# THE REPORTING OF COMPLICATIONS RELATED TO SURGICAL DEVICES

**David Rew**

## Introduction

ASGBI is committed to the promotion of the practice of safe surgery. The Association has strongly supported the development and promotion of the Confidential Reporting System for Surgery, CORESS; and it held a Patient Safety Consensus Conference in October 2009, the proceedings of which were published as a ***Consensus Statement*** in April 2010 [1].

Safe Surgical Practice covers a whole range of issues and risks, including those relating to the use and implantation of surgical devices. There have been growing anecdotal concerns about complications and adverse outcomes with a range of different surgical devices and implantables. Following a discussion at ASGBI Council in early 2010, I was asked to undertake a review of reporting systems and to propose a way in which the ASGBI could be more proactive in addressing issues around the reporting of risks arising from the use and misuse of surgical devices.

The traditional route to reporting has been the published paper and case report. For many reasons, this does not provide a satisfactory reporting system where it can take individual Units years to accumulate insight into particular risks, and where the chances both of publication and of being read by the target audience are hit and miss.

It was apparent that the most appropriate way forward was in partnership with the Medicines and Healthcare (products) Regulatory Agency, the MHRA (www.mhra.gov.uk). The MHRA is a well resourced and statutory body of the Department of Health, tasked with the administration of the safety of Surgical Devices. A working partnership was forged with the senior team at the MHRA, under the direction of Dr Susanne Ludgate, and a web link was set up between the ASGBI and the MHRA websites to encourage the reporting of device related problems on the MHRA system.

This process resulted in a symposium at the Association's 2011 International Surgical Congress in Bournemouth, which was chaired by Frank Smith, Programme Director of CORESS. This session included a presentation by Professor Bruce Campbell, Chair of the NICE Advisory Committee on Interventional Procedures, and my own talk on the progress of our work with the MHRA in respect of surgical device safety. The difficulty in getting surgeons to report their observations was perceived as a particular challenge.

Somewhat presciently, this Symposium predated by a few days a well written and hard hitting Channel 4 ***Dispatches*** documentary on the shortcomings of surgical device safety and regulation. This was linked to the May 21st 2011 issue of the ***British Medical Journal*** (volume 342), containing a range of articles on the same topics, as referenced below [2 to 10].

The focus of the TV programme and the BMJ articles was upon metal-on metal total hip replacements, implantable defibrillators and cochlear implants, but the underlying issues were highly relevant to general and vascular surgery and to the interests of ASGBI members. Complacency on these issues is no longer an option, and we wish to move forwards as quickly as possible to find practical solutions.

Among the observations and conclusions of the Channel 4/BMJ commentary were:

1. Surgical Devices are not subjected to the same degree of robust evaluation and trialling as are drugs and medicines. Many implantable devices are introduced to the market without formal clinical trials, or because their function is similar to devices already permitted and in use.
2. Regulation and evaluation of Surgical Devices is weaker in Europe than in the United States [4, 5].
3. Reporting systems are weak, and there can be considerable delays before problems with particular devices emerge. "Commercial Confidentiality" protects the industry rather than patients in the short term. It hinders disclosure of key information, and "*there is a lack of transparency in publishing research findings, device related complications, and competing interests*", as pointed out by Peter Wilmshurst [4].
4. Manufacturers can potentially have an unhealthy financial relationship with the clinicians who use and promote the use of particular devices.
5. Better registries are urgently needed, along with much greater engagement of clinicians with the reporting process.
6. It is a challenge to strike a balance between regulation, innovation and patient protection. Clinical devices have produced dramatic improvements in health measures and technical outcomes, as for example following the introduction of cardiac valves, artificial joints and vascular stents, and sometimes when the devices have been used outside their original design specifications [10].

## Surgical Devices and their classification

Mechanical and electromechanical devices are now ubiquitous in surgical practice. Over the past 50 years or so, there has been an explosion in the products and technologies which advance our trades and capabilities. Surgical devices can be classified in various ways, as by function, intended use and user group, by complexity, or by risk to the patient.

### a) Classification of surgical devices by function

This broad means of classification includes:

* Those devices which are used for surgical diagnostics, including imaging technologies and endoscopy.
* Those devices which advance our technical operating capabilities, as for example laparoscopic instruments, and electromechanical equipment such as diathermy machines or bypass pumps.
* Those devices which are implanted into the body to secure therapeutic gain, including surgical meshes, stents and grafts, and orthopaedic 'metalwork'.
* Those devices which are not in the immediate 'hand to patient' eye-line, but which are central to the way that we deliver surgical product, including anaesthetic and ITU equipment, and patient handling devices.

  We may also include computers and software systems in this definition, as these become more intrusive in the surgical care pathway, in the operating theatre, and in the recording and appraisal of our outputs. Surgeons now work in information technology directed environments, where sudden technical failure or disruption (as of digital image transmission or retrieval) can have a significant bearing on the safe conduct of surgery. A parallel can be found in the world of flight, where much innovative work on risk mitigation has originated, and in the move from analogue and manual pilot controls to digital 'fly by wire'.

### b) Classification of surgical devices by intended use and user group

We can classify surgical devices by their intended uses, and by their user groups, which fall broadly into the sub-speciality divisions of the profession. While our focus at the ASGBI is primarily upon the work of surgeons in the directly affiliated specialties, we intend that our work in progress will benefit all surgical disciplines and other medical professional groups.

### c) Classification by complexity

We may also classify surgical devices by their complexity, which has a bearing on fault recognition and fault fixing.

* Basic mechanical devices, including most surgical instruments, are characterised by robustness and simplicity of design. Direct inspection will allow a full appraisal of faults.
* Electromechanical and digital electronic devices can be difficult to evaluate and repair. Complexity adds risk, and inopportune equipment failure can compromise safe practice in a variety of ways.

### c) Classification of surgical devices by inherent risk to the patient

By convention among the regulatory authorities, devices are classed as low risk (Class I), medium risk (Class II) and high risk (Class III).

* Class I devices include patient handling equipment and demonstrably safe devices (eg. wheelchairs, operating tables, contact lenses).
* Class II devices include those with an invasive procedural use, or where the consequences of technical failure would not usually be injurious to health (eg. endoscopes, ultrasound devices).
* Class III devices include implantable devices, such as artificial joints, stents, defibrillators, biological meshes and hearing aids, where there is a significant impact of short, medium or long term failure and of adverse clinical events.

  The US Food and Drug Administration characterises Class III devices "*as those that support and sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury*". The existential problem with this definition is that these risks may not become fully apparent until the device has been in widespread and long term use. For this reason, robust long term reporting and surveillance is now essential, and why a robust programme of clinician engagement in the reporting system is now apparent. Implanted devices may have to survive intact and functional for many decades, while doing no harm either to local tissues or systemically. In the biologically reactive and corrosive environment of the human body, this is a 'big ask' for any engineered device.

## The international regulation of surgical device associated clinical risk

The regulatory environment for surgical devices is both more complex and less demanding than for drugs and medicines [5 to 8]. Europe and the US generally provide worldwide leadership in such matters. However, Peter Wilmshurst states that "*a medical device may obtain a CE (European Conformity) mark from one of dozens of notified bodies*". The MHRA confirms that the responsibility for checking the CE marking applied by the manufacturer for all except the simplest devices lies with a third party Auditing and Accreditation Body known as a Notified Body, of which there are approximately 80 across Europe.

The European Committee for Standardisation (CEN) is a business facilitator in Europe. CEN produces European Standards to meet European Union directives for medical devices (93/42/EEC), active implantable medical devices (90/385/EEC) and in vitro diagnostic devices (98/79/EC).

While the US regulatory environment for devices is more rigorous, it still has loopholes which allow individual devices to evade rigorous testing.

The International Organisation for Standardisation (ISO) promulgates worldwide proprietary industrial and commercial standards. ISO 13485 is a Quality Management Standard for Medical Devices.

In respect of Class III implantable devices in particular, there are a number of stages where regulation can help mitigate clinical risk, including:

* Design and manufacture.
* Materials selection and engineering.
* Appropriate in vitro and in vivo testing and clinical trials.
* Education and training for clinical users.
* Long term surveillance systems with ease of reporting for clinical users and patients.
* An early warning system for perceived flaws, with appropriate investigation, testing and recall.

Manufacturing standards and the quality control of materials and components for such devices are under seemingly strict and demanding regulatory and commercial disciplines. However, given the size and profitability of the device market, the possibility of counterfeit manufacture of flawed devices must also be considered.

**Device regulation in the UK**
Within the UK, there are many official bodies and agencies which have a regulatory and supervisory interest in device safety alongside the MHRA. The documentation on the Interventional Procedures Programme Process Guide of the National Institute for Health and Clinical Excellence (NICE) cites more than 20 such organisations, including:

- Individual NHS Trusts, their medical directors, and the Clinical Negligence Scheme for Trusts (CNST).
- NICE.
- Healthcare (Care Quality) Commission.
- Department of Health.
- Welsh Assembly Government.
- Northern Ireland DHSS.
- National Institute for HTA.
- National Horizon Scanning Centre.
- National Patient Safety Agency.
- NHS Connecting for Health.
- NHS Litigation Authority.
- Welsh Risk Pool.
- NHS Quality Improvement Scotland.
- NHS Research & Development.
- NHS National Technology Adoption Hub.
- Association of British Healthcare Industries (ABHI).
- Medical Devices in Scotland.
- Device Manufacturers.
- Patient organisations.
- Professional bodies, including the Royal Colleges and ASGBI.

This is clearly a complex field for any clinician to understand and work within. Streamlining and simplification is urgently needed.

**The scope of medical device related problems in the UK**
The MHRA has well established reporting procedures for Medical Device Adverse Events, which are set out on its website. In practice, very few surgeons will as yet be familiar with the system, will have visited the MHRA website, or will have used it. The challenge for the ASGBI, for the MHRA and for surgeons in general lies in understanding:

* What is the true incidence of clinically significant device related failures?
* What can be done to facilitate reporting to the appropriate regulatory authorities?
* Where/If there is a significant number of such events to justify concern, what should be done to ensure that information is reported and disseminated to other surgical users?

The MHRA quotes the following recent (2010) data for device related problems:

*There are over 90,000 medical devices on the market and 1 in 25 of hospital admissions involves an implant. The cost to the NHS is approximately £11 billion in addition to a follow-up or maintenance cost of around £200 million.*

*Eleven percent of patients in hospital suffer adverse events costing £2bn per year in additional hospital stays; 20 percent are due to medical devices and 50 percent are preventable. The medical negligence bill for device related adverse events is in the order of £460 million.*

*The challenges facing the use of medical devices relate to the increasing sophistication of the devices, the development of the necessary technical skills for implantation, the use of implants in younger patients with longer life expectancy and "local interference" with design and deployment (non approved modification).*

*Most medical device related adverse events are due to several identifiable factors. These include shortcomings in the device itself; modifications and adjustments; inadequate instructions for use (or not read); failure to perform a pre-use check; inadequate servicing and maintenance; user error, including inadequate training and inappropriate use (eg. single use); the environment in which it is used or stored; inappropriate choice of device; incompatible device combination; and the failure to report adverse events.*

The MHRA also states that:

*If an adverse device related event is recognised it is important to investigate and establish the root cause for this "failure". The Consultant should discuss the case with the involved healthcare workers and with manufacturer, and similar devices should be tested. Appropriate advice should be issued to the health service and relevant information disseminated, utilising safety notices websites and email as appropriate. If the adverse effect is serious a "medical device alert" should be issued and the device recalled pending further investigation.*

*All adverse device-related events should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA). This should include individual incidents, trends, user problems (design, handling and deployment), IFU (instruction for use) and training issues.*

*Up until 2008, over 9,000 medical device related adverse events had been reported to the (MRHA). In response, the MRHA has issued over 100 medical device alerts, 571 recommendations to improve design, quality systems and processes, 844 field safety corrective actions, and 470 different sets of advice on safer usage and training.*

In practice, there are wide areas of surgical practice where reporting of adverse outcomes is severely limited, and indeed where it may not at first appear necessary. At a seemingly simple level, as examples, we may consider the not infrequent problem of intra-abdominal adhesions and obstruction arising from biological and inert meshes, or concerns about the development of complex fistulae in patients with vacuum assisted dressings to the open abdomen (Professor Gordon Carlson, personal communication).

**The Information environment and surgical device safety**
The information provided to ensure the safe use of implants and devices often appears to be written more from a defensive liability perspective than to educate users through simplicity and clarity. For example, the Instructions for Use of vascular stent grafts in some cases run to several hundred pages. There is a need for better documentation on the use of implants and devices, written for the ease of use of the individual surgeon and of the team using the equipment.

**Factors within the surgeon's control which may lead to device failure**
The misuse or inappropriate use of devices and implants may cause clinical problems. This can occur both within the technical design brief and applications envelope of the device, and in novel clinical applications, in suboptimal clinical circumstances; or where there are unforeseen co-morbidities which affect device use. There is also concern that devices may be used 'off label', which means outside the intended design envelope. While novel uses may produce significant clinical gains, it is important that there is a continuous flow of information to the regulatory agencies so that the safety, or otherwise, of any device can be continuously appraised.

**The training and simulation environment**
'In vitro' training and simulation can be powerful tools for testing and rehearsing the applications of devices, both in the design and development phase, and subsequently in the training of individual theatre teams in the use of the devices. Simulation and team training facilities have been a long standing deficiency in surgical practice. The Armed Services have been very innovative in the development and work of surgical team training facilities, both at the National Field Hospital Trainer in York, and in the use of facilities at the Royal College of Surgeons of England.

**Inculcating a safety critical attitude**
The aviation and marine industries have been very vigorous in promoting a safety critical attitude at all levels to ensure maximum physical and governance protection for passengers (patients) and for pilots (clinicians), while supporting innovation. The Confidential Human Factors Incident Reporting Programme (CHIRP) promotes feedback and dissemination of experience on adverse events and near misses. The Safety Critical mindset and procedures are not yet embedded in surgical practice.

**Reporting systems for surgical device safety**
At present, very few reports feed back to the MHRA from surgeons. The present data covering device usage and problems is incomplete and anecdotal. A formal reporting system which recorded the use of each and every specified device over its lifespan and which made the data publicly available would be a major step forward in patient protection.

A voluntary reporting system, universally and willingly adopted by manufacturers and by the profession, would be preferable to an imposed regulatory model. However, it may well be that compulsory reporting will become the norm if the profession does not act swiftly to develop robust reporting systems for surgical device safety.

Fortunately, web-based reporting technologies are becoming increasingly familiar in the surgical workplace, as in training, appraisal and national audits. The disciplines of recording and tracking devices and physical items in hospitals and operating theatres and clinical supply chains are already well established, and it should not be unduly difficult to integrate a web-based devices reporting system, using electronic tagging (through bar codes or RFIDs) into the clinical work space.

The on-line reporting infrastructure already exists through the MHRA website, so implementation of a more robust reporting system has a low cost. The adaptation of various Surgical Association and College websites to encourage reporting and to include links to the Adverse Incident Reporting System on the MHRA website is also straightforward.

**Long term device surveillance**
By European law, manufacturers must have a post-market surveillance system in place, but there are many acknowledged problems. The post-market surveillance system is often inadequate for the risk of any particular device and is not always followed up by the Notified Body, and that high risk devices are falling under systems of customer complaint without systematic assessments in place. Concerns raised about long term surveillance include:

* The high cost per patient, particularly with the high risk devices where there may be relatively few devices used.
* The decline in physician interest over time.
* Difficulties in interpretation as to whether late adverse events are device related or not.

In setting and monitoring standards in any new regulatory framework, we will need to establish:

* Criteria for the success or otherwise of a new regulatory framework, combining voluntary and compulsory elements.
* Criteria for the risk/benefit assessments and classification of individual devices.
* Performance and cooperation monitoring and its frequency.
* The reliability of reporting systems.

Work done in the UK needs to translate into an internationally standardised system which crosses jurisdictions. Conversely, many devices are designed, manufactured and used outside UK jurisdiction, so surveillance and reporting needs to be international.

We will also need to consider matters of non-compliance with any future reporting system for surgical device safety, such as:

* Where and how will it be detected?
* Who will enforce and what action/sanctions will be in place?
* What will be the consequences of non-compliance for manufacturers, for individual surgeons, for clinical teams and for the regulatory agents/agencies themselves?
* What will be the costs of the reporting systems, and how will they be met?
* How will findings be communicated and disseminated?

There may be lessons to be learned from other safety critical industries and operating organisations, such as the civil aviation and nuclear power industries.

### The concerns of surgeons about mandatory reporting systems

There are a number of legitimate concerns which individual surgeons will feel about the voluntary reporting of device associated problems, in respect of confidentiality; the apportionment of responsibility and "blame"; the costs in time and effort in undertaking reporting; and medico-legal considerations and allegations of negligence. These concerns must be addressed, but they must also be balanced against the primary needs of the patient to be protected from harm.

### Summary and recommendations

1. The issue of surgical device safety; the limitations of present regulatory and reporting systems; and the limits on professional engagement in reporting are now a matter of public interest and debate, which must be addressed with urgency.
2. At present, there is no systematic approach to the collation or reporting of data on the use, misuse and complications arising from invasive and complex surgical devices and implants. There is a voluntary reporting process which this is almost certainly incomplete.
3. The wellbeing and protection of patients must remain the primary driver of change.
4. The MHRA is the statutory government agency charged with responsibility for medical devices, and the established working partner for the ASGBI in taking the professional advisory lead on behalf of surgeons. ASGBI will aspire to work with a wide range of professional representative bodies, including the Royal Colleges, to secure sign up to a robust reporting system.
5. The existing MHRA reporting system provides the technical and administrative framework for an enhanced surgical device reporting strategy.
6. There needs to be whole-life device registration and tracking system, such that medium and long term problems with individual devices will be picked up and addressed.
7. A culture of professionally led, cooperative, no-fault reporting (as with civil aviation fault reporting systems) and voluntary compliance is preferable to a compulsory regulatory system.
8. Transparency of reporting will bring significant professional benefits and establish greater confidence among patients and their support groups.
9. Open and trusted reporting processes will minimise commercial risk and long term cost arising from product fault or misuse, not least through early identification of problems and early recall before settlement costs escalate.

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### References

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## SURGICAL PROGRESS WITH THE ADVANCED ELECTRONIC PATIENT RECORD

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*"Time lends perspective to the view"*

The electronic patient record (EPR) is not yet mature. Time and again, initiatives driven by information technology professionals have foundered in the real world complexity of medical information and in the refusal of nature and biology to conform to simple and logical algorithms. The progress of computerisation of clinical and surgical data has thus been erratic. Individual surgeons, clinical units, hospitals and health care systems have adopted local and piecemeal solutions to the purchase of hardware and software, and to the automation of information flows. Much NHS IT development and investment has been driven by administrative and managerial requirements, rather than specifically to answer clinical questions.

As surgeons, we are focussed on the management of a specific surgical problem in any one patient at any one time. The treatment may be a self limiting event, such as the repair of a hernia, or it may be a component of a series of interventions over a longer period, such as in the management of a cancer within the multidisciplinary team process. From time to time, complications of an intentionally self limiting procedure may have long term consequences. As the clinical notes grow thicker and thicker, or as the patient moves around the various disciplines, so our ability to establish an overview or to understand the context and consequences of our own contribution becomes more restricted.

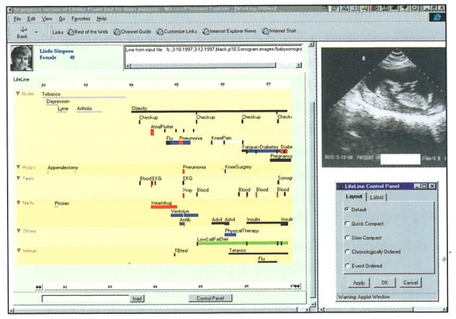
The human eye and brain can readily extract knowledge and insight from complex data which are presented in a graphically rich and visually arresting format. The starting point for my own search for a better approach to clinical data presentation was the 1869 multidimensional time structured graphic of French Engineer Charles Minard. This describes the Emperor Napoleon's catastrophic march on Moscow during the autumn and winter of 1812-1813, with 400,000 troops, and the return the following Spring with only 10,000 survivors (see ***Figure 1***).

There are considerable practical and intellectual advantages to be gained from an IT environment which similarly distils multidimensional clinical data from a range of sources into a simple, time structured and graphically rich format with the interactive functionality of modern computer software. Such a system would allow us to understand much better the contributions of multidisciplinary clinical inputs (eg. surgery, chemotherapy, radiotherapy) to the long term outcomes for each and every patient.

### The LifeLines graphical model

My search for an IT solution to this challenge led to the work of the Human Computer Interaction Laboratory at the University of Maryland, where a considerable amount of work has been done on computerised data visualisation techniques, and where a model of a time-structured, interactive patient record known as "LifeLines" was developed during the mid 1990s. LifeLines in turn grew out of a project to collate and analyse juvenile offenders' records in Maryland. The model underwent limited development, but its full clinical potential was not exploited.

***Figure 2: An early LifeLines concept graphic from the***



***HCIL Group at the University of Maryland, circa 1997. Clicking on the various bars calls up the underlying document or image, as illustrated on the right hand side of the Graphic***

The key elements of the LifeLines model, as illustrated in ***Figure 2***, are as follows:

* The Timeline on the X axis covers a user defined period, which may be the entire life of the patient, from birth to death, or it may cover a defined period, such as the duration of a defined illness.
* The Y axis displays a series of user-defined discrete categories, such as immunisation history, surgical episodes, medical episodes, histopathology results, biochemistry results, drug treatments and so on. The requirements will change according to the particular patient and the disease process under study.
* The data along the Y axis category lines can include discrete events, such as an operation or a clinic letter; or continuing events, such as a course of medication.

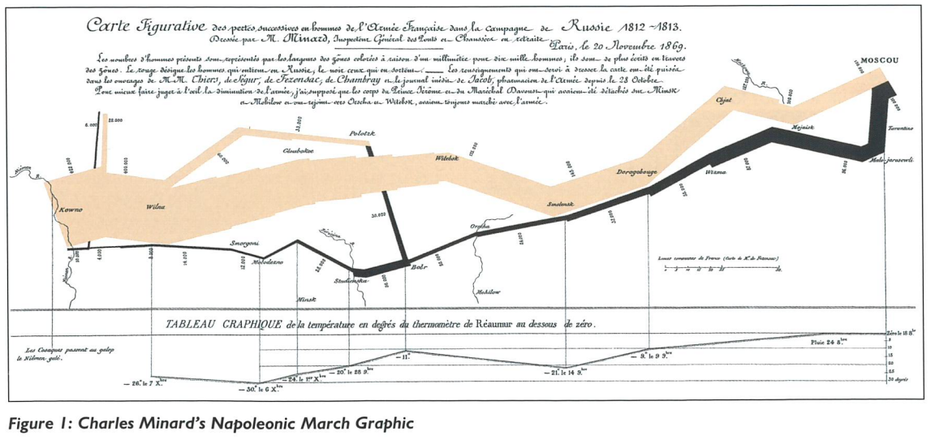



***Figure 1: Charles Minard's Napoleonic March Graphic***

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### Summary and recommendations

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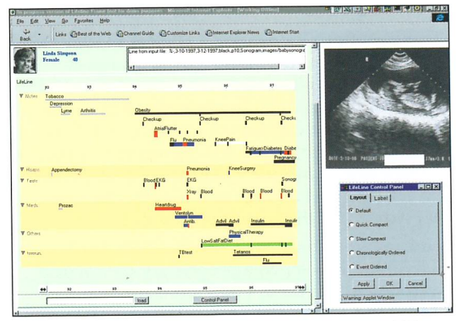
My search for an IT solution to this challenge led to the work of the Human Computer Interaction Laboratory at the University of Maryland, where a considerable amount of work has been done on computerised data visualisation techniques, and where a model of a time-structured, interactive patient record known as "LifeLines" was developed during the mid 1990s. LifeLines in turn grew out of a project to collate and analyse juvenile offenders' records in Maryland. The model underwent limited development, but its full clinical potential was not exploited.

***Figure 2: An early LifeLines concept graphic from the***



***HCIL Group at the University of Maryland, circa 1997. Clicking on the various bars calls up the underlying document or image, as illustrated on the right hand side of the Graphic***

The key elements of the LifeLines model, as illustrated in ***Figure 2***, are as follows:

* The Timeline on the X axis covers a user defined period, which may be the entire life of the patient, from birth to death, or it may cover a defined period, such as the duration of a defined illness.
* The Y axis displays a series of user-defined discrete categories, such as immunisation history, surgical episodes, medical episodes, histopathology results, biochemistry results, drug treatments and so on. The requirements will change according to the particular patient and the disease process under study.
* The data along the Y axis category lines can include discrete events, such as an operation or a clinic letter; or continuing events, such as a course of medication.

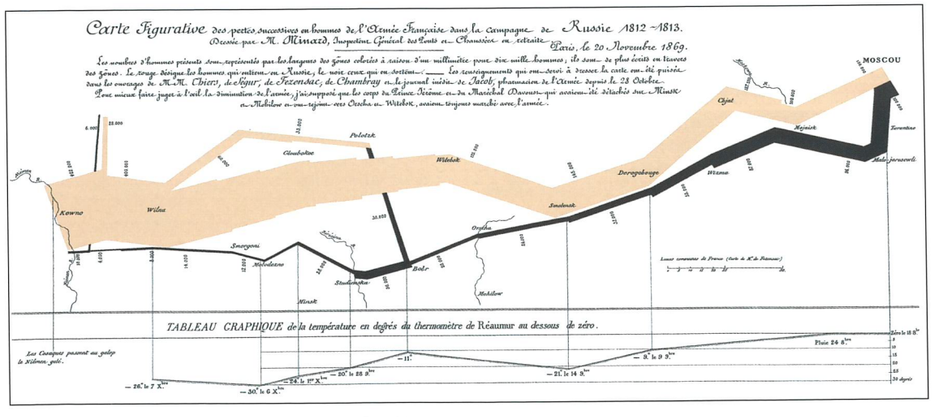



***Figure 1: Charles Minard's Napoleonic March Graphic***

Colour coding of these marks, icons and bars further helps identify the nature of the episode or item, and clickable interactivity allows the user to delve into the underlying documentation or imagery. This simple graphical device allows an entire life or clinical history to be consolidated and displayed easily and efficiently, so long as the relevant documentation is accessible to the computer.

The Maryland group enunciated a series of key steps relating to the distillation and visualisation of complex data sets, in the sequence "Overview, Zoom and Filter". This describes how the computer software presents to the observer a graphically rich overview of the data, from which he or she can zoom in on the area of interest, and filter out unwanted detail. The process applies both to individual patient records and to the analysis of data from a large collection of records.

**Development of a practical clinical model**
All hospitals in the UK have acquired a range of software systems for patient administration, document collation, results retrieval and so on from a range of different commercial suppliers, and these systems are interoperable and interactive to a greater or lesser extent. Individual clinicians and teams have also acquired a wide range of proprietary and legacy data systems for the analysis of local data.

Southampton University Hospitals NHS Trust (SUHT) has developed a proprietary clinical data environment known as HICSS, the Hospital Integrated Clinical Support System, with a local software company, Scorpio (now owned by Ascribe Software). This approach has provided considerable flexibility in developing clinical software in a rapidly changing IT environment, where technology and demands upon the system (for example, in relation to national service targets) have been in constant flux.

HICSS provides a common platform for a wide range of clinical activity data. It allows for the recording of procedures and operations, and for the storage and retrieval of documents (letters, discharge summaries, test results) and for interoperability with other systems, such as the GE PACS radiology reporting system. HICSS is linked to the Patient Master Index (PMI) and Patient Administration System (PAS). It is intended to ensure maximum interoperability between all software systems around the common HICSS spine as they are acquired.

**The Southampton Time-Structured Clinical Record**
In June 2010, we established a small working group to investigate the practicality of adapting the principles set out in the HCIL LifeLines project to the SUHT data environment. Our aim was to produce a generic graphical interface for the Trust's massive and heterogenous clinical and demographic data sets, which could be used by any clinician in the management of any patient. Subject to further refinement, this objective was met very rapidly. We now have a real time, continuously updated timeline structured profile for each and every patient, which can be displayed on the PMI Search Screen and which can be addressed interactively and intuitively by any authorised user.

This development model has a number of key features, in that:

* The category lines on the y axis are automatically populated according to the departments and services used by the individual patient, and can be expanded or modified by +/- toggles.
* The individual icons, representing documents, reports, investigations and procedures, can be clicked through to the source files.
* The X axis time line can be expanded or contracted by toggling on the dates (between birth and current date or date of death), to allow focus on episodes of interest.
* It can be adapted to provide additional functionality at will.
* It can be delivered immediately to any computer screen (in theatre, in outpatient clinics, in offices) within the Trust for whatever purpose.

**The transformative power of interactive graphical interfaces**
This universally adaptable graphical record has been developed and implemented with a few hours of programming time by a focussed team of four individuals (one clinician and three IT specialists). It provides the flexibility of a lifelong multidisciplinary medical record, or an overview of the clinical inputs and outcomes for a particular episode.

It allows any user to move intuitively the documents and episodes of interest, without having to thumb through huge reams of notes, and to see the episode

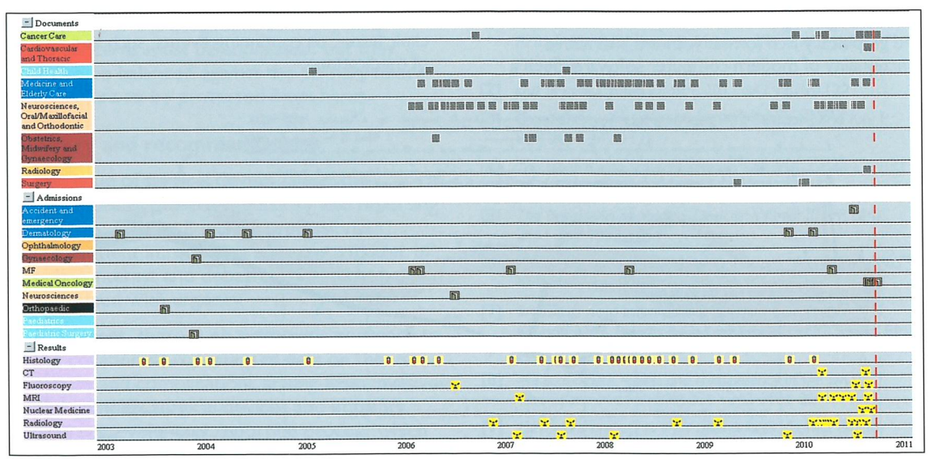



*Figure 3: A screenshot of the Southampton timeline in use. It displays the investigations and treatment of an actual patient with a complex medical history, who has attended a number of different (colour coded) departments for a range of different investigations and treatments between 2003 and 2010*



in the context of past, concurrent and subsequent events. It thus offers value in a range of clinical environments, including MDT meetings, outpatients and case conferences, and it provides a basic research tool for the study of chronic diseases of childhood and adulthood. It places discrete events and episodes in the clinical context within individual patient records in a way in which paper records and documents in conventional clinical notes folders do not.

The exploitation of this conceptual tool is still at an early stage. It has a role both in prospective studies of individual patient outcomes, and in retrospective studies. The latter are constrained by the (lack of) computerisation of early records in a common document format, which in our case seriously limits data access before the mid 1990s.

**Practical applications**
The purpose of bringing the work to the attention of a wider surgical audience at this stage is to promote awareness and discussion of a conceptual tool which can be applied generically to range of software systems in different hospitals and health care systems, and which transforms the way in which we can look at and explore clinical data.

One interesting potential application of this model is in the assignment of an accurate probability of cause of death to individual patients. There is clearly a significant difference between a patient who dies with an ongoing diagnosis of a particular disease, such as a cancer, but who dies of an unrelated condition; and a patient who has demonstrably died of the disease. The facility to look at the patient's integrated, time-structured record, where the concurrency of multiple disease processes becomes obvious. More accurate death certification based upon this model could help bring much greater accuracy to national cancer outcome statistics.

**The need for a common patient identifier in the time-structured EPR**
All of our patients move between primary and secondary care, and many move between hospitals over a lifetime and during a course of treatment. The use of different alphanumeric patient identifiers in different hospitals severely constrains the development and utility of time-structured records. The global use of the NHS number in clinical record keeping is now overdue. It would allow the progressive integration of a much wider range of clinical data, from various hospitals and from general practice, into the individual time-structured electronic patient record. This would, of course, be subject to considerations of data confidentiality and security of transmission, and possibly under the direct ownership of the patient himself or herself (a future iPhone 'App'?).

**Further developments**
The creation and refinement of the time-structured, graphically rich and intuitive EPR is only the first step to the realisation of the informative power of intelligently presented digital information. The ability to inspect with ease and gain oversight of the totality of a clinical record near-instantaneously should make clinical research and case note review much more efficient and accurate.

The next challenge for our software engineers is to develop, resource and adapt analytical and statistical tools for the interpretation of time-structured data from large cohorts of patients. Such tools will be needed to determine how the sequencing of treatments (for example surgery, chemotherapy and radiotherapy in cohorts of cancer patients) affects outcomes, and to determine which components of complex multimodality treatments are more or less effective over time.

As we have seen with Napoleon's March on Moscow, one excellent visual graphic can be worth (400) thousand data points. In seeking ways to represent large data sets in a visually intuitive fashion, the Maryland HCIL team created a time structured model for the overview of all Hollywood films produced in the 20th century, as illustrated in ***Figures 4 and 5***. In this example, the Y axis denotes an arbitrary assessment of the popularity of the film.

By substituting an individual patient record for each film record, and a disease process for each colour coded category of film, it is easy to see how colour, imagery, interactivity and the Overview-Zoom-Filter mantra could bring interest, life and insight to a complex clinical data set.

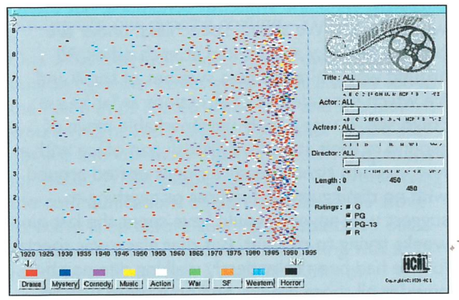



*Figure 4*

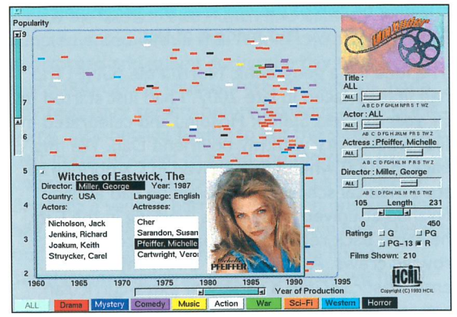



*Figure 5*

**Concluding Comments**
Graphically rich, temporally structured, interactive electronic patient records are now attainable in real time NHS Hospitals through a local initiative. Further work is needed to develop and adapt the optimum software tools to the study of large series of such records to derive clinical knowledge from the mass of underlying data.

Such EPRs provide a new set of tools for surgeons and clinical teams to collate, present and analyse their work, with applications as diverse as appraisal, revalidation, risk analysis and fundamental research. While this project remains a 'work in progress' within our own data network, an open approach and discussion of the concepts, of the possibilities and of the constraints of enhanced EPR methodologies should provide academic impetus in a range of new directions for UK Surgery PLC.

**References**
The work of the Human Computer Interaction Laboratory can be accessed and studied in greater detail on the following website:
**www.cs.umd.edu/projects/hcil**