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Reviews of books and studies

Health Devices Sourcebook. Philadelphia: ECRI, 1990, $ 165.
Health Care Standards Directory. Philadelphia: ECRI, 1990, $ 245.

ECRI is a non-profit organization which distributes information on medical devices and related matters in the USA and Canada, both through its reference books and using electronic channels. The *Health Devices Sourcebook* is described as a "directory of medical devices, trade names, manufacturers and service companies", and it sets out to provide all the basic data required by a potential purchaser of a device. Its twelve sections provide rapid access to any device, and in the section "product listings" the products of 4000 manufacturers are listed by keywords. For hospitals the price range typical for each class of devices is provided, though calls to several manufacturers may be necessary to obtain the most favourable figures. The book claims to provide "internationally accepted nomenclature and coding system", but one should realize that this does not reflect any classification accepted by international organizations since such systems hardly exist. There is currently still a need for national bodies, such as the FDA, to develop their own classifications in this important and potentially confusing field.

The Health Care Standards Directory shows ECRI at work on a broader front, providing a guide to health standards, guidelines and recommended practices; as such it is of practical importance to professionals in health care, insurance, law and government, as well as to health consumers, librarians, educators and researchers. The standards covered include those issued by medical societies, professional associations, government agencies and other bodies active in the area of health, and they are rendered accessible through a comprehensive indexing system so that they can be traced according to the topic with which they deal or the (more than 300) organizations issuing them. The section "Law, Legislation and Regulation", running to 208 pages, covers federal and state health regulations in the U.S. by title only.

The book presents only North American material, but it is of interest also to those working outside the U.S.A. and Canada, since standards are commonly hard to trace and their importance is often universal.

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Anonymous. Preoperativa rutiner (Pre-operative routines). Stockholm: Swedish Council on Technology Assessment in Health Care, 1989. Available from the Council at Drottninggatan 16, 10324 Stockholm, Sweden.

The Swedish Council on Technology Assessment in Health Care (SBU) is an independent agency within the Secretariat of the Swedish Government. It is one of the few institutions in Europe which bridges the gap between academic technology assessment and actual policy

making. SBU publishes reports on the biomedical and socio-economic value of various technologies used in health care.

"Preoperative Rutiner" does not in fact deal with preoperative routines in general, but with those diagnostic procedures, such as chest X-ray, laboratory tests and ECG studies, which have entered into clinical practice as routine measures of operative risk. The report examines the prognostic value of such routines and their usefulness – in cost-effectiveness terms – by pulling together existing literature on the matter and discussing it critically. It also provides a survey of current practice in Swedish hospitals and a health-economic evaluation of their consequences.

As expected, these diagnostic routines as practised in Sweden, and indeed in Western European medicine in general, more often reflect a historical development than a rational approach to the evaluation of operative risks. In addition, as the routine use of preoperative testing of patients is an activity in the grey zone between screening and clinical investigations, closely akin to opportunistic screening, it carries a high cost and a low effectiveness as emerges from this report. The report concludes that:

– the basis for pre-operative investigation should be a thorough history and careful physical examination of the patient,

– chest X-ray should not be used as a routine examination,

– routine electrocardiographic testing should not be performed unless specifically indicated,

– clinical laboratory tests should be performed only if specifically indicated,

– the anaesthetist in attendance should examine and interview all patients prior to surgery.

Whether these recommendations will change the behaviour of the medical profession in Sweden remains to be seen. One problem is: what is a routine case and what is not? Some surgeons may argue that they never have routine cases, and that in fact every patient is unique and deserves every fragment of attention, even if the utility of a test is marginal, so long as the investigation is not harmful and is free of cost for the patient. The consequences of this asocial attitude in a nationalized health care system is a collective punishment borne by all physicians and patients in terms of the unwise loss of resources and lost opportunities. The attitude persists because the consequences of missing a diagnosis will have to be borne by the physician and the patient in question alone.

A report like this may have a profound influence on liability issues and on the way in which surgical and anaesthesiological accidents and incidents may be judged by a court and by the media. A more detailed analysis and discussion of the legal aspects might have been useful for an international public although these aspects, at least at present, are not an issue in focus in Sweden. The ultimate – but still lacking – preoperative risk evaluation, which is reflected in the observation "It is not the drugs, but who gives them – not the procedure, but who does it that is critical" might come from SBU once Quality Assurance has been generally introduced in Swedish health care.

The report makes very interesting reading and can be recommended to everyone concerned with the subject. Although it is written in Swedish there is an excellent and extensive English summary, which can be obtained separately.

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Nicolet J-L, Carnino A, Wanner J-C. Catastrophes? Non merci! La prévention des risques technologiques et humains. Preface by Gerard Renon. Published in the series "Le Nouvel Ordre Economique". Masson, Paris, 1989, 256 pp., 180 F.

One is confronted here with an unusual book and one which offers a wealth of contrasts; technical yet at the same time emphatic, it seizes and holds the reader's attention by the very nature of the subjects with which it deals (the daily threat of the world tumbling apart in one way or another) but also by its approach to its topic; disturbing yet reassuring at the same time, it profiles the darker side of the unchallengeable process of change, the various potentials for disaster which we tend to group under the unemotional term "major technological risks" – yet at the same time it points the way to survival.

"Catastrophe? Non Merci!" is very far from being the militant pamphlet which its title might suggest. It is quite simply a serious, methodical and thorough study which carries us on a remarkable hunt – that for human error. The Flaujac catastrophe; the Three Mile Island disaster; Chernobyl; the wreck of the Herald of Free Enterprise? All these were catastrophes in which, at one level or another, human error was in evidence.

This book is above all a profound lesson in modesty, and one applicable in everyday life. The error, sometimes unforgivable, of which any one of us may be guilty and which prevents us from carrying out to absolute perfection the tasks accorded to us – this error commonly reflects the derangement of the delicate balance between Man and machine. Endowed simultaneously with intelligence, ambition, and an urge to act, Man creates for his own use machines which are ever more complex, more efficient. The wheel, a nuclear power station, the water mill and a Jumbo Jet have one thing in common; and that is of course the involvement of man. All these machines are the fruit of our imagination and, since we have created them we control them. At least, nearly.

For in creating ever faster and more powerful instruments we have necessarily brought various functions into motion simultaneously, relating variously to production, information and control. Yet Man himself remains by definition and by his very nature a single-channel entity. True, he can very often suggest the contrary in performing a series of tasks in particularly rapid succession, but it is a fact that when the links between them exceed a certain threshold, so that to all effects and purposes they are simultaneous, he can no longer handle them.

In that way we are faced with our own limitations as we confront the technology which we have ourselves brought into being. We lose control over it and we make errors, for the balance is no longer there. What has gone wrong?

One of the great merits of this book is that it poses precisely that question. It refuses to accept black-and-white manichaean over-simplifications, and it makes it clear that we shall look in vain for any fundamental and general cause of catastrophes as such. Errors occur, sometimes in cascades and in various recognizable patterns, sometimes reflecting our lack of adaptation to a situation, sometimes in fact too great a degree of adaptation (so that habituation defeats vigilance); error can also result from faults of perception, errors of interpretation; and any of these errors may be fostered by the overconfidence which results from the multiple (sometimes all too numerous) control mechanisms which we have devised.

The case histories with which the book is illustrated are not only thoroughly analyzed; they are also presented in such a way that the reader can recognize in each sequence of events something applicable to his own situation; they provide him with a standard of reference.

Above all, however, this book fulfils the promise inherent in the second part of its title. It offers a truly methodical approach – impressively demonstrated in the case studies – to the

analysis of the elements which underlie operational reliability in a complex organization. It is obvious that not everyone will come to read "Catastrophes? Non merci!" In a sense it is unfortunate that there is not a popular edition. All the same, anyone in a position of responsibility in a business or organization where one is confronted with problems of safety – and everyone whose job it is to live with technological risk and to deal with catastrophe – ought to read this book. What is more, they will thoroughly enjoy it.

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Anonymous: Olyckor och tillbud: medicinteknisk säkerhet series, part 7, Socialstyrelsen, Stockholm, (1989).

The title of "Olyckor och tillbud", a publication of Sweden's Health Service Administration in its series of reports on safety in medical technology, can be neatly translated as "Accidents and incidents", thereby providing us with a clue as to the approach which the reader may expect to the subject.

Sweden is often recognised as being a trend-setting country, especially when it comes to the planned development of its infrastructure along the lines of its elected pattern of democratic committees which set and monitor specified standards. "Olyckor och tillbud" is a further example of this process at work in the health services.

An advisory committee for Medical Technical Safety was set up in 1977 under the Swedish National Board of Health and Welfare for the purpose of collecting, analyzing and disseminating a feed-back of information relating to accidents and incidents induced during the usage of medical-technical devices. The main object was to build up a data bank covering all the types of incidents reported by users of medical-technical devices. Such users will include nurses, doctors, technicians, home help personnel and others. The present volume, which is the seventh report from the Committee, is a cumulative index of all relevant reported incidents or cases, submitted during the years 1986 and 1987, and covers 203 incidents.

One example of an important trend that has been identified in this seventh edition is the alarming increase in the number of cases reported involving aids for the handicapped and home care devices. For example, thirteen cases in which patients fell while using lifting equipment were reported. Six reported incidents with the use of oxygen concentrators were considered such a serious matter that the data have led to a further tightening of the regulations laid down by SEMKO (the Swedish Electrotechnical Material Control Board) for the use of this type of equipment.

Electrosurgery, similarly, continues to raise problems with a current shift of emphasis towards an increase in accidents during endoscopic electrosurgery. Most of the injuries to both patients and staff could have been avoided with improved routines and a higher degree of awareness amongst personnel.

The reports are for obvious reasons provided in an anonymous form where details of a sensitive nature, e.g. the name of the patient or user, are omitted. The information which is provided is however extensive; for each of the 203 cases covered in the book, there is a specification of:

1. the type of equipment, e.g. operating table,
2. the manufacturer and model involved,
3. the distributor of the equipment,

4. a description of the incident or accident,
5. the distributor's comments on the incident or accident,
6. the Committee's own comments.

Readers may well ask what results can be expected from the gathering of such information and the build up of such a data bank. In fact its value in eliminating risk is now known to be considerable, both nationally and internationally. It is truly disconcerting to discover how isolated individual hospitals and institutions really can be, with limited knowledge of their own as to the qualities, deficiencies and adverse effects of medical technical equipment. A parallel organisation set up in neighbouring Norway under the "Norwegian Institute for Hospital Research" (NIS) made the startling discovery that oxygen and carbon dioxide gas cylinders could all too easily be interchanged: a system that had been generally accepted, even at the highest levels, as foolproof, was found to have a considerable potential for patient risk. Seven almost unbelievable cases were registered and the Swedish Committee was contacted and informed; another two cases were then identified in Sweden. An expert group was quickly called together and the matter taken up at the inter-Scandinavian level where the problem, a design flaw in the coding system for the gas cylinders' connectors, was discussed and resolved.

This one incident clearly illustrates the value of this type of reporting system, and the fact that it can function disregarding the boundaries of countries. There can be little doubt that, given enough time, such reporting systems can be of great benefit to hospitals and institutions which rely upon the trouble-free functioning of their equipment. The availability of this invaluable information must help users, technicians, purchasers, dealers and hopefully also manufacturers, to raise the level of safety for the benefit of the patient.

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P.N.Bennett and a WHO Working Group: Drugs and human lactation. Elsevier Science Publishers, Amsterdam, New York and Oxford, 1988. Dfl. 451.00

If in the course of the last two years there has truly been a timely new standard work in the field of Clinical Pharmacology, then it must be "Drugs and Human Lactation". The worldwide trend back to breast-feeding, which has developed not only for psychological but also for immunological reasons, lacked until recently a corresponding scientific enquiry into the possible risks of breast feeding. Some alarming news had emerged as to the pesticide content of human breast milk but there were only anecdotal reports of adverse drug reactions in infants due to medicaments given to the mother. A statement in the 1990 edition of the "Rote Liste", the drug compendium of the Association of the German Pharmaceutical Industry (BPI), reflects the prevailing attitude of many manufacturers: "The use of any potentially dangerous drug which the mother may need post-partum should lead to the renunciation of breast feeding, even if there is to date no evidence of injury to infants". Some responsible manufacturers do today provide some data on the excretion of their drugs in the mother's milk, but often in a speculative manner.

Bennett's (and the WHO's) book should put an end to this speculative approach. In almost encyclopedic fashion (even the ATC code is there) comprehensive data are given on

more than two hundred active components of drugs. The substances have been selected according to the frequency of their use but also according to their usefulness. Time proven agents like the senna glycosides rank alongside the most recent such as zopiclone, so that information on rational drug therapy can always be found, or a compound chosen on which relevant information is available. This main part, well organized and easy to read and use (each paragraph closes with "assessment and recommendations") is complemented by six further expert contributions.

In the first of these, the WHO Working Group assesses the frequency of breast feeding worldwide, using recent official data. Thereafter the fascinating question of the effects of drugs on milk production is taken up, with attention being devoted even to those risks most recently reported. The basic principles of drug excretion in breast milk are extensively but lucidly explained in a further chapter which will prove of much value to the physician dealing with very recent drugs on which no specific information as to excretion in the milk is available. The section on drug disposal and effects in the young child is no less helpful and (like all the chapters in the book) it provides a wealth of recent references for the reader who needs more detail. The final chapter, on the passage of environmental and occupational chemicals into the breast milk, will enable the physician to deal competently with most of the questions which a concerned mother is likely to ask.

This product of three years of work by many experts and a superb editor and team of co-editors is indeed outstanding. Every responsible physician should own it.

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