THE DUTCH
SAFETY BOARD

SUMMARY

Innovation adrift

A safety investigation subsequent to media reports in april 2009 on calamities following weight-loss surgery at the Scheper Hospital, Emmen, The Netherlands

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The Hague, October 2011

THE DUTCH SAFETY BOARD

The aim in the Netherlands is to reduce the risk of accidents and incidents as much as possible. If accidents or near-accidents nevertheless occur, a thorough investigation into the causes of the problem, irrespective of who is to blame for it, may help to prevent similar problems from occurring in the future. It is important to ensure that the investigation is carried out independently from the parties involved. This is why the Dutch Safety Board itself selects the issues it wishes to investigate, mindful of citizens' position of dependence with respect to public authorities and businesses. In some cases, the Dutch Safety Board is required by law to conduct an investigation.

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This report is published in Dutch and English. In the event of any difference in interpretation the Dutch text must be regarded as binding.

CONSIDERATION

In April 2009, the Dutch press reported on problems with weight-loss surgery at the Scheper Hospital, Emmen, the Netherlands. Within a short time span, several patients died after or while undergoing weight-loss surgery.

Individuals seeking medical help and requiring treatment must be able to trust that health care institutions and providers do all they can to ensure their safety. The fatalities at the Scheper Hospital prompted the Dutch Safety Board to investigate how the parties involved in bariatric surgery at this hospital organized patient safety.

The Dutch Safety Board's view on patient safety and risk management
On 9 October 2009, the Scheper Hospital published the results of its own investigation into the deaths. This investigation concentrated on the actions of the surgeon involved, who, according to the final report of the Greve Commission, "*… did insufficiently use the opportunities provided to him by the hospital organization. He failed to organize the bariatric program effectively and to work according to clear guidelines.*"[1] Partly in response to this investigation, the surgeon removed his name from the so-called 'BIG-register', the mandatory listing of health care professionals in the Netherlands.

In the opinion of the Dutch Safety Board, however, it is rarely possible to attribute the responsibility for serious incidents to the actions of a single individual. Whenever a serious incident occurs this commonly means that also the 'safety net' around the person or persons involved has failed to function properly. The tendency to ascribe the death of patients to the malfunctioning of a single medical doctor is understandable because this person bears a large responsibility. However, such an approach contains the risk that the safety net in place will continue to be marred by shortcomings, causing the unsafe situation to persist. For this reason, the Safety Board's investigation did not focus exclusively on the actions of the surgeon involved; rather, it took into account all actors considered relevant in this particular case.

The basic assumption of this investigation is that patient safety in hospitals is a responsibility of all actors involved. This includes not only the attending physician(s) and the nursing and paramedical staff, but also their colleagues, supervisors and managers determining the context in which these medical professionals are employed. Together, they have to manage the risks for patients optimally. This is what patients expect and are entitled to expect. The assumption thereby is that all actors agree on their mutual responsibilities, and that they call on each other to account for not meeting them. This equally applies to parties involved from outside the care institution, such as the health insurer and the Health Care Inspectorate.

Innovation is common in health care, and the bariatric program at the Scheper Hospital is an example of such effort. Innovation and administering new forms of treatment are crucial for the development and improvement of health care. In this context, management of safety risks is perhaps even more important than in regular care processes. The Dutch Safety Board by no means holds the view that innovation should be avoided as much as possible. On the contrary, efforts at innovation and care improvement are essential for patients and patient safety. Whenever opportunities for care innovation are identified and exploited, however, these need to be pursued safely. This calls for attentiveness of the actors involved and sustained resilience of the overall organization. Moreover, in the case of any particular innovation it must be weighed carefully whether its safe introduction is possible at all. In the decision to introduce an innovation, one should consider whether it is possible to carry through this innovation also in the successive phases of the care process. This is particularly important because patients balance the pros and cons of the treatment, even though most of them will not be in a position to establish the full scope of the risks at stake.

1 Report by the commission on the quality of bariatric surgery at the Scheper Hospital Emmen, 16 September 2009.

Main question of the investigation
The investigation's main question is geared to the development of the bariatric surgical program of the Scheper Hospital and the ways in which relevant actors in this hospital and outside of it dealt with patient safety:

"To what extent and how did relevant actors from within and outside the Scheper Hospital ensure patient safety during the introduction and expansion of its bariatric surgery program?"

Conclusions
The study revealed that the safety of patients who underwent bariatric surgery at the Scheper Hospital was barely ensured. The Dutch Safety Board bases this view on the following conclusions:

- The introduction, launch and further expansion of bariatric surgery at the Scheper Hospital involved a non-managed process;
- The actual responsibility for bariatric surgery was almost fully in the hands of a single person, while other actors failed to act in line with their responsibility.

After an enthusiastic start, which involved comparatively uncomplicated gastric banding, the number and complexity of the bariatric surgery performed at the Scheper Hospital quickly increased. The interrelated basic safety conditions, however, were lagging behind. Monitoring of the bariatric care processes and insight into the interrelated risks were largely absent. This resulted in a drift into danger: gradual adjustments in the basic safety conditions, combined with the growth of the care options provided, resulted in a situation in which the care providers proved less and less capable of ensuring patient safety. Four circumstances played a major role in this.

The development of the Scheper Hospital bariatric surgical program implied a substantial change in the treatment options available at this hospital. Quite soon, medical staff performed complex surgical procedures, despite the hospital's lack of experience in this field, the many different care providers involved and the vulnerable patient group. To ensure patient safety in such a context at a sufficient level, those with an active role in the care process and those with the competence to define its basic safety conditions must know exactly what to expect from each other. This requires ongoing involvement and co-responsibility on the part of all actors.

First, the commitment required for bariatric surgery at the Scheper Hospital was largely absent. Neither the surgeon and his fellow-surgeons, nor the hospital board and the health insurer, sufficiently recognized that all stages of the bariatric surgical program represented a new development for the hospital in terms of the medical expertise involved. This should have occasioned the formulation of a collective safety approach. The initial, comparatively simple procedures and the subsequent expansion with ever more complex interventions in particular seem to have been conceived by all parties involved as merely a continuation of a type of procedures common in this hospital. Care providers involved did not feel the need for any special measures to ensure patient safety. The hospital mainly focused on the potential (financial) benefits of providing new types of bariatric surgery, and left the responsibility for ensuring patient safety entirely to the surgeon in charge of initiating the bariatric surgery program.

Secondly, it is relevant that the care institution and its medical specialists did not call each other to account regarding their mutual expectations. The Safety Board's investigation revealed that both parties had a stringent view of their own responsibility and that of the other party, which left no room for a collective approach of patient safety. This explains why the hospital board, but also its Medical Staff Association and the other surgeons, mainly interpreted warning signs and complaints about the surgeon involved as issues to be improved pertaining to his individual performance. These parties collaboratively initiated a trajectory towards improving the bariatric care process only after it was in fact too late to do so.

Thirdly, neither the medical specialists nor the hospital board or the health insurer, bothered about systematic monitoring of the quality and the results of the bariatric program. In part as a result, problems were not identified as such on time. In care innovation, the employment of potentially relevant information, for instance data on complications and duration of hospital stay, is an indispensable element of the safety approach. Proper data would have offered the care providers, the executive board and the health insurer more insight into the quality of the care provided, and might have contributed to earlier detection of underlying safety issues.

Fourthly, external parties allowed the situation described above to persist. The health insurer mentioned above played a major role, as financier and 'delegate client' representing the patient. This health insurer made quality agreements with the hospital, but did not monitor the hospital's compliance. Furthermore, this health insurer bargained a rate that did not do justice to the fact that bariatric surgery was a new care option provided by the Scheper Hospital. The review committee did not notice any shortcomings in the concern for patient safety, such as the absence of an adequate complication registry. Although the Health Care Inspectorate observed the absence of an adequate complication registry for several years in a row, it did not force the hospital board, as accountable party, to implement improvements. In this context, it is remarkable that the Inspectorate concluded that the hospital's safety management system compared well to that of other hospitals, while such an essential element as the proper registration of complications was lacking.

Patient safety as concerted responsibility

A major observation of the Dutch Safety Board is that the executive board and medical specialists of the Scheper Hospital had not defined their individual and shared responsibility for quality care. With the enactment of the Health Institutions Quality Act in 1996, health care institutions became responsible for quality and safety by law. The responsibilities of medical specialists regarding their care institution's quality assurance policy were further elaborated in the so-called Model Admission Contract, which since 2006 has served as a standard for the contract between individual medical specialists and care institutions.[2] It is remarkable that it is still possible today for executive boards and management teams not to be involved in the management of major medical developments and/or safety issues in their own hospital. Earlier, the Safety Board observed similar problems at the UMC St Radboud in Nijmegen.

In hospitals, apparently, it may occur that actors insufficiently coordinate their efforts to ensure patient safety. Also discussions on quality are often secondary to discussions on financial matters. Furthermore, strict agreements on the outcome of care provided and risk management (and their compliance) are absent. The Safety Board considers it essential that a health care institution's executive board, its medical specialists, the health insurer and the Health Care Inspectorate – both individually and collectively – define the quality of the care provided as well as of patient safety. This is also in line with patients' expectations.

Medical specialists have the obligation to formulate basic safety conditions required to provide responsible care; they should not introduce new treatments if the health care institution is unable or unwilling to meet such conditions. It is the care institution's duty to create the proper conditions. In addition, the care institution needs to formulate, together with its medical professionals, SMART[3]-standards framing the quality of care. The health care institution must call on the medical professionals to account for and sustain the quality of the care provided. Similarly, health insurers, in their role of financier, have the duty to co-monitor and co-ensure the quality of the care they purchase, which includes the quality of patient safety.

The Health Care Inspectorate is expected to ensure that care institutions implement quality assurance, to oversee that quality agreements are acted upon and met, as well as to intervene when care institutions fail to operate properly.

2 Model Toelatingsovereenkomst, section 2; NVZ (Dutch Hospitals Association) definitive version June 2006.

3 SMART = Specific, Measurable, Attainable, Relevant, Timely.

A shared concern among management and care providers for managing and monitoring the quality of care in a care institution calls for an environment where openness and options for learning are center-stage, and where incidents and warning signs are viewed as occasions for improvement. In this respect, the Dutch Minister of Health, Welfare and Sport recently argued: *"to realize its final responsibility in concrete ways, an executive board will need to display an active stance when it comes to picking up warning signs to intervene on time. Similarly, it is reasonable to expect from the other professionals in health care that they raise matters with the board promptly."*[4] The Dutch Safety Board subscribes to this view.

The Safety Board welcomes the upcoming Patients' Rights (Care Sector) Act, which seeks to promote the above. Legislation is not enough by itself, however, even when it allows for defining the rules and guidelines for quality in more detail. Safe care must arise from the work floor and it will not materialize unless all relevant actors explicitly choose to pursue it.

4 Letter of the Minister of Health, Welfare and Sport, in reply to parliamentary inquiries about the functioning of partnerships in hospitals, The Hague, 30 August 2011.

CONCLUSIONS

The investigation's main question centered on the development of the bariatric surgical program of the Scheper Hospital, and how those involved in both this hospital and outside of it thereby dealt with patient safety: "To *what extent and how did relevant actors from within and outside the Scheper Hospital ensure patient safety during the introduction and expansion of its bariatric surgery program?"* Based on its investigation, the Dutch Safety Board claims that patient safety of bariatric surgery at the Scheper Hospital in the period under investigation was not ensured. This observation is based on two conclusions.

Conclusion 1. The introduction, launch and further expansion of bariatric surgery at the Scheper Hospital involved a non-managed process.

a. None of the parties involved viewed the introduction of bariatric surgery as an innovation of the care provided that introduced particular risks for patients, besides the results expected. None of the parties involved within the hospital displayed awareness of the risks of bariatric surgery, its complex forms in particular.
b. The (para)medical professionals involved, the management and the board of this care institution failed to have a shared view or comprehensive approach for bariatric surgery as a shared basis for action.
c. Process monitoring was virtually absent during the period covered by the investigation. Information on care parameters was not used; the available information systems were developed from different departments with their own standards and terminology for registration of data. The data registered were not accessible to others and therefore hardly useable.
d. There was a rapid increase in the number and the kind of bariatric surgical interventions performed. Meanwhile the means and materials provided by the care organization were lagging. This allowed for the gradual emergence of a situation in which risks for patient safety increased while none of the actors noticed or addressed this.

Conclusion 2. The actual responsibility for bariatric surgery was almost fully in the hands of a single person, while other actors failed to act in line with their responsibility.

a. The surgeon, as medical professional who initiated the hospital's bariatric surgery, failed to adequately structure the medical aspects and the quality management of the bariatric care chain. Likewise, he failed to ensure compliance to quality standards. In this respect, his fellow surgeons, the General and Orthopedic Surgeons' Partnership, the medical staff and the health care institution did not intervene to correct the situation. Also, the surgeon did not manage to engage his fellow surgeons and the hospital management in a truly shared decision to expand the bariatric surgery treatment options provided. His fellow surgeons and the hospital management did not redirect his adopted course.
b. The fellow surgeons, the General and Orthopedic Surgeons' Partnership and the medical staff insufficiently took on individual and collective responsibility for the quality of bariatric surgery by adopting an attitude of non-interference and a strict interpretation of their own frames for quality management.
c. Given their professional responsibility, individual paramedical professionals insufficiently identified the problems that potentially could emerge for patient safety as a result of the sub-optimal conditions under which they had to perform.
d. In the development of new treatment options, such as bariatric surgery, as well as the organization of specific quality guarantees, the hospital executive board and the Medical Staff Association did not consider the department and sector managers and the Quality Care Office as sparring partners for the medical professional(s). Nor did the department and the sector managers and the Quality Care Office present themselves as such.
e. The executive board motivated and called on the medical professional(s) involved too little to account for the quality of the bariatric care provided in line with agreements made. The executive board did not put in place suitable registration systems supporting quality control of bariatric care.
f. The supervisory board did not actively carry out its monitoring role regarding the patient safety of the care process: it questioned the executive board not critically enough on developments in (the quality of) primary processes and the realization of the interrelated guidance and information.

Relevant parties outside the hospital:

g. The care provider of the bariatric care contracted was the Trenta Foundation, not the Scheper Hospital. The construction in which these two parties acted as main and secondary provider, respectively, did not contribute to a transparent responsibility for bariatric surgery and its quality control. It also gave rise to a situation in which the Trenta Foundation did not live up to its obligation to offer responsible bariatric surgical care.
h. Several general practitioners voiced their concerns about the quality of the bariatric surgical treatment options provided at the Scheper Hospital. Still, their warning signs did not contribute to the timely recognition of problems or adjustment of bariatric surgical care.
i. In new and evolving treatment options, such as bariatric surgery, quality control and rate corresponding to the care provided serve as basic conditions to ensure quality. The rate negotiated by the health insurer in purchasing bariatric care was not in line with the character of the care provided. The health insurer did not act on the quality and monitoring agreements on bariatric surgery made with the care provider.
j. Although several times the Health Care Inspectorate has identified shortcomings in the registration of medical actions and their results, including surgical complications, it did not impose any measures aimed at improvement. Despite attention for new developments at the Scheper Hospital, such as minimal invasive surgery, the Inspectorate did not elaborate on specific requirements for medical disciplines that employing these techniques. As a consequence, bariatric surgery as conducted at the Scheper Hospital remained outside the Inspectorate's scrutiny.

RECOMMENDATIONS

Based on the conclusions of the investigation, the Dutch Safety Board issues the following recommendations. These recommendations aim at preventing similar incidents from happening in the future and to improve patient safety in hospitals in the Netherlands.

1. To the Scheper Hospital and its Medical Staff Association:
   Make concrete arrangements about organizing patient safety in general and care innovation in particular. These arrangements must also address how all care providers active in this hospital adhere to them as well as demonstrably ensure them. Pay attention to prospective risk analysis, the registration of results and monitoring of results and care processes.

2. To the health insurer Achmea:
   Ensure proper pricing of care innovation, enter into specific quality agreements with care providers and monitor their compliance.

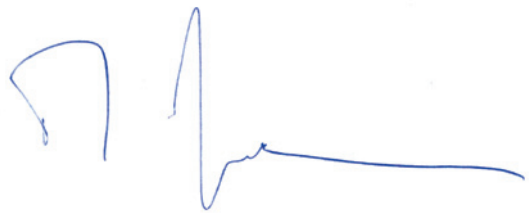
3. To the Minister of Health, Welfare and Sport:
   Be alert to care innovation processes in health care institutions. Require these care institutions to enter into agreements on ensuring the quality of these processes. Be critical in this respect and respond appropriately when basic conditions for patient safety are not met.

Innovation is important for the development of health care. This report illustrates what can happen when parties involved do not recognize or acknowledge care innovation processes as such. Innovation, as this report shows, calls for recording of results, monitoring and ongoing (opportunities for) further adjustment. Of great importance is the availability of means to respond to unforeseen circumstances, both for the quality of the care provided and for patient safety.

4. To the Dutch Association of Healthcare Insurers:
   Based on the content of this report, assess how your members interpret and carry out their responsibility for care innovation and, where needed, see to it that improvements are made.

5. To the Dutch Hospitals Association:
   Based on the content of this report, assess how your members interpret and carry out their responsibility for care innovation and, where needed, see to it that improvements are made.

After this report's publication, the Dutch Safety Board will organize a meeting with the parties to whom the recommendations were directed. The objective of this meeting is to draw lessons from this report and to discuss the ways in which these parties respond to the recommendations.



T.H.J. Joustra
Chairman of the Dutch Safety Board

M. Visser
General Secretary

Administrative bodies to which a recommendation is addressed should state their position in respect of compliance with this recommendation to the relevant minister within six months of the date of publication of this report. Non-administrative bodies or persons to whom a recommendation has been addressed should state their position in respect of compliance with this recommendation to the relevant minister within one year of the date of publication of this report. A copy of the response should at the same time be sent to the Chairman of the Dutch Safety Board and the Minister for Security and Justice.

The Dutch Safety Board

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