occurred, the statistical analysis shows that, depending on the study selected, there was the threat that it might occur in four out of every 1000 procedures or even 12 out of every 100. This makes statements like "laparoscopic appendectomy is the method of choice" premature or even irresponsible if they are based on single studies.

The non-occurrence of an adverse event in a surgical series does not mean that it cannot happen. It can, and the true rate of occurrence can be estimated from its 95% confidence interval. It is a good estimate of the worst case that is compatible with the observed data. The smaller the sample, the wider the confidence interval. This means that the upper limit of a confidence interval from a small sample is greater than that from a large sample, but this does not mean that the true probability of an adverse event occurring is larger in a small series.

Doctors and surgeons should keep this simple rule of three in mind when complication rates of zero are reported in the literature and when they have not (yet) experienced a disastrous complication in a procedure.

- 1 Troidl H, Bäcker B, Langer B, Winkler-Wilfurth. Fehleranalyse—Evaluierung und Verhütung von Komplikationen; ihre juristische Implikation. *Langenbecks Archive für Chirurgie Supplement Kongressbericht*. Heidelberg: Springer Verlag, 1993:59-72.
- 2 Hanley JA, Lippman-Hand A. If nothing goes wrong, is everything alright? *JAMA* 1983;259:1743-5.
- 3 Attwood SEA, Hill ADK, Murphy PG, Thornton J, Stephens RB. A prospective randomised trial of laparoscopic versus open appendectomy. *Surgery* 1992;112:497-501.
- 4 Kum CK, Ngoi SS, Goh PMY, Tekant Y, Isaac JR. Randomized controlled trial comparing laparoscopic appendectomy to open appendectomy. *Br J Surg* 1993;80:1599-600.
- 5 Hebebrand D, Troidl H, Spangenberger W, Neugebauer E, Schwalm T, Günther MW. Laparoscopic or conventional appendectomy? A prospective randomised trial. *Der Chirurg* 1994;65:112-20.
- 6 Frazee RC, Roberts JW, Symmonds RE, Snyder SK, Hendricks JC, Smith RW, et al. A prospective randomised trial comparing open versus laparoscopic appendectomy. *Ann Surg* 1994;219:725-31.
- 7 Tate JTT, Dawson J, Chung SCS, Lau WY, Li AKC. Laparoscopic versus open appendectomy: prospective randomised trial. *Lancet* 1993;342:633-7.
- 8 McAnena OJ, Austin O, Hederman WP, Gorey TF, Fitzpatrick J, O'Connell PR. Laparoscopic versus open appendectomy. *Lancet* 1991;338:693.
- 9 Pier A, Gotz F, Bacher C. Laparoscopic appendectomy in 625 cases: from innovation to routine. *Surg Laparosc Endosc* 1991;1:8-13.
- 10 Peters JH, Ellison EC, Innes JT, Liss JL, Nichols KE, Lomano JM, et al. Safety and efficacy of laparoscopic cholecystectomy. *Ann Surg* 1991;213:3-12.
- 11 Troidl H, Spangenberger W, Langen R, Al-Jaziri A, Eypasch E, Neugebauer E, et al. Laparoscopic cholecystectomy. Technical performance, safety, and patient benefits. *Endoscopy* 1992;24:252-61.
- 12 Collet D, Edye M, Perissat J. Conversions and complications of laparoscopic cholecystectomy. Results of a survey conducted by the French Society of Endoscopic Surgery and Interventional Radiology. *Surg Endosc* 1993;7:334-8.
- 13 Cuschieri A, Dubois F, Mouiel J, Mouret P, Becker H, Buess G, et al. The European experience with laparoscopic cholecystectomy. *Am J Surg* 1991;161:385-7.
- 14 Larson GM, Vitale GC, Casey J, Evans JS, Gilliam G, Heuser L, et al. Multipractice analysis of laparoscopic cholecystectomy in 1983 patients. *Am J Surg* 1992;163:221-6.
- 15 The Southern Surgeons Club. A prospective analysis of 1518 laparoscopic cholecystectomies. *N Engl J Med* 1991;324:1073-8.

(Accepted 15 June 1995)

New broom at the top? An interview with Anders Milton, the chairman of the World Medical Association's Council

Douglas Carnall

The week long annual assembly of the World Medical Association opens in Bali next week. The WMA has been through long years of internal conflict associated with the continuing membership of the South African Medical Association and wrangles over finance, and the question that observers of the assembly must address is: has the WMA finally turned a corner, or are there still questions over its relevance to ordinary doctors? Douglas Carnall talked to Anders Milton, the chairman of its council, about the work of the WMA and his vision of its future.

Dr Milton was born and brought up in Sweden and studied for a degree in economics before turning to medicine. He was appointed to the staff of the University Hospital at Uppsala as a nephrologist on completing his PhD. Four years ago he gave up his clinical work to become the full time secretary general of the Swedish Medical Association. He was elected chairman of the council of the WMA in April of this year.

DC: Why do doctors need the WMA?

AM: Doctors are all members of one of the classic professions. A profession is defined by two qualities: firstly, it defines its own area of work, and, secondly it has its own ethics. Medicine has had its own ethical guidelines since the time of Hippocrates, the basic rule being that you should not harm your patients—do good and not bad. However, during the second world

Anders Milton, the WMA's new chairman of council

war some doctors in some countries engaged in "scientific" research on or pure torture of both civilians in concentration camps and prisoners of war. After the second world war it was felt that this should not happen again, and a number of medical associations decided to form a world body that would define and promulgate medical ethics throughout the world, while ensuring that free medical associations would not let their members become part of an oppressive state apparatus. A doctor's first duty is to his or her patients, and he or

About the WMA

The chairman of the council is the political figurehead of the organisation, with responsibility for all its activities. The council is elected on a regional basis by individual member associations, and associations with more than 50 000 members automatically have a seat on the council. Each region also has one representative. The chairman of the council is elected by the members of the council. The secretary general runs the organisation between meetings, having similar responsibilities to the secretary of the BMA.

The WMA's secretariat was established 20 years ago in Freney-Voltaire, across the French border from Geneva. Its location enables close contact with the headquarters of the World Health Organisation, while taking advantage of France's less expensive economy.

she should not lend medical knowledge to achieve other goals. You need to have free and independent medical associations that have the power to say no to governments when they ask doctors to do things that are contrary to their ethical beliefs. And since 1947 this is what the WMA has been doing—medical ethics. All of the internationally accepted ethical declarations that guide the profession worldwide stem from the WMA. We provide ethical guidance on conduct in times of armed conflict, resource allocation, confidentiality, and a whole range of other issues.

DC: Can you point to practical examples in which the World Medical Association's actions have been of assistance to doctors?

AM: The governments of countries in conflict often want to use doctors in a partisan manner, rather than allowing them to act neutrally, treating both sides, and that's where the WMA can help. One example was in Peru, where 26 000 people have died as a result of the civil war that started in 1980. The government decided that doctors should not treat sick or wounded people who were believed to be members of the Sendero Luminoso, the main opposition group. But of course doctors were doing that anyway, because their duty was to the wounded. Some 30 doctors were imprisoned with sentences of up to 20 years—solely because they had worked as doctors and not even because they were in political sympathy with the opposition. For example, one doctor had delivered the baby of a woman who four years later became a Crown witness in a trial involving the Sendero Luminoso. She was asked who had delivered her baby, and the doctor was then imprisoned. Even if he had been aware at the time that she was a member of a terrorist organisation, he would still have been right to deliver her baby. So Ian Field and I went to Peru last December and helped to get some of the doctors released from prison. The sentences of others are to be reviewed, and we are in contact with the Peruvian Medical Association to make sure that this happens.

A similar situation arose in Chile when General Pinochet was president and there was armed conflict in the country. The government said that doctors were not to treat suspected members of the opposition, and the doctors refused to cooperate with this. The government then imprisoned the entire council of the Chilean Medical Association. The Secretary General of the WMA at that time, Dr André Wynen, who is a Belgian surgeon, flew to Chile and got them out. In Turkey a few years ago the government told doctors that they were not to treat Kurds suspected of participating in the Kurdish separatist movement, and when the Turkish Medical Association refused to cooperate with this, its whole council was imprisoned. The intervention of the WMA was instrumental in having them released.

DC: What can you do about doctors who are being asked to participate, willingly or otherwise, in capital punishment or torture?

AM: The WMA's position on this is quite clear. Doctors should not participate in inhuman treatment of prisoners or in capital punishment or in removing body parts, regardless of whether it is a decision by a court of law. Whenever an example comes to our attention, we contact the local medical association and tell them that we will stand by them in resisting participation. If they are not willing to take this action themselves, we will intervene by publicising the situation and ostracising the doctors involved. Even if we do not have any power over individual doctors, we can certainly make it impossible for them to work in other countries and cut them off from the international medical community.

DC: One of the criticisms of the WMA has been that it has not achieved sufficient public exposure for its work. What are you doing to try to raise the profile of the organisation?

AM: We no longer have the political problem of the membership of the Medical Association of South Africa, which, though democratic, has only recently represented doctors in a democratic society. This was an obstacle for other African medical associations, which refused to join while South Africa was a member, and of course the British and Swedish Medical Associations left partly because of South Africa's membership. Now we can reach out to more countries. We want to ensure not only that the ethical declarations are taught at medical schools and discussed by practising doctors all over the world but that they are in daily use. There is a lot of work to be done in the newly independent states of eastern Europe, where there has not been a tradition of a free medical profession, to help doctors to establish truly independent medical associations.

DC: One of the obstacles to the poorer countries joining is the comparatively high cost of joining the WMA (2.5 Sw fr (£1.33) for each member). How do you address this?

AM: You are right to say that it is 2.5 Sw fr per member—but this is for each declared member. For example, the Indian Medical Association has declared only 100 members, though their total membership is far in excess of this. We have countries who declare only 10 members. The expensive part isn't joining, it's getting representatives to the meetings. We are a world organisation, and we have to have the meetings somewhere. If we hold them in Europe it's cheaper for the secretariat, translators, and so on, but it's a long way from Latin America and the Far East. Inevitably some members are going to have to travel a long way to the meetings.

DC: Your scientific programme has been criticised in the past for not including truly world class speakers. Is that something that you are hoping to address?

AM: Indeed. Ian Field [the secretary general of the WMA and former secretary of the BMA] and I have

The BMA and the WMA¹

The BMA first joined the WMA in 1948 as founder member. It left after a complex wrangle over a weighted voting system that permitted the readmission of the South African Medical Association in 1983, but it retained observer status. Last year the BMA rejoined, declaring its 51 000 full members, at an annual cost of £68 000. Four BMA leaders will attend the Bali assembly: Sandy Macara, Mac Armstrong, Vivienne Nathansen, and Jim Appleyard. Nigel Duncan, the BMA's head of public affairs, is also attending the meeting in his role as the WMA's press secretary.

KONNY DOMNAUER, SWEDEN

opened discussions for the meeting to be held in October 1996. By planning at least 18 months in advance we hope to have a very good programme with very good speakers, and we are seeking sponsorship from external organisations to enable our members to come.

DC: And where will that funding come from?

AM: We have approached the different UN bodies and other organisations interested in health care, in both the developing world and the developed countries.

DC: How many member organisations come to the meetings?

AM: Well it varies a lot, as does the size of the different delegations. The Japanese bring a large delegation, the Peruvians very few. The number of votes depends on the number of declared members, and some countries can afford to bring more members than they have votes to attend the scientific programme.

DC: The assembly of the WMA has been criticised in the past for spending a lot of time on irrelevant business, ceremony, and mutual congratulation.¹ What are you going to do to improve the business part of the assembly?

AM: I think we have done quite a lot already. The Nordic countries and Britain have just rejoined, and we agreed that the workings should be reformed so that they are more efficient, streamlined, cost effective, and to the point. The organisation is now directed towards obtaining results. In our scientific meetings we will address issues such as reproductive health and women's health, which are highly relevant to the developing countries. We will be addressing issues that are relevant, and we will be doing it in a cost effective way.

DC: Some of the delegates at the assembly in 1994 said that a lot of the paperwork for the meeting was of variable quality, which inhibited the standard of discussion and debate. What are you doing to improve the main business sessions of the assembly?

AM: We are setting up an executive, consisting of the chairman, the president, and the three subcommittee chairmen, who, together with the secretary general, will participate in the preparation for the meetings. This should improve the quality of the papers and the workings of the association. We plan to set up a structure analogous to a national medical association such as the BMA, with the same high standards and a smooth way of doing things. One of the current tasks of the WMA is to revise all the ethical declarations, so that

Programme of the WMA's 47th general assembly

This year's scientific session has the theme "Population policies, reproductive health, and family planning." The keynote addresses are from Professor Haryono Suyono, Indonesia's minister of population, Professor Pauline Makinwa-Adebusoye of the Nigerian Institute of Social and Economic Research, and Professor Jean-Bernard Truc of the Hôpitaux de Paris.

The business sessions of the assembly will consider membership applications from Ghana and Uruguay and statements on the prescription of opiate drugs, health promotion, mental illness, and ethical aspects of embryonic reduction (selective abortion of multiple pregnancies that ensue from in vitro fertilisation techniques).

A lengthy ceremonial opening session will include addresses from the Indonesian minister of health, Dr Sujudi; a valedictory address to the outgoing president, Professor P Kincaid-Smith; and an inaugural address by the incoming president, Dr J Moulin.

WMA declarations²

The 1948 Declaration of Geneva restated the Hippocratic Oath in modern terms and incorporated an international code of medical ethics. The 1964 Declaration of Helsinki provided a code of ethics for experimental research on human subjects. The 1975 Declaration of Tokyo is a set of guidelines explicitly stating that doctors' involvement in torture and other inhuman or degrading treatment of prisoners is not acceptable

the content is up to date and the language is relevant to today's issues.

DC: One of the criticisms that has been made of the assembly is that votes on ethical issues are determined by the number of declared members, which in turn depends on the resources available to the national medical associations. This seems rather unfair.

AM: That was one of the problems that the Swedish Medical Association raised before it rejoined the WMA. The statutes and bylaws have been changed so that votes on medical ethics require a 75% majority of all countries voting. This prevents the countries with large numbers of declared members from dominating the proceedings. However, votes on purely financial matters remain in proportion to the number of declared members.

DC: What are the goals of the WMA in the future?

AM: Sixty five national medical associations are currently members of the WMA. We need to develop a broader membership to ensure that the declarations of the WMA are implemented all over the world.

DC: What are the practical things that members of the BMA can do to help with this process?

AM: The local divisions of the BMA should ensure that when they raise ethical issues and problems nationally those concerns are also raised at the WMA. We need that input from all member associations. The fact that the BMA is a stable and well organised body is important to us. It has staff and resources and a good track record on promoting ethical issues.

DC: You mentioned that the WMA is updating its declarations at the moment. Are there new subjects that you plan to cover in the future?

AM: One of the things that the executive will do is to consider whether there are new subjects that should be covered. New technologies present new ethical challenges, which are not as simple as those traditionally covered by medical ethics.

DC: Do you aspire to broadening the scope of the WMA's work into areas that are not specifically medical? For example, the BMA has debated motions calling for governments to end the manufacture of land mines in the European Union.

AM: Yes, we have debated the land mine issue. In another example, medical knowledge has been used in the development of weapons that are designed to blind enemy troops, which is wrong. I believe that the WMA should promote ways of resolving conflicts without resort to violence, and when violence is used, it should be restricted in some ways. We should also be taking a stance on labour issues, such as the employment of children in industry or as slave labour. As the world becomes more integrated, we shall have to demand that social and medical standards are kept fair and equal in the world.

1 Richards T. The World Medical Association: can hope triumph over experience? *BMJ* 1995;308:262-6.

2 *Medical ethics today: its practice and philosophy*. London: BMJ Publishing Group, 1993: appendices 2,3,4.