AVOIDING PITFALLS IN THE ROAD FROM IDEA TO CERTIFIED PRODUCT (AND THE HARSH CLINICAL ENVIRONMENT THEREAFTER) WHEN INNOVATING MEDICAL DEVICES

F.P. Wieringa[1,2], M.J. Poley[3], A.C.M. Dumay[4], A.F.W. van der Steen[2]

[1]TNO Science & Industry, Delft, the Netherlands; ✉ f.wieringa@tno.nl

[2]Erasmus MC, Department of Biomedical Engineering, Rotterdam, the Netherlands

[3] Erasmus MC, Institute for Medical Technology Assessment, Rotterdam, the Netherlands

[4] TNO Quality of Life, Leiden, the Netherlands

Abstract

Innovation in medical technology is a critical chain of events, ideally leading to an improved situation for patient and staff as well as a nice profit for the supplier of the innovation. Unfortunately many innovative ideas are not successful in practice. This is often due to lack of:

- Medical relevance
- Validity of the underlying technical principle
- Reliability (not only of the devices' intended function, but also of alarms)
- Ease of use, training and maintenance
- Mechanical robustness
- Compatibility with ambient factors and other devices (e.g. heat, dust, liquids, EMC)
- Extensive analysis of possibilities for improper handling (including improper connections) and use not according to intended purpose(s)
- Attention for regulatory affairs, pricing policies and reimbursement criteria of health insurance organizations

Even if a device manufacturer successfully bridges the gap between idea and certified product, the point of clinical introduction only means that now the real harsh clinical practice will prove whether, and to which extent, the projected innovation comes true. When developing medical devices, technological knowhow is just as important as knowledge of human factors, Murphy's Law and the principle of Le Châtelier & Van't Hoff (originating from chemistry) applied to people at work.

1 Driving forces behind innovative attempts

The need to innovate in healthcare delivery is socially very relevant. Forces driving the innovation needs are [17]:

- **Increasing demand for healthcare delivery** This results from demographic developments: More elderly people will need healthcare for a longer period;
- **Increasing demand for higher efficiency.** Increase in demand must be handled by (relatively) fewer healthcare workers;
- **Increasing empowerment of the patient.** Patients and healthcare consumers will have a stronger influence on healthcare delivery. Patient needs will draw more focus and attention. For home care applications, the patient can be operator as well as responsible party for selection, application and maintenance all at the same time;
- **Increase in the effect of market forces.** New markets emerge for health insurance, the healthcare (pre)procurement market and health delivery. Careful decisions must be made based on quality, patient safety and efficient use of scarce resources in healthcare.

The above stated driving forces behind innovation are quite rational and we might call them "market driven". A completely different kind of innovation can (but not necessarily always will) result from serendipity and/or shear curiosity combined with imagination and sometimes great persistence to follow a dream. The latter "curiosity driven" category of innovation can be surprisingly leapwise, but is also much more unpredictable than the first category.

Companies having a well-established market position, might be better off with improvements of existing products than with truly new principles that disturb their market, challenge their established position and maybe even render their entire production facilities obsolete [29]. This means that market driven research will anyhow find industry funding, whereas wild ideas are more likely to be judged as too risky.

Therefore, it is wise to shape the innovation climate so that there is also some room for curiosity driven research, e.g. funded by the government. During his inauguration speech as a professor of chemistry in Amsterdam 1878, J.H. van't Hoff stated: "*In order to*

understand the relations between observations, and especially for true inventions (i.e. things that not yet exist but that might be) scientific imagination is required" [61].

A mixture of market driven and curiosity driven innovation looks ideal, although the optimum setting will remain a subject of endless dispute [20]. Clinical progress is best served when both historical developments and existing practice are carefully analyzed. Innovation flourishes in an environment where the clinic (doctors and nurses) meets with the academy (scientists, engineers and human factors experts) and both openly discuss with industry.

This paper discusses critical factors that determine failure or success for innovative medical devices.

2 Important factors that determine success or failure

Unfortunately many promising initiatives for innovation are not successful in practice. Typical factors that determine the success of new devices are:

- **Relevance**
  No matter how nice the solution is, without solving a real problem it won't easily sell.
- **Validition**
  Sloppy validation of the underlying technical principle, manufacturing process or software can turn out to be very costly, especially once a product is distributed. In 2000 a prosperous manufacturer of relatively simple sterile products went out of business. Lack of sterility of simple cotton swabs caused an avalanche of claims from more than 140 firms using these simple swabs as an accessory in their sterile packaged end products [12, 21]. Validation goes broader than often thought. Note that e.g. accompanying documents of medical devices form an integral part of the device user interface and therefore their usability must be validated.
- **Exclusion of unwanted side effects**
  Investigations of incidents tend to reveal that in many cases seemingly unimportant details can cause huge effects. An anonymous example, witnessed by the first author, is a batch of automated X-ray film processors, which all broke down in a few months due to osmosis causing the fluid reservoir walls to swell so much that all mechanics jammed. The manufacturer had switched over to a new "compatible" polyurethane foam type without thoroughly testing it. Acceptance tests, constancy tests and maintenance / recurrent safety tests form a safety net for such effects.
- **R&D costs and time to market**
  Large R&D costs and long time to market are very common for even relatively simple medical devices. This is partly due to numerous strict regulations (which altogether do make sense). Hoffman provides a striking example that leap wise innovation in medical technology was much simpler in its early days: Within six weeks Earl Bakken modified a metronome circuit from Popular Electronics into a wearable battery-powered pacemaker. 3 years later Bakken's company, Medtronic, was selling implantable pacemakers for $375 each. That was in 1960. Today it takes 10 to 15 years and millions of dollars from the "*gleam in the inventor's eye*" for a product to reach the marketplace [34].
- **Reliability**
  Of course a device must perform its' intended function. Proper functionality however also includes features like alarms, which should not only reliably be activated when needed but also should NOT be activated when nothing is wrong. People tend to start ignoring unreliable alarms (so-called "cry wolf" effect) [8].
- **Ease of use, training and maintenance**
  Not all change is progress, it is e.g. still not uncommon that health care workers first have to record information on paper and later feed it into the electronic health records system thereby duplicating their work [48]. Another example: The first author witnessed a CT-scanner jammed by lack of hydraulic oil. The two underlying causes were that the lid to fill the oil reservoir could only be reached by completely removing the whole compressor and that maintenance was spread across various engineers, each assuming the oil level would suffice till the next guy would come and fill-up. Training sessions that already consult users and maintainers during development may preclude such end results. Comparing staff notes and real values for parameters like heart rate and blood pressure can reveal observer accuracies for different data presentations [35].
- **Robustness**
  Many medical devices are either transportable themselves (so they may fall or bump into objects) or are used within the vicinity of transportable devices like beds, etc. (so they are subject to being bumped into). The notorious marks of mechanical impacts at "bedside-height" are well-known in hospitals. Riding a bed or device out of the room without disconnecting all tubes, leads and cables also is a typically foreseeable situation.

- **Compatibility with ambient factors and other devices**
  Apart from mechanical loads, medical devices can be subjected to liquids, medical gases, explosive fumes, dust, heat, radiation (ionizing, electromagnetical & optical), etc.
  To illustrate that even huge projects with much pre-analysis can present problems, we give an example: Within the Netherlands a shared nationwide wireless communication system (COM2000) was developed for police, fire brigades and ambulances. The project took many years to meet the demands stated by all involved parties. When it finally was put into service, tests near 90 medical devices by an independent institute revealed that 49 of these medical devices reacted upon the radio-waves, 13 of these reactions were potentially dangerous, 25 were significant but tolerable and 11 reactions were light [33].
- **Analysis of possible improper handling**
  The difficulty of this task is huge, especially when taking into consideration that improper handling can occur during normally intended use, during reasonably foreseeable off-label use, during not reasonably foreseeable off-label use and even when someone deliberately wants to inflict harm. It is clear that it would be unreasonable to put the responsibility for both latter cases at the manufacturer, but of course the question rises: "*what is foreseeable?*" [70]. An example of use not according to intended purpose(s) might be the repeated use of a disposable return electrode for electrosurgery, which compromises hygiene and increases the risk of burns (see also improper handling). Another example is the in-house creation or modification of medical electrical equipment or systems as a product, not being certified and not having the necessary documentation for recurrent tests.

Many emerging technologies in medicine are so-called "converging technologies" (i.e. combining different technologies) thus crossing borders between traditionally separated categories of medical products such as medical devices, pharmaceutical products or human tissues [25]. The strong point about converging different disciplines is that long-known and well-mastered technologies are much more likely to function in conjunction than completely new technologies. The weak point is that each discipline also has its own specific culture and vocabulary, which means that miscommunication is likely to occur. The importance of communication should never be underestimated in any project, but this holds particularly for multidisciplinary projects.

The toughest point for most technologists remains to accept that, no matter how elegant and proven a new technological principle is, it eventually must be incorporated in such a way that people actually can work with it. You cannot successfully launch spear point technology without first carefully attaching a proper shaft to it [69].

Typically there seems to be a lack of systematic feedback between users, purchasers, designers and manufacturers of equipment [49]. Health IT-system design expert Sensmeier formulated her basic (and very practical) rules for determining user-related factors as follows [54]:

- Watch what people actually DO.
- Don't believe what people SAY they do.
- Definitely don't believe what people predict they MAY do in the future.

People that follow these above rules learn that theory and practice mostly differ (within any profession). If they subsequently use their experience to assess new methods, rules or technologies that are being forced upon them, they basically apply Murphy's law in a positive way.

3 Murphy's Law

There seem to be several possible sources for the famous law of Murphy, but most probably it dates from 1949 and was formulated by US Air Force Captain Edward A. Murphy. He had helped out the research team of Dr. John Stapp (that investigated how much deceleration a man could stand) by providing them with an acceleration sensor and some instructions on how to use it. Each experiment was quite dangerous; Dr. Stapp seated himself in a rocket propelled sled to be launched and exposed to very high G-forces. After a ride with Murphy's new instrument (strapped to the sled by others) it turned out that there was no registration. Murphy was called in, examined the sensor, saw it had been mounted in a wrong way and spoke his famous words. Murphy's law is mostly cited as: "*If anything can go wrong, it will*". But as remembered by Dave Hill (who was a member of the rocket sled team) it originally sounded: "*If there's any way they can do it wrong, they will*".

There is a subtle but important difference between both quotes. We are convinced that the latter quote not only implicates that real good engineering might preclude problems, but it also looks more in line with the further career of Captain Murphy. He left the Air Force in 1953, becoming a human factors engineer for Douglas Aircraft and worked for a series of companies before retiring from Hughes Helicopter, where he'd been a reliability engineer [57].

We are convinced that Murphy's law implicates that real good engineering might preclude problems, but not all of them (to stay in line with the law).

The best perception of Murphy's law for anybody involved in health technology innovation might be: "*If we -designers- overlook any way that they –users, or even technicians- can do it wrong, they will*". This becomes particularly important for products or procedures that are performed millions of times around the world.

An illustration of this principle might be a collection of look-a-like cases of electrocuted patients:

In 1997 the FDA released a decree that explicitly forbid the use of unprotected "banana plug" patients leads. The reason was that these 2mm diameter male plugs nicely fitted into the female device-side plug of a standard IEC mains cord (see fig. 1).

Although it may sound unlikely that somebody would do this, at least 24 cases were reported from 1985 to 1994 for the USA alone, which led to the FDA decree [22]. Of course this illustrates that indeed, expressed as a percentage of the total device handling, such mistakes are extremely rare, but not rare enough.

Fig. 1: Murphy's Law illustrated. 2mm male pins of old-style ECG-electrode lead wires normally plug into an ECG patient cable (both upper photos). These pins also fit into worldwide used female IEC mains plug (both lower photos).

Before the FDA decree, a number of manufacturers already delivered their units with protected patient cables. But some hospitals found such mutually incompatible proprietary connectors too expensive compared to the old universal system of 2mm plugs. So they bought cheaper cables from other suppliers.

In 1993 a 12-day old infant died in a US-hospital. The apnea monitor involved had been sold to the hospital with protected electrode lead wires and patient cable. However, when the infant was electrocuted, an unprotected patient cable from a second manufacturer and unprotected pre-wired electrodes from a third manufacturer were being used instead of the protected configuration.

In 2006 the anaesthesist Gilly proposed an addendum to Murphy's law: "*Whether things can go wrong or not, depends on your frame of reference*" matching earlier observations by Smalhout [28, 56]. Improving technology is important, but not enough. Trying to compel people to change their frame of reference and behavior is much more important, but this usually meets resistance as we will discuss next.

4 The principle of Le Châtelier & Van 't Hoff

Near the end of the nineteenth century, two great scientists independently researched the underlying principles of chemical equilibrium. In 1884 Van 't Hoff published his insights, followed in 1888 by Le Châtelier.

The formulation of their combined conclusion states: "*Any change in one of the variables that determine the state of a system in equilibrium causes a shift in the position of equilibrium in a direction that tends to counteract the change of the variable under consideration*" [11, 43, 44, 60].

It is our opinion that this chemical principle also holds for the introduction of change into society, including the medical society. The acceptance of change rises exponentially if the result bears fruits to the people that are forced to perform according to the new set of rules and if they are kept well-informed [64]. In health care (but also in many other disciplines) changes, however, often are enforced to fulfill management requirements rather than to solve problems encountered during daily work [2]. The result is that health care workers are confronted with extra workload, whereas they don't see any benefit for themselves or their patients. This is an undesirable situation, especially when taking into account that stress in the work environment, high patient volume and the tendency to adopt shortcuts play a significant role when things go wrong [30].

Last but not least the persistence of old habits should not be underestimated. Even if there is agreement that a change should be adopted, it remains quite difficult to actually change the way people are used to work [32, 47]. In such situations the role of leaders that continuously show a good example is the most important factor. It is simply not sufficient to only tell health care workers what to do, exemplary behavior of leaders is much more

important [27]. Giving a good example in behavior improves the safety climate. When, however, the perceived safety climate is poor, polarization will occur: managers will believe that employees are responsible and employees will believe that managers are responsible for workplace safety [50].

Beatty *et al.* produced an excellent article about modeling the delicate dynamic equilibrium of mutually coupled factors that determine an anaesthesists decision whether or not to shortcut safety guidelines, and to what extent [6]. The principle of Le Châtelier & Van 't Hoff can be applied to such models just as well as to dynamical equilibrium in chemistry.

5 The importance of clear, concise and closed-loop communication

Instruments can help doctors and their staffs to do their jobs, although in many cases early embodiments of such instruments are difficult to operate for the user and require several generations of technological improvement to become more ergonomic. The input of medical staff is a crucial component for such improvements. Ideally, developers and users thus should form a closed communication loop. Medical history has learned us that extended diagnostic tools (and especially imaging modalities) can lead to better understanding which in turn can lead to better possibilities for treatments.

Innovations in technology are not automatically also advances in medical practice. Understanding and treatment are, however, surely catalyzed by close co-operation between medical and technological professionals [68]. Positive technology impact in medicine occurs most readily when innovators augment the skills of care providers and collaborate with them, rather than seeking to displace them [63]. In such teams technicians on one hand should communicate to clinicians what they see as promising new technological possibilities, and on the other hand should use the "*Spice Girls method*" by continuously asking clinicians "*so tell me what you want what you really, really want*" [58]. In this communication process, the nursing profession should NOT be forgotten (as too often happens) because nurses form a crucial factor in the acceptance, application and routine use of medical technological devices [31, 48].

Although we just stated that good communication between clinicians and industry is an excellent thing, there is a risk that clinicians may become biased by conflicts of interest when they are too closely involved with technology development. It is a good thing that this issue has been recognized and that an open discussion has been started between academicians, clinical investigators, regulatory bodies, medical insurance companies, device manufacturers and the financial community [5].

6 Assessment of innovation

Increasingly, health care institutions, governmental agencies and health insurance organizations use a technology assessment model to decide whether a claimed innovation would work for them [52].

The discipline of health technology assessment (HTA) was originally developed some 30 years ago, with the purpose of assessing the medical, economic, social, and ethical implications of development, diffusion, and use of health technology. In the current era of cost-effective and evidence-based medicine, these assessments have great merit in finding out which health technologies provide value for money [16]. Nevertheless, such models are complex and have their limitations. The cost-effectiveness assessment of diagnostic interventions, e.g. can be quite difficult, since the influence on parameters like mortality etc. is indirect and thus hard to quantify [24].

Another aspect is the influence of waiting lists. Koopmanschap *et al.* state that economic evaluations of health care programs in countries with waiting lists should consider the possible impact of waiting on costs and health effects, especially if health loss while the patient is waiting is partly or completely non-reversible [41].

Still another thing to keep in mind is the perspective of the assessment. After all, a technology might be cost-effective from one perspective, but not from another. To give an example: according to a recent study from the Netherlands, the introduction of laparoscopic donor nephrectomy was highly cost-effective from a societal perspective, but far less cost-effective from a healthcare perspective [40]. The societal perspective is generally considered the most appropriate, as HTA is concerned with society's welfare and tries to inform public decisions that affect the whole population. Yet, it is informative to also present the results from other perspectives, such as that of the patient, the hospital, or the health care sector. Brouwer *et al.* for example suggested to adopt a two-perspective approach for medical technology assessment, presenting one cost-effectiveness ratio following a strict health-care perspective and one following the common societal perspective [10]. Especially the hospital perspective seems very relevant for successful implementation or rejection of an innovation.

The above aspects are only a few examples to illustrate the complexity of health technology

assessment. Let us for the moment assume that a certain assessment model has been chosen and applied to a new technology. If this assessment predicts that the studied technology will work for the involved organization (i.e. that it will make a positive difference to patient care, and that it is financially and operationally acceptable) then this will likely result in a positive advice to implement it in clinical practice.

Ideally it should not matter what kind of technology assessment model is being applied, provided that the outcomes are evaluated. Such evaluation feedback is an essential part of the process; HTA is not a one-time exercise, but should be an ongoing effort. Changing patterns of disease and innovations in treatments may render a once cost-effective technology less cost-effective. Having observed this, it is worth citing the important general advice formulated by Abenstein: If a hospital applies a certain technology assessment method, then after a technology of choice has been installed and been used for a while, a post-implementation review should be done. This review should go over the same assessment attributes that led to the purchase decision. It should be determined whether the expected patient volumes, results, income, and expenses indeed were seen. If not, the technology assessment process should be refined to make better decisions in the future. Finally, if the results are at a substantial negative variance from what was anticipated, abandoning the technology and adapting the assessment model should be considered [1].

A related concept worth mentioning here is the so-called "technology assessment iterative loop" described by Tugwell *et al.* stressing the need of periodic reassessment, recognizing that the job of assessment must continue throughout the life of a technology, because costs, effects, and the way technologies are used all evolve [59].

Note that closing the feedback loop is not only important for technological aspects, but for all processes within healthcare. Already in 1910 Codman stated "*Every hospital should follow every patient it treats, long enough to determine whether or not the treatment has been successful, and then to inquire, 'If not, why not?' with a view to preventing similar failures in the future*". Captain Murphy was not yet born then, but would have liked him. However, back in 1910 Codman looked too far ahead to be appreciated amongst most colleagues. Now he is recognized as the father of evidence-based medicine [45].

Not closing the feedback loop forms a serious and often observed pitfall in the road to successful innovation. Lack of preparedness to accept feedback and unwillingness to admit a wrong decision are inherent to human nature. Inventors don't like to admit that their invention is less beneficial than they thought; managers are not keen on stopping a project started by them selves and users do not easily admit they made a wrong choice (neither do politicians). However, within any innovation project (whether medical or non-medical) it is crucial to have this preparedness [46].

Health technology assessment primarily should look at the benefit for the patient. However, once a technology has shown to bring the patient significant benefit, there should also be put serious effort in optimizing the work conditions for health care workers. Minimal invasive surgery (MIS) is an example of this; it has brought patient benefits in many procedures but its human factor aspects still need optimization [51]. Much of the technology for the operating room of the future currently exists (e.g. surgical robotics, virtual reality, and telemedicine). However, in order to function optimally MIS must be integrated in a fashion that takes on board the human factor strengths and limitations of the surgical team [23].

This also applies for other new rapidly emerging technologies like electronic patient files, telemedicine, PACs, and so on. Failing to implement human factor engineering is an accident waiting to happen.

7 Incidents and their contributing factors

An Australian study concerning the root causes of incidents and potential incidents revealed the following root causes (most common root causes are listed first) [15]:

- **Procedures and guidelines**
  These are issues relating to the availability, accessibility or the absence of policy or guidelines. They can relate to misunderstanding or non-compliance with policy, procedure or established practice.
- **Human resources**
  All issues surrounding the human resources of a health care organization, including the allocation and management of staff.
- **Communication**
  The availability and flow path of information (verbal, written or electronic) between staff (including e.g. general practitioners, ambulance personnel, etc.) patient and/or family members.
- **Information**
  This concerns all documentation that arises from health care (medical records) as well as communication amongst care providers or the information that is given to a patient (or his/her

representative) on medical condition or treatment plan.

- **Equipment**
  All issues around devices, which may include: The number of different types of devices having the same function, the availability of equipment and its functionality or disfunctionality, including maintenance & repair aspects.
- **Organization**
  This concerns the organization, management and culture of a health service, which includes e.g. the need to ensure proper training of staff.
- **Physical environment**
  The design of the environment should support the operations of the health service. This issue pertains to an enormous amount of aspects, like lighting, heating/cooling, noise, sufficient space for work and storage, elevators, medical gases, electricity, ICT-facilities, pagers, phones, etcetera. Research within the Netherlands has learned that many defects within installations can remain undetected if malfunction reports by users are the only input instead of additionally performing periodic inspections [65].
- **External factors**
  Issues not within the control of the organization and external to the facility.
- **Patient factors**
  This relates to the patient's physical or mental health status. The South Australian report lists this item last (as a less common root cause). This looks odd, because the state that a patient is in when seeking medical care, will primarily determine the outcome of treatment. This category, however, must be seen in the right perspective, namely in comparison to the normally expected outcome. Prognostic models exist to identify subgroups of patients who have a very high risk of dying before hospital discharge (e.g. very old ICU patients) and such models are also being probed against the real clinical outcome to validate them [13, 14]. The "Patient factors" group concerns patients, initially not classified to be at high risk, that do get into trouble or even die (e.g. unknown allergy leading to shock, or wrong intubation due to an anomalous anatomy).

8 How technicians might improve the process

Device-related incidents are not the main cause of incidents. Yet, since the topic of this article is innovating medical devices, we will furthermore focus on technology related aspects.

Clinical practice learns that many medical devices that are clearly damaged (e.g. after falling, or crashing into a wall) are being "repaired" with tape and paper clips to make them "work" again without informing a technician. Also "user instructions" can be found written on notes taped to equipment, doors, etc. This indicates that apparently there is a need for extra information and, since somebody took the trouble of placing the instruction, it might be a long-standing problem. So, when visually inspecting medical equipment and facilities, one should "read" these signs carefully (see also fig. 2). A very practical article by Dyro *et al.* learns how to observe such "white tape applications", learn from them and solve the underlying issues [18].

Visual inspections by technicians should not only be restricted to the equipment. Also the buildings' installations (e.g. electricity, gases, water, climate control) form a critical factor in hospital performance and patient safety [66]. This is why special installation standards for medical locations exist.

Hospital installations are mostly hidden from end users and taken as granted, but they form the fundament of device safety. Neglecting installations and their interaction with devices is a pitfall in health technology which can cause serious injuries and deaths [39, 53, 67].

Fig. 2: Example of "tape analysis". Shown is an OEM supplied trolley, which by itself fulfilled all requirements of IEC 60601. Violating this standard, the trolley was retrofitted with equipment drawing more power than the built-in safety transformer was specified for. Therefore the built-in fuses sometimes blew. Following the principle of Le Châtelier & Van't Hoff, someone "solved" the problem by taping spare fuses to the keyboard support arm (see middle of photo).

Dutch hospitals are enforced by the government to have a quality control system (including their technology resources). Recently the experiences have been published from applying a system that trains hospital technicians to setup a quality control system themselves, which is then assessed by a notified body that acts as an external reference [7].

In addition to quality control methods, it is highly recommendable that medical technicians should possess some understanding of human behavior. Human behavior forms an important group of common "causes of causes". If an incident takes place, preserving the evidence logically is of primary and critical importance [55]. But it is just as important to understand the determinants and background variables of human factors when investigating incidents and accidents [26]. The "Who did it" approach must be forsaken for the approach that considers "Why" an error occurs by identifying factors contributing to error [9]. Especially in high care and highly dynamic areas where health care workers typically deal with multiple patients in parallel (e.g. emergency departments, intensive care units, cardiology wards, etc.) gaps in the essential information flow are likely to occur, e.g. due to multitasking, alarms (including false alarms...) and shift changes. Such information gaps can have large consequences [19, 42]. Medical devices are intended to support human performance in such time-constrained environments, which means they need an excellently engineered human interface.

9 Lessons learned from incidents improve design standards

The importance of human factor engineering is fortunately gaining recognition in medical technology profession, which is clearly illustrated by the third edition of IEC 60601-1, the worldwide basic safety standard for medical equipment [36]. Clause 3.137 of this standard defines "*usability engineering*" as an application of knowledge about human behavior, abilities, limitations, and other characteristics to the design of tools, machines, equipment, devices, systems, tasks, jobs, and environments to achieve adequate usability. Clause 12 of the standard (titled "*Accuracy of controls and instruments and protection against hazardous outputs*") explains that the term "usability" was chosen over the still more commonly used terms "user error" or "human error" because not all errors are the result of oversight or carelessness on the part of the operator of medical equipment. All too frequently, use errors are the direct result of poor human interface design that leads the operator to an incorrect decision. Use errors caused by inadequate usability have become an increasing cause for concern. Specifically therefore the collateral standard IEC 60601-1-6 has been established [37]. The usability engineering process described in IEC 60601-1-6 (and also in project IEC 62366/FDIS) is intended to achieve reasonable usability, which in turn is intended to minimize use errors and to minimize use associated risks [38]. However, training and mind setting on risk factors remain crucial for the users.

10 In conclusion

Before introducing a medical device into the market and even before starting the production of it, it is strongly recommended to study the technological, social, financial and organizational effects of the device from the design phase on. A device does not only affect the user, but also has impact on social contexts and supporting organizations. Also, assessing the chances for admittance to insurance provision is crucial before mass production. Systematic methods to perform these tasks are available [62]. Common sense, however, also brings a lot, therefore we list some rules of thumb.

Use the Spice Girls method and always keep asking what people really want.

Keep Murphy's Law in mind when trying to innovate and, if bad things occur, always learn from them.

Don't underestimate the effort needed to implement changes in human behavior. Use the principle of Le Châtelier & Van 't Hoff to understand the adaptation to enforced change and workload pressure. Communicate clearly and adapt the style of your message to the group that you address.

Finally, it's important to adapt in persistence (not blindly, but in a learning manner). The road to a successful innovation in medical technology is usually long and winding. The pulse oximeter is an example of a very successful innovation, invented by Dr. Takuo Aoyagi in 1974 [3]. In 2007 he wrote to the first author: "*I have experienced many bad fortune. With each of those bad fortune I changed my course. Now, I think those bad fortune guided me to good fortune, not noticed at the time*" [4]. This statement of Aoyagi, pertaining to the difficulties in R&D and engineering, also can be applied more generally: Problems will always occur despite of all efforts to preclude them. Fortunately, analyzing causes and sharing the findings will always remain a powerful feedback loop for successful and durable innovation.

Acknowledgements

We thank Dr. Wilfried Linke from Siemens Medical AG in Erlangen, Germany for his review and constructive input.

References

[1] Abenstein JP. Technology assessment for the anesthesiologist. *Anesthesiol Clin* 2006;24(4):677-696.

[2] Anonymous. Readers perspectives. Most health care CIOs do not fully understand the cultural impact of new information technology implementations. *Health Data Manag* 2007;15(5):72.

[3] Aoyagi T, Kishi M, Yamaguchi K, Watanabe S. Improvement of an earpiece oximeter. In: 13th annual meeting of the Japanese Society for Medical Electronics and Biological engineering; 1974; Osaka, 1974. p. 90-91.

[4] Aoyagi T. personal correspondence on innovating pulse oximetry. 2007.

[5] Baim DS, Donovan A, Smith J, Briefs N, Geoffrion R, Feigal D, *et al.* Medical device development: managing conflicts of interest encountered by physicians. *Catheter Cardiovasc Interv* 2007;69(5):655-664.

[6] Beatty PCW, Beatty SF. Anaesthetists' intentions to violate safety guidelines. *Anaesthesia* 2004;59:528–540.

[7] Bezemer RA, Dumay ACM. Quality for Medical Technology: a new paradigm based on ISO 9001. In: 6th Annual HTCM Conference on Responsibility in Healthcare and Medical Technology; 2007 October 3-5; Pisa, 2007.

[8] Bliss JP, Gilson RD, Deaton JE. Human probability matching behaviour in response to alarms of varying reliability. *Ergonomics* 1995;38(11):2300-2312.

[9] Bogner MS. Error as Behavior: Implications for Patient Safety. *Biomedical Instrumentation &Technology* 2006;40(1):61-63.

[10] Brouwer WB, van Exel NJ, Baltussen RM, Rutten FF. A dollar is a dollar is a dollar--or is it? *Value Health* 2006;9(5):341-347.

[11] Chaudron G, Dubrisay R. Henry Le Chatelier et l'Industrie Chimique. *Revue de Métallurgie* 1937(1).

[12] Clinipad. Customer recall letter. 2000.

[13] de Rooij SE, Govers A, Korevaar JC, Abu-Hanna A, Levi M, de Jonge E. Short-term and long-term mortality in very elderly patients admitted to an intensive care unit *Intensive Care Medicine* 2006;32(7):1039-1044.

[14] de Rooij SE, Abu-Hanna A, Levi M, de Jonge E. Identification of high-risk subgroups in very elderly intensive care unit patients. *Critical Care* 2007;11(2):Epub ahead of print.

[15] DOHSA. Improving the System: South Australian Patient Safety Report 2003-2004. In: Australia DoHS, editor., 2006. p. 36.

[16] Drummond M, Weatherley H. Implementing the findings of health technology assessments - If the CAT got out of the bag, cfan the TAIL wag the dog? *International Journal of Technology Assessment in Health Care* 2000;16(1):1-12.

[17] Dumay ACM. Innovating eHealth in the Netherlands. In: Bos L, Blobel B, editors. Conference of the International Committee on Medical and Care Compunetics; 2007 June 8-10; Amsterdam, 2007. p. 157-165.

[18] Dyro JF, Shepherd M. Enhancing Patient Safety by White Tape Analysis. *Journal of Clinical Engineering* 2005;30(3):134-144.

[19] ECRI. The hazards of alarm overload. Keeping excessive physiologic monitoring alarms from impeding care. *Health Devices* 2007;36(3):73-83.

[20] editorial. Innovation versus science? Harder economic times will force governments to ask tough questions about their investments in research. *Nature* 2007;448(7156):839.

[21] FDA. Recall of Clinipad Sterile Products Used in Prepackaged Procedure Kits and Trays. 2000.

[22] FDA. Federal Register - Medical Devices; Establishment of a Performance Standard for Electrode Lead Wires and Patient Cables. 1997. p. 25477-25498.

[23] Gallagher AG, Smith CD. From the operating room of the present to the operating room of the future. Human-factors lessons learned from the minimally invasive surgery revolution. *Semin Laparosc Surg* 2003;10(3):127-139.

[24] Gazelle GS, McMahon PM, Siebert U, Beinfeld MT. Cost-effectiveness analysis in the assessment of diagnostic imaging technologies. *Radiology* 2005;235(2):361-370.

[25] Geertsma RE, de Bruijn ACP, Hilbers-Modderman ESM, Hollestelle ML, Bakker G, Roszek B. New and emerging medical technologies - A horizon scan of opportunities and risks. RIVM, 2007. p. 116.

[26] Gerbert K, Kemmler R. The causes of causes: determinants and background variables of human factor incidents and accidents. *Ergonomics* 1986;29(11):1439-1153.

[27] Gershon RR, Karkashian CD, Grosch JW, Murphy LR, Escamilla-Cejudo A, Flanagan PA, *et al.* Hospital safety climate and its relationship with safe work practices and workplace exposure incidents. *Am J Infect Control* 2000;28(3):211-221.

[28] Gilly H. Patient safety and medical device incidents in anesthesia. Biomedicinska Elektronika. Zagreb, 2006.

[29] Haas C. De ivoren toren - of het aardige van de universiteit. In: Afscheidscollege; 1995; Groningen, 1995. p. 20.

[30] Hakimzada AF, Green RA, Sayan OR, Zhang J, Patel VL. The nature and occurrence of registration errors in the emergency department. *Int J Med Inform* 2007.

[31] Happ MB. Preventing treatment interference: the nurse's role in maintaining technologic devices. *Heart Lung* 2000;29(1):60-69.

[32] Henderson AJ, Davies J, Willet MR. The experience of Australian project leaders in encouraging practitioners to adopt research evidence in their clinical practice. *Aust Health Rev* 2006;30(4):474-484.

[33] Hensbroek R. Gevoeligheid van 90 medische apparaten voor C2000/TETRA portofoons – praktijkmetingen. TNO Prevention and Health, Leiden, 2004.

[34] Hoffman W. Taking The Pulse Of Medical Technology. *Minnesota Medicine* 1994(Nov.).

[35] Hug CW, Clifford GD. An analysis of the errors in recorded heart rate and blood pressure in the ICU using a complex set of signal quality metrics; Poster P7D.6. In: Computers in Cardiology; 2007 0ctober; Durham NC USA, 2007.
[36] IEC. IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. Third edition 2005-12 ed, 2005.
[37] IEC. IEC 60601-1-6 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability. 2.0 ed: International Electrotechnical Commission, 2006. p. 145.
[38] IEC. IEC 62366/FDIS 2007: Medical devices - Application of usability engineering to medical devices. This final draft is expected to become an international standard end 2007.
[39] Kington T. Hospital gas mix-up suspected of killing eight patients in Italy. Sydney Morning Herald May 8 2007.
[40] Kok NF, Adang EM, Hansson BM, Dooper IM, Weimar W, van der Wilt GJ, *et al.* Cost effectiveness of laparoscopic versus mini-incision open donor nephrectomy: a randomized study. *Transplantation 2007* 2007;83(12):1582-1587.
[41] Koopmanschap MA, Brouwer WB, Hakkaart-van Roijen L, van Exel NJ. Influence of waiting time on cost-effectiveness. *Soc Sci Med* 2005;60(11):2501-2504.
[42] Laxmisan A, Hakimzada F, Sayan OR, Green RA, Zhang J, Patel VL. The multitasking clinician: Decision-making and cognitive demand during and after team handoffs in emergency care. *Int J Med Inform* 2006.
[43] Le Châtelier HL. Énoncé général des lois des équilibres chimiques. *Comptes Rendus Academie Science* 1884;99:786-788.
[44] Le Châtelier HL. Sur les lois de l'équilibre chimique. *Comptes Rendus des Séances de l'Académie des Sciences* 1888;106.
[45] Mallon WJ. *Ernest Amory Codman: The end result of a life in medicine*. Philadelphia: W.B. Saunders, 2000.
[46] Matthyssens P, Vandenbempt K, Berghman L. *Waardecreatie en innovatie in de industrie - Nieuwe denkkaders versus oude gewoontes*.
[47] Maxton FJ. Old habits die hard: changing paediatric nurses' perceptions of families in ICU. *Intensive Crit Care Nurs* 1997;13(3):145-150.
[48] Nelson R. Electronic health records: useful tools or high-tech headache? *Am J Nurs* 2007;107(3):25-26.
[49] NHS. Design for patient safety - A system-wide design-led approach to tackling patient safety in the NHS. In: Health Do, editor., 2003. p. 84.
[50] Prussia GE, Brown KA, Willis PG. Mental models of safety: do managers and employees see eye to eye? *J Safety Res* 2003;34(2):143-156.
[51] Reijnen MM, Zeebregts CJ, Meijerink WJ. Future of operating rooms. *Surg Technol Int* 2005(14):21-27.
[52] Rutten-van Mölken MP, Van Busschbach JJ, Rutten FF, editors. *Van kosten tot effecten - Een handleiding voor evaluatiestudies in de gezondheidszorg*. Maarssen: Elsevier, 2001.
[53] Sanders FBM, de Mol BAJM, Monteban E, Ale BJM. Verslag onderzoekscommissie brand OK Twenteborg ziekenhuis; 2007.
[54] Sensmeier J. Survey says: care, communication enhanced by IT. Nurses report ups and downs of current systems. *Nursing Management* 2006;37(10, Supplement):2,4,6,30.
[55] Sheperd M. Preserving the Evidence! The First Step in an Incident Investigation. FDA, User Facility Reporting; Issue No. 23, 1998.
[56] Smalhout B. De dood op tafel. In: Inauguration speech of professor in anaesthesia; 1972; Utrecht, 1972.
[57] Spark NT. The Fastest Man on Earth - Why Everything You Know About Murphy's Law is Wrong. *Annals of Improbable Research* 2003;9(5).
[58] Stannard R, Rowe M, Chisholm M, Halliwell G, Brown M, Beckham V, *et al.* Wannabe: Virgin Records 1996.
[59] Tugwell P, Bennett K, Feeny D, Guyatt G, Haynes RB. A framework for the evaluation of technology: the technology assessment iterative loop. In: Feeny D, Guyatt G, Tugwell P, editors. Health care technology: effectiveness, efficiency, and public policy. Montreal: Institute for Research on Public Policy, 1986. p. 41-56.
[60] van 't Hoff JH. *Etudes de Dynamique Chimique*. Amsterdam: F. Muller & Co., 1884.
[61] van 't Hoff JH. De verbeeldingskracht in de wetenschap. In: Inaugural speech as professor of chemistry; 1888; Amsterdam, 1888.
[62] van Boxsel JAM, Schoone M. TERTZ een technologie toets voor de zorgsector. *Health Management Forum* 2005;01:36-37.
[63] Vosburgh KG, Newbower RS. Moore's Law, disruptive technologies, and the clinician. *Stud Health Technol Inform* 2002(85):85:88-13.
[64] Wagstaff R. Reflecting on change. *Nursing Management* 2006;13(2):12-17.
[65] Wieringa FP, Leefmans A, Van Melick RGM. Oriënterend onderzoek inzake de algemene veiligheid van medische technologie in Nederland. TNO Prevention and Health Leiden, 2002. p. 31.
[66] Wieringa FP, Leefmans A, Diaz LJ, van Abkoude GMA. *Elektrische veiligheid in medisch gebruikte ruimten*. Delft: Dutch Standardization Institute NEN, 2004.
[67] Wieringa FP, Teirlinck CJPM. TNO report KvL/P&Z 2006.107 Onderzoek naar de brand in operatiekamer 8 van het Twenteborg Ziekenhuis te Almelo. Leiden: TNO Quality of Life; 2007.
[68] Wieringa FP. Pulse Oxigraphy - And other new in-depth perspectives through the near infrared window. Rotterdam: Erasmus University; 2007.
[69] Wieringa FP. Propositions. Cubic 2007:16.

[70] Wiklund ME. Addressing the problem of medical device misuse. Medical Device & Diagnostic Industry 2005.