

Cardiovascular Computer Devices: Balancing Novelty, Flexibility and Safety

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Abstract

Without cardiovascular devices the success of modern medicine would be poorer and many lives now saved would be lost. Many devices now rely on computers, either in their standard recognisable format, or hidden in devices ready to run at the push of a button and without any need to load or start a program. This invasion by computing into cardiology has brought with it many advantages. Diagnoses and treatments not possible several years ago are now in use daily in many hospitals or clinics and have become indispensable. The ability to introduce novelty, user flexibility and diversity, as well as clear presentation of results has reaped many advantages.

Nevertheless, computers have brought with them problems, many of which have a direct bearing on patient safety. In the UK, the National Patient Safety Agency (NPSA) collates all reports of medical safety incidents, and the Medicines and Healthcare products Regulatory Agency (MHRA) deals with incidents specifically involving medical devices. Most other countries have similar bodies. In their latest report, the MHRA indicated that there had been over 9000 UK device incidents in the previous year, of which over 1800 involved a serious injury and over 200 a death. Of the total incidents, 13% were life support and 4.5% imaging. There are now worldwide efforts to reduce these device incidents and deaths.

Specific computer problems can relate to the device not behaving as planned in the design, either because the device was not correctly programmed, or unexpected conditions appeared, or because of external interference or other influences. Also, clinical staff can often use devices in unintended ways, either because the functions were not clear, or because staff became lost in the many layers of user interaction. Versatility is not always a positive feature.

There is much that can be learnt, either as a clinical user, developer or manufacturer of cardiovascular computer devices by reviewing safe design. Some of the issues are reviewed in this paper.

1. Introduction

Recently there have been significant efforts to improve the safety of healthcare. A lead has been taken by the World Health Organization. They have issued many useful documents and statements. Their view of medical device safety can be summarized as “Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the *purposes intended* *they will not compromise the clinical condition or the safety of patients, or the safety and health of users* *provided that any risks* constitute acceptable risks when weighed against the benefits to the patient” [1].

In the UK, organizations have been set up to record, monitor and act on healthcare safety. Taking a lead in all safety issues is the National Patient Safety Agency (NPSA). Their document “Building a Memory” gives a definition of a patient safety incident as “Any unintended or unexpected incident that could have or did lead to *harm for one or more patients*” [2]. This allows incidents that did not actually cause harm to be reviewed, as the potential for harm was there, and a similar incident could lead to serious harm. The document is titled “Building a memory” because such events should not be forgotten.

The complexity of improving safety is not forgotten. Taking a realistic position, the National Patient Safety Agency in “Engaging Clinicians” reminds us that every day more than 1 million patients are treated safely and successfully in the British healthcare system, but that evidence also tells us that in complex health care systems things will and do go wrong, no matter how dedicated and professional the staff [3].

Thinking specifically of medical devices, it is worth considering a recent report from The Health Foundation [4]. They reviewed surgical operations, as any such operation has the potential for harm. Their findings were astonishing. Issues over equipment and medical devices were more common than had been expected. In nearly one on five operations, the equipment was either faulty, missing, used incorrectly, or the staff in the operating theatre did not know how to use it.

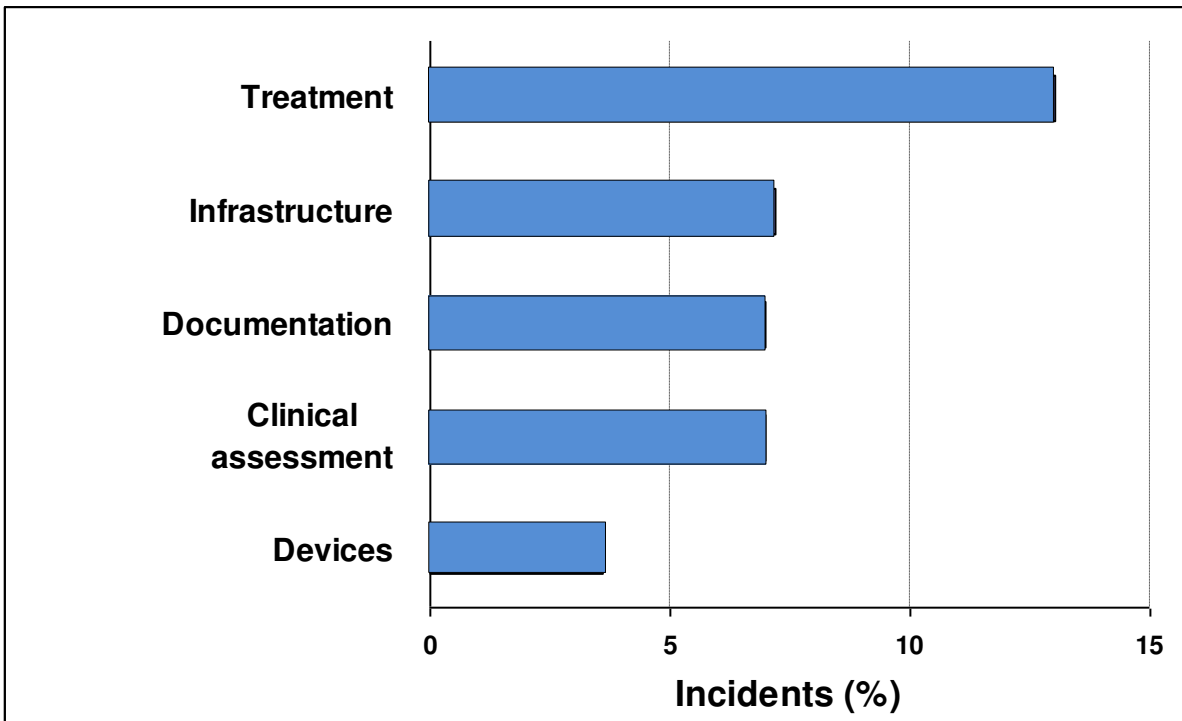


Figure 1. Review of annual incidents reported by the UK National Patient Safety Agency.

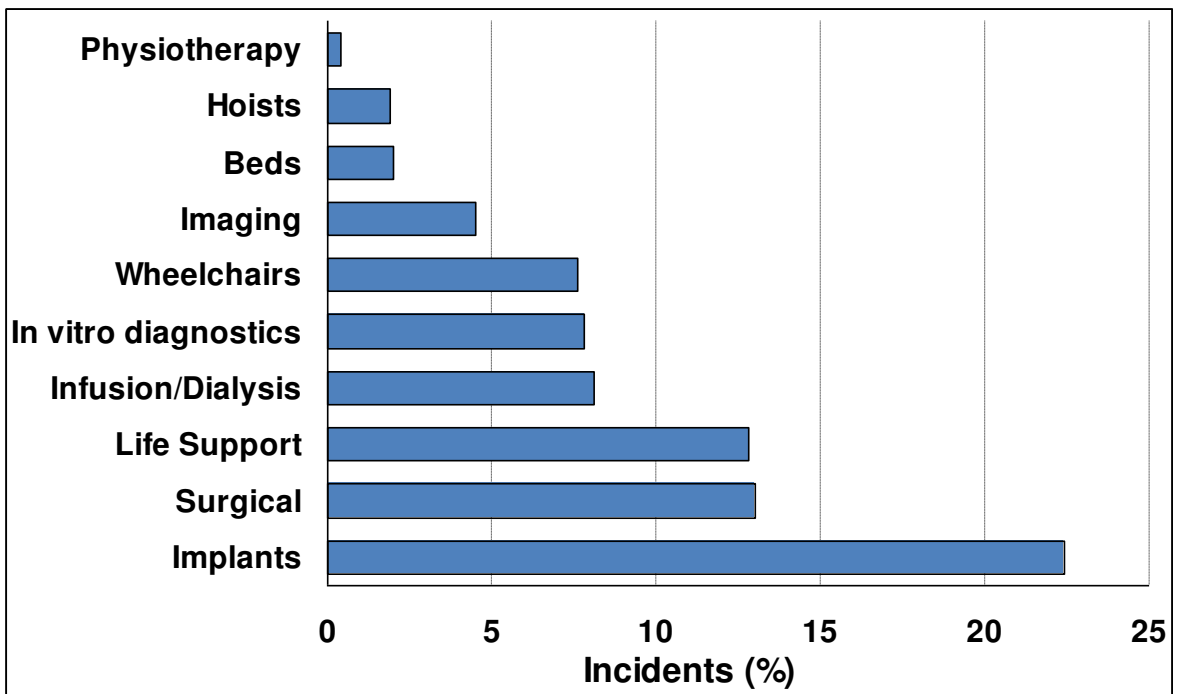


Figure 2. Review of annual medical device incidents reported by the UK Medicines and Healthcare products Regulatory Agency (MHRA).

2. Device safety data

2.1. UK National Patient Safety Agency

Every 3 months figures relating to safety incidents are released by the NPSA on a rolling annual basis. The latest figures indicate that 1,131,530 incidents were reported by hospitals and medical clinics in one year [5]. These take into account drug and other problems as well as equipment or device incidents. Overall, devices featured in between 3 and 4% of reported incidents (see Figure 1).

2.2. UK Medicines and Healthcare products Regulatory Agency

Medical device incidents must also be reported to the MHRA as they are the body that must follow up device problems. The MHRA also acts as the Compliant Authority for the UK, enforcing the Medical Devices Directives. This helps to bring together safety and regulation.

The latest figures provided by the MHRA are given in Table 1 [6]. Figure 2 gives the percentage of incidents involving different types of medical devices.

Table 1. Summary of annual medical device incidents.

Devices incidents	9099
Serious	1885
Death	202

It should be noted that these figures do not indicate that the device caused the injury or death, but only that a device was associated with the incident. It is usual to find that there are many causes of incidents, of which the device itself is only one factor. However, even if a user fails to use a device correctly, more careful design of the device with sufficient thought for those who were to use the device may have prevented the incident.

There have been many investigations into specific incidents and their causes. Jacobson and Murray [7] collected and published 140 case histories of medical device incidents from all over the world, covering every type of device. Sadly many involved serious injury or death. One common thread was that device incidents usually had many interrelated causes. They were what are known as system problems.

It can also be noted that not all device incidents are reported to both the NPSA and MHRA, and underreporting is always a possibility. However, when there are differences between the reporting bodies, the MHRA does find that it receives the reports of the serious incidents.

2.3. Cardiovascular computer devices

Fifty years ago the use of computers in medicine and more specifically in cardiology was just beginning, and in those days the developments tended to be research based or as trial devices. Now the use of computers is all pervasive. When a medical device is switched on it is likely that there will be some computer control within the device, even if the user never interacts with the device as they would do with a personal computer.

Some common cardiovascular devices that use computing technology are listed in Table 2. This is only for illustration and is not meant to be definitive.

Table 2. Examples of cardiovascular devices that use computing technology.

Pacemaker
Defibrillator
Monitor
Ventilator
Automated blood pressure
Drug infusion
Electrocardiograph
Holter ECG
Electrophysiology system

2.4. Computing problems

The sources of problems for cardiovascular computing technology are many, and they can all lead to safety incidents.

A list of some of the problems is given in Table 3.

Table 3. Problems associated with cardiovascular computer devices.

External interference
Poor user concentration
User misunderstanding
User expectation
Condition not in design
Design failure

External interference can result in the mode of pacemakers or implantable devices being accidentally changed.

Poor user concentration results in inappropriate device settings, but often with better device design such problems could have been avoided.

User misunderstanding is also often related to device

design, and could have been avoided by better consideration of how the device would be used in often hectic clinical conditions. A common problem still occurs over the setting of filters on electrocardiographs that can distort the ECG, producing ST segment distortion that can be mistaken for ischaemia.

User expectations are often strong. If a device gives a result, it will be assumed that it is correct. There are many examples where this is not the case. One example that keeps arising is the use of electrocardiograph devices for fetal monitoring. It is possible for these devices to lock onto the maternal heartbeat and present double that frequency as the fetal heart rate. Because the rate can be similar to that expected, a problem may not be noted, even when the fetus is in danger. Research will undoubtedly improve these devices, but in the meantime users need to realise that devices are never perfect.

Sometimes situations arise that were never in the design, and devices simply fail. This has happened with defibrillators.

In addition, there are design failures. This is rare, but the human designer can never be completely certain that their design is perfect.

3. Discussion and conclusion

There are many good design principles that should be followed, and some are listed in Table 4. However, these should not be seen as a hurdle or as a disincentive to develop new devices. If researchers have a good idea that will solve a known clinical problem they should be encouraged to take on the challenge of developing a good clinical device that is safe,

Table 4. Computing design principles.

Take a systems approach
Treat the “Risk analysis” seriously
Understand the users
Keep the design simple
Do not include unnecessary features

It is important to remember that medical safety incidents are frequent, but thankfully serious medical device incidents and deaths are not frequent. However, one even death is one too many.

Cardiovascular computing devices require great care in planning and design, to give users useful, safe and easy-to-use devices that will improve patient care.

Acknowledgement

I acknowledge Professor Bertil Jacobson of the Karolinska Institute in Stockholm who sadly died in 2009. He was a great and enthusiastic advocate for patient safety, and a meticulous co-author of “Medical Devices: Use and Safety”.

References

- [1] World Health Organization. Medical device regulations: global overview and guiding principles. 2003.
- [2] National Patient Safety Agency. Building a memory: preventing harm, reducing risks and improving patient safety. The first report of the National Reporting and Learning System and the Patient Safety Observatory. UK, 2005.
- [3] National Patient Safety Agency. Engaging clinicians; a resource pack to help you promote patient safety and the reporting of incidents amongst healthcare staff in training. UK, 2005.
- [4] The Health Foundation. Evidence in brief: how safe are clinical systems? Primary research into the reliability of systems within seven NHS organisations and ideas for improvement. UK, 2010.
- [5] National Patient Safety Agency. Patient safety incident reports in the NHS; England, Issue 14. 2009.
- [6] Medicines and Healthcare products Regulatory Agency. Device bulletin: Adverse Incidents Report 2009. UK Department of Health, 2010.
- [7] Jacobson B, Murray A. Medical devices: use and safety. Elsevier; Edinburgh. 2007.

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