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The paradox of quality improvement: errors are treasures

The medical profession has no place for its mistakes. Yet mistakes do occur, and the simplistic view that there can be no error without negligence is inadequate. In an impressive and thoughtful article Lucian Leape touches the nucleus of the problem that health care has in dealing with errors.

In Anglo-American literature the threat of malpractice litigation is often the motive for analyzing errors and accidents. But Dr. Leape, one of the investigators involved in the Harvard Medical Practice Study of errors and iatrogenic damage in hospitals (1990), offers a positive approach to the backside of quality. The starting point is that mistakes and errors are inevitable, in health care as in other fields. If we can accept that errors will always occur, it becomes a challenge to use the experience derived from them for preventing accidents. In an editorial David Blumenthal calls this the paradox of modern quality improvement. Only by admitting and forgiving errors can their incidence be reduced.

But is the medical profession willing to transform medical errors into medical treasures? The answer is disappointing. The profession shows (with rare exceptions) an ostrich-like attitude. In contrast to what has happened in high-technology industry and in aviation, the relatively high error and accident rate in health care has not stimulated more concern or greater efforts at error prevention.

Health care providers have difficulties in dealing with human error. In education and daily practice physicians and nurses simply learn to regard mistakes as unacceptable. Errors are associated with personal failures; fallible doctors are considered incompetent. Processes of socialisation play a role in constituting this attitude. The profession has developed unattainable standards

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requiring them to practice in an error-free or nearly error-free manner. Medical education teaches a strong sense of responsibility for the patient; and patients have granted physicians extraordinary autonomy in return for a supposedly guaranteed quality of care.

When the inevitable errors then occur, patients feel betrayed and the "infallible" physicians are strongly tempted to intellectual dishonesty, covering up their mistakes instead of facing them. Physicians become emotionally isolated with their mistakes. It seems that no one can help them; they failed.

"The medical profession has simply no place for its mistakes". This is an important reason why the medical profession follows a "perfectibility" model in the prevention of errors and accidents, involving training and punishment. But the action developed is only reactive and inefficient. Leape notes: "prevention systems that rely on an error-free performance are doomed to fail". The thesis of his article is: "if health care workers will succeed in reducing medical accidents, they have to change fundamentally the way they think about errors and why they occur".

The medical profession can learn from psychological and human factor research in aviation or in high-technology industry. To understand human errors, normal human cognitive functioning must first become understandable. Leape refers to the cognition theory described by James Reason as a framework for research. In daily life, the functioning of people rests on a great many automatisms based on an array of mental models known as "schemata". Skills, rules and knowledge are involved. Psychological factors (such as fatigue, sleep, illness, alcohol, frustration, stress) play an important role in the creation of errors, slips, mistakes and misinterpretations. In industrial safety research, accidents are commonly found to be the outcome of latent failures and unsafe conditions. Conceptual errors in design (inborn errors in the system) result in latent loss of safety. Psychological precursors make errors manifest.

For such reasons, the successful prevention of accidents, near-accidents and errors demands a systemic approach: design, construction, maintenance, allocation of resources, training and development of operational procedures must be integrated in a total conceptual safety management. The good design constructs a system that makes it difficult for individuals to make errors! The aviation model is an applicable one for improving hospital safety. This model is based on four integrated steps. Firstly, design for aircraft construction provides built-in safety zones to absorb human errors (e.g. duplicating or triplicating instruments, provision of buffers, automatic feedback systems). Secondly, procedures are standardized to the maximum extent possible (checklists in the cockpit). Thirdly, the training of crews, examination and re-certification are all highly developed

and rigidly implemented (pilots have to be examined every 6 months). And finally, safety has been institutionalised (national and international safety procedures, certification).

By contrast, the medical model is still focused on incidents and individuals. Underlying failures in the system are rarely looked for. The medical model has no design with built-in possibilities to absorb errors. Development of standardisation and task design is poor. Although education and training is highly developed, the periodic testing of performance is not yet accepted. Nor has safety management as a rule been institutionalised.

Leape pleads for implementation models in health care analogous to those already developed in some other disciplines, like the aviation model. There is no need to discover the wheel again. He gives some directives. First we have to define the problem exactly. At the same time we can start routine identification and registration of errors, accidents and near-accidents. That calls for another attitude, involving the reporting of errors as a means of preventing accidents and damage. A positive attitude to errors is needed. In procedures we have to take account of human limitations in complicated situations (e.g. a checklist in the operation theatre). Standardisation of equipment and devices must have high priority. In addition the institutionalisation of safety management in health care has to be encouraged.

It is clear that safety has its cost. Developing systems for data-collection is expensive. But if our goal remains health care without unnecessary errors, we have to invest. First one must incur the expense; the profit will follow.

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The risks of central venous catheterisation

Catheterisation of the subclavian vein is frequently performed in order to obtain venous access when infusion solutions cannot be given through peripheral veins (i.e. in patients with inadequate peripheral veins) or in order to insert monitoring devices. Central venous catheterisation involves a considerable risk of acute and late complications. It must be performed only when strictly indicated; one must weigh up the potential benefit and risk of inserting a central line. Experienced doctors using the best available techniques can keep the complication rate low. When a catheter has to be left in place for a relatively

long period, special attention must be devoted to the risk of septic infections and thrombosis.

In a prospective randomized trial Mansfield et al. (University of Texas, Anderson Cancer Centre, Houston) compared an ultrasound-guided insertion technique with standard insertion procedures. The trial was terminated after 824 patients had been treated, at which time an interim analysis showed that ultrasound guidance had no effect on the success of catheterisation. The investigators recorded a 9.7% incidence of complications (both in the case- and in the control groups): the problems comprised misplacement (6%), arterial puncture (3.7%), pneumothorax (1.5%) and mediastinal haematoma (0.6%).

In total 100 failed attempts (12.2%) at catheterisation were observed. Failure was more common in patients with a high or a low body-mass index and after prior major surgery in the region or previous catheterisation. A failed attempt at insertion was the strongest statistical predictor of a complication: 28% of patients in whom attempted catheterisation had failed experienced complications versus 7.2% of the patients in whom catheterisation was successful. The number of needle passes was also strongly associated with the rates of failure and complications (up to 24% problems after three passes). Physicians have to be discouraged from making more than two attempts by themselves.

When catheters remain in place for a week or longer, thrombosis may develop in some patients, with the risk of pulmonary emboli. Other risks are those of nosocomial infections and septicemia. Raad et al. (also from Anderson Cancer Centre, Houston) reported on postmortem examination of 72 consecutive patients with indwelling central venous catheters (43 having subclavian vein catheters). The main duration of catheterisation was 63.7 days. On the surface of all catheters a fibrin layer was noted. Mural thrombosis was detected in 27 of the catheterised veins and mural haemorrhage, ulceration, calcifications and inflammation were found in 35 of the catheterised veins. In seven patients a catheter-related septicemia had occurred. Where there were signs of thrombosis in the catheterised vein, a strong association was found between catheter sepsis and thrombotic vascular pathology.

Besides improving insertion techniques, other localisations for venous access can be used, notably the jugular and arm veins. The most important rule to ensure patient safety is, however, to avoid the unnecessary use of central lines, and to ensure that when they are strictly indicated they are introduced and maintained by physicians with appropriate experience.

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Mansfield PF, Hohn DC, Fornage BD, et al. Complications and failures of subclavian-vein catheterization. N Engl J Med 1994;331:1735–8.
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(Procto)colitis: a common complication of NSAIDs?

In a letter to the editor of the *Lancet*, Michael Gleeson et al. from the General Hospital of Jersey (Channel Islands) report 23 cases of proctitis, proctocolitis and colitis developing during therapy with non-steroidal anti-inflammatory drugs (NSAIDs). The clinical course of NSAID-associated colitis was frequently mild and the condition improved rapidly on withdrawal of the NSAIDs and treatment with oral sulphasalazine or mesalazine. One patient had to undergo a colectomy. Another patient had a recurrence of the colitis after re-exposure to a NSAID. A variety of NSAIDs were involved, most commonly diclofenac (12 cases) and mefenamic acid (5 cases). As 38% of the new cases of colitis turned out to be associated with the use of non-steroidal anti-inflammatory drugs, Gleeson et al. advance the possibility that NSAID-associated colitis is a common but under-recognised form of colonic disease.

Back in 1992, Allison et al. had already drawn attention to the relationship between non-steroidal anti-inflammatory drugs and lower gastrointestinal bleedings. In post-mortem autopsies in 8.4% of the users of NSAIDs ulcers were found in the small intestine versus 0.6% in non-users. As early as 1987, Bjarnason et al. found evidence for inflammation of the small intestines in nearly three-quarters of patients on long-term treatment with NSAIDs. These authors undertook a systematic search of literature in order to identify possible adverse effects of NSAIDs on the large and the small intestine. They found that ingested NSAIDs may cause non-specific colitis and that patients with collagenous colitis are often taking NSAIDs. Small intestinal inflammation due to NSAIDs has also been reported frequently in the literature. Occasionally intestinal ulcers, bleeding and perforation have been related to NSAIDs. Sometimes the effects on the small and large intestines were asymptomatic, sometimes life threatening.

In new patients with proctitis or colitis a thorough inquiry into the history of drug usage has to be done. Non-steroidal anti-inflammatory drugs may be a common cause. Whenever long-term treatment with NSAIDs (especially the fenemates) is to be undertaken, the prescriber should be aware of the effects on the small intestines and the colon.

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Wheelchair-related accidents

In the United States there are about one million wheelchair users. The United States Consumer Product Safety Commission (USCPSC) has estimated that in 1992 there were some 55 000 wheelchair-related accidents which were serious enough to cause injured persons to seek medical attention. In the past 15 years 770 deaths in wheelchair accidents were reported to USCPSC (51.3 per year); in 60% of cases the accident had occurred in an institution or hospital.

One of the tasks of the USCPSC is to monitor non-fatal product-related accidents on an ongoing basis through its National Electronic Injury Surveillance System (NEISS). This system utilises data from all hospital emergency departments in the USA. Within the NEISS database a sample of 2084 wheelchair-related accidents causing non-fatal injury between 1986 and 1992 was analyzed. Of the patients who sustained injuries 7.6% were bystanders or attendants (bumped into, run over, tripped over by a wheelchair, etc.). The mean age of injured wheelchair users was 61 years, with peaks between 20 and 39 years and between 80 and 89 years; 62.5% were females. The major causes of accidents were related to falls and tips (73%), secondary causes being associated with furniture, stairs, etc. (41%) and transfers (17%). Most of the accidents occurred at home; about 20% occurred in nursing homes, 16% in public places and 5.5% on the street. The most common injuries sustained were contusions and abrasions (33%) and lacerations (28%). Fractures occurred in 20% of the accidents. Head, neck and face were affected in 35% of the cases. The lower extremity was involved in 33% and the upper extremity in 15% of the cases. Twelve percent of the injured patients was admitted to hospital.

In the United Kingdom the incidence of wheelchair-related accidents among 500 000 users was previously estimated at 20 000 injured persons per year. Dudley et al. reported one or more accidents to 27% of 174 wheelchair users. Many accidents with older wheelchair users occurred with transfers (getting into and out of the bed or wheelchair, or onto or off the lavatory). In other reports

attention was drawn to the poor conditions of many wheelchairs. Malfunctioning brakes, soft or punctured tires, absent or defective footrest plates and torn arm-rest coverings were found in a sample of hospital wheelchairs.

Anonymous. Chariots of fear: wheelchair-related accidents. Lancet 1992;340:1263.
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Ummat S, Kirby RL. Nonfatal wheelchair-related accidents reported to the National Electronic Injury Surveillance System. Am J Phys Med Rehabil 1994;73:163–7.

Powered wheelchair accidents caused by electromagnetic interference

Accidents with powered wheelchairs and motorized scooters can be caused by electromagnetic interference problems. The FDA has received many reports of unintentional powered wheelchair movements, probably caused by interference with electromagnetic sources such as radio and television stations, cellular telephones and citizen band radios. Some accidents resulted in serious injuries to the users. The FDA has ordered measurements to protect the users: they are establishing minimum immunity levels to interference by radiated electromagnetic energy as well as educational programs to warn users of the potential hazards of electromagnetic interference and information on means of avoiding these risks.

Problems with electromagnetic interference can also happen with electrically powered medical devices. The U.S. Food and Drug Administration has urged the reporting of problems with medical devices and powered wheelchairs possibly caused by electromagnetic interference with their controls.

Nightingale SL. From the Food and Drug Administration: possible electromagnetic interference problems with wheelchairs and other medical devices. JAMA 1994;272:344.

Episiotomy: too often an unnecessary and unfriendly cut

Mediolateral episiotomy is a minor operative procedure frequently performed during delivery. It is performed to prevent severe perineal laceration, to avoid trauma of the fetal head and to shorten the second stage of labour. The rates of episiotomy vary widely between obstetricians (and midwives), between hospitals and between geographical regions. In France episiotomy is performed in 28% of all deliveries as against 61% and 62% in the United Kingdom and USA. In

Latin America trainees in obstetrics are taught to carry out episiotomy routinely.

The appropriateness (or otherwise) of episiotomy has been discussed earlier in the literature; opinions prove to be divided on the efficacy of routine episiotomy and some studies suggest a higher rate of postpartal perineal pain in women who had undergone episiotomy. The appropriateness of episiotomy has now been the subject of three separate studies, undertaken in Argentina, Denmark and the Netherlands respectively.

The Argentine Episiotomy Trial Collaborative Group compared the outcomes of routine and selective performed episiotomies in a randomised controlled trial in eight city public maternity hospitals in Buenos Aires, Neuquen and Rosario. 1555 nullipara (np) and 1051 primipara (pp) women were recruited and divided into two groups. In a "selective group" (778 np + 520 pp) episiotomy was carried out only where particular reasons for it existed (foetal distress or the threat of severe perineal laceration); the mean frequency in this group proved to be 30% (np: 39%; pp: 16%). In a "routine" group (777 np + 531 pp) episiotomy was carried out according to pre-existing practice, the actual mean rate attaining 83% (np: 97%; pp: 70%). Severe perineal laceration was rare in both groups (1.2% vs. 1.5%). In the selective group 28% fewer women required perineal repair. Complaints of perineal pain and complications of wound healing and dehiscence were also significantly less common in the selective group compared with the routine group. This collaborative study group concluded that episiotomy rates above 30% cannot be justified and that routine episiotomy should be abandoned.

In the Netherlands, the National Obstetric Database (1990) covered 81 579 hospital-based deliveries with an episiotomy rate of 39%. The rates varied extensively between 15% and 68% among the 108 hospitals involved. In a subgroup of 43 309 gynaecologist-supervised spontaneous, occipito-anterior vaginal deliveries of live-born singletons, Anthony et al. studied the relationship between the performance of episiotomies and the occurrence of severe third-degree perineal lacerations (including subtotal tears of the anal sphincter and complete disruption of the sphincter). The episiotomy rate in this subseries was 31%. They found an overall severe tear rate of 1.4% (1.0% of subtotal tears, 0.4% of total tears) The severe tear rate varied between the hospitals (0–6.5%), but no difference was found between deliveries performed by gynaecologists, house-officers or midwives. Dutch white women and Asian (Chinese and Indonesian) women had a higher risk of severe perineal laceration than Mediterranean, Creole and Hindu women. The use of episiotomy was associated with a fourfold decrease in third-degree lacerations. However, the figures showed that in order to prevent one (sub)total tear 84 episiotomies had to be performed (np:

48 and pp: 106). In hospitals with a high and a low episiotomy rate no difference in the incidence of third-degree perineal tears was found.

In a second paper on this same observational study from The Netherlands, Zondervan et al. investigated the determinants of the risk of using episiotomy. Instrumental delivery, parity, length of second stage of labour and ethnicity were each found to have an effect on the episiotomy rate. In teaching hospitals fewer episiotomies were performed than in other hospitals.

Another observational study was carried out at the Aarhus University Hospital (Denmark). All the 2188 spontaneous vaginal occipito-anteral deliveries of singletons performed by 43 midwives over a period of 10 months in 1989–1990 were included in the study. Midwives with fewer than 20 deliveries in the study period were excluded. Midwives and deliveries were divided into three subgroups: a group of 14 midwives (808 deliveries) with a low episiotomy rate ($< 34\%$), a group of 15 midwives (783 deliveries) with a median episiotomy rate (34–48%) and finally a group of 14 midwives (597 deliveries) with a high episiotomy rate ($> 48\%$). A low episiotomy rate was found to be associated with a greater likelihood of an intact perineum after delivery (37.5% vs. 31.5% vs. 25.5%); however, there was also a slight, non-significant, tendency towards more perineal laceration. The overall rate of third-degree tears was 1.7%; again there was no significant difference between the three groups. The high episiotomy rate was correlated with a high performance of prophylactic (routine) episiotomies (14% vs. 31.5% vs. 42%). Brink Hendriksen et al. concluded that a restrictive approach to episiotomy does not lead to more severe perineal laceration. More important, however, is their remark that the wide variation in episiotomy rates can reflect the fact that there is considerable unnecessary medical treatment.

To influence the behaviour of midwives at this point Brink Hendriksen et al. provided interventional feedback of episiotomy rates to a group of 30 midwives in another 10-month follow-up period (2250 deliveries). They succeeded in decreasing the incidence of episiotomies in this group from 37.1% to 30.5%. The higher the rate of episiotomy during the first observation period, the greater the reduction attained. Compared with the outcome of the first observation period, the number of women with an intact perineum increased by 3.2%. It was found that 3.4% more women experienced perineal laceration, but the overall incidence of third-degree ruptures remained unchanged. In the low frequency episiotomy group of midwives, a tendency to more severe perineal laceration was seen. These Danish investigators therefore recommend that an intervention strategy to decrease unnecessary episiotomies should probably be restricted to midwives with episiotomy rates above 30%.

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Zondervan KT, Buitendijk SE, Anthony S, et al. Frequentie en determinanten van episiotomie in de tweedelijnsverloskunde in Nederland. (Frequency and determinants of episiotomy in Dutch gynaecologist-supervised deliveries.) Ned Tijdschr Geneeskd 1995;139:449–52.

Does the doc' recognise the bundle branch block?

One-hundred-and-fifty-eight doctors representing various specialisms and having varying degrees of seniority, all working in hospitals in London or Essex, were asked to mark the PR and QT intervals in a standard electrocardiogram. The anonymous questionnaires were collected on a single morning to avoid communication between doctors about the answers. The respondents included 20 house officers, 39 senior house officers, 49 registrars, 21 senior registrars and 29 consultants. Their specialities were medicine (60), cardiology (23), surgery (10), cardiothoracic surgery (7), anaesthetics (28) and emergency medicine (10).

It turned out that 74% of the doctors did not have sufficient knowledge to measure a PR interval. The poorest result came from house officers (19 of 20 failed). However, 17 of 29 consultants also failed to give a correct answer. Incorrect answers came from 22% of the cardiologists, 75% of the anaesthetists, 8 of 10 emergency doctors and from all surgeons. The duration of the QT interval (an important basic measure in assessing patients with a predisposition to arrythmia, including those suffering from overdosage of certain drugs) was only defined correctly by 24% of all doctors (none of whom was an emergency physician!). "How can recorded interpretations of electrocardiograms be compared, if individuals doctors use their own criteria to define its basic features?" ask the authors of the article.

Montgomery H, Hunter S, Morris S, et al. Interpretation of electrocardiograms by doctors. Br Med J 1994;309:1551–2.

Low back pain: the risk of medical intervention

Low back pain is one of the most common reasons for people to consult a physician. Often the physician can identify no anatomical substrate for the

patient's complaints; symptoms and anatomical findings are only correlated with one another in a small proportion of cases. I remember patients with severe long-term complaints in my GP practice, in whom no abnormalities could be found, as well as patients with a whole series of abnormalities on the lumbar spine X-ray, who had no complaints at all. Twenty years ago we already knew that degenerative abnormalities on X-rays of the spinal column gave no useful information about the clinical condition of the patient.

Even with new magnetic resonance imaging techniques (MRI), diagnostic uncertainties still exist. Jensen et al. performed MRI examinations on 98 asymptomatic people. Two neuroradiologists, who were unaware of the clinical status of the patients, were asked to read the scans. To reduce the possibility of bias in interpretation, 27 abnormal MRI scans from patients suffering low back pain were mixed randomly with the scans from the asymptomatic individuals. Only 36% of the scans of asymptomatic people turned out to be normal. A disk bulge at at least one level was found in 52% of the scans; 27% showed a protrusion and 1% an extrusion. Abnormalities of more than one intervertebral disk were found in 38% of all scans. The prevalence of bulges correlated with age.

Other studies have similarly indicated that MRI examination has not only a low sensitivity but also a low specificity for testing the causal relation between low back pain and abnormalities of the intervertebral disks. This means that imaging studies provide only a weak prediction of the need for surgery and its outcome and do not improve diagnostic certainty. There is a risk of undertaking unnecessary surgery with poor outcome as well as a risk of making (or keeping) people ill simply by telling them the results of the radiodiagnostic and imaging tests. In the United States an increase in the rates of lumbar spine surgery is partly attributed to the availability of new imaging techniques. Yet surgery is clearly not always necessary and sometimes it is contraindicated. Most patients improve without an operation. The decision to operate has to be the result of carefully weighing the benefit and the risk.

Two other interesting studies on the outcome of medical intervention in cases of low back complaints were recently published. Deen et al. analyzed early failures after lumbar decompressive laminectomy for spinal stenosis. Degenerative stenosis is a common problem in elderly patients. In appropriately selected patients surgical results are generally good. However, despite improvements in neuro-imaging diagnostic techniques, 35% of patients have residual or recurrent symptoms postoperatively. Deen et al. analyzed the medical history of 45 elderly patients who had undergone surgery and experienced a poor outcome. They found that only 23 of the patients had preoperative symptoms of neurogenic

claudication. The others variously had low back pain without a radicular component (15), peripheral neuropathy (3), atypical leg pain (3) or degenerative hip disease (1). Only 10 patients had radiographic evidence of severe lumbar stenosis. In 10 patients surgical decompression was inadequately performed. The disappointing outcome of decompression was partly due to inadequate surgery, but mostly due to inappropriate selection.

The management of low back pain starts in primary care. The adage must be: most patients will improve without medical intervention. Malmivaara et al. conducted a controlled trial among 186 employees of the city of Helsinki, Finland. They had presented themselves with acute nonspecific low back pain to the city's occupational health care centres. The patients were randomly assigned to three treatments: bed rest for two days ($n = 67$), back-mobilizing exercises instructed by physiotherapists ($n = 52$) or continuation of ordinary activities as tolerated ($n = 67$, control group). The patients in the control group experienced better recovery than those prescribed either bed rest or exercises. After one week 59% of the bed-rest group, 64% of the exercise group and 80% of the control group had resumed their work (after two weeks respectively 81%, 89% and 98%). The control group also suffered pain for a shorter period and it was less intense.

One must repeat: most complaints of low back pain disappear spontaneously. Making use of radiodiagnostic and imaging techniques can provoke somatic fixation and unnecessary operative intervention. The patients of physicians with defensive behaviour are at risk. Selection of patients for surgery has to be done carefully. And finally: if operation is to be performed at all it must be adequate.

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Deyo RA. Magnetic resonance imaging of the lumbar spine; terrific test or tar baby? N Engl J Med 1994;331:115–6.

Jensen MC, Brant-Zawadzki MN, Obuchowski N, et al. Magnetic resonance imaging of the lumbar spine in people without back pain. N Engl J Med 1994;331:69–73.

Malmivaara A, Häkkinen U, Aro T, et al. The treatment of acute low back pain — bed rest, exercises, or ordinary activity? N Engl J Med 1995;332:351–5.