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World Health Organization

MEDICAL DEVICES: MANAGING THE MISMATCH

An outcome of the Priority Medical Devices project

Increasing complexity of medical technology and consequences for training and outcome of care

Background Paper 4

August 2010

Contents

Preface

In 2007, at the request of the Government of the Netherlands, the World Health Organization launched the *Priority Medical Devices (PMD)* project to determine whether medical devices currently on the global market are meeting the needs of health-care providers and patients throughout the world and, if not, to propose remedial action based on sound research.

The project gathered the information required by conducting literature reviews and surveys, and by convening meetings of specialist consultants.

The project addressed various complementary issues:

- the global burdens of disease and disability;
- guidelines on clinical procedures for the management of diseases and disabilities;
- projections of future burdens of disease and disability in the context of demographic trends;
- cross-cutting issues, such as the training of medical device users, medical device design, contextual appropriateness of medical devices, and regulatory oversight;
- catalysts of, and barriers to medical device innovation and research.

The original objective of the *PMD* project was to identify gaps in the availability of medical devices. The findings of the project showed that gaps in the availability of medical devices is not the primary issue, but rather a number of shortcomings spanning several facets of the medical device sphere. This result prompted a change of direction in which the project shifted its focus onto the many shortcomings related to medical devices.

These problems, challenges, and failures amount to a mismatch, rather than a gap, that prevents medical devices from achieving their full public health potential.

The *PMD* project also produced a report *Medical Devices: Managing the Mismatch* aimed at achieving two objectives: the first, to inform national health policy-makers, international organizations, manufacturers and other stakeholders of the factors preventing the current medical device community from achieving its full public health potential; the second, to provide a basis on which all players in the medical device scene can together use the findings and recommendations of the *PMD* project to make public health the central focus of their activities.

This paper is part of a series of documents produced as background material for the *PMD* project report. The following papers are available as part of this series:

1. A stepwise approach to identifying gaps in medical devices (Availability Matrix and survey methodology)
2. Building bridges between diseases, disabilities and assistive devices: linking the GBD, ICF and ISO 9999
3. Clinical evidence for medical devices: regulatory processes focussing on Europe and the United States of America
4. Increasing complexity of medical devices and consequences for training and outcome of care
5. Context dependency of medical devices
6. Barriers to innovation in the field of medical devices
7. Trends in medical technology and expected impact on public health
8. Future public health needs: commonalities and differences between high- and low-resource settings

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Introduction

Technology innovates constantly. This simplifies certain aspects of life, and makes others more complex, A fact easily observed in the field of medicine. One of the tendencies is to treat patients with procedures that are less invasive, and thanks to new medical techniques and devices, this trend is increasing. For example, the use of laparoscopic instruments has meant that surgical procedures in the abdominal area are now possible via tiny incisions in the skin. Treatments with the use of colonoscopes (for bowels) and catheters (for blood vessels) are other examples. Many of these procedures are not only very much dependent on technology, but are also technically complex to perform. Such is the trend: new technologies require competent health professionals who are continuously expanding their breadth of knowledge and expertise. The surgical robot is probably one of the most important examples of this trend.

While these new technologies are often advantageous for the patient, health professionals often encounter difficulties in using devices associated with these technologies, which can increase the risk of accidents and complications during surgery. For example, hand–eye coordination problems can occur when using long instruments inserted via small incisions or natural openings. Both the degree of freedom and haptic feedback are reduced, and a scope is needed to present an image on a screen, from which the health professional works. Recently, a report published by the Netherlands Health Care Inspectorate (IGZ) *(1)* showed that the introduction of minimally invasive surgery resulted in higher risks of complications for patients.

This paper investigates the consequences of the complexity of medical technology. It begins with a study of the literature and explores the role of nurses, because they are often common users of these medical devices. Four treatment examples are then discussed. The problems related to the equipment used and the consequences on the ‘learning curve’ of four treatment methods described in the literature are provided. Finally, an outline is discussed that could lead to an improved design methodology of devices, protocols and training.

The use of complex medical devices

Stephenson and Freiherr *(2)* indicate that according to the Food and Drug Administration (FDA) of the United States of America, 9% of the medical device failures are directly related to use error. They mention that the actual rate of use-related errors is probably much higher. Use errors in anaesthesiology, for example, account for as much as 90% of the deaths and injuries to patients *(2)*. Indicated mistakes result from poor equipment design, confusing, poorly-written, or disregarded warning labels, and equipment manuals. Stephenson and Freiherr mention further that health-care professionals often have little time to read the multitude of device manuals or instructions carefully due to constraints of time and capacity. The design of medical devices must consider everyday use by health-care professionals or patients to make them easier to use. Many experts believe this approach has the most potential for reducing use errors *(2)*.

While an adverse event involving a medical device is often attributed to either use error or device failure, the causes are typically multifactorial *(3)*. In an investigation of several incidents involving medical devices, Amoore and Ingram *(3)* explore the various causes of the incidents and the protections that minimized or prevented adverse consequences. They mention the following relevant user factors: mistakes, omissions and lack of training, with background factors – device design, storage conditions, or hidden damage; misleading indicators; confusing software features; and physical layout of equipment when in use – causing the adverse events in many of the incidents *(3)*. Protections that prevented or minimized the consequences included staff vigilance, operating procedures, displays and alarms *(3)*.

With the advent of fast-acting drugs, the infusion pump is one of the most pervasive electronic medical device in acute care (hospitals). Nunally et al. demonstrated that the infusion pump is an example of a device around which many errors occur *(4)*, despite the importance of its correct operation. Incident reports in the FDA database implicate interface programming as a significant aspect of adverse outcomes. Nunally et al. performed a study of infusion pump-programming performance by experienced health-care professionals in a major urban teaching hospital *(4)*. Their findings indicated that practitioner experience with device programming does not necessarily increase proficiency. This suggested that a complex menu structure makes programming difficult and inefficient – it impedes the development of mental models sufficient for reliable device operation. In effect, this causes operators to become disoriented in the interface structure *(4)*.

The design of a device's user interface often contributes to the chance of a user making an error in using the device. However, there is evidence that the majority of such errors are attributable solely to the user and that the primary method of error prevention is to retrain the user *(5)*. Johnson *et al*. conducted a qualitative study to assess health-care employees' attitudes towards device use errors and the prevention of adverse events *(5)*. The top three reported factors leading to the adverse event were the user, design problems and lack of training. The top three reported prevention strategies, in decreasing order of frequency, were retraining the user, redesigning the device and telling the user to be careful. Johnson et al. *(5)* indicate that these results suggest that health-care employees put emphasis on the traditional view of blaming and retraining the user. That being said, many adverse events in medicine are the result of poor interface design rather than human error.

High-quality, functional design of emerging medical devices in an increasingly complex clinical and technological environment requires an understanding of a device's context of use, workload, and the environment in which it will be used; that is, the device's ease of use, its placement in the clinical workflow, and the integration of user feedback in the design process *(6)*, all of which provide maximum benefits to health-care quality. This is all part of what is called 'human factors engineering', which involves the application of principles about human behaviours, abilities and limitations, to the design of tools, devices, environments, and training in order to optimize human performance and safety.

It is important that medical device manufacturers involve such engineering in the design process from the outset and perform usability testing. Furthermore, it is important for a multidisciplinary team to be involved in product evaluation and purchasing decisions. Health-care organizations should expect an optimized and tested (standardized) user interface in the medical devices they purchase *(7)*, because such qualities are critical to patient safety.

Problems with medical equipment: evaluation among nurses

During the past decade, health-care delivery has seen the introduction of ever more sophisticated and complex equipment. This means that the medical devices first used in critical and intensive care units are now integral requirements in the delivery of patient care in acute wards. Although physicians are responsible for the treatment, it is often the nurses who are the primary users of such medical devices *(8)*.

The influence of the operator on the effective and safe application of medical technology is generally underestimated. In an investigation on incidents involving defibrillators in the US *(2)*, it was concluded that the majority of the incidents were due to incorrect operation and maintenance. A study of 2000 adverse incidents in operating theatres in Australia showed that only 9% were due to pure equipment failure *(9)*. In two reports on the use of critical care equipment by nursing staff, 19% *(10)* and 12.3% (*11)* of nurses, respectively, indicated that they had used equipment improperly, which had consequently harmed a patient. It is inevitable that there are numerous adverse or 'near-miss' incidents that go unreported *(11)*. Fouladinejad and Roberts *(11)* also showed that training in the use of equipment is a very minor activity, with less than 1% of departmental time spent on providing or receiving training (staff with higher levels of expertise required less assistance from technical personnel). They concluded that critical-care equipment can be utilized more fully, cost-effectively and safely if a formal and regular training programme is implemented *(11)*.

In another study, 323 registered nurses working in a 500-bed tertiary care hospital were surveyed to determine what and how they initially learned about the medical devices they use, and the consequences of their use *(8)*. McConnell and Fletcher found that the most frequently identified methods of initial learning were trial and error (self-taught) and reading the user instruction manual. Furthemore, at least 90% of respondents indicated that their first encounter with a device was when they simply learned its purpose, function, and operating concepts *(8)*. The most frequently identified method of initial learning was reading the user instruction manual. Furthermore, 87.1% of respondents indicated they had received instruction about a device from another staff member, typically another registered nurse *(8)*. Another finding was that medical device use causes more than 75% of staff nurses to feel stressed. In addition, this study showed that around 10% had used a medical device improperly, which had later harmed a patient *(8)*. In response to these findings, McConnell and Murphy *(12)* have concluded that the introduction of sophisticated health-care technology does not guarantee high-quality patient care.

A study by Kiekkas et al. *(13)* aimed to determine the perceptions of nurses who work in critical-care units about positive and negative effects related to the use of technological equipment and to identify relationships between these perceptions and demographic characteristics of study participants. Kiekkas et al. surveyed 122 critical-care nurses to elicit their perceptions regarding the use of technological equipment. The outcome of this study was that the majority of nurses recognized the positive effects of equipment regarding patient care and clinical practice. However, at the same time, they agreed that use of equipment possibly leads to increased risk due to human errors or mechanical faults, increased stress and restricted autonomy of nursing personnel *(13)*. The use of machines does not add to nursing prestige and this may be related to decreased autonomy. Human errors, mechanical faults and increased stress do not seem to come as a result of time constriction but rather of inadequate education *(13)*. Therefore, it is desirable for undergraduate and continuing education to respond efficiently to the needs of contemporary critical care.

In 2008, the Technical University Delft, in the Netherlands (MISIT group, Department of Biomedical Engineering) received remarkable conerns from two hospitals (one academic and one peripheral). "Our [operating room (OR)] nurses are not educated well enough anymore to handle the equipment in the OR; can you help us?" To investigate this problem, two pilot studies were started. The Technical University Delft, in the Netherlands performed an inquiry of 27 OR nurses in a peripheral hospital to get insight into the problems with equipment use during laparoscopic cholecystectomies. The nurses indicated a number of difficulties using the equipment. These included the:

- camera (white balance is sometimes forgotten, focusing is difficult because of the plastic sheet, connection to the monitor can be too difficult due to the numerous wires to connect);
- light source (image is sometimes too dark, and solution to problem is not clear; if light source needs to be replaced, nurses do not know how to do it or where to find a new bulb);
- laparoscope (scope can cause burns);
- diathermy devices (a number of different devices are used, with different settings and not always enough time to check the settings, or differences between the settings are not always explained);
- insufflator (not enough experience with connecting CO_2 gas, no warning when the bottle is almost empty, faulty connection of cables and wires, use of foot pedals, numerous cables); and
- monitor (when the image is poor or missing, it is too difficult to find the problem, it is difficult to achieve the right colour settings; when someone incorrectly adjusts the knobs, it requires a lot of time to readjust the settings/ connections).

Some general problems with equipment were also mentioned: equipment is not well introduced to the nurses; and if something is not working the nurses do not have enough

background to solve the problem. Instruction manuals are too complex, are not available in native languages and can often not be found. Therefore, equipment that is not used daily is particularly prone to use error.

The OR nursing environment is influenced by requirements for increased acuity and patient throughput, and by constantly changing technology *(14)*. The specialty practice of the OR nurse is complex. Although the specialty practice is based on the core body of nursing knowledge, continuous expansions of knowledge and skills in medical device training and current trends are needed if practitioners are to maintain competence *(14)*. These studies indicate that appropriate and certified educational and training strategies can be used (or designed) to address the aforementioned clinical governance and risk management issues.

Training equipment users to operate medical equipment effectively and safely is one of the most important and difficult tasks of clinicians/engineers *(15)*. Hooper et al. *(15)* indicate that as medical equipment proliferates and becomes more complex, the task of training also becomes more difficult. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) requires that all equipment users (clinicians and nurses) be trained annually in the proper procedures for the equipment they use, and that the training should be documented *(15)*. Training for clinicians to use an instrument is called 'skills training'; for nurses, the term 'education' is used. All learning related to new instruments is referred to as the 'learning curve'; this will be discussed in turn.

Learning curves

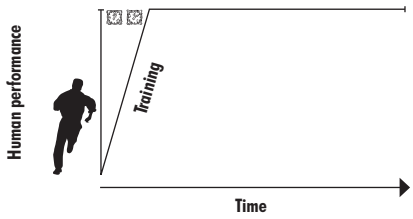
A learning curve in the context of skills training refers to the time taken and/or number of procedures an average practitioner needs to be able to perform a procedure independently with an acceptable outcome *(16)*. A complex hierarchy of factors is involved in the learning curve *(17)*, factors like guidelines, protocols and standards for clinical governance agreed upon by the medical fraternity are vital. Institutional policies, the surgical team and the case mix (the types of patients treated in an institution) are also relevant. Another factor is the individual, e.g. the characteristics of the surgeon, such as attitude, capacity for acquiring new skills and previous experience *(18)*. The learning curve, therefore, may depend on the manual dexterity of the individual surgeon and his background knowledge of surgical anatomy. The type of training the surgeon has received is also important: for example, the use of box trainers and practising on animal tissue for learning laparoscopic surgery techniques have been shown to facilitate the process of learning *(19)*. The slope of the curve depends on the nature of the procedure and frequency of procedures performed in a specific time period (Figure 1). Many studies suggest that complication rates are inversely proportional to the volume of the surgical workload *(20)*. The rapidity of learning is not significantly related to the surgeon's age, size of practice or hospital setting *(21)*.

Who decides when a learning curve has been met? Who is responsible for setting and monitoring standards for new technologies? Currently, individual practitioners are responsible for the ethical use of new (to them) technologies. It is physicians' ethics that govern their use of new technologies; physicians are responsible for the requisite training and experience to know the intervention is safe for their patients. Institutional practitioner credentialing at the local level, despite its faults, is often the primary control of the use of a (new) technology.

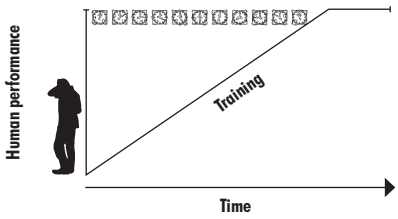
Leaving the responsibility of setting standards regarding learning curves in the hands of individual physicians or local institutions is ultimately subjective; it is possible that this subjects patients to a higher risk of complications (e.g. during the early phase of learning of laparoscopic procedures). The importance of proper training prior to the use of medical devices increases as medical technology advances – increasingly complex surgical procedures are being carried out e.g. laparoscopic surgery. Leaving the responsibility of creating credentialing programs to individual physicians could be a risk. Unfortunately, depending on the country, there may be few current checks on the expertise of surgeons aspiring to be laparoscopic surgeons.

Figure 1: Learning curve related to design

Quick learning curve: well-designed device (i.e. effective human factors engineering) that requires little training.



Slow learning curve: poorly-designed device (i.e. not easy to use) that results in poor performance even after extensive training.



Examples of clinical treatments

Four examples of clinical treatments where medical instruments play a critical role will be discussed, as will one example of a 'simple' device used by patients.

Colonoscopy

Colonoscopy is a standard medical procedure in which a long and flexible endoscope is inserted into the rectum for inspection of the large intestine or simple interventions. Patients have indicated dissatisfaction with procedures performed by trainees, particularly those early in the learning curve *(22)*. Pushing the endoscope tip from its distal end via a long and flexible tube leads easily to buckling when the tip meets sharp curves in the intestinal wall. Buckling is accompanied by painful cramps and makes it difficult to complete the procedure. Additionally, an increased frequency of minor adverse events associated with such procedures has been described *(23)*.

Learning curve for colonoscopy

Steering errors are one of the reasons for the high learning curve of colonoscopy. Current steering wheels do not work intuitively; the wheel is not ergonomic and controlling the tip of the colonoscope is difficult. As a result, it is difficult to control the endoscopy by combinations of horizontal and vertical movements offered by the steering wheels.

A study by Tassios *et al. (24)* evaluated over 1400 colonoscopies with trainees, and showed that more than 180 procedures are required before a trainee can be considered competent. An expert (someone with more than 430 colonoscopies) had a success rate of 91% whereas trainees achieved a success rate of not more than 77% after practising in 180 procedures. A study by Dafnis *et al. (25)* also showed that completion rate increased with experience. They concluded that the major reason for differences in completion rate is the difference in competence of endoscopists. They also found large variations between endoscopists at each level of experience (numbers of performed procedures) in the ability to perform a complete colonoscopy. Hence some endoscopists need more training than others to achieve competence. Dafnis *et al. (25)* suggested monitoring endoscopists to maintain and improve performance. Another method to reduce the learning curve is the use of simulators *(22)*.

The impact of endoscopic training on procedural time and cost was investigated using a large database *(26)*. It was shown that involvement of a surgical resident prolonged procedure time by 10 to 37%, with an estimated academic institutional financial loss of US$ 500 000–1 000 000 per year. The implementation of training simulators in the training process could partially reduce the adverse financial impact associated with training and could also decrease adverse events and discomfort for patients *(22)*.

Improved instrumentation

One way to solve the steering problems associated with colonoscopies would be to develop a joystick mechanism. In an experimental setting, the joystick-controlled colonoscope allowed for better control, shorter intervention times and a shorter learning curve *(27)*. Despite such findings, the company that is the market leader in the field of colonoscopes has not improved the ergonomics of the older design.

Other possibilities to improve steering are still in experimental stages, e.g. inchworm devices specialized for locomotion in the colon developed at the Scuola Superiore Sant'Anna, in Pisa, Italy *(28)*. These have two types of actuators: a clamper and an extensor. The clamper is used to adhere or clamp the device onto the substrate while the extensor generates a displacement in the colon.

A new way of locomotion developed in Delft *(29)* is based on a rolling donut that is positioned around the endoscope tip. The donut functions like a circular caterpillar; it is constructed from three flexible stents that have high friction with the intestinal wall. The resulting Rolling-Stent Endoscope contains a steerable mechanism by which the tip can be bent in all directions over a very large angle.

Minimally invasive surgery

Minimally invasive surgery started in 1987 with the first laparoscopic cholecystectomy. This operation technique is based on access to the body of a patient via a limited number of round cannulas (trocars inserted via small incisions in the skin) *(30)*. The method of access allows the introduction of thin rigid instruments to treat the internal tissue of a patient. In order to be able to observe the actions, a small camera is introduced through one of the trocars. Minimally invasive surgery can be applied to the abdomen (laparoscopy), chest (thorascopy), and joints (artheroscopy). As this discussion is mainly concerned with the abdominal applications of the technique, most of the material presented herein will pertain to laparoscopy. The laparoscope equipped with a video camera system is used to observe the interior of the abdomen. It consists of a rigid tube, containing a lens system and an optical fibre channel. This channel is connected to a xenon light source that illuminates the operation scene. The lens is connected to the video camera and a monitor. In this way, a two-dimensional (2-D) image is presented to the surgeon, enabling him to observe the internal anatomy of the patient and to control instrument handling.

There are several limitations when using the minimally invasive technique *(30)*. Most of these limitations involve the technical and mechanical nature of the equipment. For laparoscopic surgery, the surgeon manipulates the tissue via laparoscopic instruments, inserted through small incisions with limited freedom of movement; the surgeon has no direct

contact with the tissue (no manipulation by hand). Due to friction and, in general, the poor ergonomic design of the instruments, the feedback of perceptive information is reduced *(31)*. Working remotely means no three-dimensional (3-D) visual information is available, which further compounds the difficulties of this technique. Consequently, the surgeon receives only indirect information, which is the most important distinction between the laparoscopic procedure and open surgery.

The risk of complications during laparoscopy ranges between 2% and 4% – higher than in open abdominal surgery *(1)*. One of the reasons for such a high risk is intra-operative injury: the traumatization of soft tissues while trying to securely grasp, stretch, and manipulate them. In a national survey of US hospitals, Deziel *et al. (32)* found that laparoscopic cholecystectomy had a significant rate of bile duct injuries that, in half of the cases, were recognized post-operatively and mostly required anastomotic repair. Fletcher *et al. (33)* reported that, in Western Australia, after the introduction of the laparoscopic cholecystectomy, the cases with intra-operative injury increased from 0.67% in 1988–1990 to 1.33% in 1993–1994. Laparoscopic cholecystectomies have a nearly twofold higher risk of damage to the bile duct, bowel, and vascular structures than does open surgery *(33)*. To prevent these errors root cause analyses can be performed.

Learning curve of minimally invasive surgery

The enthusiasm for laparoscopic surgery has increased rapidly over the past decade. There is a large amount of literature showing advantages of minimally invasive surgery and its acceptance by the public. Laparoscopic surgery is more difficult to master and is associated with a longer learning curve than conventional open surgery. The skills required for laparoscopic surgery are not intuitive. The surgeon needs specific psychomotor skills to control the long instruments through a pivoting point, to compensate for the problems with reduced depth perception and viewing the 3-D anatomical environment on a 2-D monitor image and to compensate for the reduced haptic feedback. These aspects lead to a long learning curve, which has been documented *(34–36)*.

Complex procedures, such as prostatectomy and nephrectomy, require more time to learn. Vallancien *et al. (37)* reported that more than 50 difficult operations are necessary to acquire adequate skills, provided that such operations are performed sufficiently frequently. They also reported that the learning curve shows that eight of 10 of the major complications of the procedure essentially occurred during the first 100 cases. Soulie *et al. (38)* observed a decreased complication rate (from 9% to 4%) after the first 100 procedures.

As far as training is concerned, the introduction of laparoscopic techniques in surgery caused many unnecessary complications *(1)*. This resulted in the development of laboratories to hone skills, involving the use of box trainers with either innate or animal tissues but without objective assessment of skill acquisition *(19)*. Simulation systems, and especially virtual reality (VR) simulators, may provide a solution to the lack of objective assessment. The term `virtual reality´ refers to a computer generated representation of an environment that allows sensory interaction, thus giving the impression of actually being there. The advantages of VR simulators are the automatic measurement of, and feedback on performance; and unlimited repetitions of exercises in a challenging and safe training environment to strengthen psychomotor skills. In the past decade, several VR simulators have been developed and studied *(39)*. However, the training effects of VR simulators are still not fully understood, and educators are reluctant to structurally adopt VR simulators into the surgical curricula on a large scale until tests prove its efficacy. Validation of a new VR simulator is essential in order to determine how the simulator should be used in surgical curricula *(40)*. A recent prospective randomized controlled trial showed that the use of a VR simulator combined with box training leads to better laparoscopic skill acquisition *(41)*.

Scheerer *et al. (42)* determined the benefit of training in a laboratory for senior residents. Training included laparoscopic suturing, as well as didactic and laboratory components. They showed that the performance scores of surgical residents increased significantly and persistently as a result of focused laboratory skills training. Significant improvements were seen with trocar insertion, crural closure, division of short gastric arteries, and fundoplications. An interesting finding reported is that in skills training every task should be repeated at least 30 to 35 times for maximum benefit *(43)*. The distribution of training over several days has been shown to be superior to training in one day *(44)*.

Robotic surgery

A recent technology in the field of surgery is robotic surgery. A surgical robot is a master-slave system with multiple arms operated remotely by the surgeon from a master console. The surgeon controls a robotic arm that operates on the patient, and an endoscopic camera provides a 3-D image to the surgeon. The instruments are cable driven, and provide seven degrees of freedom. The system gives the surgeon the illusion that the tips of the instruments are in his/her hands, giving the impression of being at the surgical site. The motivation to develop surgical robotics is rooted in the desire to overcome the limitations of current laparoscopic technologies (limited degrees of freedom, mirroring and scaling of movement, and the 'fulcrum effect'),[1] as well as to extend the benefits of minimally invasive surgery. Currently, there is only one trademark of surgical robot commercially available. Lafranco *et al. (45)* gave an extensive overview of the advantages and disadvantages of these robotic systems (Table 1).

The health-care market is becoming more and more competitive. Many institutions are interested in presenting themselves as having the most advanced technological equipment and the latest treatment and testing modalities *(45)*. Use of a surgical robot fulfils this purpose. Indeed, robotic devices seem to have more of a marketing role than a practical one *(45)*. Whether or not robotic devices will grow into a more practical tool remains to be seen.

Disadvantages of robotic systems

There are several disadvantages to these systems *(45)*. First of all, robotic surgery is a new technology and its uses and efficacy have not yet been well established. To date, most studies conducted have looked at

1 The fulcrum effect refers to the interference caused by the body wall while using instruments during surgical procedures.

Table 1. Advantages and disadvantages of conventional laparoscopic surgery and robot-assisted surgery

	Conventional laparoscopic surgery	Robot-assisted surgery
ADVANTAGES	Small and (relatively) simple instruments to use	More depth-perception cues
	Affordable	Improved dexterity through: • seven degrees of freedom • elimination of the fulcrum effect • ability to scale motions
	Ubiquitous	
	Proven efficacy	
	(Limited) haptic feedback	Improved ergonomic design for surgeons
DISADVANTAGES	Less depth-perception cues	Very expensive complex equipment
	Compromised dexterity due to: • limited degrees of motion • the fulcrum effect • scaling of instrument tip movements relative to hand movements	High start-up and maintenance costs
		Requires a highly-trained staff with extra skills in manipulating the robot
		Benefit not proven in randomized trials
	Poor ergonomic design	No haptic feedback

Source: Adapted from Lafranco *et al. (45)*.

feasibility, with few long-term follow-up studies. If robotic surgery is implemented, many procedures will have to be redesigned to optimize the use of robotic arms and increase efficiency, though these will likely improve over time.

Another disadvantage of these systems is their cost. With a price tag of US$ 1.4 million, their cost is often prohibitive. Whether the price of these systems will fall or rise is a matter of conjecture. Some believe that with improvements in technology and as more experience is gained with robotic systems, the price will fall *(46)*. Others believe that improvements in technology, such as haptics, increased processor speeds, and more complex software will increase the cost of these systems *(47)*. Also at issue is the problem of upgrading and maintenance of these systems; how much will hospitals and health-care organizations have to spend on maintenance and upgrades and how often? In any case, many believe that to justify the purchase of these systems they must gain widespread multidisciplinary use *(45, 47)*. Due to the complex technology used, failures can easily occur and therefore the safety of these systems remains an issue that requires further investigation.

Additionally, the size of these robotic systems is a disadvantage. Operating rooms are already crowded with personnel and equipment; it may be difficult for both the surgical team and the robot to fit into the OR. Some suggest that miniaturizing the robotic arms and instruments will address the problems associated with their current size. Others believe that larger operating suites with multiple pedals and wall mountings may be needed to accommodate the extra space requirements of robotic surgical systems. Regardless, the lack of compatible instruments and equipment with robotic systems is also a potential disadvantage as it could increase reliance on tableside assistants to perform part of the surgery *(46)*. Without doubt, new technologies will be developed to address shortcomings such as this. Indeed, most of the disadvantages identified will be remedied with time and improvements in technology.

Many studies concluded that a large number of robotic laparoscopic procedures are safe and feasible, for example, robotic-assisted laparoscopic radical prostatectomy (RALP) *(48,49)*. At the moment this treatment is the most important application for robotic surgery. A review by Ficarra *et al. (50)* contributes greatly to the evaluation of the results of RALP. The authors observed that RALP has been widely used in the past five years. They state that the learning curve is shortened compared to conventional laparoscopic radical prostatectomy. The oncologic data are only preliminary, but it seems reasonable to assume that RALP will allow for better continence recovery than conventional procedures. According to the most recent comparative analyses, blood loss may be diminished in RALP compared to the standard radical prostatectomy procedure, but no significant advantage is found in terms of postoperative pain, however. Concerning overall operating time, which includes setting up the robotic system, the standard open procedure provides a major advantage. Although many papers (>70) were included in the review by Ficarra *et al. (50)*, most of the studies were considered as level 4 of evidence and only three nonrandomized comparative studies were considered as level 3b of evidence.[2] While RALP appears to be a feasible procedure, a hypothetical superiority over the conventional procedure remains to be proven. More high-quality randomized clinical trials with long-term follow up, using validated methods of assessment, need to be performed.

Robotic surgery techniques are still developing. The applications for robotic surgery are expanding rapidly in many different surgical disciplines. Only time will tell if the use of these systems justifies their cost. If the cost of these systems remains high and they do not reduce the cost of routine procedures, it is unlikely that there will be a robot in every OR and thus unlikely that they will be used for routine surgeries. Questions about malpractice liability, credentialing, training requirements, licensing, and safety are all valid. It remains to be seen if robotic systems will replace conventional instruments in less-demanding procedures.

Learning curve of robotic surgery

Chang *et al. (51)* showed that incorporation of the surgical robot into surgical practice requires dedicated training to achieve mastery. They studied the learning curve for intracorporeal knot tying in robotic surgery. Baseline laparoscopic knot completion took 140 seconds (range 47–432), whereas robotic knot tying took 390 seconds. After initial robotic training, time decreased by 65% to 139 seconds. With more training, completion times and composite scores were improved and errors were reduced.

Recently a new training device came on the market that can be used to train surgeons in using the robotic operating system.

Endovascular interventions

During endovascular interventions in

2 The Oxford Centre for Evidence-based Medicine ranks evidence obtained from non-consecutive study or without consistently applied reference standards as level 3b evidence. Evidence obtained from case-control study, poor or non-independent reference standard is classified as level 4 evidence (http://www.cebm.net/index.aspx?o=1025,accessed 20 February 2010).

interventional radiology a guide wire/catheter is introduced into the vascular system. Access to the internal body is achieved by creating an access to the bloodstream by introducing a sheath. This method allows the introduction of catheters, guide wires, balloons, stents and other devices and instruments. An X-ray machine with real-time fluoroscopy provides the interventional radiologist with a 2-D image of the operating region and the instruments being used. Although interventional radiology has great benefits for the patient (being minimally invasive which facilitates accelerated recovery), it poses a series of challenges to the interventional radiologist, including *(52)*:

- difficulty in manoeuvring the long flexible catheter;
- friction with the vessel wall, which hinders movement of the catheter;
- poor force feedback from the catheter tip, resulting in unknown pressures at the tip;
- no direct sight line; visual feedback is only obtained via an X-ray image; and
- loss of depth perception, since only 2-D visual information is available.

These challenges suggest that performing an intervention using a catheter is very difficult. Such difficulties emphasize the need for effective training methods for interventional radiologists, with the primary goal of improving the efficiency of the procedure and reducing errors.

Need for training

To be able to meet the growing demands of interventional radiology and endovascular therapy, many more interventional radiologists need to be trained in procedures that are becoming increasingly complex. Until recently, fellows obtained their first basic skills training during diagnostic angiography procedures. This traditional method of training is disappearing, however, because other diagnostic methods are becoming available. This gap in training can be filled in several ways.

Training on animals, bench models (skill boxes) and VR training have all been suggested as solutions to this problem *(53–57)*. The first solution, however, has been met with considerable resistance by the public in many countries; furthermore, animal experimentation is too costly to be applied as a full-scale training tool. Problems exist with bench models as well, because objective assessment of performance is difficult to obtain. Training on VR simulators does not have these problems and seems therefore to be a good alternative. However, the effectiveness and efficiency of VR trainers in interventional radiology have not yet been studied. It is only recently that VR training for vascular interventional radiology procedures has become available. Most studies on VR training in medicine come from publications discussing endoscopic surgery, or minimally invasive surgery *(52,58–60)*, and further studies are needed to determine the effectiveness of VR training in radiology.

While similarities exist between interventional radiology and endoscopic surgery (in both fields special long tools are used, inserted through small incisions), certain interventional radiology techniques, such as stenting and embolization, have their own intrinsic demands, end-points and complications. Furthermore, interventional radiology techniques are not necessarily related to any 'classical' vascular surgical techniques, either. All of this makes the demands for VR training in this field unpredictable.

Neequaye *et al. (61)* performed a literature study on the methods available for endovascular skills training and assessment of skills. This field also requires a different set of skills than does open surgery. It was shown that simulation based training shortens the learning curve. Lin *et al. (62)* analysed outcomes of patients undergoing carotid artery stenting; the outcomes demonstrated fewer procedure-related complications, reduced fluoroscopy time, and lower contrast volume with increased physician experience. A number of studies indicated that simulation-based training allows the early part of the learning curve to take place without exposing patients to unnecessary risks *(62,63)*. Iliac and renal angioplasty showed similar improvements with simulator training *(61)*.

Complications

Neequaye *et al. (61)* and Mas *et al. (64)* reported that a range of clinical specialists are interested in performing carotid artery stenting, e.g. interventional radiologists, cardiologists, neurologists, and neurosurgeons. Neequaye *et al. (61)* indicated that there are potentially catastrophic results of technical errors in carotid artery stenting as evidenced by the recently published EVA3S trial, which was terminated prematurely as a result of an excess stroke and death risk (9.6% in carotid artery stenting compared with 3.9% after endarterectomy) *(64)*. The trial was criticized because relatively inexperienced interventional radiologists performed the carotid artery stenting. To ensure that only appropriately trained individuals carry out such high-risk procedures, structured training programmes underpinned by objective measures of proficiency, must be developed. Neequaye *et al. (61)* concluded that tools for such programmes are already available, but that organization of such programmes needs to make full use of modern simulation techniques for technical and non-technical skills training. Unfortunately, the effectiveness of VR endovascular training is not yet established *(61)*. Furthermore, Neequaye *et al. (61)* indicated that reliability, feasibility and validity are still issues with these training programmes.

Medical devices used by patients

Devices are increasingly being moved from exclusive use in specialized health-care settings to community- and home-based care. In these new environments, devices may be used by untrained and unskilled users (e.g. patients) *(65)*. An example is the hand-held, battery-operated meter that patients with diabetes use to check blood glucose levels. In an article by Rogers *et al. (66)*, the authors showed that a device that is classified as `simple´ by the manufacturer, may not be simple in practice. A task analysis was conducted showing that three steps were involved in using the blood glucose meter, but implementation of those steps required the user to perform 52 sub-steps *(66)*. Special instruction/training was given to the user, but these instructions were too complex to understand, or were poorly worded *(66)*. A global measure of readability showed an 8th grade education was required to read the manual (readable by approximately 58% of the US population). Diggory *et al. (67)* evaluated the use of an inhaler by elderly patients (aged between 71 and 91 years

old, with a mean age 83) and found that 24 hours after being trained in its operation, 65% of them could not use the device at all. Comparable findings were discovered when evaluating the use of hearing aids *(67)*.

The in vitro diagnostic device is another example of a device that can be potentially misused. Laboratory errors can negatively impact patient safety *(68)*. Bonina *et al.* argue that it is important to classify laboratory errors by relating them to their potential effects on patient outcomes, allowing definition of the relevance of the error itself. The authors give an example: in a critical situation, a haemolyzed sample is probably less problematic than sample mismatching or a turn around time that is too long. However, abnormal haemolysis that prevents sample analysis can lead to a request for a new sample, which prolongs the turn around time and could potentially be very harmful for critical patients *(68)*. Siekmeier and Lutz *(69)* analysed all in vitro device notifications between 1999 and 2006 in Germany (registered by the Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM; Germany's Federal Institute for Drugs and Medical Devices) and found a large number of product defects, but also a large number of laboratory use errors. They suggested a number of measures, such as sufficient information and training of patients using in vitro diagnostics (IVDs), include information on the limitations of the methods and the risks related to erroneous results, as well as relevant causes of user errors that could influence safety *(69)*.

Preferred process of designing medical equipment

High-quality, functional design of emerging medical devices in an increasingly complex clinical and technological environment requires an understanding of the device's context of use, workload, and the environment in which it will be used. That is, the device's ease of use, its placement in the clinical workflow, and the integration of user feedback in the design process *(6)*, all of which provide maximum benefits to health-care quality. This is all part of 'human factors engineering', which involves the application of principles about human behaviours, abilities and limitations to the design of tools, devices, environments, and training in order to optimize human performance and safety.

Different stages of device design, protocols and training

The development of improved instruments, protocols and training tasks can reduce errors and enhance the quality of medical interventions. Therefore, it is valuable for continuous evaluation of these improvements to be considered. The methodology described by den Boer et al. (70) can be used for this process. They describe three stages of evaluation: 1) technical experiments, 2) simulated experiments and 3) clinical settings.

New medical devices must first have a technical evaluation to assess reliability and safety, as well as to test specific functions. According to den Boer et al. *(70)*, the functionality, safety and ergonomics form part of the technical evaluation and could be analysed in a laboratory setting. The technical evaluation should be followed by an experimental evaluation simulating the clinical setting, without risk to the patient *(71–73)*. After the quality and safety of the prototype have proven sufficient, evaluation in clinical practice is needed *(70)*.

It is valuable for protocols, in addition to new technology, to be tested in a simulated clinical setting *(74)*. Furthermore, determining whether or not the quality and effectiveness of the new protocols are significantly better is needed prior to implementation in a clinical setting. It is valuable if training in these new protocols is present at each of the three stages of development *(70)*.

Training has two aspects: a learning aspect for the resident to acquire new tasks, and a controlling aspect for the supervisor to evaluate the correctness of performance and the efficacy of learning *(75)*. Training can also be initiated at three stages *(70)*. Stage 1 includes training in basic tasks and coordination (e.g. hand-eye coordination tasks, suturing tasks, or VR simulators) *(76–78)*. Stage 2 includes simulated protocol tasks, tissue handling, operation planning, and risk prevention; animals or VR simulations can be used to improve surgical skills at this stage *(59, 79–82)*. Stage 3 includes ensuring analysis of both the correctness and efficacy of task performance *(70, 83)*.

Problems related to evaluation of medical devices

There are a number of problems inherent in the way new medical devices are evaluated *(70)*. Issues include the lack of clinical trials and thorough analyses of new devices/surgical instruments. In addition, FDA approval of a new medical device does not automatically indicate that the performance is better *(84)*. The limited surveillance that products receive after entering the market can result in less effective treatments and delays in identifying risks *(84)*.

Generally, case studies are used to determine the 'feasibility' of medical devices. This evaluation includes a number of problems *(70)*, which often are not mentioned. The studies tend to be performed by top experts, and results may not reflect average outcomes. There is generally not a standard on which to evaluate instruments, and objectivity is jeopardized when the company pays for the evaluations. Surgeons are unlikely to blame the instruments, focussing instead on other factors that may have led to complications. A study by Verdaasdonk et al. *(85)* showed that most incidents with equipment are not reported, meaning the problems with

Table 2. Stepwise analysis of quality and efficiency in medical device design

	Evaluation parameters		
Stage	Device development	More depth-perception cues	Training programme
0 – Instrument tests	Reliability Instrument characteristics Safety	—	—
1 – Technical experiment	Functionality Ergonomics Safety	—	Basic tasks or drills Coordination Correctness
2 – Simulated experiment/ Animal experiment	Functionality Ergonomics Safety	Safety Quality	Simulated surgical actions Simulated protocol tasks Tissue handling Planning operation Risk prevention
3 – Clinical setting	Functionality Ergonomics Efficiency Safety	Safety Quality Efficiency	Planning operation Risk prevention Correctness Efficiency

Source: den Boer *et al.* *(70)*.

a complex medical device will not easily become visible; and as a consequence no action will be taken to improve the device.

Standardization

A number of studies have shown that between 39% and 46% of adverse events resulting from misuse of medical devices take place in the OR *(86–89)*. In most of these studies, the cause is only indicated as operation related. A recent observational study *(85)* investigated the incidence of problems with technical equipment during laparoscopic procedures. In 87% (26/30) of the procedures, one or more incidents with technical equipment (49 incidents) or instruments (9 incidents) occurred. In 22 of those incidents (45%), the technical equipment was not correctly positioned or not present at all; in the other 27 (55%), the equipment malfunctioned as a result of a faulty connection (9), a defect (5), or the wrong setting of the equipment (3). In 10 cases (20%) the exact cause of equipment malfunctioning was unclear.

Ergonomic improvements and standardization of equipment in conjunction with checklists prior to surgery have been suggested *(85)*. Variation in medical devices between hospitals (and even within the same hospital) is one of the causes of these accidents. Suppose, for example, that all cockpits in a particular airplane were designed according to the specifications of the captain. This would result in an unlimited number of design variations. For safety reasons this does not happen. Standardization is a key issue in the field of medical devices, and would reduce the number of accidents. Except for the maximal size, there are no clear guidelines in building or outfitting a new hospital or OR. Even with the new integrated ORs, hospital staff are asked how they want the OR designed or structured. Verdaasdonk *(90)* showed that a checklist can reduce the number of incidents in the OR by more than 50%. Hence, when medical devices are not intuitive to use (or standardized), other measures could be taken to ensure that no errors are made.

Ergonomic design of instruments and the OR can improve treatment by decreasing fatigue and discomfort of the surgeon *(91–93)*. Additionally, methods to assess mental and physical workloads on surgeons could be developed and applied, in order to detect and to reduce pressures *(91–93)*. Additionally, methods to assess mental and physical workloads on surgeons could be developed and applied, in order to detect and to reduce pressures *(94,95)*. An article by Rogers et al. *(66)* demonstrated how human factors engineering could be applied to glucose meters and medical devices in general. Blood glucose meters, specifically designed for patient use, were reviewed via a task analysis. Users reported a number of problems, contrary to manufacturer's claims about ease of use (for more discussion on this see section on medical devices used by patients). The possibility for design-induced human error was demonstrated, which is a strong argument for the importance of human factors engineering.

Evaluation of the surgical process

When laparoscopic or similar equipment is investigated, the current quality analysis is mostly restricted to the analysis of the post-operative outcomes of patients in terms of morbidity, mortality, survival, and more recently the analysis of learning curves *(70)*. Standards exist for the design phase of medical devices (Medical Device Directives 93/42/EEC, prEN 1331, ISO 9000/IEC guide 51), but not for objectively evaluating the functionality of instruments during peroperative use *(70,91,96)*.

Aviation and production industries employ detailed process analyses to determine the quality and efficacy of the process. In industry, for example, human–machine interactions are modelled; human errors or technological failures in complex production processes are also analysed *(10, 97–99)*. A similar methodology was developed by Sjoerdsma et al. to describe and analyse the surgical process *(100)*. Aviation, for example, requires extensive training and testing in simulators, before and after completion of education. In the field of surgery, similar analysis and training methods could be used to improve surgical outcomes.

Peroperative task analysis

Objective analysis of the surgical process and the devices used therein are even more important now that the technological complexity of medical interventions is increasing. The Minimally Invasive Surgery and Interventional Techniques group at the Delft University of Technology has developed a methodology to describe and analyse the surgical process *(70,100)*. This methodology consists of seven steps that can be used to measure the correctness and efficacy of task performance, protocols and the instruments used *(70)*: 1) define the aim of the study (e.g. compare different procedures), 2) define parameters to describe the process, 3) define quantitative measures to analyse correctness and efficacy of the procedure *(101-103)*, 4) record the peroperative process, 5) analyse the peroperative process in accordance with the aim *(104-108)*, 6) evaluate outcome and discuss detected problems in a multidisciplinary team, and 7) find the solutions to the problems that most negatively influenced the outcome for the patient.

Achieving the goals

A medical devices unit or organization could track the introduction of new devices and implement measures on training of complex medical device use. This unit or organization could also take any necessary action to promptly protect the public if a problem is detected, and encourage health-care professionals and industry to discuss problems related to medical devices.

Conclusions

New technologies are entering medical practice at an astounding pace. This is motivated in part by patients who request (and increasingly expect) minimally invasive procedures that result in minimal damage to healthy tissue. The 'side-effects' resulting from the introduction of new, often-complex technology in health care, however, can be considerable—both for patients and health professionals.

This paper has shown the consequences of the increased complexity of technology used for the treatment of patients. Three facts emerged:

1) the devices are often not well designed for the medical environment in which they are used;
2) the user is often not trained properly to use these devices; and
3) the (new) procedures often result in long learning curves for health professionals.

These three facts influence outcome of care. It has been shown that it is valuable to develop a standardized methodology for the evaluation of the quality of medical devices and the analysis of complications resulting from their (mis)use. This can be done by introducing various methods, such as a video monitoring system. It is better that new equipment and instrumentation not be introduced without a thorough evaluation of its functionality (Technical Evaluation), followed by monitoring its use in clinical practice (Health Technology Assessment). These evaluations can be facilitated by a biomedical engineer or similar health-care professional. If the benefit of an instrument or device cannot be proven through these assessments, it should not be introduced. Standardization of equipment can solve many user problems; indeed this measure has been used effectively by aviation and industry. Training and (continuing) education are important components of standardization, to ensure safety. Any programmes standardizing medical practices and the use of medical devices could include training curricula, including credentialing methods for the post-training period (e.g. every half year). Implementing such measures as part of an overall programme of standardization will help to reduce errors and improve care.

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