Serious Adverse Events in Hospitals

Could this have happened here? Examples and experience gained from investigation of serious adverse events 2010–2013

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Could this have happened here? Examples and experience gained from investigation of serious adverse events 2010–2013
Svikt i samhandling, kommunikasjon og kompetanse i alvorlige hendelser …… kunne det skjedd hos oss? Eksempler og erfaringer 2010–2013 fra Undersøkelsesenhetens arbeid med varsler om alvorlige hendelser i spesialisthelsetjenesten (§ 3-3a i spesialisthelsetjenesteloven) (Rapport fra Helsetilsynet 3/2014)

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The director's foreword

In a society built on welfare, services must have broad backing in the general public. If patients are to have trust in the delivered services, these must be reliable and of high quality. A key premise for trust is that patients and others perceive the delivered services as being of high quality and reliable. Sound supervision of the services helps foster trust.

The specialist health services have a duty to notify the Norwegian Board of Health Supervision of any serious, adverse and unexpected incidents (the reporting system, Section 3-3a of the Specialised Health Services Act). The reporting system was the outcome of a political process that followed next-of-kin's negative experiences in meeting the health and care services after unexpectedly losing a loved one during hospital treatment. Patients' next-of-kin were also critical of the way the supervisory authority had met them when they attempted to file complaints regarding the medical care their loved ones had received.

In order to deliver prompt and thorough supervision of serious adverse events in the specialist health service, and in order to assure that open dialogue forms part of this supervision, the supervision authority must continually exert itself to refine its supervisory methodologies, to improve its capacity and to raise its level of expertise. In order to gain an understanding of what has happened, and to ensure that all pertinent information is gathered, the agency must work swiftly and in close contact with those involved in the actual events and those affected by them. It is the task of the Norwegian Board of Health Supervision to investigate and analyse root and immediate causes, and to assess whether sound healthcare was given. The intention is to promote learning in the services, thus lowering the risk of events recurring. However, we are aware that there is a need to boost our expertise, especially as regards safety and organisational studies. Such upskilling efforts require close collaboration with the Norwegian Board of Health Supervision's local offices, which are represented by County Governors. Emphasising safety and risk is one way of sending a message to the health service as to what the supervisory authority is looking for in hospitals as part of the work to assure that the delivered services are safe.

Unexpected and serious adverse events are about people, and about hospitals and health personnel who want to do a good job – but who sometimes fall short. However, first and foremost such events are about patients in need of medical treatment, and about their immediate family. It is the experience of the Norwegian Board of Health Supervision that relatives often have relevant and solid information about what has happened – information that supplements and adds new layers of understanding to the accounts given by health personnel and their leaders. Combining information from next-of-kin with that supplied by staff thus produces a comprehensive picture encompassing as many aspects of the events as possible.

The Norwegian Board of Health Supervision has observed that certain areas appear to be decisive for patient safety, and the hospitals' management should make active use of these insights in order to build safe services. We have found good management to be a recurring theme in our investigations. Leaders that are deeply committed, curious, goal-oriented and knowledge-focused usually create settings that promote openness and organisational learning. Communication, too, is key for the delivery of sound services. Nowhere is this more relevant than in the communication among staff and collaborating entities. Supervisory experience has shown that when failures occur in patient care, communication and collaboration are critical areas. Additionally, expertise and skills play a salient role;

appropriate competence at the right time is a cornerstone of sound delivery of services. Adequate competence in the first stages of the patient treatment pathway has emerged as crucial for a positive outcome.

The Norwegian Board of Health Supervision expects the services to be proactive when unexpected events occur, and not to await the supervision authority's investigation and response. Laws and regulations express society's requirements to the services on behalf of the service's users. It is our ambition that this report will showcase high-quality supervision built on regulatory requirements, and stimulate reflection and learning in the organisations delivering services.

Jan Fredrik Andresen

A few notes on the report

This is the first report published by the Norwegian Board of Health Supervision's Investigation Unit for Serious and Adverse Events following the introduction of the regulatory requirement regarding a reporting system for serious adverse events in the specialist health service. This requirement is established in Section 3-3a of the Specialised Health Services Act.

In the commissioning letter instructing the Norwegian Board of Health Supervision to establish an Investigation Unit, the Ministry of Health and Care Services stated that it expects an annual report, and that the report is to focus on how to realise the learning potential from the preceding year's cases.

This report consists of a collection of articles. They detail examples and experience from the unit's work in acting on reports received between 1 June 2010 and 31 December 2013. In part one of the report we describe adverse events which were reported to the Norwegian Board of Health Supervision, how they were handled, and what conclusions the agency arrived at in these cases. The second part consists of articles that present statistics and overviews from two disciplines (emergency medicine and birth care) we have chosen to focus on. This section also contains statistics illustrating the total number of reports by discipline and hospital, and shows how the Norwegian Board of Health Supervision has responded to the reports.

This report has two objectives:

- to contribute to the hospitals' own analysis and reflection based on the reports (with a view to enhanced learning),
- to provide an account of serious adverse event reporting and the processing of such reports by presenting numbers and statistics.

The hospitals' medical and other professional communities form one of the principal audiences for this report. In featuring these examples, the Norwegian Board of Health Supervision wishes to promote reflection and discussions within the hospitals and foster constructive debates on patient safety, the risk of failings and the potential for improving patient care.

PART 1: EXAMPLES AND EXPERIENCES FROM THE NORWEGIAN BOARD OF HEALTH SUPERVISION'S RESPONSE TO REPORTS REGARDING SERIOUS ADVERSE EVENTS IN THE SPECIALIST HEALTH SERVICE

ARTICLE 1: The Norwegian Board of Health Supervision's Investigation Unit for Serious and Adverse Events – the unit's remit and work methodology

Reports to the Norwegian Board of Health Supervision concerning serious adverse events in the specialist health services – establishment of the reporting system

The work of the Norwegian Board of Health Supervision shall promote patient safety and drive improvements in the health service. This also applies to the Investigation Unit for Serious and Adverse Events' actions in response to reports of serious adverse events in the specialist health service under Section 3-3a of the Specialised Health Services Act.

In the spring of 2010 a number of serious adverse events in the specialist health service became the focus of public attention. Several young patients died while undergoing treatment. Faced with the unexpected loss of a family member, the next-of-kin were vocal in their criticism of the health service and the supervision authority. They were angered by the health service's response to questions how these deaths could have been allowed to happen. They also had unpleasant encounters with the supervision authority when they approached the agency in order to file a complaint regarding medical treatment.

On 1 June 2010 a decision was made to set up a reporting system. This was implemented immediately. Pursuant to Section 3-3a an obligation was imposed on the specialist health services to report adverse events to the Norwegian Board of Health Supervision: *"In order to ensure supervisory response, hospitals and service providers under contract with hospitals or regional health authorities shall immediately report any serious adverse events to the Norwegian Board of Health Supervision. Serious adverse events are deaths or significant harm to the patient where the outcome is unexpected relative to the foreseeable risk."*

At the same time, the Norwegian Board of Health Supervision was given clear instructions on how to approach this task. The agency was instructed to:

- work more swiftly and engage in more dialogue with those who were involved in the event itself and those who were affected by it, so that the agency gains an understanding of what has happened, and in order to ensure that all relevant information is gathered,
- investigate and analyse, and undertake assessments as to the soundness of the delivered services,
- promote learning in the services and thus help reduce the risk of events recurring.

"Report received" – what does the Norwegian Board of Health Supervision do with the reports it receives?

The intention underlying the legal requirement to report adverse events is to enable the supervision authority to quickly contact and talk with those who were involved in the event or affected by it; to gain an understanding of what has happened, and ensure that relevant facts are gathered. The Norwegian Board of Health Supervision's Investigation Unit considers every single report individually, collects information on the event, and evaluates its response in each case with a view to ensuring an appropriate supervisory response.

Reports are sent to the Norwegian Board of Health Supervision via e-mail, and are addressed to varsel@helsetilsynet.no. No later than the following working day, a case officer who is also a healthcare professional telephones the contact person indicated in the e-mail. We gather information on the course of events and any organisational issues that may have played a role in shaping events. If we need to look at patient records and other information to fill in the blanks and make a decision on how to respond to the report, we request the necessary documentation. Jointly with the Office of the County Governor in the county of the service provider, the Norwegian Board of Health Supervision then determines whether to undertake urther supervisory monitoring and action in the case, and what steps to take.

What type of supervisory response is appropriate: on-site inspection or other supervisory action?

If the initial processing of the report has failed to provide sufficient information and to give us an understanding of events, we sometimes perform on-site inspections in the hospital shortly after the event. This is done in cases concerning serious and complex events; if more than one patient care entity is involved, and if there is a risk of the incident recurring. During the on-site inspections, we have talks with the health personnel involved in the adverse events and their leaders. Relatives are offered an opportunity to talk to the inspection team, giving them an opportunity to share their experiences and information on what has happened.

However, in many cases other supervisory responses are more appropriate. Following the initial fact-finding stage, a substantial share of the reports (see Table 6) is forwarded to the County Governors for further supervisory action. Here the adverse event is investigated further, and the Office of the County Governor determines whether medical attention was sound, as well as whether the service provider is organised appropriately. In many cases, the County Governor deals with a series of supervisory review cases, complaints and reports on issues causing concern, all relating to the same hospital. The Norwegian Board of Health Supervision closely monitors the County Governors' work with incident-based supervision, and assists them through systematic upskilling measures, and ongoing guidance as needed.

If the initial investigation reveals signs of serious deficiencies and indications that the delivery of healthcare is not sound, the Norwegian Board of Health Supervision may upscale its supervisory activities and review the written documentation in the case. In some cases, the Norwegian Board of Health Supervision requests a written account from the hospital outlining what measures have been taken in response to the serious adverse event. The hospital is given a deadline by which to respond, and once we have received a reply we evaluate whether the case can be closed or requires further action.

Patient records and documents outlining the service provider's organisation are reviewed both during on-site inspections and in connection with normal incident investigation. The course of events is mapped out in considerable detail, and if necessary we obtain expert reports from external specialists. Once we have gained an understanding of what has happened, and which factors may have affected the outcome, we specifically assess whether the patient received sound medical care and whether the organisation was managed and run in a sound and appropriate manner. Our conclusions result in a report which is sent to the hospital where the event in question took place. Sometimes we also meet with the hospital after the case has been closed.

We thoroughly process and evaluate all the reports we receive. Very often the reports concern patients that were quite seriously ill, and who were at risk of serious complications and death, even with the best possible treatment. In cases where the Investigation Unit's first telephone conversation with the hospital results in solid and plentiful information indicating

that the patient received sound treatment and follow-up, it is sometimes possible to establish almost immediately that there are no indications of deficient healthcare. In order to examine serious adverse events in greater detail, we also occasionally study patient records.
In approximately 40% of all reports submitted between 1 June and 31 December 2013 we concluded that there was no indication of any deficiencies in the patient care, and that there was therefore no need to engage in any further supervisory activities (see Table 6).

Experiences to date...
The remit given the Norwegian Board of Health Supervision to create a reporting system has proven to be both challenging and rewarding.

Unexpected and serious adverse events are about people, hospitals and health personnel who want to do a good job, but who sometimes fall short. But first and foremost such events are about patients in need of medical treatment, and about their closest family. Through our work with the reporting system we, the Investigation Unit for Serious Adverse Events, meet family members in great distress undergoing a life-changing crisis. Nevertheless, we have found that they embrace the opportunity to talk to us. We have learned that relatives often have relevant and solid information about events – information that supplements and adds new layers of understanding to the accounts supplied by health personnel and leaders. The contribution of the patients' next-of-kin gives us a fuller picture of events.

We also meet health personnel who have been deeply affected by events. Our experience is that they wish to assist in our investigations so that "what happened here" will not happen again. We are told that the external assessments provided by the supervision authority are a helpful tool for hospitals working under great pressure and subjected to stringent time constraints and where the danger of serious failings is sometimes in the air.

The task we have been given, and the extraordinary circumstances surrounding each event have challenged the Norwegian Board of Health Supervision, especially as regards know-how. We need staff that are able to carry out vigorous investigations, who are able to ask questions that are to the point – both in meetings with health personnel who are experts in a range of medical fields, and in encounters with next-of-kin going through a personal calamity. We need interdisciplinary expertise that enables us to analyse causality, and to evaluate and determine whether the patient was given sound medical care, and whether the organisation is run as it should. Furthermore, we need employees that are able to communicate their conclusions in a manner that encourages reflection and learning, both in the professional communities and at management level in the hospitals.

The Investigation Unit for Serious and Adverse Events currently has on its staff, and co-operation agreements with, doctors specialised and experienced in – among other fields – anaesthesia, obstetrics, paediatrics, internal medicine and psychiatry. We have also hired biomedical laboratory scientists and nurses with special training in psychiatry, intensive medicine and midwifery. All our employees have many years' work experience from the specialist health service, and in cases where this is required we request expert reports from external specialists. We also have lawyers on staff with extensive health law experience. However, the Norwegian Board of Health Supervision sees a need for greater expertise and skills in safety and organisational science, so that we as the supervision authority can do even more to foster a philosophy of safety, stimulating the hospitals to work in a directed and systematic manner to bring down the risk of serious adverse events.

It is the experience of the Investigation Unit that a prompt start-up of investigations and dialogue with the service providers results in better information, giving the Investigation Unit

an idea of the course of events at an early point in the process. This gives us more data, forming a better basis for robust supervisory assessments.

Both the Norwegian Board of Health Supervision and the organisations subject to supervision have found that the reporting criteria, such as they have been framed by Parliament, contain certain challenges. "Seriousness" and "foreseeable risk" are important terms in the legislation; however, these concepts often prove unwieldy when applied in practice.

A lack of clarity regarding what to report to whom sometimes results in uncertainty, and may affect the health service's reporting culture – so that it errs, be it in the direction of over-reporting or that of under-reporting. If the Norwegian Board of Health Supervision is to receive those reports targeted by the legal provisions, the duty to report adverse events needs to be defined as precisely as possible. The specialist health service, the Norwegian Board of Health Supervision, other relevant bodies and the general public should all be in agreement about what the most serious events are, requiring supervisory action which evaluates whether the patient has received sound medical care and whether the service provider is organised in a sound manner.

In addition to the supervision authority's processing of reports concerning serious adverse events, the organisations are subject to a statutory requirement to address non-conformities within their own organisations, see Section 3-4 of the Specialised Health Services Act. A resilient reporting and processing system for non-conformities is one of the key constituents of any management's systematic work to ensure sound medical care and better practice. Methodical reviews of serious adverse events and other reports of errors and inadequacies help cut the risk of unintended and critical events and deficiencies.

The hospitals' own handling of the situation after a serious adverse event has been reported to the supervision authority may play a role in determining the Investigation Unit's subsequent supervisory response. We have seen that hospital managements vary in their approaches to serious reportable events. While some show initiative and quickly respond by starting internal review processes that run parallel to the Investigation Unit's investigation, others assume a more passive approach and await developments. Obviously, there are many reasons that account for this, such as inadequate resources or a lack of expertise and skills for this type of investigation. Regardless of these differences, we have observed that all service providers make active use of the Norwegian Board of Health Supervision's reports when these are made available, and put in place the necessary changes following the supervision authority's investigation and conclusion.

We are told that the external assessments provided by the supervision authority are seen as helpful by the hospitals, where everyday work can be intense. Where appropriate, the agency's investigation also addresses interaction and communication among and within service providers and how they interface with the municipal health services. Our investigations also help raise awareness in the hospitals as to the importance of involving relatives and patients in their serious adverse event reviews. The Investigation Unit has found that our efforts to promote change are especially effective when the hospitals undertake their own investigation immediately after the incident, often simultaneously with our own supervisory response.

ARTICLE 2: What happens when the most vulnerable patients suddenly fall critically ill and are admitted to hospital

The two articles that follow tell the story of a teenage boy with Down's syndrome who was brought to the A&E Department of a university hospital with a diaphragmatic hernia that was so large that it was in the process of obstructing air passages and impeding blood circulation. Ten hours later, he died of cardiac arrest. Upon being transferred to the university hospital, there was a failure to understand the severity of his illness and that his life was in danger. As a result, the hospital did not ensure that he was seen by a specialist in time. The boy's mother was at his side throughout. She reported that the staff at the hospital did not pay attention when she told them that the boy's agitation and his many movements meant that he was very distressed and in great pain.

In the first article we give the mother's take on events, as communicated to journalists and the Norwegian Board of Health Supervision. The second article summarises the course of events uncovered by the Norwegian Board of Health Supervision's investigation, and the agency's conclusion in the matter.

Information provided by the patient's family can be decisive

Many of the unexpected and serious adverse event reports in the specialist health services received by the Norwegian Board of Health Supervision become the subject of public attention. This was the case after a teenage boy with a cognitive developmental disability was acutely admitted to a university hospital due to a large diaphragmatic hernia.

The boy was non-verbal, but his mother saw clearly that he was in great pain and was getting worse. She informed the receiving nurses and physicians, and those who attended him following hospitalisation. During the inquiry that followed his death, the Investigation Unit for Serious Adverse Events spoke with the mother about what had transpired. We have learned that relatives often have relevant and solid information about events – information that supplements and adds new layers of understanding to the accounts supplied by health personnel and leaders. Family members' contribution gives the supervision authority a fuller picture of the events.

The boy's mother was interviewed by different media and has given us permission to make use of this material. The excerpts cited below are taken from the interviews she gave TV2. She describes her experience of the hours from when her son was seen at the A&E Department in the evening until he died in the hospital ward the following morning:

"He couldn't speak up, but he let us know in his way. I could tell from looking at him that he was in pain the whole time."

Having first been seen at a medium-sized hospital, a local consultant had the boy transferred to a university hospital. He had known the boy from birth and accompanied him in the ambulance. The consultant wanted to make sure that the hospital receiving the patient understood the severity of the patient's condition, and wished to ensure that the surgical procedure would be carried out soon. The mother says:

"He told them that Sindre was critically ill, that he needed to be assessed for surgery, and examined carefully. The doctor said loud and clear that they should pay attention to what I said: Listen to his mum, she knows the boy."

In the A&E Department he was given a cursory examination by an inexperienced doctor who was of the view that surgery could be put off to the following day. The doctor moved the boy to a ward where he could spend the night.

On the ward he was given more painkillers, but no consultant in gastrointestinal surgery came to examine him during the night. Although the patient was watched over by a nurse who remained in his room during the night, she left the room in the morning when the new shift was coming on duty. As she left, the nurse woke up the boy's mother. Expecting another nurse to take over, the mother fell asleep again. When the boy's mother woke up again a little later, she saw that she was alone with her son. She approached the bed, turned the boy around and saw that his face had turned blue: *"When I turned Sindre around his face was blue. I ran to the door screaming that he was dead! At that point lots of people came running into the room."*

She very much feels the loss of her son, but also expresses a desire to use the Norwegian Board of Health Supervision's report in her fight to make sure that nobody else will have to go through what she has suffered. In particular, she believes the health service needs to learn more about how to meet people with cognitive developmental disabilities. **Link to the story on TV2:**
http://www.tv2.no/nyheter/innenriks/ helse/-sindre-doede-fordi-han-hadde-downs-syndrom-3921029.html

http://www.tv2.no/nyheter/innenriks/ helse/sindre-15-ble-innlagt-med-brokk-doede-morgenen-etter-3856963.html

Specialist expertise, communication and dialogue with family can be critical in assuring sound medical help

What happened?
After several days of diarrhoea, stomach pains and vomiting, including vomiting blood, a teenager with Down's syndrome was admitted to a medium-sized hospital. He was non-verbal, but was very agitated, and it was clear to his mother that he was in great pain; computer tomography showed an exceptionally large diaphragmatic hernia. The stomach and parts of the liver had been displaced upwards into the thoracic cavity. Moreover, several of the thorax's major structures had been pushed out of their normal position. He was transferred to a university hospital for surgery; the mother and a consultant from the medium-sized hospital accompanied the patient in the ambulance. After having seen the CT images of the abdomen and thoracic cavity the secondary on-call consultant and the on-call gastrointestinal surgeon decided that the patient needed surgery, but that this could wait until the following day providing that his clinical condition did not indicate otherwise.

The patient was admitted to the A&E Department, and was briskly examined by an inexperienced and overworked doctor. The tertiary on-call, a senior consultant, was busy in surgery, and left it to the junior doctor to assess the patient's condition and degree of urgency in terms of surgery. The mother and the consultant from the smaller hospital informed the doctor in the A&E Department that they were worried about the boy's clinical condition, which had deteriorated in the ambulance en route to the university hospital. The

doctor in the A&E Department, however, did not find the patient's clinical condition to be very poor, nor did he observe that the child was in much pain.

The patient was given a bed on the ward. The doctor did not give clear instructions to the nurses on how the patient was to be monitored. He informed the tertiary on-call consultants of his findings, but they did not themselves examine the patient. Nor did the doctor inform the mother of his assessment, or what type of treatment he was planning for the patient. As the shift was a very busy one, he then turned his attention to other duties. Over the course of the night the doctor's pager ran out of battery, making it impossible to get hold of him via the paging system.

At the same time, the doctor informed the nurses on the ward that the patient was not to have any more painkillers unless they were prescribed by a doctor. When the patient became increasingly agitated and showed more and more signs of pain, the nurses contacted the tertiary on-duty consultant surgeons, who continued busy. The consultant surgeons asked the nurses on the ward to get in touch with the paediatrician who was on call at home. Instead, the nurses decided to contact the anaesthetist on duty to prescribe painkillers. The anaesthetist repeatedly prescribed painkillers until the patient was free of pain, but failed to notify the surgeons of this.

Nurses watched over the patient throughout the night, but in the early morning hours they woke up the child's mother and asked her to look after her son while they prepared the change-of-shift report meeting. The mother fell asleep, and when she woke up almost an hour later found her son lifeless in bed. Attempts at resuscitation were made, but did not succeed. The post-mortem examination showed that the cause of death was cardiac arrest and pulmonary collapse on the left side. Signs of mucous membrane bleeding and an abundance of blood were found in the stomach, and attributed to the mechanical pressure on the organs resulting from the large diaphragmatic hernia.

The course of events was mapped out in detail and deficiencies in the delivery of healthcare were identified

Shortly after the event, the Norwegian Board of Health Supervision performed an on-site inspection. We interviewed the healthcare professionals and their leaders, and reviewed the patient records and documents describing the service provider's organisation. We invited the mother to talk with us, and share her version of events. The course of events was mapped out in detail. We requested expert statements from specialists in the fields of gastroenterological and paediatric surgery. Failures in healthcare provision were detected, and possible causes of systemic error were identified.

Competence and communication – key elements in ensuring sound patient care

It was clear that the university hospital had not prepared well for this patient. The hospital had seen the radiographical images before his arrival, presenting a dramatic picture with an unusual and potentially serious and life-threatening condition. The patient was not seen by a specialist in the A&E Department, and none of the receiving nurses or physicians who saw him and examined him understood the seriousness of his condition or that it was life-threatening. Major diaphragmatic hernia with clinical symptoms such as growing agitation, pain and bleeding in the stomach indicated that the herniated contents were being squeezed, and that blood circulation was in danger of obstruction. The expert medical specialists who assisted in the investigation pointed out that in such cases a qualified clinical examination and assessment followed by immediate surgery are essential if serious complications and death are to be avoided. The fact that the boy was not examined by a specialist in the A&E Department resulted in a series of failures in his treatment and follow-up. The Norwegian

Board of Health Supervision concluded that the healthcare given the boy had not been medically sound.

The patient had a cognitive developmental disability, Down's syndrome, and was non-verbal. As time progressed, he became increasingly agitated. The mother and the doctor who accompanied him in the ambulance repeatedly voiced their concern that his agitation meant that he was in great pain and distress. Establishing a patient's case history and examining patients with developmental disabilities and who are non-verbal can be difficult. When carrying out clinical examinations it is therefore of great importance to listen to the input from next-of-kin and others who know the patient well.

Patients with a potentially life-threatening surgical condition must be examined by a doctor with clinical experience, and must not be left to doctors lacking in experience who are overburdened with duties. In such cases the hospital must put to use all relevant expertise and skills. Establishing good procedures that ensure that high-risk patients are examined thoroughly is a management responsibility. This applies all the more when the work load is considerable, and when doctors lacking in experience are the ones to admit the patients. Sound medical treatment is inextricably linked with competence. It is essential that the staff on duty in the A&E Department possess the appropriate expertise and skills for accurate medical evaluations and assessments which are often of a very complex nature. Moreover, the staff delivering healthcare must be able to identify high-risk patients.

Sound medical treatment also depends on ample and clear communication and information sharing. Doctors must give unambiguous instructions regarding the patient's care and how the patient is to be followed up on the ward, and the health personnel involved in treatment of the patient must liaise in order to make sure that critical information is passed on. Importance must be given to what next-of-kin have to say, and they must be kept informed of developments, but health personnel must not leave family members to observe a seriously ill patient. Ensuring that there are good procedures in place for communication and interaction among health personnel, and between health personnel and patients/next-of-kin is a hospital management responsibility.

What has the hospital done following the death?
The hospital has:

- added to on-duty staffing with one additional specialty registrar in the A&E Department until 21:00, in addition to a resident who is on duty around the clock,
- introduced an on-call shift for tertiary on-call gastroenterological senior consultant surgeons specialised in different areas, so that there are two consultants on-call around the clock,
- set up a dedicated emergency ward operated by the on-duty team, with a view to ensuring continuity in the assessment of acutely ill patients not in the post-operative or intensive care unit,
- introduced procedures for patients being transferred from other hospitals so they are assessed by the tertiary on-call senior consultant responsible for the section,
- introduced new guidelines for prescribing and administering opioids on the ward.

Points for reflection and discussion in the health trusts

- Could something like this have happened here?
- How can we prevent something like this from happening here?

ARTICLE 3: Investigation of unexpected events in the health service – why and how?

An expectation has been expressed that the Norwegian Board of Health Supervision shall respond to reports of serious adverse events by analysing their causes. Moreover, the Norwegian Board of Health Supervision shall undertake an assessment of whether the healthcare given was sound. In other words, the supervision authority should frame its investigation in a manner that enables it to draw conclusions regarding the circumstances surrounding the event. These activities are intended to promote learning in the services and thus help reduce the risk of events recurring. This requires a number of steps, including a detailed survey of the course of events. The agency also needs expertise and know-how in the fields of safety and organisations. This article has been written by the former assistant director of the Norwegian Board of Health Supervision Geir Sverre Braut, and describes an analytical tool that may be useful in conducting systematic investigations and identifying the causes underlying serious adverse events.

When unintended and unexpected events occur in the health service, it is evident that the general public wishes these adverse events to be examined closely. Health staff, patients and relatives also wish to learn more about the circumstances surrounding such events. Investigations can serve a range of different purposes, such as promoting learning with a view to bringing down the risk of or, ideally, avoiding similar incidents in the future. Organisations that systematically review unintended events with a view to assuring sound treatment and better practice are likely to set themselves such goals. In many cases one also wishes to identify who was responsible for the incident, e.g. in order to penalise the person responsible or pave the way for action for damages, or as part of supervisory activities. Regardless of *why* an investigation is performed, in selecting the methodology of choice it is important to make sure the investigation will detect all relevant causes.

Let us use a hypothetical example. An ambulance brings a patient suffering great pain to an A&E Department in a small hospital. Upon arrival at the hospital, a morphine injection is administered intravenously. The nurse leaves the patient for a brief moment in order to take a call from the patient's next-of-kin. When the nurse returns to the patient, he is not breathing. The nurse runs to the nurses' station to call the Rapid Response Team. Attempts are made at resuscitation, but the patient continues lifeless.

An event of this type inevitably and immediately results in a great commotion, both among the staff and the patient's family. It is very likely that the event would be reported to both the police and the Norwegian Board of Health Supervision. All the agencies will have to make their own assessment of what has happened. In addition, the event will be discussed among the hospital's staff and different professional communities in the hospital.

A number of questions will be asked in the ensuing discussion:

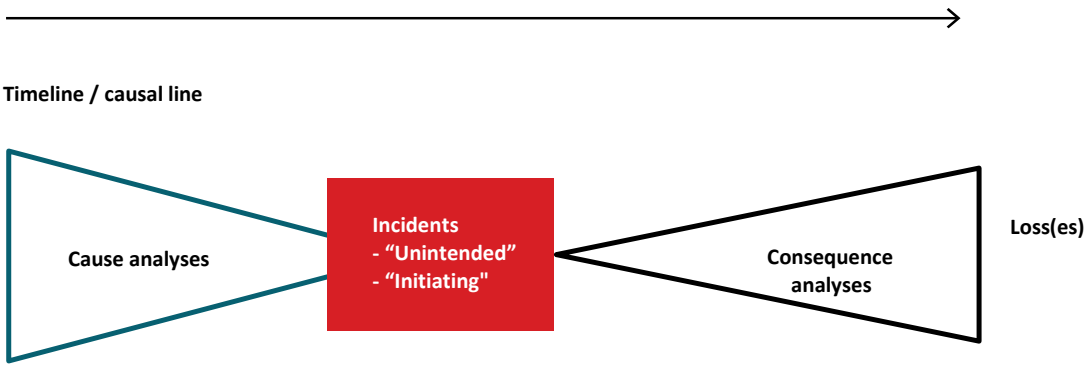
- What dose of morphine was administered?
- Had the patient already been given morphine in the ambulance?
- Why did the nurse have to leave the patient?
- How long was the patient left unobserved?
- Were any attempts at administering antidotes made?

- Was CPR attempted before the Rapid Response Team got there?
- How much time elapsed before CPR was begun?
- Were resuscitation equipment and antidote available in the A&E Department?
- Did the nurse in question have the required competence and training?

A model for systematic causal event analysis

Irrespective of who is to conduct an investigation, we must assume that data on the event is collected in a manner that is systematic and verifiable.

Regardless of the investigation's ultimate objective we may assume that the investigation will present a series of cause-effect mechanisms grouped along a timeline. This can be achieved through a range of techniques, such as systematic analysis based on the so-called "bow-tie" diagram (Aven T et al., 2008):



In our hypothetical example, first of all we must decide on how to define the unintended event. The health staff tend to point to the actual death as the unintended event; however, this is rarely a fruitful approach. In this model, the death is the loss itself. However, before determining which event one considers to be the initiating cause of the death in the model above we must first be clear about the objective underlying the investigation.

In our example we might, to begin with, consider *the respiratory arrest as the unintended event.* Respiratory arrest is a well-known complication associated with morphine use. It is the kind of event for which preventive measures may already be in place, and which the organisation should be prepared to handle. Measures to prevent adverse events from occurring and emergency preparedness are usually known as barriers. However, very few (if any) barriers are ever entirely satisfactory. This type of investigation should therefore include an assessment of the adequacy and effectiveness of the various barriers.

Into this "bow-tie" figure we might also enter our findings, and supplement these with our assessments, supplying us with answers to our initial questions. We can then move on to the following distribution of questions with the corresponding answers on their respective sides of the diagram.

AC (analysis of causes) = questions and answers related to the barriers that might have hindered the respiratory arrest.

CA (consequence analysis) = questions and answers related to the barriers that might have

prevented the respiratory arrest from resulting in a death.

- What dose of morphine was administered? (AC)
- Had the patient already been given morphine in the ambulance? (AC)
- Why did the nurse have to leave the patient? (AC)
- How long was the patient left unobserved? (CA)
- Were any attempts at administering an antidote made? (CA)
- Was CPR attempted before the Rapid Response Team got there? (CA)
- How much time elapsed before CPR was begun? (CA)
- Were resuscitation equipment and antidote available in the A&E Department? (CA)
- Did the nurse in question have the required skills and training? (AC and CA)

This kind of investigation is likely to result in valuable insights that also offer food for thought, thus promoting learning in the A&E Department. In addition, such investigations also give the inspection team and the police a basic understanding of the causal factors.

Systematic analysis and food for thought as pathways to better practice

If one wishes to learn from unintended events, it can be assumed that proximity, both in terms of place and time, is vital. The investigation must in other words be carried out in the vicinity of and shortly after the incident. It follows from the above that the service providers should investigate most safety incidents themselves, while also showing due respect to any police and/or supervisory agency investigation that may be ongoing at the same time. It goes without saying that service providers carrying out their own investigation need to respect any data collection carried out by the police and/or supervisory authority. Despite this, in most cases there is no reason why such organisations should put off embarking on their own investigations, analyses and reflections.

Correspondingly, the authorities should strive to present their causal analyses in a language and professional framework that enables the service providers to make use of these assessments in their own, subsequent learning efforts. Assuming that the causal analysis resulting from the supervisory investigation can also be used independently of the authorities' formal and legal conclusions, such an analysis is likely to be useful in the organisation’s work to process lessons learned.

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ARTICLE 4: When small children are seriously ill – more specialist expertise and better information sharing can reduce the risk of serious adverse events

In this article we describe a case in which a small child with a serious heart condition experiences complications a couple of weeks after a major surgical intervention, and dies. Having carried out an on-site inspection and investigated the adverse event very thoroughly, the Norwegian Board of Health Supervision concluded that the hospital should have had more specialist expertise available more swiftly and that information sharing among health personnel who saw the patient during the course of events was inadequate.

What happened?
A child not quite two years old with a very serious congenital heart condition underwent a major surgical procedure at a university hospital in December of 2012. The procedure and the immediate post-operative period were relatively uncomplicated.

On the 16th day after the operation the child experienced increasing respiratory distress. A thorough assessment of the patient showed a collapse of pulmonary tissue and pleural effusion (fluid in the cavity between the pulmonary pleura). A bronchoscopy (an examination of the lungs using video technology) showed aberrant anatomy in the form of a tracheal bronchus (meaning that there are small bronchi branching off the windpipe). The patient was intubated relying on visual guidance, with the end of the tube placed 2 cm above the carina (which is the point where the windpipe divides into the two main bronchi).

Following this procedure the patient's condition improved, and removal of the tube was scheduled for three days later. The child's family asked to be advised of any changes in its condition, and were offered a family room nearby where they could sleep. The child was given sedatives during the night, but continued restless. Following a sudden movement of its head, the child experienced a sudden oxygen saturation drop and low pulse, and at 04:02 the alarm signalling arrest went off. Advanced resuscitation was immediately initiated, and the on-duty anaesthetist responsible for the thoracic surgery department came quickly.

The nurses suspected that the tube might have become dislodged, and told the anaesthetist that the tube should be removed. Having examined the patient, the anaesthetist felt the ET-tube to be positioned correctly, and continued to ventilate the child through the existing tube. The clinical examination merely consisted of listening to the lungs with the stethoscope. The doctor did not examine the tube's position by looking through a laryngoscope (an instrument to look into the respiratory passages) herself. There was no capnograph (a device used to measure the gas composition of exhaled air) available. The doctor had not been informed of the child's aberrant pulmonary anatomy, and that this patient was at particular risk if the tube was dislocated.

The thoracic surgeon who arrived was advised of the anaesthetist's judgement regarding the tube's position. Due to the gradual deterioration of the patient's condition, the thoracic surgeon suspected pericardial haemorrhage and elected to open the thorax surgically, followed by open-chest cardiac massage. However, there was no haemorrhage into the pericardial space. The thoracic surgeon found that the stomach was full of air, and asked the

anaesthetist to inspect the position of the tube. The anaesthetist then discovered that the tube lay in the oesophagus, and it was removed at 04:20. The child was then given air via mask, and recovered quickly. A new tube was inserted, and the child's condition stabilised.

The patient's family members were not called, and were only informed of the acute incident the day after. Three weeks later the child died. It was concluded that death had been caused by the serious brain damage suffered in connection with the tube's dislocation.

Reporting and on-site inspection
Pursuant to Section 3-3a the Norwegian Board of Health Supervision was notified of the event and a decision was made to perform an on-site inspection in order to learn more about the event and any relevant organisational issues. The inspection team talked with the family, the health personnel involved in the event, and the management at the relevant hospital departments.

The Norwegian Board of Health Supervision found that...
The interviews revealed that the anaesthetist who was on-call at the hospital had little experience in assessing and managing children under two with cardiac conditions. She had informed the management of this before she started doing on-call shifts in the thoracic surgery ward. The consultant who had overall anaesthesiological responsibility for the patient was on-call from home 20 minutes away. The Norwegian Board of Health Supervision noted that had advanced anaesthesiological expertise been available at the hospital, this might have enabled the healthcare personnel to detect the dislocation of the tube at an earlier point, leading to swifter repositioning of the tube.

The investigation of the Norwegian Board of Health Supervision also showed that the patient records did not clearly enough indicate the potential risk factors associated with intubation or the abnormal findings made in the bronchoscopy regarding the windpipe. The anaesthetists only conveyed this information in speaking when changing shifts, and failed to make notes of these findings in the patient's medical records. Passing on relevant and significant background information to health personnel coming on duty through spoken communication only is fraught with risk.

The child's family were upset that the hospital had failed to brief them of the acute situation that arose over the course of the night, especially given the fact that they had made it clear that they wished to be told of any change.

The Norwegian Board of Health Supervision concluded that the patient had received treatment that was not medically sound, see Section 2-2 of the Specialised Health Services Act. The anaesthetist should have listened to the experienced nurses when they expressed concern, and inspected the pharynx in order to ensure that the tube was positioned correctly. We stressed that the hospital carries responsibility for sound operations at the hospital and is responsible for facilitating sound practices by the health personnel. This also involves responsibility that those on-call are able to immediately access other health professionals with the required expertise and skills in the event of acute situations.

What has the hospital done following the death?
The hospital has implemented:

- a more restrictive selection of specialty registrars who are given on-call duties and charge of the thoracic surgery ward,
- new reporting procedures before the tertiary on-call senior consultant paediatric anaesthetist leaves the hospital,

- a new layer of on-duty staff including specialist anaesthetists on-call and present at the hospital around the clock,
- new documentation procedures for anaesthetists treating patients at the thoracic surgery ward,
- training in how to handle unintended tube dislocation at internal training sessions and reports,
- more rigorous procedures for involving/informing next-of-kin when serious adverse events occur in patient treatment.

Points for reflection and discussion in the health trusts

- Could something like this have happened here?
- How can we prevent something like this from happening here?

ARTICLE 5: "Better safe than …." – risk assessment and patient safety on the labour ward

The Investigation Unit for Serious and Adverse Events received a report from a university hospital regarding a serious adverse event in connection with a premature birth. Our investigation uncovered a number of factors, including that necessary equipment was not available when needed by the doctor called to attend the birth, and that midwives' time was not allocated in a manner that allowed satisfactory pre-birth monitoring.

What happened?
A pregnant woman with symptoms indicating a risk of premature birth was hospitalised for observation. She was given treatment to stop labour and this worked well for a few days, before labour pains intensified again. The patient was transferred to a labour ward, where she received further treatment to halt labour, and the on-duty paediatric registrar was notified. The paediatric registrar informed the tertiary on-call senior consultant responsible for the NICU (hereafter referred to as the NICU-doctor).

The NICU-doctor informed the patient and the nurse at the NICU, prepared the required equipment and remained at the hospital awaiting a possible birth. She had brought her regular on-call mobile telephone. The patient had symptoms of a developing infection, and the gynaecologist seeing to the patient therefore decided to taper off contraction-suppressing treatment and allow the patient to go into labour. However, there was a failure to convey this information to the NICU or the NICU-doctor.

It was a busy night at the labour ward. The midwife in charge of the patient had to attend to other duties and could not give priority to being with the patient at all times. The midwife asked the patient to ring for her if she felt the need to push. When the need to push arose, the patient rang for the midwife, and the gynaecologist was called to examine the patient. At this point birth was imminent, and the gynaecologist asked the midwife to call the paediatrician. Instead, the midwife called the NICU-doctor, using an on-call pager that was only for daytime use. Some time was lost until this misunderstanding was cleared up. As a result, the child was born before the NICU-doctor or the paediatrician got to the delivery room. The final pre-birth preparations had not been completed at this point, leading to further delays.

The child did not breathe when it was delivered, and resuscitation was begun. The child was approximately four minutes old by the time the alarm BIRTH EMERGENCY was raised, and the anaesthetist and NICU-nurse arrived with the specialist equipment. Ventilating the child was difficult, and a more experienced paediatrician who was not on-call, but who was available, was brought in.

Eventually the staff succeeded in intubating the child, and its condition improved temporarily, but when the child was 13 minutes old its condition took a sudden turn for the worse. The positioning of the tube was checked, and the doctors suspected that the lung might have been punctured. Radiographs of the thorax were therefore ordered, and these were done in the delivery room. Only when the x-rays had been analysed confirming the suspicion of a punctured lung, was action taken to remove the air from the pulmonary cavity. This proved difficult because there was tension pneumothorax (excess pressure in the thoracic cavity).

Other resuscitation actions were continued, but circulation was not re-established and a decision was made to put an end to any further treatment when the child was approximately 70 minutes old. The post mortem examination confirmed that death was caused by tension pneumothorax.

The investigation of the Norwegian Board of Health Supervision showed that...
An on-site inspection was carried out, and the Investigation Unit for Serious and Adverse Events talked with the involved health personnel and their leaders. The Investigation Unit inspected the ward and spoke with the child's mother (the patient) and its father. We received a copy of procedures and other relevant governing documents. We mapped the work load on the night in question, and the staff described their collaboration protocols and procedures for calling up medical staff.

We concluded that there was no sign of any deficiency in connection with the resuscitation carried out after the NICU-doctor arrived in the labour room. The decision whether to await analysis of the radiographic images or start treatment based on a suspicion of a punctured lung is a tricky clinical decision. With hindsight, it is evident that treatment should have started before the x-rays were ready. We found no sign of any deficiency in the monitoring and information provided to the patient and next-of-kin.

Despite the above, the Norwegian Board of Health Supervision arrived at the conclusion that the healthcare given the patient prior to birth was not medically sound. In our report we pointed out a number of issues, including:

- The equipment that was needed was not made available as quickly as it should have been to the doctor who was called, and midwife services were inadequate or allocated in a manner that did not allow for adequate monitoring of the patient prior to birth.
- The procedures for correct calling up of the paediatrician at night were not known well enough, resulting in delays before the paediatrician could commence advanced resuscitation.
- The protocols and procedures for calling in supplementary midwife services at times when there is a great work load, and the criteria for calling up the paediatrician when very premature babies are born, were not clear.

The Norwegian Board of Health Supervision requested a written account from the hospital detailing what actions are planned to set right the problems we identified in our supervisory report.

Following the Norwegian Board of Health Supervision's conclusion, a supervision meeting was held with the hospital management, and the leaders of the two clinics and wards. At the meeting, the Norwegian Board of Health Supervision provided an account of the report and its decision, and the findings were discussed. It was a constructive meeting, and both the Norwegian Board of Health Supervision and the hospital representatives appreciated the opportunity to give feedback and clear up misunderstandings and assumptions.

Overall, it appears that the hospital has become more aware of its reporting obligation. We have also been told that this inspection has aided the service provider in its own ongoing work to improve patient safety and quality in other departments.

What has the hospital done following the death?

- Both labour wards have introduced an around-the-clock, overall on-duty physician on

the rota. The physician is to oversee the overall picture, allocate resources, and is not given any duties in connection with actual deliveries.

- The hospital has introduced an on-duty paediatrician with around-the-clock on-site presence.
- The criteria for information to be given to, and for calling in, paediatricians in connection with deliveries have been listed in greater detail.
- The correct contact details (telephone numbers etc.) for the paediatrician in emergency situations have been clarified.
- Both clinics have thoroughly reviewed the case, and several arenas have been created in which staff from the two clinics can meet. These include shared simulator and emergency situation training.

Points for reflection and discussion in the health trusts

- Could something like this have happened here?
- How can we prevent something like this from happening here?

ARTICLE 6: "Building, brick by brick" – on the supervision of the Women's Clinic at Bergen Hospital

Pursuant to Section 3-3a of the Specialised Health Services Act, hospitals shall immediately report any serious adverse events to the Norwegian Board of Health Supervision. The Norwegian Board of Health Supervision's Investigation Unit for Serious and Adverse Events considers every single report individually; gathers information on the adverse event, and jointly with the Office of the County Governor in question considers and makes a decision on the appropriate response to each case. In many cases the report, together with the collected data and documentation, is forwarded to the County Governor for further supervisory action. The article below is written by the Chief County Medical Officer Helga Arianson of the Office of the County Governor of Hordaland. It gives an account of how reports of serious adverse events at the Women's Clinic at Bergen Hospital, jointly with complaints that had been filed and other information, in March 2013 led to a supervision of the Women's Clinic by the County Governor of Hordaland.

Background

The County Governor of Hordaland has followed developments at the Women's Clinic in Bergen closely for a number of years. The Office of the County Governor has performed scheduled supervisions, and has processed a range of complaints regarding specific adverse events. The clinic had reported several of these events to the Norwegian Board of Health Supervision, and on-site inspections were carried out in two cases. Despite what struck us as professional and good relations, we had concerns about many of the incidents, and about the way the clinic responded to our inquiries. However, we found that looking at each case individually did not give us any understanding of what was going on. We therefore made a decision to collate all the information taken from individual cases, supervisions and statistics and study this data in conjunction with each other. We wished to see if this would give us a more all-round and overall sense of the situation and the issues at the clinic.

What information did we study?

We reviewed 20 complaints and incidents which had been sent to us for investigation over a two-year period, 2011-2012. We looked at trends in the occurrence of perineal tears, including their decline. We reviewed perinatal deaths, and studied the frequency of deliveries involving surgical intervention.

The supervision was performed on the basis of

- statistics,
- an examination of 20 incident investigations (2011-2012),
- an examination of perinatal mortality,
- monitoring and action on the number of large perineal tears (grade III–IV), and the decline in such tears,
- other correspondence and contacts with the Women's Clinic.

Satisfactory results

Annually, there are about 5000 births at the Women's Clinic in Bergen, and the clinic has reason to be proud of many of its achievements. The clinic has the lowest incidence of caesarean sections in the country. The outcome of birth care measured as perinatal mortality and as morbidity (Apgar after five minutes) shows that the Bergen Women's Clinic scores on a

par with the national average.

Many women expressed dissatisfaction
On the downside, a recurrent theme in the complaints was that the women treated at the Women's Clinic in Bergen felt that they had not been heard. The complaints indicated a lack of patient involvement, poor communication and shortcomings in the healthcare the women had received when giving birth. Several of the complaints were upheld. Moreover, there were several cases where we identified problems of communication and inadequate patient involvement, even though the Clinic had not actually been in breach of health legislation.

Dialogue was difficult
When a complaint is filed, the Office of the County Governor always requests a copy of the patient's medical records and interviews the involved health professionals and their leaders. The responses we received from the Women's Clinic mostly elaborated on the basic facts, but respondents did not give any personal views on actions, decisions that were made or interventions that were performed during birth.

For many years, we had monitored and repeatedly discussed and questioned the incidence of large perineal tears. We had also inquired about measures to reduce their occurrence. Many other women's clinics in Norway had succeeded in cutting the incidence of perineal tears from 5% to approximately 2% in less than one year (intervention studies). The steps taken to achieve this were simple and well-known. At the Women's Clinic in Bergen it took eight to nine years to bring down the incidence of perineal tears down to about 3%. We thought that this was too long.

In meetings and discussions with the management of the Women Clinic, representatives from the Office of the County Governor found the discussion of individual cases and problems to be fraught with difficulties. It was difficult to get our viewpoints, questions and comments across.

In some of the interviews carried out during investigation of serious adverse events, the Office of the County Governor learned that many physicians reported an unwillingness within the organisation to discuss matters such as the incidence of caesarean sections at the Women's Clinic. Some of the physicians believed that caesarean sections were sometimes resorted to without alternatives having been explored sufficiently.

Was the culture for learning at fault?
The County Governor was of the view that there was a need for change. What we saw was a culture with no room for critical questions or critical assessment of activities. This was found to be the case both in individual cases and more generally. Following an overall review we believed that it was fair to describe the dominant culture at the clinic as a threat to patient safety. The clinic's reputation had already suffered due to the negative publicity resulting from several stories run by the press, and there were those who had no confidence in the clinic's birth care. It was the conclusion of the County Governor that responsibility rested with the clinic's management, and that the management needed to address this problem.

The management has assumed responsibility and taken charge
In a meeting in which we explained our assessment and presented the draft for our report, we presented the facts and our assessments and conclusions (the non-conformities, see the fact box) to the clinic management and the hospital management respectively. The management was given a deadline of two days to comment on any factual errors, but did not

make any remarks. Following the County Governor's report, both the hospital's and the clinic's managements have made efforts to set right the problems identified by our Office, and considerable work is ongoing in this regard. This type of transformative process takes time, and the Office of the County Governor will monitor developments for as long as we consider necessary.

What did the supervision reveal?

The following factors resulted in the Women's Clinic failing to safeguard patient safety adequately:

- The management did not adequately facilitate the involvement of the patient in making choices about birth, see Section 4e) of the internal control regulations in the health and care service.
- The management had failed to attend sufficiently to the views expressed by the hospital's own staff, or given the staff's observations due importance. The hospital has a culture that discourages critical questions to the management, especially about the threshold for caesarean sections. As a result, problematic issues are not aired with the management and important opinions among the employees are therefore on occasion ignored, see Section 4d).
- The management does not always abide by national guidelines, in that the practice regarding overdue pregnancies is not in line with national guidelines; see Section 4g).
- The Clinic's response to deficiencies in specific cases fails to inspire trust. It appears as if the management does not want to recognise its own failings and that it is unwilling to implement the needed adjustments, see Section 4g).
- The clinic management has not made sufficient use of the lessons provided by statistics, serious adverse events, input from the supervision authority and national guidance to analyse and adjust the clinic's own activities so that patient safety is assured adequately, see Section 4h).

Link to the supervision report from the County Governor of Hordaland
http://www.helsetilsynet.no/no/Tilsyn/ Tilsynsrapporter/Hordaland/2013/ Helse-Bergen-HF-Haukeland- Universitetssykehus- Kvinneklinikken-2013/

ARTICLE 7: When antibiotics need to be used – fast

The Norwegian Board of Health Supervision's Investigation Unit for Serious and Adverse Events regularly receives reports concerning patients with signs of serious infection/sepsis and where treatment with antibiotics was started too late. Young patients with no prior history of illness suffering from severe infections often display few symptoms for some time before there are signs that their organs are seriously affected. However, once patients develop respiratory symptoms and their circulation is affected the situation can become critical very quickly, and the prognosis worsens substantially. Starting patients with suspected sepsis on intravenously administered broad-spectrum antibiotics therefore plays a decisive role for the course of the disease and its outcome. This article describes the story of a young man who was hospitalised with symptoms of a serious infection. There were delays in several areas: being seen by a physician, transfer to the intensive care unit, and not least starting him on antibiotics.

What happened?
After four days' illness, during which he had felt poorly, run a fever, been nauseous and had diarrhoea, a young man was referred to the A&E Department. Upon arrival he was triaged and tagged as red, and a physician was to see him shortly. When the receiving nurse saw the patient, he was alert and in satisfactory condition. He had few specific symptoms but was generally weak, and had a temperature of 36.3°C. His blood pressure was low (82/48 mm Hg), his pulse 115. The respiratory rate was 36 and his oxygen saturation rate 75%. The nurse ordered blood tests and administered fluids intravenously, as well as oxygen by nasal catheter.

After half an hour, the medical unit's primary on-call specialty registrar saw him. The physician examined the patient and measured blood gases which confirmed that the blood oxygen content was far too low. Lactate levels were high (signifying an accumulation of lactic acid) and there was an electrolyte imbalance (salts in the blood). The blood tests also indicated a low white blood cell count (1.5), elevated C-reactive protein (CRP 320), kidney failure and liver involvement. A radiography of the thorax showed possible opacity consistent with pneumonia. The primary on-call specialty registrar concluded that the patient was too ill to remain on a normal ward, and contacted the intensive care unit. At this point, treatment with antibiotics had not started.

The ICU was full, and the anaesthetist assessed the patient in the A&E Department. The anaesthetist believed the patient to suffer from serious pneumonia, but concluded that he did not require intensive care and could remain in the observation room on the heart and lung ward. The anaesthetist contacted the secondary on-call consultant at the medical ward and following a discussion among the doctors in charge of the patient he was moved to the heart and lung ward.

Although broad-spectrum antibiotics were prescribed while he was in the A&E Department, treatment with antibiotics was not started until the patient got to the observation room. At this point, the patient had been at the hospital four hours. After arrival on the ward, the patient's condition deteriorated rapidly. He died three hours after he got to the observation room, seven hours after being admitted to hospital. The post mortem examination showed that he died of a serious infection that had resulted in a systemic reaction (pneumococcal

sepsis).

The investigation of the Norwegian Board of Health Supervision showed that...
The Investigation Unit for Serious and Adverse Events carried out an on-site inspection at the hospital together with the Office of the County Governor and had talks with the health professionals involved in treating the patient, and with their leaders. We also reviewed the hospital's procedures and guidelines.

The Norwegian Board of Health Supervision concluded that the medical treatment given the patient had not been sound. The Norwegian Board of Health Supervision believed that a lack of focus on objective signs of serious sepsis and the amount of time allowed to elapse before starting the patient on antibiotics were not in line with sound medical practice and constituted a violation of the requirement to sound treatment under Section 2-2 of the Specialised Health Services Act. The agency concluded that the underlying cause for the failure to deliver sound medical care was inadequate procedures.

The A&E Department lacked procedures and outlines for:

- follow-up of those patients in greatest need of medical help,
- nurse-physician communication on the patient's condition,
- starting patients on antibiotics if they are left in the A&E Department for a long time,
- allocation of responsibility when the patient is referred from one unit to another, and more than one on-call physician is involved.

The Norwegian Board of Health Supervision requested that the service provider address the identified non-conformities and report back to the agency.

What has the hospital done following the death?
The hospital has:

- reviewed patient flow in the A&E Department for seriously ill patients, stressing accurate triaging,
- reviewed procedures for starting treatment when patients remain in the A&E Department for a long time,
- created procedures for moving patients to a ward when the caregivers involved in treating the patient differ in their views on the patient's condition.

Points for reflection and discussion in the health trusts

- Could something like this have happened here?
- How can we prevent something like this from happening here?

ARTICLE 8: The County Governor of Vest-Agder's supervisory action on suicide-related reports: long-running monitoring and action

The Office of the County Governor has been asked to write an article about its supervisory response to reports of suicide in mental healthcare patients. Assistant County Medical Officer Toril Hagerup Jenssen has written this article, which takes a retrospective look at the County Governor's long-running work on monitoring suicides and serious suicide attempts. In addition, the article details the experiences made after introduction of the reporting system under Section 3-3a of the Specialised Health Services Act.

There are few things as dramatic as suicide; taking one's life is the ultimate expression of human despair. Losing a family member to suicide is different to losing somebody to a death they have not chosen or an accident; knowing that a loved one died of their own volition poses a number of questions that are of a different order of complexity. Moreover, having a patient take their own life is also an immense strain on those caregivers who treated or were in contact with the patient.

The County Governor of Vest-Agder has been concerned about suicide and its implications in the county for some years. Between the spring of 2003 and the late summer of 2004, we received a total of nine reports of suicide or very serious suicide attempts among patients who were in hospital or had recently been discharged from mental healthcare, impelling us to question how the hospital was addressing this problem. We asked Professor of Psychiatry Lars Mehlum to examine the cases, and comment on how the hospital catered to the needs of patients at risk of suicide. His remit also included questions as to whether the care provided by the hospital was well-structured and systematic. His conclusion at the time was:

The hospital has failed to set up a system ensuring that documentation, diagnosis, treatment and follow-up of patients at risk of suicide and their next-of-kin is medically sound and in accordance with regulatory requirements. The hospital has not made any systematic use of the experience of suicide-related events in its quality improvement work.

In response to this the hospital assured the County Governor that they would take action in those areas where systematic deficiencies had been identified. In the period between the summer 2005 and the summer of 2006 the Office of the County Governor received a further ten reports of suicide or serious suicide attempts among patients undergoing psychiatric treatment. Starting with the reported cases, we then performed a new supervisory assessment of whether the care delivered to patients at risk of suicide was well-structured and systematic. Our conclusion echoed that of professor Mehlum a couple of years before. We observed that the hospital failed to meet the requirements of the internal control regulations for the health and care service, in that the Quality Council had not performed any systematic evaluation of the reported events. In a meeting with the hospital we discussed the need to perform systematic suicide assessments of patients, and that upskilling measures needed to be put in place in order to assure this.

However, the hoped-for improvement in the hospital's statistics failed to materialise. In 2009 and 2010 we received reports from the Clinic for Psychiatric and Addiction Treatment (abbreviated as KPA in Norwegian) relating to 16 suicides and 12 serious suicide attempts.

Since setting up the reporting system, the Office of the County Governor has been contacted by the Norwegian Board of Health Supervision about a total of 25 reports concerning suicides or serious suicide attempts between January 2011 and December 2013. Nine of the cases involved serious suicide attempts. Three of these cases are still being processed.

The patients in question were either admitted to psychiatric hospital, or had been discharged shortly before they attempted to take their lives. Additionally the Clinic for Psychiatric and Addiction Treatment, KPA, also notified the County Governor directly of events that were not judged to be reportable to the Norwegian Board of Health Supervision. Overall, 41 suicides have been recorded among patients suffering from mental health issues in the county of Vest-Agder since 2009, as well as 25 serious suicide attempts. These figures tell a miserable tale. If the county were to report traffic fatalities of this magnitude, the general public would have been clamouring for preventive action.

What did we find?
The County Governor of Vest-Agder has therefore made a decision to initiate an incident investigation every time there is a suicide report or serious suicide attempt, bar a few exceptions. Our evaluation of sound medical practice is based on national suicide prevention guidelines for the mental healthcare sector.

Twenty-three incident investigations have been completed. We found that the assessments carried out by the hospital prior to the suicides or suicide attempts were satisfactory as regards systematic approach, content and structure and met national guidelines in eleven instances. In nine cases, however, we found that there had been no screening for suicide risk at all, and in a further three cases we concluded that there was material room for improvement. In the eleven cases with satisfactory suicide risk assessments, we also found medical record-keeping to be of consistently high quality and the treatment offered the patients to have been medically sound. Notably, this was not the case in several of the other cases we inquired into. The gender ratio was very even, with twelve women and thirteen men. The ages ranged from 16 to 76 years.

Over the years that the Office of the County Governor systematically monitored suicide-related adverse events, it is evident that the hospital has become more systematic in its management of suicide risk. However, much remains to be done. In our view, the fact that assessment of patients and follow-up was unacceptable in nine of the twenty-three cases will not do. We have noted that these cases have been given very thorough consideration in the Quality Council at the Clinic for Psychiatric and Addiction Treatment (KPA), and as a rule, our conclusions and those of the Quality Council are in line.

What next?
Improving practice is, inevitably, an ongoing process. We contacted the hospital and inquired into how they employed the findings from incident investigations in their systematic quality-driving work. In early 2014 the Quality Council invited us to a meeting at which the Clinic for Psychiatric and Addiction Treatment, KPA, reported on their own inquiries into all the cases in which patients had taken their lives. The meeting was attended by the Office of the County Governor, members of the Norwegian Board of Health Supervision's Investigation Unit for Serious and Adverse Events and representatives from the KPA. The Clinic is now implementing measures to improve practice in meeting patients who may be at risk of suicide. In the meeting we discussed how the insights gained from a systematic review can be used in the hospital's efforts to better prevent suicide in the mental healthcare service in Vest-Agder.

Statistically, the number of reports is not very high, and much care should be exercised in interpreting annual fluctuations as indicators of steady change. If we look at the reports received from the early 2000s until now, we can see that there has been a significant rise in the number of both reported suicides and suicide attempts. However, there is nothing to indicate that this is anything beyond a rise in the number of reports, rather than an actual rise in the number of suicides or other serious attempted suicides in this patient group. The rise is in other words evidence of an improvement in reporting practice in mental healthcare, possibly indicating greater awareness of this issue.

We have observed that since introduction of the reporting system there are fewer reports made directly to the Office of the County Governor. It seems to us that the reporting system has enhanced the hospital's awareness of the reporting requirement for serious adverse events. The collaboration between the Office of the County Governor and the Norwegian Board of Health Supervision has been very fruitful, with much information being shared via the telephone and new insights gained in the process. We have found that the calls give us a good baseline when we embark on incident investigations, and help us focus and structure our investigations. We have also seen that the reporting system speeds up the data gathering process, resulting in better exposition of each case.

The existing collaboration between the two agencies, the Norwegian Board of Health Supervision and the Office of the County Governor, is one of the cornerstones of the reporting system, and is critical to our ability to supervise the hospitals.

Although it is impossible to know with any degree of certainty whether a patient will take his or her life, patients being treated by the specialist health services have a right to sound assessment and treatment. Sound medical practice is critical to reducing the risk of suicide. The objective underlying our supervisory activities is to facilitate and drive quality improvement in the health service, and we are confident that supervisory monitoring and response to these tragic events is vital in this regard.

ARTICLE 9: Health service providers and interaction when the patient is in prison

In this article we describe an adverse event in which a young man with chronic risk of suicide took his own life in prison, a few days after being returned to prison after a stay in an acute psychiatric ward at a large hospital. This serious adverse event illustrates the need for a binding collaboration between the hospital and appropriate partner organisations in prison. Prisoners are a patient group with complex health issues who need high-quality health services. The services needed by this group can only be delivered through long-term, comprehensive and integrated efforts.

What happened?
A young man who was seriously mentally ill and at high risk of suicide took his own life while remanded in custody. Before being arrested for a serious criminal offence and placed in custody, he had been a patient at the regional psychiatric centre, abbreviated as DPS in Norwegian. At the time of his arrest, the young man had completed his treatment at the regional psychiatric centre, the DPS clinic. Throughout the time he was remanded in custody he experienced suicidal thoughts, and had treatment at the prison's psychiatric outpatient clinic, which is a specialist health service within the mental healthcare sector. He had a combination of pharmacotherapy and psychological treatment, and was offered a certain range of activities. Because he was found to be at chronic risk of suicide he was checked at certain, frequent intervals in his cell. No individual treatment plan had been drawn up for the patient.

He was assessed for suicide risk. Being found to be at significant risk, he was then referred to the acute psychiatric division at the hospital. Upon admission to the hospital, his treatment programme at the prison's psychiatric outpatient clinic was brought to a close, but the outpatient clinic did not send a discharge summary or complete clinical summary to the hospital where he was being treated. At the hospital, a decision was made to attempt a course of treatment with ECT (electroconvulsive therapy). Halfway through this course of treatment, he told a consultant that he no longer heard voices or had suicidal thoughts. Nor did he have any plans of taking his life, he said. He wished to discharge himself and return to prison. The hospital saw no grounds to section him under the Mental Healthcare Act, and he was therefore discharged.

The consultant attempted to get in touch with the prison's psychiatric outpatient clinic when the patient was transferred to jail but was unable to make contact.

When the patient returned to prison, he was first seen by a nurse in the prison's health ward. The prison's health service knew the patient, and the nurse carried out a standard interview to assess his condition. The patient brought prescriptions for his regular medication, but had not been given a discharge summary from the emergency psychiatric ward. This was sent to the prison a few days later. The patient told the nurse that his hospital stay had done nothing to change his condition. He stated that he had no plans of taking his life, but that he continued depressed, and had suicidal thoughts. The nurse set up a programme of frequent checks and scheduled a doctor's appointment for the following week so that he could be given a new referral to the prison's psychiatric outpatient clinic. Objects posing a potential hazard were removed from the cell.

Five days after his return from the hospital to jail, the patient was found in his cell, dead. He had unpicked and loosened a cable from the ceiling, and hung himself from the cable. While waiting for the paramedics, the prison staff attempted to resuscitate him in accordance with internal procedures. Upon arrival, the paramedic team gave the patient CPR and took him to hospital. However, they were unable to resuscitate him and he was pronounced dead.

The Norwegian Board of Health Supervision's investigation and conclusion....
The Norwegian Board of Health Supervision performed an on-site inspection, and visited both the prison's health ward, the prison's psychiatric clinic and the emergency psychiatric ward in the hospital where the young man had been a patient.

The Norwegian Board of Health Supervision concluded that the follow-up and healthcare given the patient throughout the course of treatment had not been unsound. The fact that the prison's psychiatric outpatient clinic ended his treatment programme and failed to send a discharge summary to the hospital's emergency psychiatric ward is not in line with good and sound practice, but it did not result in unsound patient treatment on this occasion. The same applies to the fact that the hospital did not post the discharge summary until five days had elapsed after the patient had discharged himself and been returned to prison.

We made note regarding the fact that patients serving or due to serve long sentences require comprehensive and well co-ordinated treatment programmes. All levels and units of the service must have good arrangements in place for communication, interaction and treatment planning. Individuals in need of care and treatment from more than one entity must be assured dignified treatment, and a genuine opportunity for user involvement. Transitions among treatment segments entail a risk of delays and interruptions in treatment which can, in turn, create greater risk of inadequate treatment. Individual treatment plans can be useful in assuring continuity in treatment in this type of situation.

The Norwegian Board of Health Supervision issued a recommendation to the prison's health department and the prison psychiatric service to review their co-operation plans and procedures for information sharing internally and with the external specialist health service. Furthermore, the supervision authority recommended that the hospital consider the need to enter into binding collaboration agreements with relevant partners in the prison. Long-term, comprehensive and integrated efforts are the key to providing high-quality health services to a patient group with complex health issues.

Points for reflection and discussion in the health trusts
- Could something like this have happened here?
- How can we prevent something like this from happening here?

ARTICLE 10: Reports to the Norwegian Board of Health Supervision and reports to the Norwegian Knowledge Centre for the Health Services – a challenge for the hospitals

The specialist health service is subject to multiple reporting obligations and differentiating among these can be difficult. The interpretation of their respective reporting obligations is full of challenges, both for the specialist health service and the Norwegian Board of Health Supervision. If the supervision authority is to receive reports in line with the regulatory intentions, the reporting obligation must be defined as precisely as possible.
This article discusses the issues related to the current reporting systems, as they are framed in the Specialised Health Services Act. Terms such as seriousness and foreseeable are important concepts featuring repeatedly in the legislation; however, defining them in practice often results in ambiguity.

There is a lot to keep in mind!
The hospitals and caregivers are subject to multiple reporting obligations. If a serious adverse event occurs in the specialist health service, the hospital's primary duty is to attend to the patient, next-of-kin and the health personnel involved in the incident. Next, the hospital management shall be briefed on and be involved in further action regarding the incident, and the event must be reported in the internal system for non-conformity management. If an unexpected death occurs, the police must be alerted.

If a serious adverse event occurs, that is, a death or significant patient harm, the Norwegian Board of Health Supervision shall be notified within 24 hours, see Section 3-3 a of the Specialised Health Services Act. In addition, redacted case reports shall be sent to the Norwegian Knowledge Centre for the Health Services. This is done both in the case of potentially and actual serious outcomes, see Section 3-3 of the Specialised Health Services Act. The intentions behind the two provisions governing the reporting obligation differ somewhat from each other. The objective underlying the obligation to report cases to the Norwegian Knowledge Centre for the Health Services is to promote learning, prevent the recurrence of similar incidents and to enhance patient safety. The reason for the specialist health service's additional obligation to notify the Norwegian Board of Health Supervision of the gravest adverse events is to ensure an adequate supervisory response.

Which adverse events are subject to the reporting obligation?
The two reporting categories reflect different degrees of severity. However, in the health services the concept of seriousness is an ambiguous one. The Specialised Health Services Act defines seriousness as follows: "*Serious adverse events are deaths or significant harm to the patient, where the outcome is unexpected relative to the foreseeable risk.*"

While a patient death is unequivocal, the definition of significant harm is a question of judgement. In many cases, deaths and significant harm can follow from illness; the fatal outcome may occur in spite of, independently of, or as a result of treatment. In many cases it is difficult to tell whether the outcome was unexpected relative to the expected risk. Pursuant to the Specialised Health Services Act, adverse events are only reportable to the Norwegian Board of Health Supervision if significant patient harm or death occurred.

According to the preparatory works (Prp. 91 L (2010-2011) to the Act on Municipal Health and Care Services etc.), the question of whether an adverse event is reportable also depends

on the following: "In considering whether an adverse event is reportable under this provision, importance shall be given to whether it may be the consequence of any errors, negligence or mishaps at the system or individual level, whether there is uncertainty as to the course of events, and whether the matter appears to be complex."

Why did Parliament see a need for both a notification and a reporting system?
Given that two separate reporting systems were set up, we must assume that the legislators believe that patient safety issues with a serious outcome should be handled differently to less severe cases. It appears that the legislature sees a need for distinct approaches depending on whether the cases are serious or presumed to be less serious. The legislators in other words expect a more thorough sifting of evidence for the severest adverse events, permitting a more rigorous exposition of events and possible causes. If we are to reserve the most resource-intensive methodologies for those cases in greatest need of such exhaustive examination, both the Norwegian Board of Health Supervision and the reporting individual or organisation must be in a position to identify and give priority to the relevant adverse events.

What is the adverse event?
In traffic and industry the consequence of an "error" or an accident usually involves harm to staff or property. In contrast, when errors occur in the health services, as a rule it is not the staff or property that suffers, but a third party: the patient. Another factor setting adverse events in healthcare apart from "harm" or "unintended outcome" in traffic and industry is that in the health services the person affected by error was rarely healthy when admitted to hospital.

If a patient is to be treated for a minor condition, from a medical point of view the treatment is only recommended if the treatment-associated risk is very low. However, it is rarely non-existent. The more serious an illness or an injury, the higher the acceptable risk associated with treatment. As a rule, both the course of illness and illness-associated factors are highly complex. Any treatment steps must be decided on the basis of a statistical analysis of the risk involved, with all the inherent uncertainty of such an analysis.

A clinical example
Take for example a patient with non-metastatic colorectal cancer. If he is not treated, the patient is almost certain to die within three to five years. Surgical intervention provides for a 70-95% probability of curing the patient, but the operation itself involves a risk of patient death. This risk is approximately 1%. In addition, the operation entails a 10% risk of serious complications, and an overall risk of more than 35% of minor complications. Successful treatment depends on the nature of the tumour, knowledge of which is limited prior to resection. The risk of complications and death also depends on the patient's overall health.

Anastomotic leaks are a potentially serious complication for this type of surgery. They occur quite frequently, but cancer survival is the paramount objective in the longer term. Statistically, the discrete treatment-related factors do not impact greatly on patient outcome. If a serious complication develops or if a patient dies (patient outcome), it is unlikely that a subsequent investigation will uncover any single, specific cause (event). Instead, the number of anastomotic leaks is taken as a short-term quality indicator. In order to uncover weaknesses or deficiencies in quality, the quality of the medical care (or the positive treatment result) in the short and long term must therefore be measured and monitored over time, and the results (outcomes) must be weighted relative to the patients' risk profile.

Measuring quality
The monitoring of quality requires clinical research and quality registers. This approach gives

a better general overview of all complications and of what percentage of treated patients do experience complications; moreover it permits causal analysis of any quality non-conformities over time. Improvements or otherwise in the quality indicators may be the result of a range of different factors – such as the introduction of new instruments, changes in the set-up of a treatment pathway or individual factors.

Non-conformity systems also play an important role in quality-driving efforts. Such systems detect deficiencies not identified by registers, and highlight non-conformities across different sets of diagnoses and procedures.

Different reporting systems only represent a small segment of adverse events or complications, and fail to distinguish between events resulting from avoidable "errors" or accidents and those that follow from inherent, unavoidable risk in the treatment itself. Nor do they discern what share of the patients do well or fare poorly. Non-conformity analysis only serves to spot those events that were the outcome of avoidable risk. These are also the cases best suited to individual assessment and/or investigation.

Careful analysis of individual cases is usually taxing and resource-intensive. Cases dealing with complications during surgical procedures or interventions where there is no suspicion of inadequacies usually involve complications that were, in fact, foreseeable. As such, they are not well suited to individual investigations or inquiries. This is especially obvious in cases where high-risk treatment options are chosen because the alternative, non-treatment, would involve an even greater likelihood of serious patient outcome. In order to ascertain whether the treatment is adequate, it is necessary to register the frequency of different types of complications and figures for final treatment outcome and compare these figures with the inherent risk of the treatment. While this requires the expenditure of considerable resources, such registration is essential if we are to steer clear of misinterpreting the statistics.

Reporting systems do not provide for this type of quality measurements. The material they present is too sketchy and does not allow for this type of statistical processing.

How does outcome impact on the obligation to report?
Section 3-3a of the Specialised Health Services Act must be interpreted such that only serious outcomes are reportable to the Norwegian Board of Health Supervision. Obvious deficiencies frequently result in patient harm; however, often a considerable amount of time elapses before the ultimate patient outcome is clear. In some cases, the service provider awaits the outcome before deciding to report an incident, posing a number of problems. Section 3-3 of the Specialised Health Services Act sets out the Norwegian Knowledge Centre for the Health Services' reporting duty: the Centre must report any signs of significant system-level failure it identifies to the Norwegian Board of Health Supervision. In reality, this happens only rarely.

A lack of clarity regarding what to report to whom sometimes results in uncertainty, and may affect the health service's reporting culture – so that it errs both in the direction of over-reporting and that of under-reporting. At the Norwegian Board of Health Supervision we process all the reports sent to us, and based on the information we obtain we make a decision on further action. We do this regardless of whether the adverse event is, strictly speaking, reportable or not. Our remit as supervisory authority obliges us to examine all reports; it is up to the bodies subject to the reporting obligation, i.e. the specialist health services themselves, to fully grasp what this obligation comprehends. When we receive a report, the Norwegian Board of Health Supervision determines whether the case was reportable or not and informs the service provider of our assessment regarding reportability.

If the Norwegian Board of Health Supervision is to receive those reports indicated in the legal provisions, the duty to report adverse events needs to be spelt out with the greatest possible accuracy. Both the specialist health services and the Norwegian Board of Health Supervision constantly grapple with the challenges involved in understanding and interpreting what the reporting obligation means in practice. The specialist health service, the Norwegian Knowledge Centre for the Health Services, the Norwegian Board of Health Supervision and the general public should have a common understanding of what constitutes a very serious incident, i.e. an adverse event requiring supervisory action to evaluate whether the patient has received sound medical care, and whether the service provider is organised appropriately.

The Norwegian Directorate of Health's guidelines to Section 3-3 of the Specialised Health Services Act define key concepts underlying both reporting systems. These concepts and definitions also apply to reports under Section 3-3a. The Norwegian Directorate of Health's guidelines are to be revised and it is hoped that this will help tighten the criteria for reporting, both as regards Section 3-3 and Section 3-3a.

The Norwegian Board of Health Supervision has launched a project to give the service providers a helping hand in framing better reporting criteria for the mental healthcare sector. Other healthcare areas might also benefit from better reporting criteria. This is the case for birth care, where healthcare professionals have done considerable work, resulting in the Norwegian Medical Association's birth care guidelines. We are aware that neonatal care specialists have embarked on a similar process.

Ultimately, however, it is the individual healthcare worker, in some cases jointly with the management and quality department at their hospital, that needs to make a decision on whether an adverse event is reportable to the Norwegian Board of Health Supervision under Section 3-3a of the Specialised Health Services Act. In this context, it is important to consider whether the adverse event falls within or beyond what may be considered foreseeable risk. Determining the role of foreseeable risk is a difficult and taxing task, both for the hospitals and for the Norwegian Board of Health Supervision. If we are to achieve a more accurate selection of reportable cases, there is a need to discuss how to interpret the obligation to report, conceivably in addition to more detailed criteria in certain fields.

PART 2: STATISTICS AND ACTIVITY MEASUREMENTS

ARTICLE 11: Reports from the field of emergency medicine – a review of all reports from June 2010 to September 2013

In the emergency medical disciplines of anaesthesiology, pre-hospital emergency medicine and intensive care medicine, things move at break-neck speed, and errors can have disastrous consequences.

Emergency medicine therefore has a long history of working systematically to reduce the occurrence of unintended events. In particular, great emphasis has been placed on training and simulation, in addition to major efforts to build up emergency preparedness. Quantifying the impact of these efforts is difficult, and we do not have detailed up-to-date knowledge on the frequency of unintended events in Norwegian emergency medicine from the past few years. Anaesthetist and R&D director Erik Soligård at St. Olav's hospital (formerly Senior Advisor at the Norwegian Board of Health Supervision) is the author of this article, and in it he presents an overview of serious adverse events from the emergency disciplines that were reported under Section 3-3a of the Specialised Health Services Act since the Norwegian Board of Health Supervision set up its reporting system in 2010.

Between June 2010 and September 2013, the Norwegian Board of Health Supervision received 53 reports of serious adverse events in the emergency disciplines. On receiving a report, the Norwegian Board of Health Supervision conducts telephone interviews with the hospitals. This information, often in combination with data taken from patient records has been reviewed systematically and categorised based on patient characteristics, patient outcome, and type of incident, incident characteristics, and other factors that may have contributed to the event.

Patient characteristics

The reports received by the Investigation Unit for Serious and Adverse Events are divided into two categories: somatic healthcare and mental healthcare. The Norwegian Board of Supervision's staff, all with relevant healthcare training and experience, categorise the reports into specific areas of specialisation. Our review showed that 53 of the reports pertained to adverse events in the areas of anaesthesiology, intensive care, ambulance/pre-hospital care or the Emergency Medicine Communication Centre (EMCC). Table 1 shows the distribution among the various disciplines. Adverse events in emergency medicine correspond to approximately 15% of the reports deriving from somatic medicine. Two of these reports related to service providers engaged in non-profit or commercial activities. The distribution of reports by health region is provided in Table 2.

The varying number of reports is primarily evidence of differences in the service providers' reporting culture. It is highly questionable whether they reflect the total number of serious adverse events, and whether it is possible to generalise on the basis of these figures.

Table 1 Distribution of number of reports among the emergency disciplines

Field	*Number of reports*
Anaesthesiology	15
Intensive medicine	19
Pre-hospital services	10
Emergency Medicine Communications Centre (EMCC)	9

Table 2 Distribution of reports from the emergency services by health region

Regional Health Authority (RHF)	*Number of reports*	*Percentage of reports*	*Percentage of patients*
South-Eastern Norway Regional Health	36	68	57
Western Norway Regional Health	6	11	21
Central Norway Regional Health	9	17	12
Northern Norway Regional Health	2	4	10

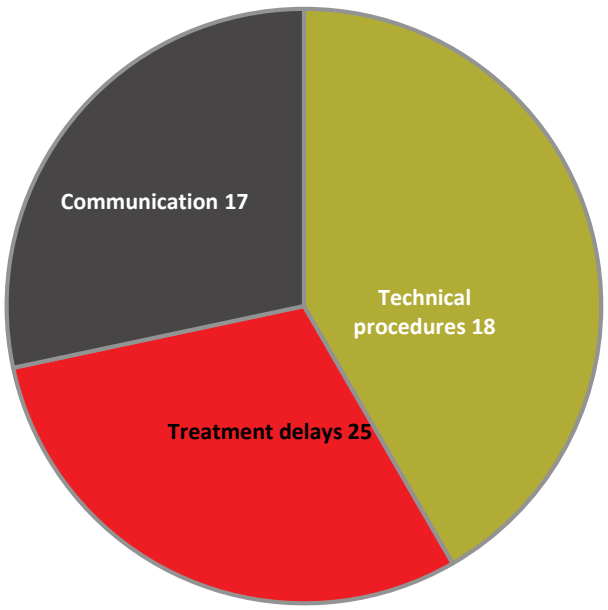
The gender ratio among the patients was fairly balanced, with 28 men and 25 women. Median age was 59 years (0-89).

The cases came from the following disciplines: internal medicine (34), surgery (16) and paediatrics (3). The patients' primary diagnostic area was mostly within cardiac and pulmonary disease, see Table 3.

Table 3 Number of reports by diagnostic area

Cardiac	17
Pulmonary	9
Infections	8
Brain	4
Gastrointestinal	4
Accidents	4
Miscellaneous	7

Figure 1 number of reports by cause



Patient outcome
Only serious events are reportable to the Norwegian Board of Health Supervision, i.e. events leading to patient death or significant patient harm. This is mirrored in the fact that 43 of the reports concerned patient deaths, and ten were about events involving significant patient harm.

Type of adverse event and possible cause
All reports are categorised according to what happened, and attempts are made to establish the cause of the event. As most adverse events are complex, and such events can have more than one cause, the overall number of incident types and causes may exceed the number of cases. Based on the data obtained by the Norwegian Board of Health Supervision, we have grouped adverse events according to their assumed causes. The classification is carried out by our staff, who are healthcare professionals.

There is a widespread perception that many of the unintended events derive from "mistakes" made during technical procedures such as intubation. However, our data shows that such "errors" are only identified as causes in about one third of all cases. Of the 53 reports, four related to incorrect intubation; five to failure to recognise tube dislocation; four were cases of aspiration during induction of anaesthesia; three reports followed from complications in the use of the heart-lung machine/ECMO, and two concerned central line insertion.

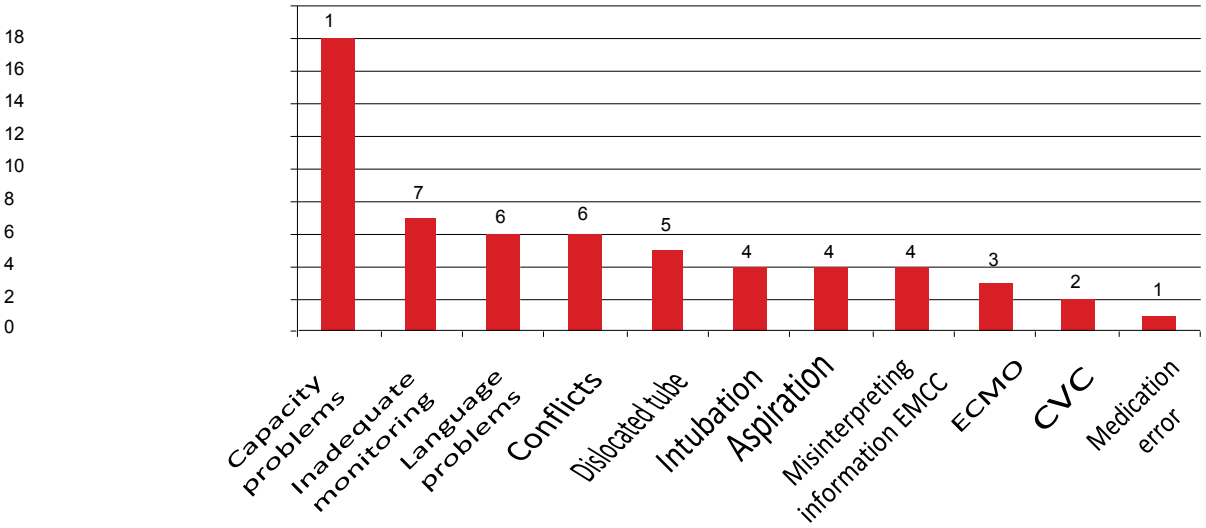
In 25 of 53 adverse events reported, the principal problem was treatment delays, e.g. delayed start of treatment for sepsis, or delays in moving patients from the intensive care unit to a different hospital with access to more advanced expertise. Capacity issues were cited in 18 of these adverse events; however in only four was the problem that there were multiple simultaneous demands on the time of healthcare professionals. Inadequate monitoring of patients was recorded in seven incidents.

Communication problems or a lack of communication was cited in seventeen reports. In six of

these the patient and/or their next-of-kin had a native language other than Norwegian.

Professional disagreements among staff also occur. Conflict among different medical specialisations was cited in four cases, and nurse-physician disagreement twice. In four cases, there were misunderstandings or problems in interpreting information given by callers to operators handling emergency calls. Wrong medication was reported in only one instance.

Figure 2 Number of reports by type of adverse event



In 11 cases, specialty registrars were reported as the physician in charge of a patient, but only in four of these cases was inadequate conferral with a specialist given as a likely contributing factor to the incident. Failure to assist a specialty registrar was only reported on one occasion.

Summary

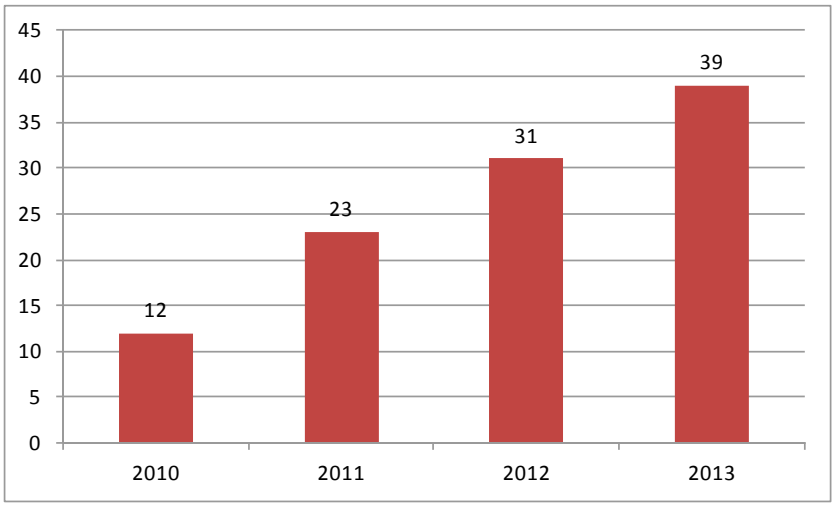
This analysis indicates that capacity constraint is a dominant problem. Other important challenges that need to be addressed are the need to improve communication, interaction and patient transfers. The emergency disciplines are quite good at technical procedures and drilling practical procedures, which may explain why deficient technical procedures was cited as cause in only one third of the adverse events. However, this does not imply that drilling in such procedures should be scaled down; to the contrary.

ARTICLE 12: Reports concerning adverse events in birth care 2013

12% of all serious adverse event reports under Section 3-3a of the Specialised Health Services Act 2010-2013 came from the birth care sector. This article presents statistics by health region, and briefly outlines the type of adverse events reported in 2013.

In 2013 the Norwegian Board of Health Supervision received 39 reports concerning adverse events in birth care. Under Section 3-3a of the Specialised Health Services Act, two of these reports were not reportable, because the events were consequences of treatment delivered by the primary healthcare service. There has been a rise in the number of reports relating to birth care incidents (Figure 1) since the reporting system was introduced; however, the rate of increase has been smaller than the corresponding rise for other disciplines.

Figure 1 Number of birth care reports

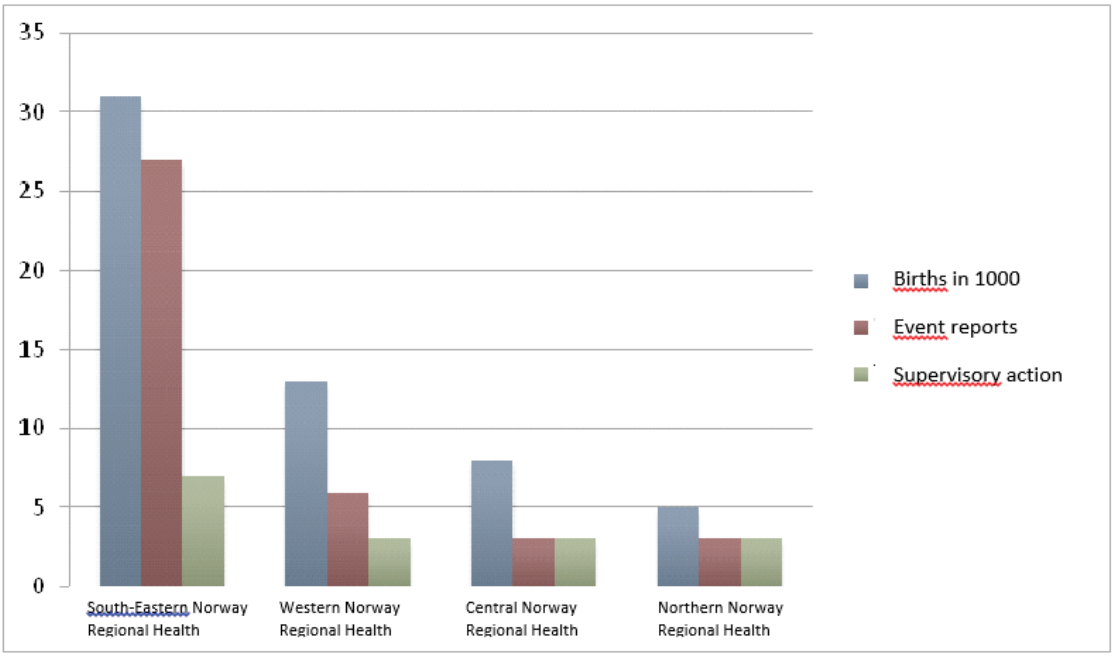


Of the 39 reports, 26 concerned child deaths. A further ten children suffered considerable harm, and in three cases the outcome was uncertain. There were no reports in 2013 concerning death or serious harm to mothers during pregnancy or childbirth.

Of the 26 children who died in connection with birth, 15 deaths were reported to the police. A full post-mortem examination was requested in eight cases, but to date no police inquiries have been initiated in any of the cases that were reported to the police.

Most of the reports came from the South-Eastern Norway Regional Health Authority. As this health authority also had a higher rate of reports per 1000 deliveries, however, the high number of reports cannot be attributed to the fact that this is the health region with the greatest number of births (Figure 2).

Figure 2 Number of delivery-related reports in the health regions



Incident investigations were initiated in 18 cases (Figure 2). Three of these involved on-site inspections. A further 14 cases were forwarded to the appropriate County Governor for supervisory action, and the Norwegian Board of Health Supervision took supervisory action in one case.

Of the cases leading to incident investigation, nine cases involved suspected deficiencies in the interpretation or performance of foetal monitoring. In ten adverse events, the supervisory authorities addressed the question of undue delays in delivery or treatment start. In seven of the incidents inadequate interaction, primarily between physician and midwife, was an important contributing factor to the child dying or suffering harm.

Three on-site inspections were carried out. One involved a visit at a university hospital, one at a medium-sized delivery ward and one at a smaller delivery ward. All cases involved impending asphyxiation during delivery with serious changes in CTG (cardiotocography, used in electronic foetal monitoring). Uterine ruptures occurred in two births due to a combination of the mothers having undergone caesarean sections in previous births and problems related to the birth in question. At present, the three incident investigations following from these inspections have not been finalised.

ARTICLE 13: "Report received..." – statistics on the reporting system's level of activities

The article presents statistics from 2010 to 2013 covering all reports to the Norwegian Board of Health Supervision concerning serious adverse events in the specialist health service; see Section 3-3a of the Specialised Health Services Act. The statistics present an overview of the reports by health authority and discipline, and of the Norwegian Board of Health Supervision's supervisory response to these reports.

Which hospitals reported adverse events?
As per 31 December 2013 the Norwegian Board of Health Supervision had received 857 reports; 72 in 2010, 140 in 2011, 246 in 2012 and 399 in 2013.

Table 1 and Figure 1 show the number of reports received per four-month interval, starting with the third four-month interval in 2010 (the last four months of 2010), to the third four-month interval in 2013 (the last four months of 2013). The number of reports received per four-month interval ranges from 39 (in the second four-month interval in 2011) to 146 (in the third four-month interval of 2013). From 2010 to 2013, there was a distinct rise in the number of reported adverse events.

Figure 1 Number of reports per four-month interval, from the last third of 2010 (Sept.-Dec. 2010) to the last third of 2013 (Sept.-Dec. 2013)

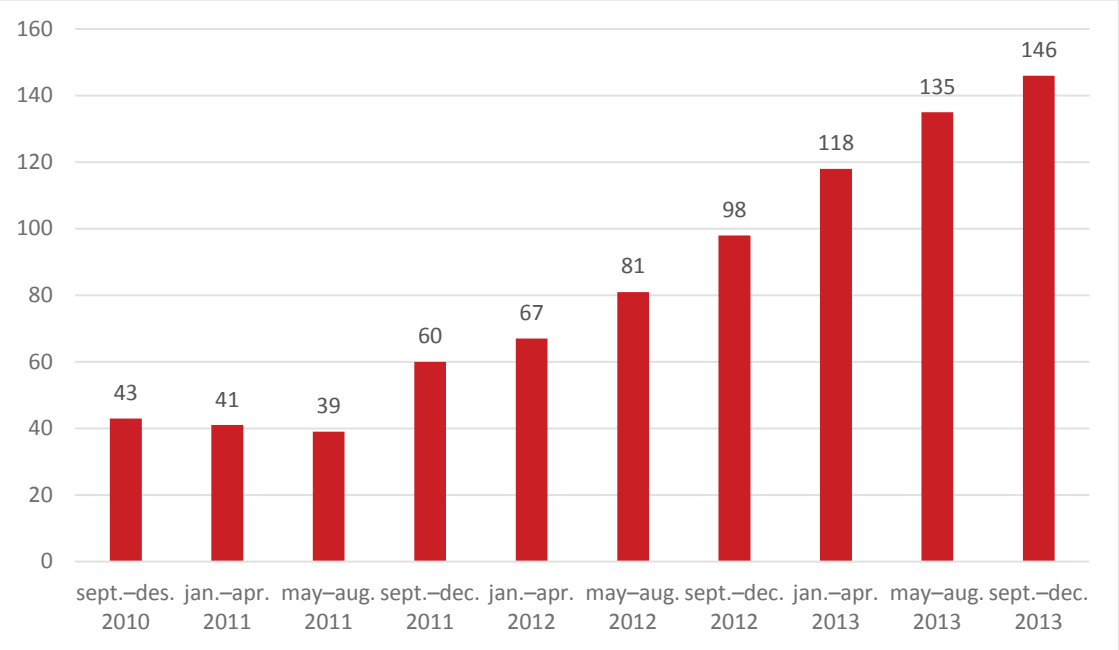


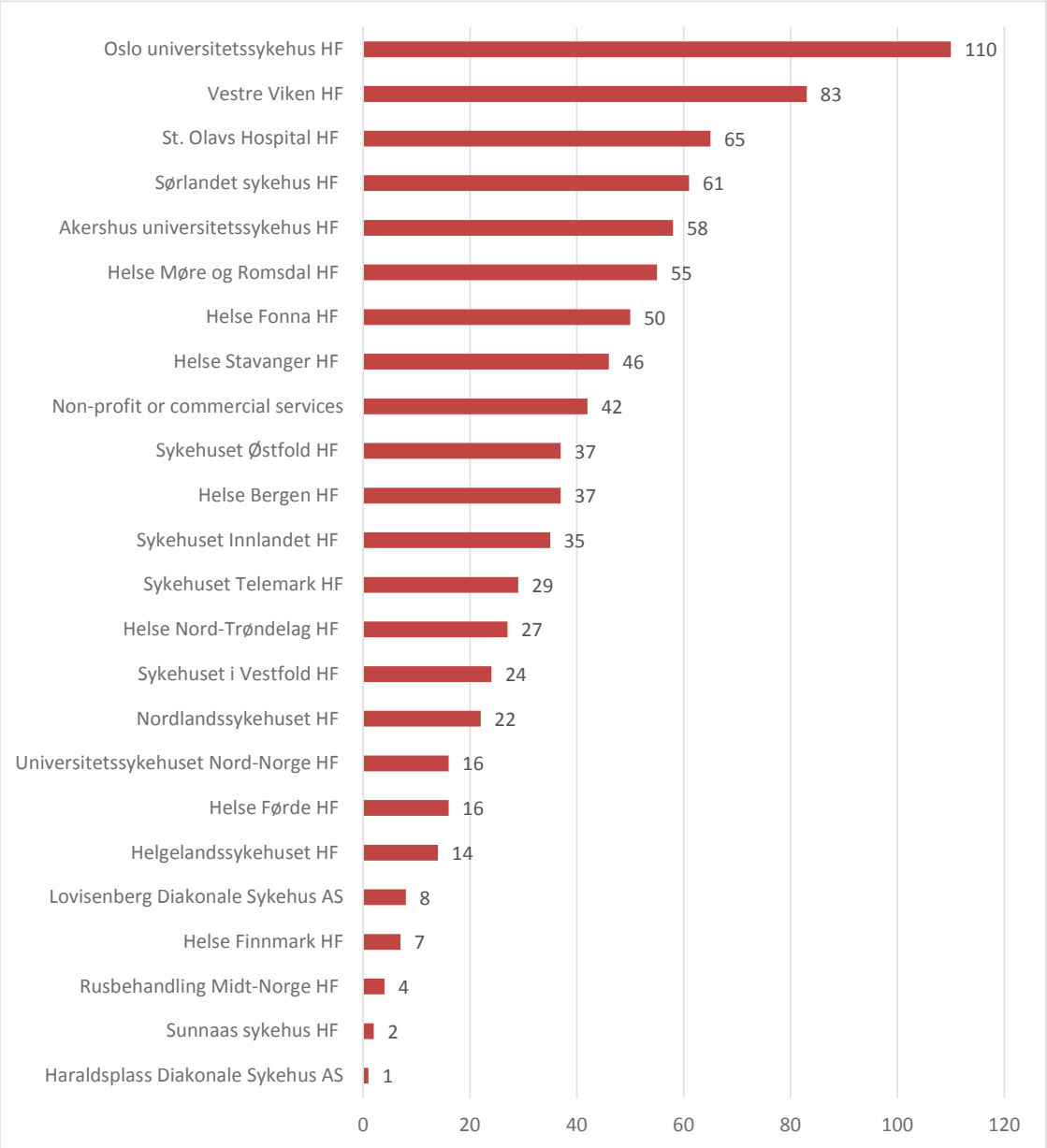
Table 2 indicates the number of reports by Regional Health Authority (RFH), hospital (HF) and institution (see also Figure 2). Norway has a total of 25 hospitals, and apart from the four hospital chemists (one for each region: Sykehusapotekene, Sjukehusapoteka Vest,

Sykehusapotekene i Midt-Norge and Sykehusapotek Nord), all health trusts are represented in the tables. The non-profit and commercial service providers have been grouped together within their respective regional health trusts, except for Diakonhjemmet Hospital, Lovisenberg Diaconal Hospital and Haraldsplass Diaconal Hospital, which are presented separately.

The following service providers accounted for the majority of reports received 2010-2013:

- Oslo University Hospital (110 reports)
- Vestre Viken Hospital (83 reports)
- St. Olav's Hospital (65 reports)
- Sørlandet Hospital (61 reports)

Figure 2 Number of reports 2010–2013 by hospital

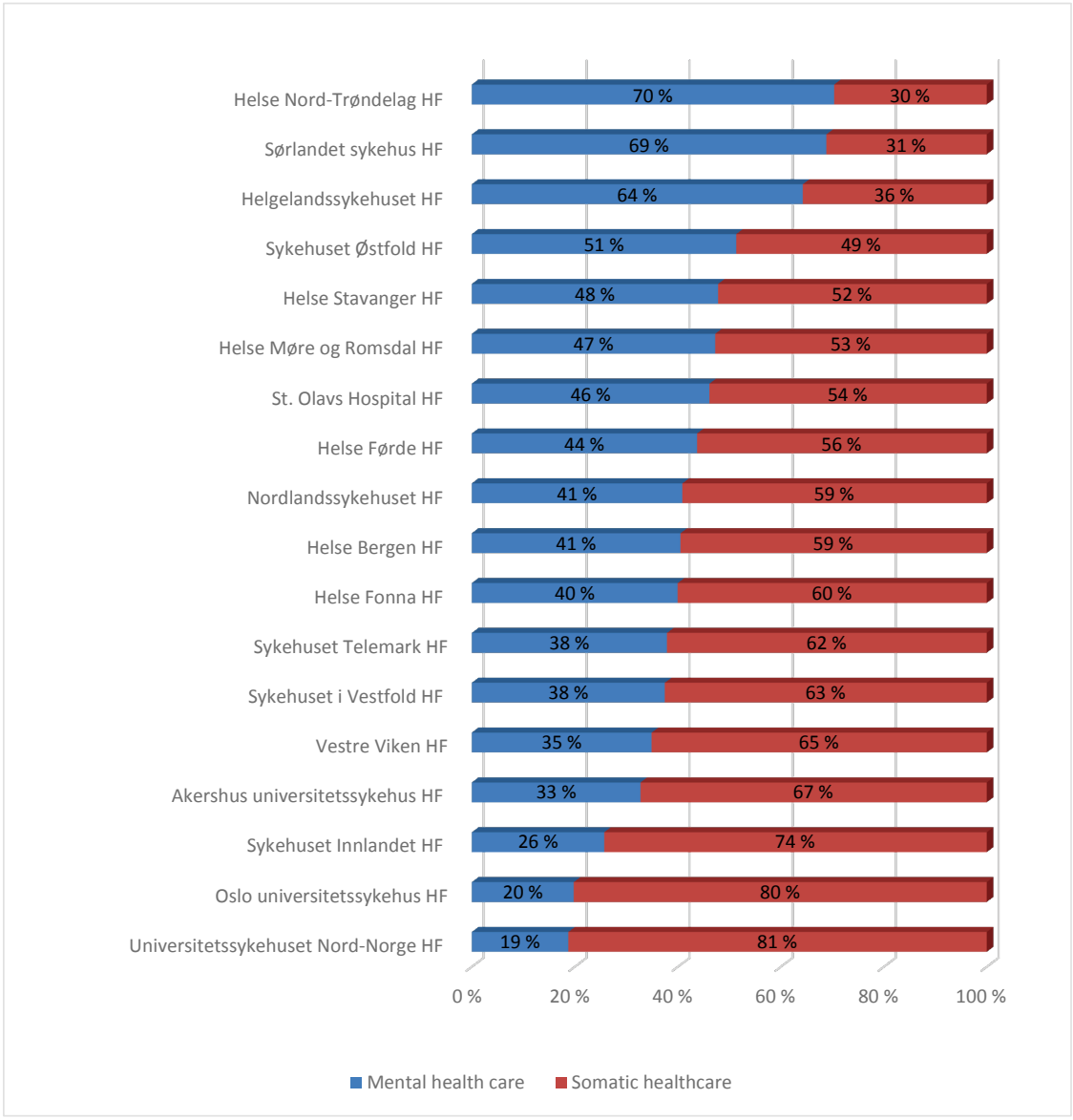


42% (362 reports) of the reports 2010-2013 pertained to mental healthcare and 58% (495

reports) to somatic health services (Table 3).

The distribution of cases (somatic health services versus mental healthcare) varies greatly among the hospitals. 70% of the reports from the Nord-Trøndelag Hospital relate to mental healthcare patients; the corresponding figure for the University Hospital of North Norway is 19% (Figure 3).

Figure 3 Number of reports 2010–2013 by mental and somatic healthcare



The number of reports from each hospital naturally reflects the size of the respective hospital and its level of activities. Overall, the largest number of reports comes from the large hospitals, with fewest relating to the small hospitals. However, there are some exceptions to this trend.

Figures 4 and 5 show the number of reports received from the various hospitals, relative to

their respective size.

As the ratio of mental versus somatic healthcare reports varies greatly among the hospitals, the figures differentiate between somatic and mental healthcare reports, listing them separately.

In order to compare the size of the hospitals, we have used data on activity levels (source: www.npr.no).

We have used the number of outpatient mental healthcare consultations for adults in 2012 as an indicator of mental healthcare activity. Somatic healthcare activity is measured in number of overnight hospital stays and day treatments in 2012.

Had the hospitals' reporting rates been identical, all the dots in the figure would be distributed along a straight line. However, this is not case. The hospitals that lie above the line have an above-average reporting rate, and those below the line have a reporting frequency that is below-average. There is no way of telling which reporting rate is spot on, i.e. the frequency at which there is no under- or over-reporting of adverse events. There is not much variation in reporting frequency among somatic healthcare providers, but all the more among mental healthcare provides.

For somatic healthcare reports:
The hospitals with the highest number of reports relative to their level of activities are Helse Fonna Hospital, Vestre Viken Hospital and Oslo University Hospital. At the opposite end of the scale are Bergen Hospital, Innlandet Hospital and Sørlandet Hospital, with the lowest number of reports relative to their level of activities.

For mental healthcare reports:
The hospitals with the highest number of reports relative to their level of activities are Sørlandet Hospital, Helse Fonna Hospital and Nord-Trøndelag Hospital, while Innlandet Hospital, Akershus University Hospital, Vestfold Hospital and University Hospital of North Norway had the lowest number of reports relative to their level of activities.

Figure 4 Number of reports from somatic healthcare 2010–2013 relative to the size of the hospitals' level of activities

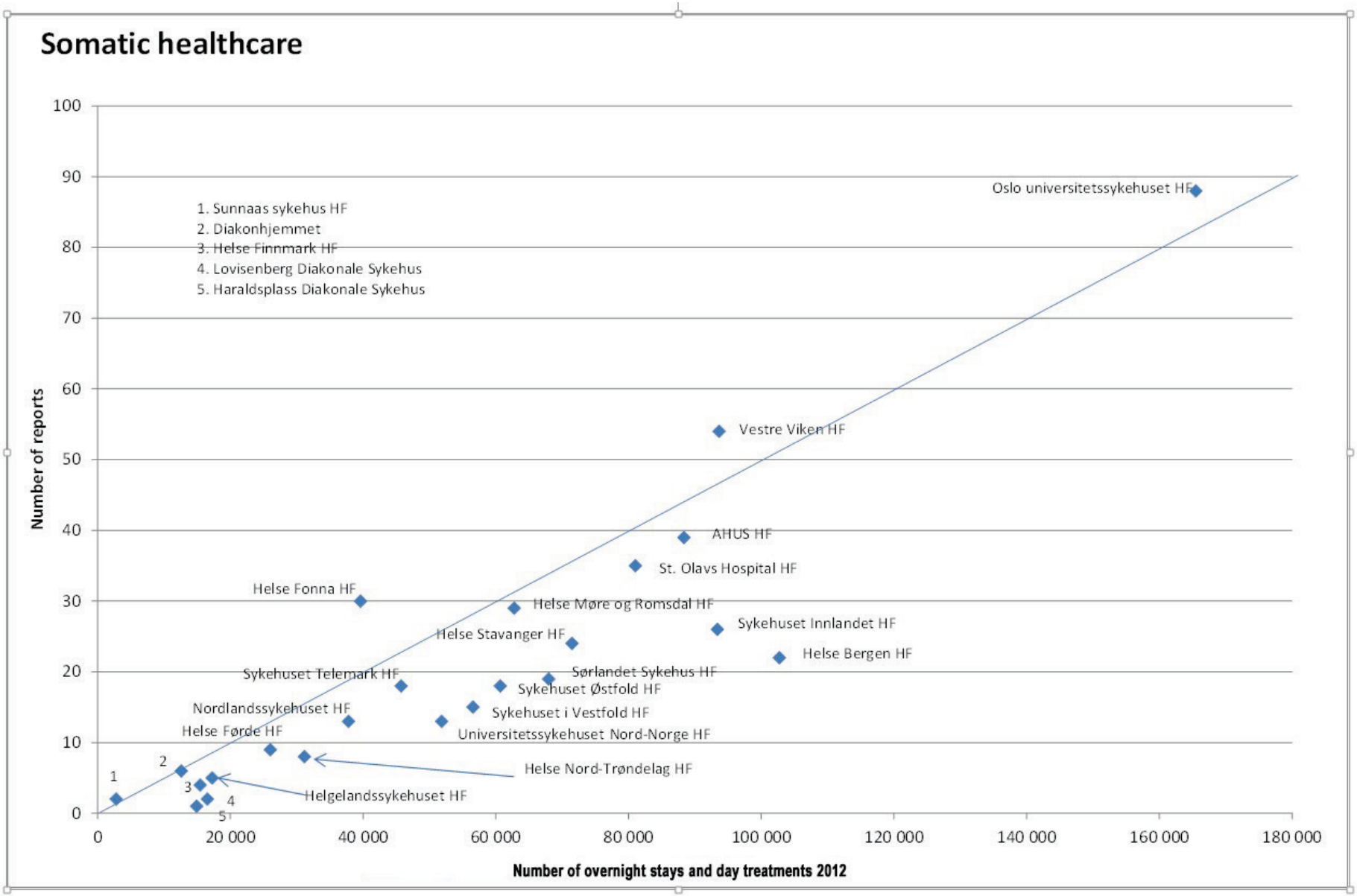
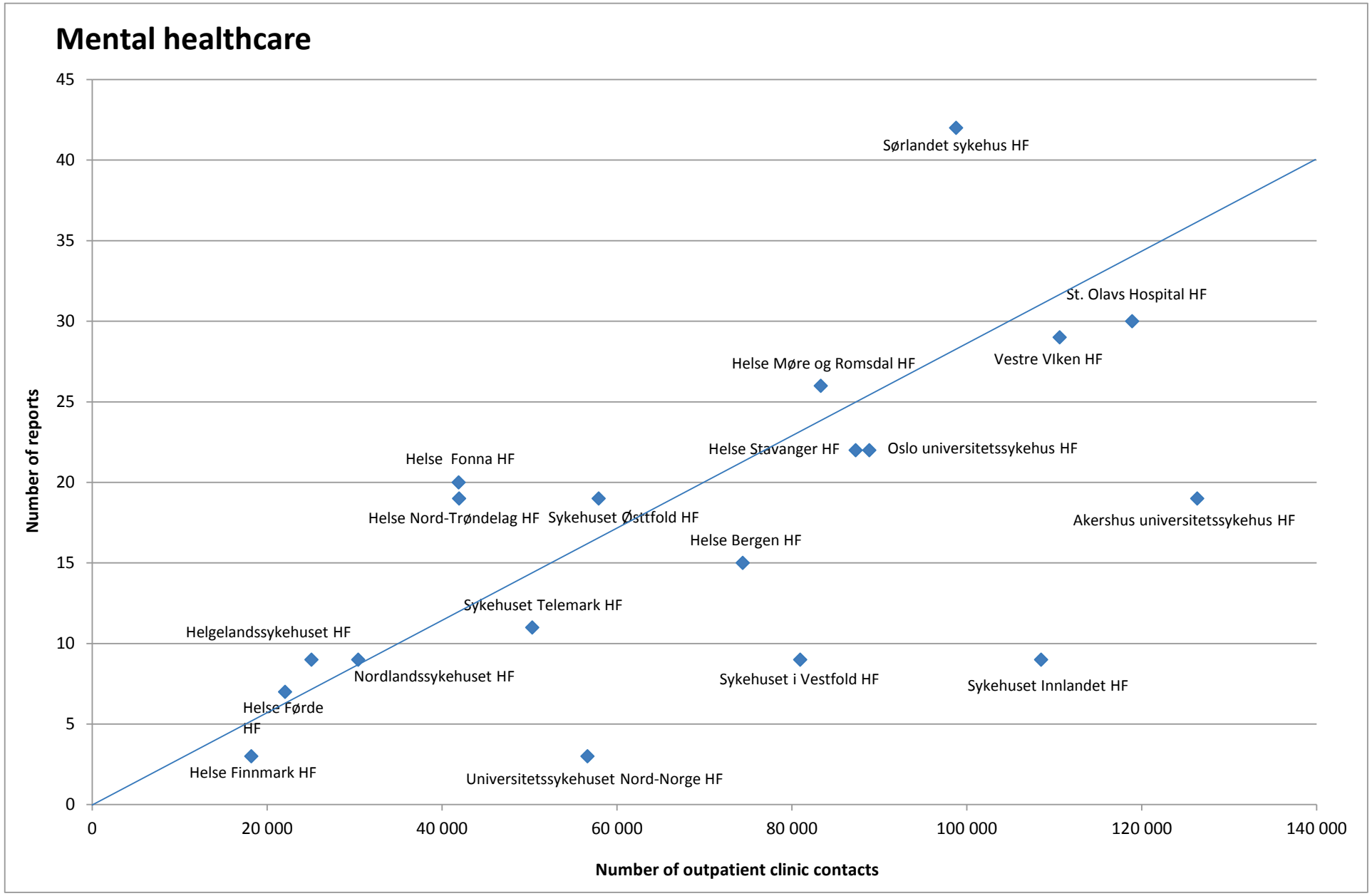
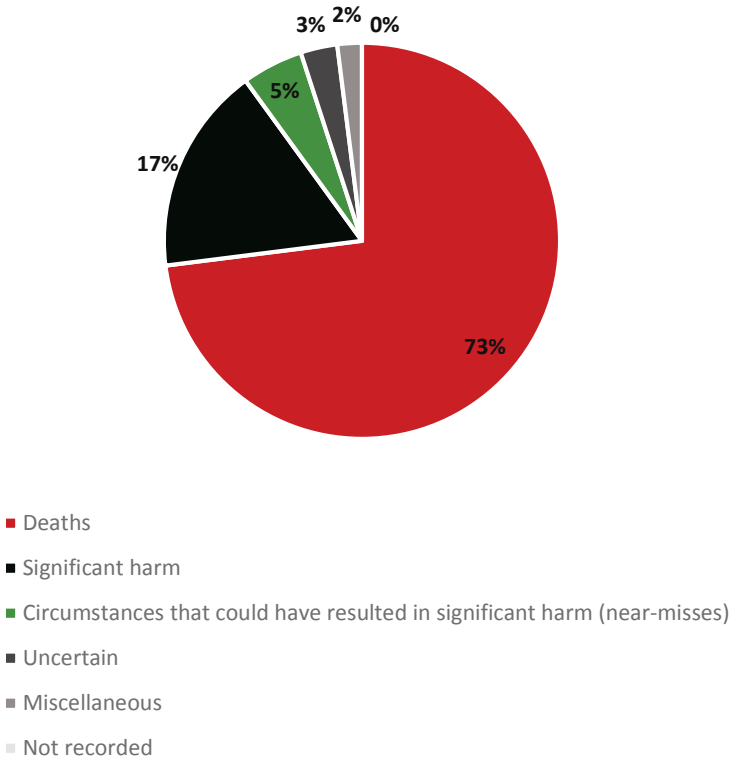


Figure 5 Number of mental healthcare reports 2010–2013 relative to the hospitals' level of activities



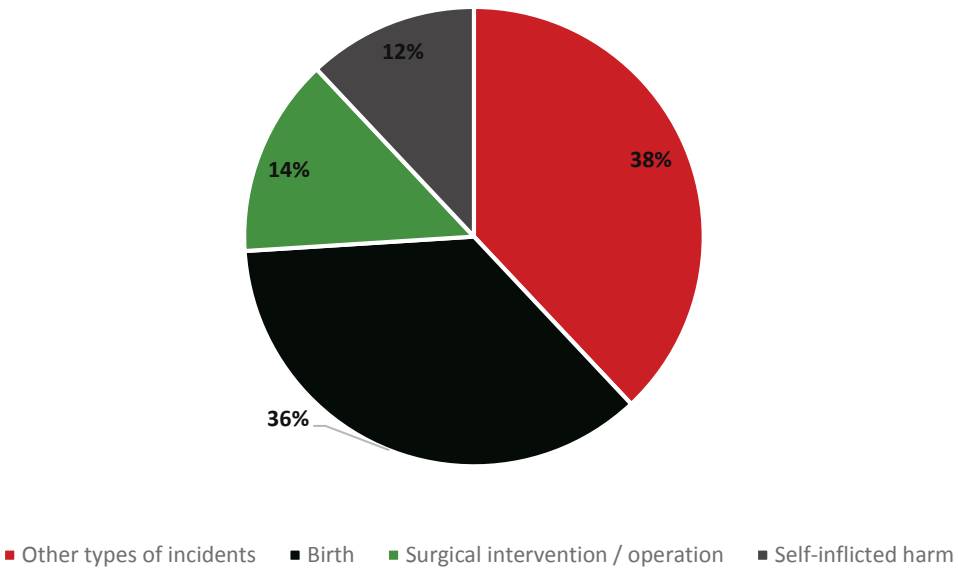
What types of adverse events did the hospitals report?
The hospitals shall notify the Norwegian Board of Health Supervision of the most serious adverse events. 73% of the reports in the 2010-2013 period concerned unexpected deaths (Table 4 and Figure 6).

Figure 6 Percentage of reports 2010–2013 by extent of harm



Many reports (38%) concerned unintended events that occurred in connection with self-inflicted harm (suicide, suicide attempts, self-harm, overdose), surgical interventions/procedures (14%) or births (12%) (Table 5 and Figure 7).

Figure 7 Number of reports 2010–2013 by type of incident



How does the Norwegian Board of Health Supervision process the reports?
Once we receive a report, we gather information from the hospital in question. All reports are then assessed by the Investigation Unit for Serious and Adverse Events' interdisciplinary team. Next, each case is discussed with the Office of the County Governor in the county in question, resulting in an agreement on how to handle the report from there.

As per today we employ the following categories in our assessment of reports:

- **Ordinary report processing:** If the report concerns a case where, following the initial assessment, we find no sign of deficiency or grounds for further supervisory monitoring or action, the case is closed. A reference is made to the internal control regulations for the health and care service, and a request that the service provider carry out an internal review of the case is made.

- **Further supervisory monitoring and action by the County Governor:** If the report concerns a case where we following our initial assessment find indications of deficiency or grounds for further supervisory monitoring or action, the Norwegian Board of Health Supervision transfers the case to the Office of the County Governor for further supervisory action.

- **On-site inspection by the Norwegian Board of Health Supervision:** In reports that relate to highly complex, multifaceted cases, and in which the course of events is open to question; in cases involving many parties and where serious deficiencies are suspected, as well as in some other cases, we carry out on-site inspections to ensure a thorough investigation of the incident.

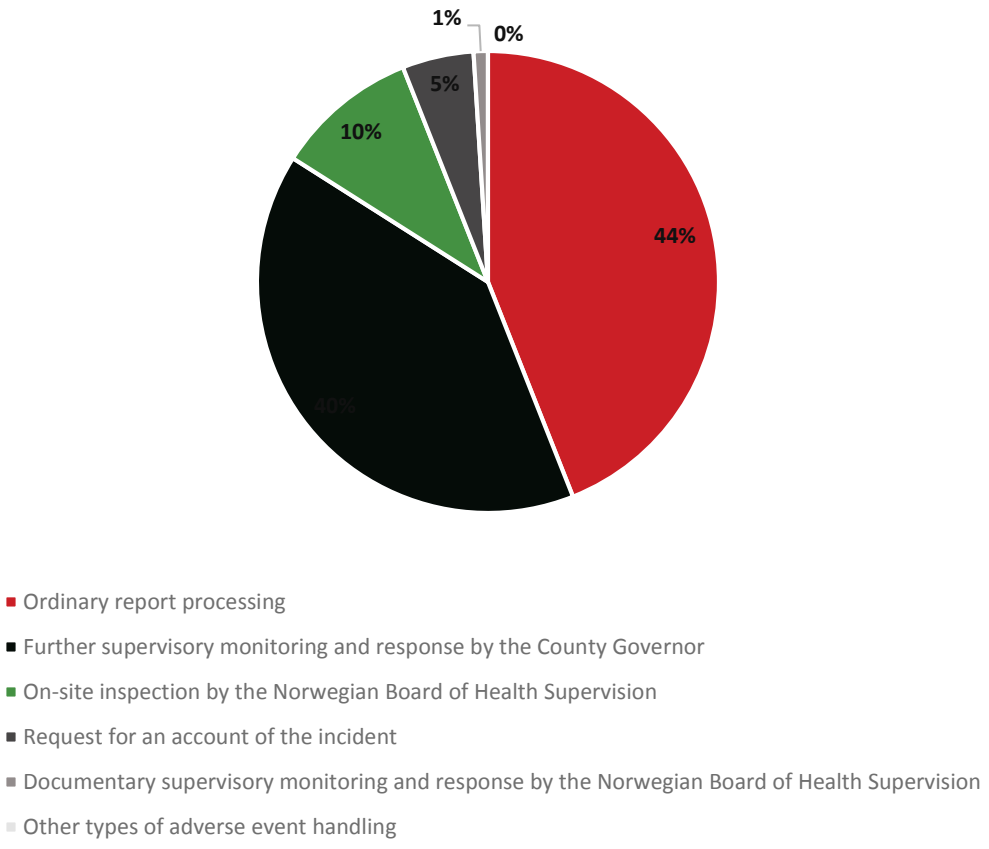
- **Requesting an account of the adverse event:** In some reports we ask the hospitals to carry out their own investigation/review. The Norwegian Board of Health Supervision asks the service provider a number of questions, both specific and general, and sets a deadline for the reply. Once we receive a reply, we monitor the case and take any action we consider necessary until we consider the investigation to have been completed, and we believe the

hospitals to have implemented the required measures.

- **Supervisory monitoring and response from the Norwegian Board of Health Supervision based on an investigation of written records:** In a few cases the Norwegian Board of Health Supervision makes a decision to initiate a documentary incident investigation in relation to the hospital itself. Documentary incident investigations are based on an examination of written records. This means that the Norwegian Board of Health Supervision contacts the hospital directly without any preliminary processing by the Office of the County Governor.

  In 2010-2013, 5% of the reports (amounting to 46 reports) resulted in on-site incident investigation by the Norwegian Board of Health Supervision, and 44% (373 reports) were handled by the County Governors (Table 6 and Figure 8).

Figure 8 Number of reports 2010–2013 by type of response



The tables

The tables below are provided for those wishing to study the reporting system's statistics in greater detail.

Table 1 Number of reports by four-month interval

Four-month interval	
Last third (Sept.-Dec.) of 2010	43
First third (Jan.-Apr.) of 2011	41
Second third (May-Aug.) of 2011	39
Last third (Sept.-Dec.) of 2011	60
First third (Jan.-Apr.) of 2012	67
Second third (May-Aug.) of 2012	81
Last third (Sept.-Dec.) of 2012	98
First third (Jan.-Apr.) of 2013	118
Second third (May-Aug.) of 2013	135
Last third (Sept.-Dec.) of 2013	146

Table 2 Number of reports by regional health authority (RHF), hospital (HF) and institution

	2010	*2011*	*2012*	*2013*	*Total*
Central Norway Regional Health Authority	**9**	**36**	**45**	**66**	**156**
Møre og Romsdal Hospital	**8**	**12**	**14**	**21**	**55**
Møre og Romsdal Hospital Clinic for Mental Healthcare	3	3	5	15	26
Kristiansund Hospital	1	3		1	5
Molde Hospital	1	2			3
Volda Hospital				1	1
Ålesund Hospital	3	4	9	4	20
Nord-Trøndelag Hospital		**6**	**10**	**11**	**27**
Nord-Trøndelag Psychiatric Clinic		4	6	9	19
Levanger Hospital			2	1	3
Namsos Hospital		2	2	1	5

	2010	*2011*	*2012*	*2013*	*Total*
Non-profit or commercial service providers			**2**	**2**	**4**
Blå Kors Lade Treatment Centre			2	2	4
Not registered	**1**				**1**
Not registered	1				1
Rusbehandling Midt-Norge Hospital			**2**	**2**	**4**
The Trondheim Clinic			2	2	4
St. Olav's Hospital		**18**	**17**	**30**	**65**
St. Olav's Hospital, Division for Mental Healthcare		10	8	12	30
St. Olav's Hospital Orkdal Hospital		2	1		3
St. Olav's University Hospital, Trondheim		6	8	18	32
Northern Norway Regional Health Authority	**10**	**9**	**15**	**26**	**60**
Helgeland Hospital	**1**	**2**	**5**	**6**	**14**
Helgeland Hospital Mosjøen	1		1		2
Helgeland Hospital Psychiatric Centres		1	3	5	9
Helgeland Hospital Sandnessjøen		1	1	1	3
Finnmark Hospital	**3**		**1**	**3**	**7**
Finnmark Hospital, Clinic for					
Clinic Hammerfest	1		1		2
Clinic Kirkenes				2	2
Non-profit or commercial service providers		**1**			**1**
Finnmarkskollektivet (substance abuse)		1			1
Nordland Hospital	**4**	**4**	**4**	**10**	**22**
Nordland Hospital Bodø	2	2	3	3	10
Nordland Hospital Lofoten				1	1
Nordland Hospital, Mental Healthcare and Substance Abuse Clinic	1	2	1	5	9
Nordland Hospital Vesterålen	1			1	2

	2010	*2011*	*2012*	*2013*	*Total*
University Hospital of North Norway	**2**	**2**	**5**	**7**	**16**
Miscellaneous	1				1
University Hospital of North Norway Harstad			1		1
University Hospital of North Norway Narvik			1		1
University Hospital of North Norway Psychiatric Wards				3	3
University Hospital of North Norway Tromsø	1	2	3	4	10

South-Eastern Norway Regional Health Authority	**40**	**61**	**136**	**243**	**480**
Akershus University Hospital	**2**	**3**	**25**	**28**	**58**
Akershus University Hospital Lørenskog	2	3	14	20	39
Akershus University Hospital, Division for Mental Healthcare			11	8	19
Diakonhjemmet sykehus AS			**2**	**5**	**7**
Diakonhjemmet Hospital			2	5	7
Non-profit or commercial service providers	**4**	**5**	**4**	**13**	**26**
Aleris Hospital and Medical Centre – Oslo	1			1	2
Borgestad Clinic Blå Kors South, Bragernes			2	4	6
Borgestad Clinic Blå Kors South, Skien				1	1
Curato Røntgen (radiographic clinic)		1			1
The Feiring Clinic (heart clinic)				2	2
Salvation Army's Street Hospital		1			1
The Glittre Clinic		1			1
Godthaab Health and Rehabilitation Centre				1	1
Hernes Institute				1	1
Hjelp24 NIMI Ekeberg	1				1
Incita	1				1
NKS Grefsenlia (mental health issues)				1	1
The Origo Centre (substance abuse treatment)		1			1
Psychiatrist with private practice			1		1
Rehabiliteringssenteret AiR (rehabilitation)			1		1

	2010	*2011*	*2012*	*2013*	*Total*
Stiftelsen Fredheim (substance abuse treatment)	1				1
Stiftelsen Kirkens Bymisjon (Church City Mission)		1		1	2
Unilabs Røntgen Drammen (radiology)				1	1
Lovisenberg Diakonale Sykehus AS (Lovisenberg diaconal hospital)	**4**	**1**	**1**	**2**	**8**
Lovisenberg Diaconal Hospital			1	1	2
Lovisenberg Diaconal Hospital, Lovisenberg Regional Psychiatric Centre (DPS)	1			1	2
Lovisenberg Diaconal Hospital, Psychiatric Ward	3	1			4
Oslo University Hospital	**6**	**15**	**33**	**56**	**110**
Oslo University Hospital, Aker Hospital	1	3	1		5
Oslo University Hospital, EMCC (Emergency-medical Communications Centre)		1	3	7	11
Oslo University Hospital, Clinic for Mental Health and Dependence		4	10	8	22
Oslo University Hospital, the Norwegian Radium Hospital				4	4
Oslo University Hospital, Rikshospitalet	2	1	11	24	38
Oslo University Hospital, Ullevål Hospital	3	6	8	13	30
Sunnaas Hospital			**1**	**1**	**2**
Sunnaas Hospital			1	1	2
Vestfold Hospital		**2**	**9**	**13**	**24**
Vestfold Hospital, Mental Health and Substance Abuse Clinic			3	6	9
Vestfold Hospital, Larvik			1		1
Vestfold Hospital, Tønsberg		2	5	7	14
Innlandet Hospital	**2**	**6**	**7**	**20**	**35**
Innlandet Hospital, Division Elverum Hamar, Hamar			1	3	4
Innlandet Hospital, Division Gjøvik	1	1	1		3
Innlandet Hospital, Division Kongsvinger	1		1		2
Innlandet Hospital, Division Lillehammer		5	4	8	17
Innlandet Hospital, Division Mental Healthcare				9	9

	2010	*2011*	*2012*	*2013*	*Total*
Telemark Hospital	**6**	**3**	**9**	**11**	**29**
Telemark Hospital, Kragerø				1	1
Telemark Hospital, Notodden		1			1
Telemark Hospital, Psychiatric Clinic			4	7	11
Telemark Hospital, Skien	6	2	5	3	16
Østfold Hospital	**5**	**6**	**14**	**12**	**37**
Østfold Hospital, Fredrikstad	3	1	4	5	13
Østfold Hospital, Mental Healthcare Clinic		2	10	7	19
Østfold Hospital, Moss	2	3			5
Sørlandet Hospital		**9**	**16**	**36**	**61**
Sørlandet Hospital, Arendal		1	3	4	8
Sørlandet Hospital, Mental Health Clinic		7	10	25	42
Sørlandet Hospital, Kristiansand		1	3	7	11
Vestre Viken Hospital	**11**	**11**	**15**	**46**	**83**
Bærum Hospital	1	2		10	13
Drammen Hospital	4	4		16	24
Kongsberg Hospital			2	1	3
Ringerike Hospital	2	1	1	6	10
Vestre Viken, Clinic for Pre-hospital Services		2		2	4
Vestre Viken, Mental Health and Substance Abuse Clinic	4	2	12	11	29
Western Norway Regional Health Authority	**13**	**34**	**50**	**64**	**161**
Haraldsberg Diakonale Sykehus AS (Haraldsplass Diaconal Hospital)		**1**			**1**
Haraldsplass Diaconal Hospital		1			1
Helse Bergen Hospital	**1**	**11**	**11**	**14**	**37**
Haukeland University Hospital		5	7	9	21
Haukeland University Hospital, Mental Healthcare Division	1	6	4	4	15
Haukeland University Hospital, Voss Hospital				1	1
Helse Fonna Hospital	**11**	**11**	**9**	**19**	**50**
Haugesund hospital	6	2	4	8	20
Helse Fonna, Mental Healthcare Clinic	1	6	5	8	20
Odda Hospital	1	1		1	3

	2010	*2011*	*2012*	*2013*	*Total*
Stord Hospital	3	2		2	7
Helse Førde Hospital	**1**	**2**	**5**	**8**	**16**
Førde Central Hospital	1	1	5	2	9
Førde Hospital Mental Healthcare		1		6	7
Helse Stavanger Hospital		**9**	**20**	**17**	**46**
Stavanger University Hospital		2	13	9	24
Stavanger University Hospital, Psychiatric Division		7	7	8	22
Non-profit or commercial service providers			**5**	**6**	**11**
Haugaland A-centre (Addiction Treatment)			1		1
Betanien Hospital				4	4
Jæren Regional Psychiatric Centre (DPS)			1		1
Kolibri Medical				1	1
Solli Regional Psychiatric Centre (DPS)			2		2
Volvat Medical Centre, Bergen				1	1
Voss Regional Psychiatric Centre (DPS)			1		1
In total	**72**	**140**	**246**	**399**	**857**

Table 3 Number of reports by somatic and mental healthcare/substance abuse

Somatic/mental healthcare / substance abuse	*2010*	*2011*	*2012*	*2013*	*Total*
Mental healthcare/substance abuse	19	60	111	172	362
Somatic healthcare	53	80	135	227	495
In total	**72**	**140**	**246**	**399**	**857**

Table 4 Number of reports by extent of harm

Extent of harm	*2010*	*2011*	*2012*	*2013*	*Total*
Deaths	39	112	184	292	627
Significant harm	16	18	47	65	146
Circumstances that could have resulted in significant harm (near-misses)	8		2	27	37
Uncertain	3	8	4	11	26
Miscellaneous	5	2	9	3	19
Not registered	1			1	2
In total	**72**	**140**	**246**	**399**	**857**

Table 5 Number of reports by type of event

Type of incident	*2010*	*2011*	*2012*	*2013*	*Total*
Suicide	8	44	75	105	232
Surgical intervention/procedure	11	16	25	66	118
Birth	12	23	31	39	105
Miscellaneous	11	17	30	32	90
Suicide attempts/self-harm	7	10	22	37	76
Emergency life-saving treatment	2	8	5	26	41
Medical examination/diagnostics	4	4	12	20	40
Medical treatment	4	2	19	9	34
Overdoses/intoxication	1		7	13	21
Infections	1	1	6	11	19
Intensive care/monitoring	2	1	4	12	19
Use of medication	1	4	4	6	15
Use of medical devices		1	1	11	13
Homicide/violence	3	5	2	3	13
Falls	2	3	3	5	13
Use of blood/blood products	1	1		2	4
Medical research				1	1
Not registered	2			1	3
National total	**72**	**140**	**246**	**399**	**857**

Table 6 Number of reports by supervisory outcome

Supervisory conclusion	*2010*	*2011*	*2012*	*2013*	*Total*
Further supervisorymonitoring and response by the County Governor	29	69	99	176	373
Ordinary report processing	34	57	81	170	342
Requests for an account of the incident			53	36	89
On-site inspection by the Norwegian Board of Health Supervision	6	14	13	13	46
Documentary supervisory monitoring and response by the Norwegian Board of Health Supervision				4	4
Miscellaneous	3				3
In total	**72**	**140**	**246**	**399**	**857**

Svikt i samhandling, kommunikasjon og kompetanse i alvorlige hendelser …… kunne det skjedd hos oss? Eksempler og erfaringer 2010–2013 fra Undersøkelsesenhetens arbeid med varsler om alvorlige hendelser i spesialisthelsetjenesten (§ 3-3a i spesialisthelsetjenesteloven)

Oppsummering av Rapport fra Helsetilsynet 3/2014

I denne rapporten har Statens helsetilsyn samlet erfaringer og eksempler fra arbeidet med oppfølging av varsler om alvorlige hendelser som vi har mottatt fra spesialisthelsetjenesten i perioden fra 1. juni 2010 til og med 31. desember 2013. Vi beskriver eksempler på varsler og hendelsesforløp fra ulike fagområder, hvordan tilsynsmyndigheten har håndtert varslene og vurderingene tilsynsmyndigheten har gjort. Videre presenterer vi statistikk som gir oversikt over det totale antall varsler fordelt på fagområder og helseforetak, og over hvordan Statens helsetilsyn har arbeidet med varslene.

Spesialisthelsetjenesten skal varsle Statens helsetilsyn ved alvorlige og uventede hendelser. Denne varselordningen ble etablert våren 2010 etter at flere alvorlige hendelser i spesialisthelsetjenesten fikk stor oppmerksomhet i offentligheten.

Formålet med ordningen er at tilsynsmyndigheten raskt skal skaffe til veie opplysninger og få oversikt etter en alvorlig hendelse, det vil si ved uventet dødsfall eller alvorlig pasientskade i forbindelse med behandling i spesialisthelsetjenesten. Statens helsetilsyn skal jobbe tettere på helsepersonellet og sykehuset som er involvert for å sikre innsamling av relevant informasjon både om selve hendelsen og om hvordan virksomheten blir ledet og drevet. I sitt arbeid med å gjennomgå hendelsen skal tilsynsmyndigheten skal også etterspørre og høre pasienters og pårørendes erfaringer. Videre skal tilsynsmyndigheten undersøke og analysere årsakssammenhenger, gjøre forsvarlighetsvurderinger og samtidig stimulere til læring i tjenestene. Samlet sett skal tilsynsmyndigheten bidra til å redusere risiko for at det samme skal skje igjen, og dermed understøtte sykehusets eget arbeid med pasientsikkerhet.

Fagmiljøene i helseforetakene er en viktig målgruppe for rapporten. Statens helsetilsyn ønsker at rapporten skal bidra til refleksjon og debatt i spesialisthelsetjenesten om pasientsikkerhet, risiko for svikt og muligheter for forbedring i pasientbehandlinge

Report from the Norwegian Board of Health Supervision

Previously published in full-text version in English

3/2009 Summary of a two-year study of suicides in the mental health service
8/2002 Quality in healthcare - the role of government in supervision and monitoring in Norway: A description of the Norwegian governmental model of supervision and monitoring to ensure quality in healthcare and a discussion on its possible usefulness in health sector development in Sub-Saharan Africa

Publications 2014

An English summary is available at www.helsetilsynet.no

1/2014 Oppsummering av satsinga på tilsyn med helse- og omsorgstenester til eldre 2009–2012 (A summary of supervisory work in the health and care services for the elderly 2009-2012)

2/2014 Helsepersonells opplysningsplikt til barnevernet. Oppsummering av kunnskap fra tilsyn mv. (Health professionals and their reporting requirement to the child welfare services. A summary of experiences from supervision, etc.)

3/2014 Svikt i samhandling, kommunikasjon og kompetanse i alvorlige hendelser …… kunne det skjedd hos oss? (Could this have happened here? Examples and experience from investigation of serious and adverse events 2010-2013)

4/2014 Helsestasjonen - Hjelp i rett tid? Oppsummering av landsomfattende tilsyn med helsestasjoner 2013 (Health Centres – help when needed? Summary of countrywide supervision of health centres in 2013)

Publications 2013

An English summary is available at www.helsetilsynet.no

1/2013 Oppsummering av tilsyn med verksemder som er godkjende for å handtere humane celler og vev til assistert befruktning (A summary of supervision of service providers approved for the handling of human cells and tissue for assisted reproduction)

2/2013 Glemmer kommunene barn og unge i møte med økonomisk vanskeligstilte familier? Kartlegging og individuell vurdering av barns livssituasjon og behov ved søknader om økonomisk stønad. (When facing families in difficulties, are the municipalities forgetting children and young persons? Surveying and individual assessment of children's life situation and requirements in connection with claims for financial support.) Summary of countrywide supervision 2012

3/2013 "Ikke bare ett helseproblem……" Oppsummering av landsomfattende tilsyn i 2011–2012 med spesialisthelsetjenesten: behandling av skrøpelige eldre pasienter med hoftebrudd ("Not just a health issue ....." A summary of countrywide supervision of the specialist health services in 2011-2012: treatment of frail elderly patients with hip fractures)

4/2013 Spesialisthelsetjenestens håndtering av henvisninger og utredning av pasienter med tykk og endetarmskreft. (The specialist health service's handling of referrals and assessment of patients with colon and rectal cancer.) Summary of countrywide supervision 2012

5/2013 Tvil om tvang. Oppsummering av landsomfattende tilsyn i 2011 og 2012 med tvungen helsehjelp til pasienter i sykehjem (Questioning co-ercion. Summary of countrywide supervision 2011 and 2012 of compulsory healthcare for patients in nursing homes)

6/2013 "Vi får satt fokus, blir bevisstgjort og må skjerpe faget vårt ekstra…" En deskriptiv undersøkelse av tilsyn med kommunale helse og omsorgstjenester til eldre ("It helps us focus, raise awareness, and keeps us on our toes professionally ...." A descriptive study of the supervision of municipal health and care services for the elderly.)

7/2013 Oppsummering av tilsyn med handtering av humant beinvev til bruk på menneske (Summary of supervision of the handling of human bone tissue for use in humans)

Annual supervision reports *(Tilsynsmelding)*

The Norwegian Board of Health Supervision publishes annual supervision reports. These are used to brief the public on cases of importance for the Norwegian Labour and Welfare Administration's social services, child welfare services, health and care services, and so as to promote public debate about these services.

The full-text versions of the post-1997 annual supervision reports are available in Norwegian at www.helsetilsynet.no. A few articles from each issue are also published in English.

In the series Reports from the Norwegian Board of Health Supervision, findings and experience from the processing of complaints and supervision of social services in Nav (the Norwegian Labour and Welfare Administration), the child welfare services and the health and care service are made available.

The series is published by the Norwegian Board of Health Supervision. All the series' publications are available in full-text version at
www.helsetilsynet.no

HELSETILSYNET
tilsyn med barnevern, sosial- og helsetjenestene

SUMMARY

Report from the Norwegian Board of Health Supervision 3/2014

Could this have happened here? Examples and experience from investigation of serious and adverse events 2010-2013

This report consists of a collection of articles which detail examples and experience from the agency's work to monitor and act on reports received between 1 June 2010 up to 31 December 2013. We describe examples of reports and events from a range of professional fields; the supervision authority's response to the reports, and their conclusions.

Furthermore, we present statistics that illustrate the total number of reports, presented by professional areas and hospitals. The figures also illustrate how the Norwegian Board of Health Supervision has worked with the reports.

The specialist health services have an obligation to notify the Norwegian Board of Health Supervision of any serious and unexpected events. The reporting system was set up in the spring of 2010 after a number of serious adverse events in the specialist health services became the focus of public attention.

The objective of the system is to enable the supervision authority to quickly obtain information and gain an overview of a serious incident, i.e. if an unexpected death has occurred, or if a patient is harmed seriously in connection with specialist health treatment. The Norwegian Board of Health Supervision is to oversee the health personnel and hospitals more closely, with a view to ensuring that the relevant information about the adverse event itself is gathered, and about how the service provider is managed and run. In their work to review the event, the supervision authority shall also inquire into and listen to the experiences reported by the patients themselves and their next-of-kin. Furthermore, the supervision authority shall examine and analyse causality, assess whether treatment and proceedings have been sound, and also promote learning in the services. The supervision authority's overriding objective is to help reduce the likelihood of events recurring, and thus underpin the hospitals' own patient safety work.

One of the principal target readerships for this report are the healthcare professionals and management in the hospitals. The Norwegian Board of Health Supervision wants the report to encourage reflection and discussions in the specialist health services on patient safety, the risk of deficiencies and the potential for improving patient care.