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Chapter 2

Controlling the Risks of Mechanical Heart Valve Failure using Product Life Cycle-based Safety Management

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2.1 INTRODUCTION

Biomedical implants and devices are one of the most important developments of the biomedical industrial progress in modern health care (Starr, 1986). Highly skilled professionals and stringent manufacturing processes are essential to ensure quality and long-term performance, but assessing the safety and risk of failure are equally important. However, analyses of safety are usually focused on technical qualities, neglecting problems with the implant/carrier interface, limitations in durability, and the high expectations of both clinicians and patients. In the near future, we are likely to see the development and use of so-called smart devices, which are programmable in a similar way to pacemakers for cardiac stimulation, raising new and more complex safety issues (de Mol et al., 1995; Black, 1996).

When the risk is lethal and the implant difficult to replace, risk control strategies are difficult to generate and to execute. Structural failures of mechanical heart valves pose great challenges for risk control (de Mol et al., 1994, 1995). Other frequent, disabling, and sometimes lethal, complications of a mechanical heart valve are bleeding and thromboembolism in the presence of the mandatory use of anticoagulant therapy. Recently, self-test kits in the form of a home-laboratory have become available for patients to keep the blood thinning well within the safe range. So, patients are now exposed to two devices: the valve and the blood-thinning tester, both of which enhance survival but also introduce complexity and additional risk. The self-test named CoaguChek® has been used by over 15,000 patients so far and is currently under investigation by several groups. (Hasenkam et al., 1997)

We studied the unprecedented number of mechanical heart valve failures of Björk-Shiley convexo-concave (BScc) mechanical heart valves, which were manufactured between 1979 and 1986. Failure of BScc valves has been reported for over 20 years, with the first fracture of this type reported in 1978. A poorly controlled design and manufacturing process have led to fatigue fractures, in spite of corrective attempts by the manufacturer. Worldwide, approximately 82,000 valves have been implanted and an estimated number of 650 fractures have been reported. A US Congress Committee and investigators established shortcomings on the part of the Food and Drug Administration, and fraud with manufacturing records ("the phantom welder"), inadequately trained personnel, misrepresentation of risks of fracture by the management and reworking of valves rejected in the process of quality control (Committee on Energy and Commerce, 1990; van der Graaf, 1998). The manufacturer failed to report fractures to the FDA, while marketing activities were continued despite the awareness of the problems. When it came to communicating the risk of fracture to prescribers and patients, no adequate implant register existed. Therefore, many patients either did not
know they carried a BSc valve or could not be tracked for risk information. Although basically an engineering issue, the problem was compounded by inappropriate responses by doctors, hospitals and health authorities (de Mol et al., 1997a). In The Netherlands, heart valve failures were also observed with Hemex Duomedics (Baxter Inc.) and Medtronic Parallel (Medtronic Inc.) valves. Disputes about resources and scientific research requirements inhibited the development of an effective worldwide risk strategy.

A systemic safety management approach needs a structural and political basis in society at large (Cromheecke et al., 1998). Professions are inclined to focus exclusively on the subsystems and tasks they can control and tend to exclusively promote their view as the single risk control solution. In The Netherlands, we were able to overcome public outrage and potential conflicts of interest through the establishment of the so-called Björk-Shiley convexo-concave study group, in which all implanting centres were joined. A register of all patients was established and continuous follow-up, in the sense of a longitudinal cohort study, was carried out (de Mol et al., 1994; van der Graaf et al., 1992). Parallel technical analysis of retrieved valves was carried out by the Delft University of Technology and Rice University, Texas. The clinical records, incident data, and the technical information provided the input for reports by the inter-university working group on cardiovascular implant retrieval analysis. In this working group, pathologists, metallurgists, cardiologists, and surgeons reviewed explanted and fractured valves (de Mol et al., 1997b). Ultimately this work led to the concept of the product life cycle-based safety management and Barrier Analysis, which were developed, between 1992-1997.

In this paper, we first focus on product life cycle-based safety management for implant failure on the basis of our experience with the BSc valve problem. Second, adverse events and accidents are reviewed and the analyses used to develop a safety management system. Third, the components of the subsystem that represent barriers to undesired scenarios and outcome are reviewed.

### 2.2 TESTING MEDICAL DEVICES

Since June 1998, all medical devices to be used in Europe are supposed to be certified for their safety and efficacy by a notifying body. Industry, health authorities and users have drawn up standards of performance for different classes of device. Clinical tests are required but, especially in the surgical arena, randomised clinically controlled trials are rarely carried out, while the many observational studies provide conflicting information (Horton, 1996). Therefore, safety is only really assessed in long-term observational studies after the devices
are in use with patients. Standards, however, are lagging behind the newest developments and tested devices in real use may not to live up to expectations. As regards in-vivo durability and long-term biocompatibility, there is little consensus on the test results of implants such as heart valves (de Mol, 1996a). Therefore, the explantation (removal) of implants and subsequent analysis is important to assess whether the degradation process predicted prior to implantation is similar to the observed wear. In the overwhelming majority of cases there is no reason for the explantation and further examination of hip prostheses, pacemakers, breast implants or heart valves. Therefore, only in cases of evident failure of an implant, studies are carried out to assess and explain the failure mode. Devices to support patient self-management are even more complex to assess. Apart from the reliability of the device, effective and safe patient-management is also determined by the user who acts interactively with the device. The patient's capability depends on their physical status, training and education, support and confidence in the physician, the device and himself.

Conclusions from these studies will only be valid where several analyses of implants of the same type are carried out and where there are guidelines regarding preservation and analysis of the implant. These data only become meaningful in conjunction with epidemiological data, manufacturing records and comparisons of performance with other brand types. The findings of such studies may have serious financial implications for manufacturers and pose a liability problem for manufacturer and prescriber alike (de Mol and Fielder, 1997a).

A structured approach to investigation of device failures and the control of risk for the remaining implant bearers is therefore required. The observations and conclusions of the failure analysis provide the input for risk control and safety management measures. This interdependence explains why poor failure analysis results in poor damage limitation (de Mol and Fielder, 1997a). The threat of litigation and the fact that the failure analysis may be biased by hindsight generate disputes between interested parties about the observations and analyses. Judicial tests regarding engineering and managerial decisions are especially difficult. Should engineers and manufacturer have known, ten years ago, according to the scientific evidence available at that time, that their provisions to warrant durability were faulty and defective and, being so, to what extent?

From the point of view of safety management, learning, improving and preventing damage are the primary objectives of a failure analysis. Second, safety management has to be executed within a systems approach (Bignell and Fortune, 1984), aiming ultimately at a better design for the system. As the systems approach in health care safety is relatively undeveloped, attempts to explain accidents often result in blaming some person or party. This contribution
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aims to illustrate the value of a systems approach to enhancement of device safety. A transparent and structured approach to analysing device failure is presented which is used in the development of both safety management systems and risk communication strategies.

2.3 TREATMENT OF HEART VALVE DISEASE AND VALVE FAILURE

The heart consists of two pump chambers, which have an inlet and outlet valve. One chamber sends the supply of oxygenated blood to the various organs such as brain, kidneys, legs etc. The other chamber pumps oxygen-depleted blood from the heart to the lungs where it is re-oxygenated. The first system is more vulnerable to infections and rheumatic fever, and degenerates faster due to ageing. Generally, younger people have to undergo valve replacement because of valve deformation and leakage due to infection or birth defects, while older people tend to undergo valve replacement for degenerative disease. Progress in technology enables us to carry out open-heart surgery with the aid of a heart-lung machine, in sicker and older people. Valves of biological material such as bovine and porcine pericardium, and even human allografts, are available. However, their limited durability and scarcity mean that the large-scale use of mechanical heart valves is necessary. Mechanical heart valves are designed to outlive the patient in terms of durability. In contrast to biological substitutes, the mechanical heart valves require lifelong anti-coagulation therapy. The level of anticoagulation has to be regularly checked, usually by visiting a special anticoagulant clinic. Self-management by a finger-prick, however, provides more frequent testing and reduces time-consuming visits to a clinic.

2.4 VALVE FAILURE IN A SYSTEM'S PERSPECTIVE

Between April 1993 and April 1997, the Interuniversity Working Group on Cardiovascular Implant Retrieval examined three types of valve failure:

Type 1 failure related to leakage of the valve due to compression, which was later explained as a combination of design shortcoming, surgical error, and special disease. This series of four cases appeared to be an institutional problem.

Type 2 failure was related to the fact that a suture wedged between the ring and the closure disk, which caused impingement or blockage. This failure mode is predominantly a surgical error. The valve cannot open and the patient dies. Since 1982, this event has been reported for that type of valve at a rate of 0.5 % of implantations. In 1997, we studied two cases.
Type 3 failures were the fractured BScc valves, resulting in escape of the disk within the valve, which leads to the patient’s death. The failure mode is considered a technical shortcoming, and is the type of failure discussed in this chapter. Due to the number of failure of the BScc valve (type 3) and the duration of the problem (since 1979), we were able to identify the steps in the failure cascade.

2.5 BARRIER ANALYSIS OF THE BSCC FAILURE

The descriptions that follow of the shortcomings in the system, mark barriers which were supposed to prevent the failure in the first place or at least to reduce the damage toll to patients and the system. Barrier analysis may be used to investigate accidents, considering the reasons for the failure of barriers and whether sufficient barriers exist. Although the concept was developed to investigate the impact of physical violence or energy on vulnerable objects (e.g., people), barriers may be also administrative. Another potential of barrier analysis lies in its focus on human error to be overcome by reinforcing barriers or designing more reliable barriers to decrease vulnerability. Referring to the description of the string of failures and the product life cycle-based system, the connections between components are similar to barriers.

a) The primary cause of BScc valve failure was fatigue due to design and manufacturing flaws. Originally, the valve had two struts, which were welded into the flange. Due to a relatively low but serious number of strut fractures, it was decided to make the major strut out of one piece and to weld the minor strut. Although never confirmed by clinical tests, the manufacturer also decided to enlarge the opening angle and to change the flat disk into a convexo-concave-shaped disk. Although welding of the alloy used in this ring was, even at that time, a substandard technique, the new design requirements asked for a special welding procedure, which made the welding even more critical. Therefore, welding could not even at that time be considered an appropriate technology (van der Graaf et al., 1992; de Mol et al., 1997b).

b) Lack of training and qualified personnel to carry out the welding resulted in numerous valves of poor quality and a high rate of rejection. Drug and alcohol abuse was also discovered among factory workers during manufacturing, which was a continuous, 24-hour operation.

c) The valve was a commercial success thanks to aggressive marketing. Reports of strut fracture were known to the manufacturer, but valves that were not accepted by quality control were repolished or remilled and declared acceptable for implantation.
d) In spite of FDA (Food and Drug Administration) orders, the manufacturer refused to adjust the quality control procedures.

e) Due to shortcomings within the FDA, no adequate measures were instituted and the management was able to deliberately mislead the health care authorities.

f) Due to the lack of procedures on authority and communications between the FDA and the Dutch health inspectorate, valves that were prohibited for the USA market could still be implanted in The Netherlands.

g) Cardiac surgeons allowed themselves to be impressed by the tough marketing approach of the manufacturer. Claims of superiority were never proven but made this valve commercially one of the most successful.

h) The risk control of this problem was initially left completely to the manufacturer in the hope that they were monitoring any problems worldwide. Although cardiac surgeons also are supposed to be in charge of risk control, they delegated this responsibility to cardiologists, who in turn had their own responsibilities.

i) There was no register of implanted valves or patients, either in the hospital or with the manufacturer. No follow-up was carried out. In The Netherlands, approximately 2,300 valves were implanted and it took 16 fractures and 14 deaths before the problem in our small country became clear.

j) The problem was played down by health authorities, manufacturer, and the cardiac profession. Hard data on the number of cases and the aetiology of failure remained scarce or were deliberately made confusing. The manufacturer approached cardiac surgeons and health authorities with reassuring, and misleading ‘Dear Doctor’ letters.

k) Risk communication was extremely diffuse and provided only on an occasional basis by all parties involved, including consumer organizations. All media, from consultation room to prime time television, were used. So far, only the responsibility of the manufacturer and his parent Pfizer Inc. has been established. Criminal prosecution for that could be settled with 20 million U.S. dollars.

l) Patients with BSc c implants arrived at a class action settlement with Pfizer Inc. on behalf of Shiley Inc. In the case of a strut fracture, BSc c carriers were entitled to a fixed amount of compensation, which differed between countries and carriers. The settlement also
provided 17 million dollars for research in order to develop diagnostic tools in order to monitor the technical status of the valve. So far, in spite of spending 37 million dollars in a five-year period, no useful or beneficial medical strategy for patients has been developed.

m) The settlement between carriers and manufacturer is supposed to be supervised by an U.S. judge. The stakes for the lawyers representing the class and Pfizer are high. Regarding the technical and "scientific" implementation, a supervisory panel of scientists appointed by the parties is taking care of so-called clinical guidelines and future scientific research. The local professional communities, who usually draw up practice guidelines, remain excluded.

In 1995 and 1997, the seven patients who suffered a BScc strut fracture died, in spite of the two risk control strategies (de Mol and Fielder, 1997a).

2.6 THE PRODUCT LIFE CYCLE-BASED SAFETY MANAGEMENT SYSTEM

The industrial concept of risk and quality management can also be applied to device and implantation manufacturing (Bignell and Fortune, 1984; Perrow, 1987; Wagenaar and van de Schrier, 1997). The product life cycle-based safety management system includes all persons, hospital departments, and health care authorities involved with a product. This system is divided into four subsystems, which correspond with phases according to the product's life cycle.

Phase A: Design and manufacturing
In this phase, direct involvement with design and manufacturing is provided by designers, employers, and the quality assurance division. However, interests related to the design and manufacturing process are also attributed to the parent company, venture capitalist funding, subcontractors, unions, and share holders.

Phase B: Regulation and marketing
Although a marketing strategy is developed as soon as a product is taking shape, access to the market is determined by the regulatory authorities. In this phase, user instructions and proper indications for use are developed and tested. The secondary interests to the process lie with the licensing agency, marketing organization, distributing organization, and clinical research institutes.
Phase C: Implantation and control of patient risks
In this phase, implantation of the device takes place. In the case of heart valves, the implantation centre is also the referral centre where problems after implantation must be diagnosed and resolved. The implementation of the indication for implantation, user instructions, information to patients, and provisions for follow-up take place in this phase.
In phase C, product handling is carried out by the purchasing department, operating room storage, all operating room (OR) personnel, surgeons, and in a remote sense, by the team providing the aftercare. The secondary interests relating to the process lie with hospital organization and management, budget control section, insurance company, participating specialities such as cardiology and physiotherapy, and the inpatients complaint agency.

Phase D: Performance and follow-up
The device is now carried by the patient and serves its purpose. However, adjustments and maintenance are carried out within or without a planned follow-up scheme. Only active devices, such as pacemakers, can be adjusted. However, we know that devices can migrate or show minor changes, which can be diagnosed on X-ray, as is the case with hip prostheses and breast implants. In this phase, an assessment has to be made as to whether the implants are fulfilling their expectations, from the point of view of the carrier as well as the health care provider. Registration, follow-up, and early-warning and quick-rating schemes have to be made operational in this phase.

Figure 3 gives a more detailed overview of the processes controlled by persons and institutions. The authorities involved are subdivided into pro subsystem or life cycle phase, and connected to each other as components. The primary involvement with the product lies with the patients, the family doctor, or the controlling specialists in the community hospitals. The secondary interests lie with the health authorities, which, together with manufacturer and implanting hospital, are supposed to carry out the post marketing surveillance. Pathologists, ambulance services, and patient/consumer organizations may also have an interest when problems arise in this phase. Action by these secondary interested parties is essential for acceptable and successful intervention in case of failure of the device. They are important as they represent the potential sources of conflict of interest. The way these people and organizations interact on the basis of their task to control risk provide the foundation for application of the barrier concept (Kirwan and Ainsworth, 1993).

Designing barriers for protection is difficult and complex, requiring input from designers (phase A), safety people (phase B), and operators (Phase C), and have to be tested in the accident-prone environment (Phase D). The accident analysis approach based on barrier analysis also provides a strong basis for the product life cycle-based safety management system.
Figure 3: The product life cycle-based safety management system. It includes all persons, hospital departments, and health care authorities involved with a product.

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<th>Handling</th>
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2.7 ACCIDENT REPORTS, ANALYSIS AND RISK PERCEPTION

A product life-cycle safety management system approach is a generic framework that describes, understands and anticipates people, interests and authorities in the area of safety maintenance and risk control. It may be applied to classes of events related to devices or to equipment, which may have a shorter or longer life cycle.

Prior to applying the product life cycle-based concept, a phase of recognition has to be passed. The events must have been primarily attributed to device failure, a substantial number of events must have occurred and there must have been a substantial threat to patients. Large-scale failure of devices may have a large or small time window. When the adverse events are
scattered around the world in several centres, the number of failures and the effectiveness of a risk control strategy are difficult to assess. Public outrage may mobilize consumer organizations but may also cause large conflicts of interest, hampering solutions. However, when a product life cycle-based safety management system as a concept is adopted, one may anticipate frictions as summarized above.

Therefore, incident reporting and analysis remain the central means of both discovering and learning from adverse events. Within the framework of post marketing surveillance and duty to follow up, adequate incident reporting at higher aggregation level provides the data essential for activating supra-institutional risk control by means of product life cycle-based safety management. Our group developed a systematic incident identification system, an easy-to-handle digital form, which provides data for analysis and the maintenance of a register (Wagenaar and van de Schrier, 1997).

Temporary paralysis due to thromboembolic events is a common complication or performance endpoint in mechanical heart valve failure. The rate of thromboembolism is considered a measure of technical performance. However, we found that in several cases, in which at first sight the mere presence of a valve was held responsible for the complication, shortcomings in patient management were partly responsible for the adverse outcome. Of course, the presence of a mechanical heart valve remains under all circumstances a dominant risk factor, which narrows the safety margins.

The type of failure determines the type of action to be taken by doctors and patients. The wedging of a suture was considered by surgeons as an "all-in-the-game" event, which was considered completely unacceptable by the patient. This results in a continuation of the usual practise by surgeons, but patients will sue the hospital and/or the manufacturer for negligence and so far they have done that successfully (Vincent et al., 1994).

In conclusion, accident monitoring and risk perception determine largely whether the product life-cycle systems approach will be activated. However, once operationalized, actions and effects do occur within subsystems and components. This process follows basically the Risk Assessment and Control cycle as described by Hale (1995). In the BSc application nearly all relevant parties eventually embarked on effective actions. However, the timing, communication and effectiveness of the actions remained questionable. Risk communication and effective assessment of control actions therefore need further description.
2.8 CONTROL STRATEGIES AND RISK COMMUNICATION

Risk control for medical implants is extremely complicated. In case of failures and threats to the interests of stakeholders within the subsystems of the product life cycle, logical alliances and agreements may fail completely when other subsystems and components are not taken into consideration. Good examples are the ‘Dear Doctor’ letters of the manufacturer in order to minimize the risk and to protect the interest of shareholders (Fielder, 1993, 1994). The manufacturer's information to health authorities, doctors and patients was established to be misleading, due to the conflict of interest between all parties involved. But positive actions may also be frustrated by one-direction communication. Parts of the settlement agreement between patients and manufacturer regarding new research and indications for operative treatment were never implemented, because the health authorities and medical profession were not included. With respect to scientific approaches of risk estimation, the medical profession will accept these new findings only if they are scientifically credible and when all prerequisites for transforming these findings into new practice guidelines have been fulfilled. The health authorities on the other hand, are left with a public-health problem in the sense that they have to care for the patients falling victim to outlet strut fractures and the costs of dealing with the ongoing problem.

As society and life are full of risks, risk communication mainly serves the purpose of increasing the acceptance of risk with the parties involved (Bignell and Fortune, 1984; Perrow, 1987; Calman, 1996; Fitzpatrick, 1996). In the case of the BSc valve carriers, the risk of outlet strut fracture has been established by "body counting". The population at risk was known, as was the number of documented outlet strut fractures. The risk of fracture depended on the opening angle, the age of the patient, the size of the valve, and the position of the valve in the heart. The risk varied from 0.5% to 2% per year (van der Graaf et al., 1992). Technical research revealed that there was a tremendous variation in fracture patterns (de Mol et al., 1997b). It is virtually impossible to make any prediction within relevant time frames of months to one year. Given the size of the substrate it is unlikely that, with conventional diagnostic tools, prefracture signals can be detected.

Therefore, basically two risk control strategies were available (Koornneef et al., 1996):

1. Preventive explantation of the valve

In this strategy, the immediate risk of the reoperation to remove the risky heart valve varies from 2 to 5% and has to be balanced against the cumulative risk of fracture within the estimated life expectancy of the patient.

2. The run-for-your-life option

When there is no obvious gain of life expectancy after balancing the risks the patient is left
with the 'run-for-your-life' option, which requires immediate access to cardiac surgical care in the event of failure. However, this strategy depends on an early diagnosis by lay people in the community, availability of ambulance and helicopter services, immediate referral to a cardiac surgical centre and instant emergency reoperation. Past experience with the series of seven consecutive deaths makes clear that ambulance services, community hospitals, family practitioner, and cardiac surgical centre do not co-operate and communicate adequately. In all cases, the patient himself or the relatives were able to make the instant diagnosis of strut fracture and valve failure, but they were simply ignored by the experts.

When taking a closer look at the parties involved in emergency care in The Netherlands, and the way their tasks and obligations are bureaucratically separated and fragmented, it becomes obvious that survival depends largely on luck and personal strength of the patient. Ambulance drivers are daily briefed on where to bring cardiac emergency cases and may refuse to transport patients dying from a valve fracture to a cardiac surgical unit. Seven deaths in a row obviously diminish the credibility of the medical authorities in the handling of the crisis (de Mol and Fielder, 1997a; Koornneef et al., 1996; Sandman, 1991).

The patient's quality of life may be affected by carrying a risky device continuously and receiving disquieting messages from the media (Fielder, 1994; Kallewaard et al., 1997). On the other hand, risk communication may improve communication and effectiveness of risk control strategies and increase the acceptance of the residual risks to the patient (risk taker), the doctor (risk controller) and the public (justice).

A risk communication programme should serve the following objectives:

1. Awareness of the danger
2. Information with respect to the individual exposure
3. Counselling with respect to risk control and prevention
4. Providing new information in order to decrease uncertainty
5. Ensuring that solutions accord with principles of justice

The societal impact of dangers and the willingness to embark on a risk communication and control strategy depend on the safety culture. As medical devices are designed and manufactured with the aim of zero failure and high durability, the safety culture with respect to the technical performance is highly developed in phase A and phase B. However, in phase C and phase D, the primary controllers of risk and performance of the device have to monitor many other implants. They therefore rely heavily on the intrinsic safety generated in phases A and B, though the awareness and expression of safety culture in phases C and D differ in terms of intensity and effectiveness.
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The product life cycle-based safety management system provides a model that may guide the contents of the message as well as the number of people / components to be informed in order to achieve the effect of re-enforcing barriers, changing duties in order to co-operate effectively and communicating the nature of the risk. So, sender, receiver, copyholders, and contents of the message may be guided by the product life cycle-based safety management system. The system also allows predictions on acceptance of the message as risk perception and safety culture / awareness of the parties can be described.

2.9 SYSTEMS CONTROL AND ASSESSMENT

2.9.1 Systems control

Safety management is expensive and demands many resources, especially when a crisis materializes. Effective decision making relies on adequate information being available. Safety crises in relation to implants were characterized by incomplete data and uncertainty regarding risks and the effectiveness of risk control strategies. Therefore, within the subsystems or product life cycle phases, platforms must be created with a hierarchy of risk control. We propose in phase A the management of a manufacturing company is in charge, in phase B the health authority, in phase C the implanting physician, and in phase D the controlling physician closest to the patient.

Reviewing the problems with the BScc valves, the root causes of failure in the various subsystems varied. In phase A, the management was fraudulent, in phase B, the health authorities were incompetent, in phase C, the physicians in charge were ignorant, and in phase D, the general practitioner or controlling cardiologist was still not informed and so was unaware. In phase D a dedicated relationship is lacking as attending physicians take care of many risks, which fortunately rarely materialize and therefore cannot take on the task of monitoring specific devices, though they should report failures. So, in terms of system control, an information and communication platform is required as well as knowledge of devices, risks, and tools to estimate risks and their consequences. In phase C, specialities, such as cardiovascular surgery, plastic surgery, and orthopaedic surgery, may create their own statutory safety committees based on self-regulation. These rulings relate to topics such as a register of patients, follow-up criteria to carry out clinical studies with devices, and guidelines as to how to deal with technical and marketing information provided by manufacturers.

In phase B, health authorities may, as with the licensing process for drugs, draw up regulatory and technical committees to assess devices. In phase A, the risk of product liability and competition on safety and performance are supposed to force the manufacturer to comply
with the safety standards. A safety board for medical devices should have the expertise to deal with the actual risk control within the system but also to execute the political and societal demands from the point of view of individual and public health care.

### 2.9.2 Assessment of effectiveness

The efficacy of the model can only be finally assessed by its outcome. For this purpose, and applied to the BSc valve problem, Koornneef et al. describe a risk intensity assessment model (RIA). Such a model enables the assessment of the level of system integrity as a threshold for containing damage due to device failure.

The model uses the parameters of the former DIN 19250 standard:

1. The "consequence/risk" parameter, reflecting the seriousness of harm or loss, which varies from minor injury to a catastrophe with many fatalities
2. The "frequency and exposure-time risk" parameter, reflecting duration of exposure to harmful conditions, which may vary from seldom to permanent
3. The "possibility of avoiding risk" parameter, reflecting options to divert/control imminent danger, which varies from possible under certain conditions to hardly possible
4. The "probability of risk realization" parameter, reflecting prevalence of failure, which may vary from a very low probability to a relatively high probability

Risk control measurements may be directed towards one or several of these thresholds, which should result in reinforcement of the system integrity and an overall reduction of potential injury and damage.

The RIA model indicated that the preventive replacement strategy of risky BSc valves was the strategy to be preferred, but Dutch cardiac surgical centres took a different approach. Some centres opted for many preventive reoperations of the valve, others gave preference to explantation of the valves most at risk and the wait-and-see options for others. The latter group paid a higher death toll in outlet strut fracture (six of the seven deaths, the other death refused to be operated on even though it was recommended) and is now forced to carry out more reoperations, at still higher risk, as patients have grown older. So, three years later it is confirmed that according to the point of view of systems control, preventive explantation has provided the most effective damage control.

We must be aware that the medical speciality primarily focuses on strategies aimed at individuals. Risk strategies for populations belong to the public health sector, which did not
recognize the BScc problem. However, on an individual basis, it is the decision of the doctor and the patient to opt for one of the two strategies, based on the best information available. However, this supposes that the best information is available to the decision-making doctor and patient. This tends to be information which they feel confident with, as it is generated within their own professional discipline, though it may not always be the best available (de Mol and Fielder, 1997a; Fielder, 1994 and 1996).

2.10 RESOURCES AND MULTIDISCIPLINARY RESEARCH: THE NEED FOR A NATIONAL DEVICE SAFETY BOARD

Reporting, analysing and learning from adverse event reports is expensive, especially with large-scale enterprises. Usually, funding for prevention is only allocated where it can be attributed to the price of a device. Pre-implant testing is an accepted manufacturing cost. The costs of maintaining a register of heart valve carriers are still not determined or allocated to any party. Are these costs to be paid by the manufacturer, institution, or any other authority? This raises questions about the control, confidentiality, the extent of a register and its cost effectiveness. Research might reveal not only shortcomings on the part of the manufacturer, but also on the part of health authorities and doctors.

Doctors might anticipate questions about why they selected the BScc valve amongst others, why they ignored early reports on strut fracture, why they kept the extent of the problem from patients at risk and how they judged the technical and clinical research supporting the market approval of the BScc valve. These questions usually arise when a design or material failure cause implant dysfunction (de Mol and van Gaalen, 1996b). In the BScc case, it could be argued that the manufacturer should promote and fund technical research to confirm the liability, clarify the extent of the problem, and result in the recognition of many cases to be compensated. On the other hand, critical research carried out by an interested party will lack scientific credibility and objectivity. However, health authorities that are publicly funded were also reluctant to fund investigation. As it is obvious that the manufacturer is liable for the damages, the authorities refused to take any funding initiative. They referred to the legal obligation of the manufacturer, who in his turn had his own damage control agenda.

In The Netherlands a small grant was only made available from the Health Authority after the threat of a legal procedure by the Consumer Organization. This provided the basis for substantial technical and epidemiological research, providing some basic information to enhance decision making, in spite of its chronic under-funding. For less spectacular device failures, dedicated research programmes to fill the gaps of knowledge are still lacking. Lack
of funding and delays in obtaining information are hampering the development of risk control strategies.

Procedures to recognize and analyse serial device and implant failures will be well founded when based on the product life cycle-based management system. Involvement of public bodies to facilitate research, funding and execution of strategies can be achieved only if a succinct and objective presentation is made by the parties involved. This requires a proactive and continuous effort to assure the safety of implants and devices. To avoid difficulties with access and bureaucracy, national agencies or safety boards, similar to the Transportation Safety Boards or Pharma Vigilance System, should be instituted.

2.11 CONCLUSIONS

We demonstrated with the BScc valve failures the value of the concept of product life cycle-based safety management at the supra-institutional level. Incident reporting, incident analysis and risk perception largely determine the threshold for institutional or supra-institutional safety management. Safety management identifies the key players, a hierarchy of risk control, and guides the content and flow of risk communication. Last, but not least, it discriminates between parties really "touching" the implant and parties taking a recognized societal interest in the implantation process. The potential for conflicts of interests can be clarified and anticipated. In close conjunction, the risk intensity assessment model enables estimations about the effectiveness of damage control. For a device such as CoaguChek®, which also enables patient self-management of anticoagulant therapy, extra classes of risks, conflict of interests and pitfalls in communication can be identified.

Putting these concepts into practice depends largely on public awareness, political responsibility and legal liability. Lack of knowledge, funding and safety management tools can be overcome, once a proactive approach is chosen by the key role players in the life cycle phases: the manufacturer (A), the Health Authority (B), the Doctor (C) and the patient (D). A national device safety board could provide the administrative platform to harbour knowledge, experience and factual guidance of safety management.
Chapter 2

2.12 REFERENCES

Product Life Cycle-based Safety Management
