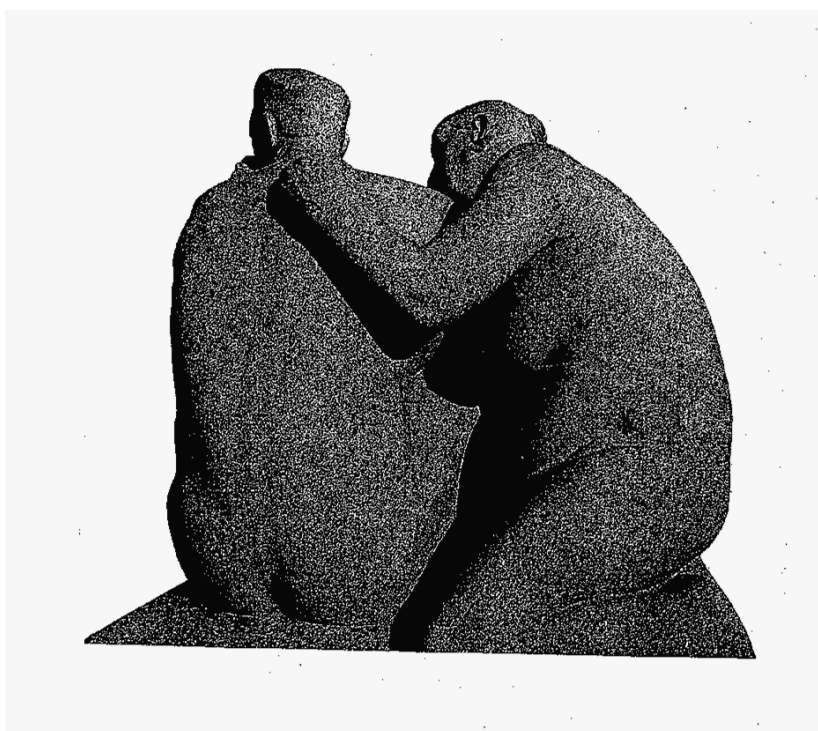




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Guidance document for the countrywide supervision of the specialist health services in 2011

System audit: Treatment of elderly patients with cerebral stroke



31 August 2012. This guidance document has been prepared under the regulations that were in force at the time it was approved. The new Act relating to Municipal Health Services etc. entered into force on 1 January 2012, resulting in some amendments to the laws and regulations that apply to the specialist health services.

Approved by Lars E. Hanssen 7 December 2010

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1. Introduction

1.1. Background

The Norwegian Board of Health Supervision has chosen services for the elderly as a strategic focus area for the years 2009 to 2012. A decision has been made to perform countrywide supervisions in the following areas:

- 2010: municipal social and health services for the elderly
- 2011: specialist health services for the elderly
- 2012: interaction among the various levels in relation to health services for the elderly

As part of planning its supervisions in 2011, the Norwegian Board of Health Supervision performed a risk assessment in order to identify up to 15 of the most important risk areas within the specialist health services for elderly persons (1). The outcome of this exercise informed the choice of subjects: acute cerebral strokes and hip fractures. This guidance document provides an account of the supervision of treatment of elderly persons who have suffered an acute cerebral stroke.

Cerebral stroke is a serious disease that can have a great adverse impact on patients. In Norway, about 15 000 persons experience a cerebral stroke every year. The occurrence of stroke rises significantly with age, and two-thirds of all stroke victims are patients above the age of 75 (2).

In April 2010, the Norwegian Directorate of Health published national clinical guidelines for the treatment and rehabilitation of patients with cerebral stroke (3). This guidance document is to a large extent built on these guidelines.

The supervision is to be performed as a series of system audits in accordance with applicable procedures.

The guidance document has been prepared by a working group consisting of: Senior Advisor Anne Christine Breivik (to 13 September 2010), Assistant County Medical Officer Jo Kåre Herfjord, Senior Advisor Elin Kværnø (from 13 September 2010), Senior Advisor Berit Holthe Munkeby, Senior Advisor Kurt I. Myhre, Senior Advisor Wenche Skjær and Senior Advisor Aud Frøysa Åsprang (in overall charge).

1.2. What the supervision covers

The principal objective of this supervision is to examine whether the specialist health services by means of systematic management and improvement ensure sound treatment of elderly persons diagnosed with cerebral stroke, regardless of whether the stroke is ischemic, i.e. caused by an infarction or whether it is the result of a haemorrhage.

For the purposes of this guidance document, elderly persons are defined as persons above the age of 80.

The patient group at the centre of this supervision are frail elderly persons.¹ This patient group requires a more comprehensive treatment and rehabilitation approach than younger and fitter patient groups. There is a need not only to consider the stroke itself, but also to give attention to the patient's overall state of health. The principles for attending to frail elderly patients with acute disease largely overlap with the principles for multidisciplinary team-based stroke care. One of the basic principles in stroke treatment is that rehabilitation measures and functional task training are started at the same time as acute observation, assessment and medical treatment are carried out. Parallel to these processes, steps must be taken to prevent complications.

Elderly patients admitted with acute cerebral stroke come from a variety of different living arrangements. Some come from their own home, some from sheltered housing and others from nursing homes. Regardless of their prior living arrangements, patients are entitled to the same treatment, and entitled to treatment that is medically sound.

WHO defines stroke as sudden signs of focal or global disturbance of cerebral function of vascular origin, lasting more than 24 hours (or leading to death).

The blood supply may be interrupted by a blood clot (cerebral infarction) or haemorrhage (5).² Transient Ischemic Attacks (TIA) is a condition that closely resembles cerebral strokes. This is a condition involving temporary reduction in the blood supply to the brain, often called a mini-stroke. TIAs are defined as having symptoms lasting less than 24 hours, and are therefore not defined as cerebral strokes in clinical terms. The services provided by the specialist health service to patients with TIA are therefore not covered by this supervision.

The national clinical guidelines for the treatment and rehabilitation of cerebral stroke recommend that all such patients are treated in stroke units that combine acute treatment with early rehabilitation. The guidelines describe combined stroke wards as follows: *"an organised treatment of stroke patients in a geographically delimited unit with regular beds, staffed by a multidisciplinary, specially-trained team with standardised protocols and guidelines for diagnosis, observation, acute treatment and early rehabilitation."* This supervision is to examine whether the hospital ensures that elderly patients with stroke are given medically sound treatment and rehabilitation, independent of whether they receive care in a so-called stroke unit or in a different type of ward.

In order to define the scope of the supervision, we have selected the following areas at risk of deficiencies that may significantly and adversely impact on the patients in question:

- Observation, assessment and treatment during the first 24 hours after admission to hospital,
- Early rehabilitation,
- Preventing complications and secondary strokes.

¹ "Frailty is a physiological syndrome, characterized by decreased reserve and diminished resistance to stressors, resulting from cumulative declines across multiple physiologic systems, and causing vulnerability to adverse health outcomes including falls, hospitalization, institutionalization and mortality." (4)

² "Stroke is defined as rapidly developing clinical signs of focal (or global) disturbance of cerebral function, lasting more than 24 hours or leading to death with no apparent cause other than that of vascular origin."

We have decided to review observation, assessment and treatment during the first 24 hours after admission to hospital, because this is the most critical phase. For a couple of the subjects addressed by the supervision the critical phase extends beyond 24 hours, and hence so does the focus of the supervision.

The audit shall cover the period from the time the patient is transferred from the A&E Department until the individual patient is discharged from the hospital. If the patient is moved between different wards in the hospital, the supervision is to monitor the entire course of the hospital stay. However, if the patient is transferred to a different department because an additional medical problem requiring treatment somewhere else arises, the audit shall not pursue the patient's course of treatment during his or her hospital stay. An example of this would be a patient who breaks a hip after a fall in hospital, and is transferred to the orthopaedic/surgical department for treatment. In this case, the audit's review of this case would end upon the patient's transfer to the orthopaedic/surgical ward. Pre-hospital treatment and/or treatment in the A&E Department are therefore not covered by this supervision. However, the organisation of hospitals may vary, resulting in somewhat different distribution of duties among the A&E Department, the intensive care unit, the observation ward (if the hospital has one), and the stroke unit/ward. Some of the duties to be reviewed in this supervision may therefore be handled by the A&E Department in some hospitals, and on the wards in others. Such duties include taking blood specimens and starting up intravenous fluid management, which will be included in the audit. Even though these tasks may have been performed in the A&E Department, it should be relatively easy to check whether they have been performed or not by examining the patient's medical records. In other words, this kind of verification does not require any interviews or other forms of confirmation from the A&E Department. However, interviewing the person bearing overall responsibility for treating strokes may be appropriate, with a view to establishing the distribution of responsibilities between the stroke unit/ward and the A&E Department.

If the cerebral stroke was caused a blood clot in the brain, thrombolytic therapy may be an appropriate treatment. This type of therapy is only possible if the municipal health service, the pre-hospital unit and the hospital's A&E Department have a well-working collaboration. However, inter-level collaboration is not one of the focus areas of this supervision. Treatment must be initiated swiftly (no later than three hours after symptom presentation), and patients under the age of 18 or above 80 should not be given thrombolytic treatment. We have therefore decided not to include thrombolytic therapy in this supervision.

Having suffered an acute cerebral stroke and undergone initial treatment and early rehabilitation while in hospital, most patients will be in need of further rehabilitation. Such rehabilitation can either be provided by the specialist health services or by the municipal health services, and is not covered by this supervision.

Measures implemented by the hospital in order to plan patient discharges and discharge-related collaboration with the municipality or other units in the specialist health services are not part of this supervision. Nevertheless, in a couple of cases we have pointed out that discharge summaries are appropriate sources for the investigation of the health trust's practice to ensure continuation of necessary treatment.

1.3. Legal basis

In connection with this supervision, it is primarily the requirement to sound services, see Section 2-2 of the Act relating to the Specialist Health Services, etc. (the Specialist Health Services Act) that is pertinent.

The health service is obliged to establish a system for internal control in order to ensure sound services, see the Regulations on Internal Control Systems in Social Services and Healthcare (the internal control regulations). The regulatory requirements to internal control shall ensure that day-to-day work is planned, organised, performed and improved in accordance with the requirements set out in or in pursuance of social and health legislation, in this case specifically Section 2-2 of the Specialist Health Services Act.

Section 5 of the Regulations on Habilitation and Rehabilitation contains a provision regarding patient involvement, see Section 1-3 litra b and Section 3-1 of the Act relating to Patients' Rights (Patients' Rights Act), which is relevant for this supervision as regards early rehabilitation.

National professional clinical guidelines

The Norwegian Directorate of Health's national clinical guidelines for treatment and rehabilitation for cerebral stroke were prepared by the health authorities and the relevant professional communities as a result of a close collaboration. Clinical practice in line with the recommendations issued in these guidelines will promote evidence-based treatment of satisfactory quality for this patient group. This means that if a choice is made to deviate significantly from the recommendations supplied in the guidelines, such decisions must be documented and explained.

The guidelines also include a number of recommendations on the organisation of care. These recommendations are primarily directed at the service provider's management.

1.4. How to interpret and use the guidelines

The requirement to sound quality of services pursuant to Section 2-2 of the Specialist Health Services Act is discussed in Chapter 3. The chapter also details what this means in terms of activities and processes that are covered by the supervision. The requirements to management, organisation and governance set out in the internal control regulations are described in Chapter 2, and discussed and put in concrete terms in relation to the subjects covered by the supervision. Detailed and specific requirements are listed in Chapters 2 and 3. In Chapter 4, these requirements are linked and presented as audit criteria. In order to understand what medically sound treatment means in connection with treating elderly stroke patients, Chapters 2, 3 and 4 must therefore be read together.

In order to assess whether patient treatment is medically sound, all the audit criteria and sub-criteria must be considered jointly. Only once all these pieces are viewed in conjunction with one another, is it possible to identify any non-conformities that clearly indicate the elements of patient treatment that are deficient, or that entail a risk of deficiency, and which elements of the internal control process are not working. See Chapter 4.1.

2. The role of internal control systems for the treatment of elderly stroke patients

Compliance with regulatory requirements to internal control is a prerequisite for medically sound treatment of elderly stroke patients.

Section 4, subsection one, of the Internal Control Regulation states that the service provider's internal control system shall be appropriate for the size of the organisation and its specific nature, activities and risk factors. The scope of the internal control system must be appropriate. It must be comprehensive enough to comply with the requirements set out in or in pursuance of health legislation.

Section 5 of the Internal Control Regulations states that the service provider's internal control system shall be documented in the form and scope that is necessary, based on the nature of the service provider, its activities, risk factors and size. This means that discretion must be exercised in assessing what measures are required, and in considering which procedures must be set out in writing. It is a prerequisite that treatment of elderly stroke patients shall be subject to management, and that the medical soundness of the health services that are provided shall be ensured through systematic procedures and not be contingent on individual persons.

The audit criteria provide the framework for the requirements, but there is scope of action permitting a range of solutions and adjustments. When performing the audit, allowances must be made for this, for instance in connection with the service providers' use of multidisciplinary capabilities. While not all service providers may have a speech pathologist, it is possible to give other professional groups specialised training so that this part of a speech pathologist's responsibilities can be handled by staff members who are not speech pathologists in the acute phase. Alternatively, service providers can purchase speech pathologist services.

2.1. Organisation and planning

It is possible to organise the treatment of elderly stroke patients in a number of different ways within the various health trusts. However, all acute stroke patient shall receive health care that combines acute therapy and rehabilitation with multidisciplinary collaboration and early mobilisation. This type of healthcare is often gathered in a single ward, and often known as the stroke unit.

A stroke unit can consist of a single patient room or encompass an entire department, and may be known under a completely different name. Regardless of how it is organised, the activities and resources associated with this unit within the health trust shall be managed and co-ordinated by the same organisational entity. If the health trust has organised these healthcare services in a manner involving personnel from more than one clinic, this organisational entity may be the health trust's managing director.

Independent of how it is organised and what it is called, the stroke unit shall form an easily recognisable structure with dedicated staff, a clearly identifiable management, well-established procedures and the necessary expertise and skills.

The health trust's management shall, through a working system of internal control, ensure compliance with health legislation, so that elderly stroke patients are given sound medical

care.

The health trust shall have set targets for quality and activity levels for the treatment of elderly stroke patients, and these targets shall be known and reflected in the healthcare given this patient group. An example of a quality target might be that elderly patients with cerebral stroke are to be treated by a multidisciplinary team attending to both medical therapy and rehabilitation simultaneously. Activity targets might describe the number of stroke patients for whom services can be provided in the acute stage, and how an intake in excess of this level will be handled.

2.2. Multidisciplinary treatment teams (management of staffing and competence)

Giving elderly stroke patient sound healthcare in the disease's acute phase requires good multidisciplinary collaboration in all phases of patient care. All elderly stroke patients are to be assessed by a multidisciplinary team that defines treatment and rehabilitation objectives in co-operation with the patient and/or next-of-kin, and draws up and implements a treatment and rehabilitation plan.

The team must have a regular meeting schedule and collaboration structures that provide for multidisciplinary collaboration in therapy and rehabilitation. Everybody in the multidisciplinary team must be familiar with and adhere to the meeting schedules and other forms of collaboration. Furthermore, it must be established which team member is responsible for making decisions and has the authority to do so. The same applies to authority to initiate and follow up a variety of treatment steps, including rehabilitation measures. Everybody in the team must know who does what, and at what times different actions must be carried out. Decisions made in the multidisciplinary team and other pertinent information regarding objectives and treatment of each patient must be passed on to the personnel involved in the work.

The national clinical guidelines for treatment of cerebral stroke and post-stroke rehabilitation recommend that healthcare professionals from the following fields be represented in the multidisciplinary team:

- consultants (neurologist, geriatrician, specialist in internal medicine)
- nurses, including nurses specialised in stroke care
- physiotherapist
- occupational therapist
- speech pathologist

Involving auxiliary nurses/health caregivers or other professional groups in the team may also be appropriate if they are involved in caring for stroke patients. The supervision shall concentrate on whether the responsibilities listed in Chapter 3 are handled in a sound manner. Sound healthcare depends on satisfactory collaboration among the various healthcare professions. One example of multidisciplinary co-operation might be compensating for the absence of a speech pathologist by looking into whether anybody else in the team has had specialised training enabling them to handle some of the speech pathologist's duties, or whether it is possible to purchase speech pathology services.

Staffing levels shall make it possible to perform the duties that must be carried out, day and night, and every day of the week, including holidays and public holidays. This applies

both to the total number of staff on duty, and means that the on-duty staff shall have the expertise and skills required to handle relevant responsibilities and additional duties they may be given. Patients must be offered multidisciplinary healthcare at all times, not only during the daytime on normal working days. This is especially important in treating this patient group, because stroke patients must be assessed by a multidisciplinary team. While one cannot expect the same level of access to qualified staff in evenings, weekends, public holidays and holidays, patient care must be multidisciplinary also outside of regular working hours. Access to physiotherapy and occupational therapy may be limited after regular working hours and on days that are not work days, and physiotherapists and occupational therapists must therefore give priority to those patients most in need of their specialist services. In such situations other professional caregivers may take over some of the physiotherapists' and occupational therapists' duties. Starting up rehabilitation measures may be a case in point. However, if the nursing staff are to carry out specific physiotherapy or occupational therapy tasks, they must be given the necessary training.

Indications of the level of multidisciplinary care given to patients should be found in patient records, minutes/summaries from meetings of the multidisciplinary team, and in patients' rehabilitation plans.

Nurses on such teams have numerous duties related to acute treatment, observation, preventing complications and patient care, some of whom require extensive help and care, stimulation, early mobilisation and rehabilitation. In order to provide effective stroke treatment, all these duties need to be attended to. This is why it is also recommended that the unit has a stroke nurse in charge of continuity, upskilling and co-ordinating nursing. Alternatively, these responsibilities may be handled by a different person. What matters is that the various functions are attended to.

The staff must have special training/specialist qualifications stroke treatment and rehabilitation. In addition, the unit must have a plan for in-house training and upskilling, including multidisciplinary training. Furthermore, it should be clear who is responsible for ensuring that the staff have the relevant expertise and skills. The various functions must have clearly-defined competence requirements, and the staff shall have been trained in their respective duties. The unit must have a plan for training and follow-up of new employees and temporary staff. Everybody on the unit shall be familiar with and understand the adopted procedures, including the service provider's non-conformity system. Only staff who are familiar with the procedures may attend to patients unsupervised. New and temporary staff must be provided additional follow-up.

Shortage of resources poses a risk factor. In order to ensure a sound allocation of resources, the organisation must be aware of any variations occurring in the work load, and such variations must be acted upon in planning shift rotas and other necessary activities.

Change-over from one shift to the next are a potential threat to the continuity of patient care, and must therefore be organised so that all the required information is passed on, and all necessary tasks handed on to the next person. This applies to all staff groups.

The organisation must have made clear who co-ordinates and follows up staff that belong to a different unit in organisational terms, and there must be clearly-defined criteria for the situations in which additional staff and/or staff with different or higher levels of expertise

must be called in. This is also important in situations where some of the stroke treatment is handled in the A&E Department. Treatment given outside of the stroke unit itself and in the A&E Department must also be subject to professional management by the individual(s) responsible for the hospital trust's stroke treatment.

2.3. Facilitating good practice and a multidisciplinary approach to treatment

Hospitals are large organisations that deliver services both day and night, and throughout the entire year. Acute cerebral stroke must be treated swiftly, independent of the time of day it happens. Stroke treatment involves a range of professional groups and more than one unit at the hospital. It is important that newly employed health professionals and temporary staff working in the hospital know how to treat acute cerebral stroke, see Chapter 2.2. This applies also if some of the treatment is handled in the A&E Department, see Chapter 3.2. In order to make sure that elderly stroke patients receive sound treatment, the hospital must have written procedures ensuring the most critical stages in diagnosis, assessment, observation, acute treatment, early rehabilitation and prevention of complications.

Therefore, critical stages in the treatment and rehabilitation pathway must be identified, both generally and for individual patients. Such risk assessment must address problem areas in the treatment of elderly stroke patients. Risk assessments can be based on both knowledge of the sort of problems typically experienced in these type of services, and on issues that are specific to this patient group. For instance, one might undertake a risk assessment of whether early rehabilitation can be implemented as planned.

The measures required to minimise any danger of deficiency shall have been implemented. Such actions include written procedures, training, re-allocating staff, adapting the premises, control measures such as internal audits, and changes to existing procedures. It is important that appropriate priority-setting is ensured, and that priorities are set in line with the health trust's outcome and activity targets for the treatment of elderly stroke patients. Furthermore, there must be systems to ensure that appropriate health professional capabilities are employed.

All staff shall be familiar with their responsibilities and have clear authorities that plainly outline their responsibilities and authorities. The descriptions of the various functions should be set out in writing. As a minimum, this applies to those duties considered critical in patient treatment and where there is a danger of deficiency.

Routines, procedures and other necessary measures based on national clinical guidelines shall be established. In the event of practice deviating from the above, such deviation must be substantiated by valid arguments. Routines, procedures and other necessary measures shall be unambiguous and adapted to the capabilities of the staff involved. The routines and procedures that are adopted shall be well-known among the staff, who shall comply with these. The routines and procedures shall work, regardless of who is on duty. Risk assessments based on the complexity and degree of urgency in the work process, as well as on the staff's educational qualifications and experience, in-house training and staff turnover, all play a role in determining whether procedures must be set out in writing or not. This is an area where service providers are at liberty to draw their own conclusions and act accordingly.

2.4. Non-conformity processing

The health trust shall have a working non-conformity system that monitors and identifies, corrects and prevents any deficiency or danger of deficiency in the treatment of elderly stroke patients. Such a non-conformity system can consist of non-conformity forms, improvement forms, books for reporting, evaluations or meetings, for example. If any deficiencies are found or known, this shall lead to improvements in patient treatment. Any non-conformities must be managed systematically so that the health trust learns from errors that are identified. Serious cases of patient harm shall be reported and addressed; in addition, any failures in the day-to-day routines must be detected, reported and addressed.

Creating an organisational culture characterised by transparency in the face of deficiencies, errors and inadequacies is not easy. Priority shall be given to non-conformity processing, and the organisation shall work on such processing on an ongoing basis with a view to ensuring that the services provided are sound. Everybody providing health services to elderly stroke patients shall be familiar with the stroke unit's or ward's procedures for non-conformity processing, and report any non-conformities. The leaders shall monitor and take action to correct any non-conformities. It is also a leadership responsibility to ensure that the corrective measures have the intended effect and that procedures are changed when required. Non-conformities that are not corrected at the appropriate level within an acceptable time frame or that involve more than one unit/actor, need to be handled at a higher level within the organisation.

2.5. The management's assessment as to whether the treatment provided to elderly stroke patients is sound, and action in response to such findings

It is the responsibility of the health trust's uppermost management to ensure that framework conditions facilitate care for elderly stroke patients in compliance with regulatory requirements in health legislation. The uppermost management also carries responsibility for compliance with general treatment objectives. Clinic and department heads shall monitor and be familiar with the actual day-to-day situation, and implement any measures that may be required. The management shall ensure that compliance with the adopted targets and procedures is controlled systematically, all with a view to ensuring that the treatment provided to this patient group is medically sound. This can be done in a variety of ways, including random checks, evaluations, internal audits and management reviews (strategic meetings). Another component of management follow-up is a well-functioning non-conformity system.

3. Medically sound treatment of elderly stroke patients

3.1. General points on stroke

There are just under 15 000 new cerebral strokes every year in Norway. Of these, 11 000 are first-time strokes, and about 3 500 are repeat strokes. In 2007, 11 056 patients were admitted to hospital with acute cerebral stroke. On average, the patients spent 11.5 days in hospital. Median time spent in hospital was 5-6 days (6).

Although mortality across the population following stroke has fallen over the last few

decades, the age-related occurrence of new strokes appears to be relatively stable. Because the population is aging, the number of stroke cases is expected to rise in the next few years, with a 50% increase in the occurrence of cerebral strokes expected in the period up to 2030. (7)

About 85% of strokes are caused by a cerebral infarction (ICD-10 code I63)³, and approximately 10% follow from brain haemorrhages (ICD-10 code I61). This guidance document addresses treatment for both categories.

Risk factors

The occurrence of cerebral stroke rises significantly with age. 65% of all strokes affect patients above the age of 75. The risk is somewhat higher for men than for women. Despite this, in absolute figures more women than men are affected, because women live longer.

The most important modifiable risk factor for stroke is high blood pressure. Other risk factors include smoking, diabetes, overweight, atrial fibrillation, hyperlipidaemia (for cerebral infarction), carotid stenosis (constriction of the carotid artery), low socio-economic status and high levels of alcohol consumption. It is likely that genetic factors play a role as well. Studies have shown that having a first-degree relative who has had a stroke gives a 30% greater risk of having a stroke oneself. (8)

Outlook

Mortality within the first month of a stroke is 15-20% (2) and up to 20% of stroke patients have to move to a nursing home after they fall ill. A third of stroke survivors experience a significant decline in their functioning ability, making them dependent on help from others in activities of daily living (ADL). Approximately another third of stroke survivors undergo a decline in their ability to function, but become mostly self-reliant. One third of surviving patients recover entirely or almost entirely. (3)

The long-term consequences of the stroke depend in great measure on how much of the brain is damaged, and where the damaged area is situated. The most common effects of stroke are paralysis in parts of the body, speech problems and cognitive impairment (sensory disturbance, understanding and reasoning). An important purpose of rehabilitation is limiting the long-term effects of the stroke through helping the patient make optimal use of their residual functioning ability.

Patients that have had a cerebral stroke are at significant risk of having a secondary stroke. The risk is about 10% in the first year after a cerebral infarction, followed by a 5% annual risk of suffering another stroke. Overall, the risk of having a secondary stroke after a cerebral infarction is 30% over a five-year period. (3)

Patients who have survived a cerebral infarction are also at greater risk of other vascular events, such as heart attacks. Secondary prevention of cerebral stroke has been shown to be very useful, bringing down risk with as much as 50 to 70%. (9)

³ ICD-10 is an international classification of diagnoses. The specialist health services are obliged to use this in order to provide a basis for statistics.

3.2. Observation, assessment and medical treatment during the first 24 hours after hospital admission

As mentioned in Chapter 1.2, this supervision does not address the treatment given to stroke patients in the A&E Department. However, our review of patient records may include evaluation of certain tasks performed in the A&E Department, if the hospital's organisation of patient care makes this necessary. However, there is no need to do interviews or perform other forms of verification in the A&E Department. In some cases an interview of the person bearing overall responsibility for stroke treatment may be appropriate, with a view to establishing the distribution of responsibilities between the stroke unit/ward and the A&E Department.

It is very important that each hospital has clear, written and well-established guidelines/procedures for who is responsible for the various duties, and for the collaboration between the A&E Department and the stroke unit or ward. See Chapters 2.2 and 2.3.

Part of the assessment of and medical treatment for cerebral infarction and cerebral haemorrhage are identical. Where treatment and assessment for the two conditions differ from one another, this will be clearly indicated in the text.

3.2.1 Observation

Physiological homoeostasis

According to the national clinical guidelines, the objective of general observation and treatment in the patient's acute phase is to stabilise physiological homoeostasis in the patient. In other words, one wants to make sure that basic functions such as breathing, oxygen saturation, blood pressure, pulse, fluid balance, electrolyte balance, pH and blood sugar are within the normal range. Keeping these functions stable is especially important for patients with acute cerebral stroke. Optimising the supply of oxygen and nutrients etc. to the brain will help preserve the cells in the vicinity of the injured area.

Respiration, oxygen saturation, blood pressure, pulse, fluid balance, temperature and blood sugar must be observed for all new stroke patients for at least the first 12 to 24 hours, and longer for patients who are unstable. The national clinical guidelines do not provide any clear guidance for how closely patients shall be monitored, or for how long. This supervision reviews the observations made in the first 24 hours after the stroke.

Respiration and oxygen saturation

Respiratory distress is common in patients with acute cerebral stroke. Approximately 60% of all patients with acute cerebral stroke develop hypoxia (meaning that the blood's oxygen saturation falls below 95%) during the first 24 hours after onset. The blood's oxygen saturation level must be measured and assessed several times per 24-hour period for patients with acute cerebral stroke.

Blood circulation (blood pressure and pulse)

In the acute phase, optimising the brain's blood supply is crucial. Regular measurements of blood pressure and pulse are therefore an integral part of the observation of stroke patients. Both high and low blood pressure can lead to adverse consequences for the patient, and are associated with a decline in the patients' functioning ability. Existing studies do not indicate that lowering blood pressure should be standard procedure for all

patients with acute cerebral stroke.

All patients with acute cerebral stroke must have their blood pressure monitored.

Fluid balance

About half of all stroke patients are dehydrated when admitted to hospital, or shortly after admission. Dehydration increases mortality in stroke patients, and patients' fluid balance must therefore be stabilised by providing them with intravenous fluids during the first 24 hours after the event.

Temperature

During the first 24 hours the patient's body temperature must be taken and assessed several times. Body temperatures above 37.5° C within the first 24-48 hours after the onset of symptoms of cerebral stroke are linked with increased mortality and lower post-stroke functioning ability.

Blood glucose

Elevated blood glucose is associated with a poorer outcome. This is the case both for patients with diabetes and those who do not have diabetes. According to the clinical guidelines, patients' blood glucose must therefore be checked and assessed regularly, a minimum of four times in the first 24 hours. Patients exhibiting very high or low levels must be checked more frequently.

Neurological status

Shortly after admission to hospital, the patient must be examined for neurological deficits. This examination may be performed in the A&E Department in some hospitals, and in the stroke unit/ward in others. Assessment scales must be used so it is not left up to the individual staff member to decide how to perform the assessment.

There are several assessment scales being used, all of which cover the core elements consciousness, speech and motor function. Using the simple tool SSS (Scandinavian Stroke Scale) the assessment takes less than five minutes (10). NIHSS (National Institute of Health Stroke Scale) is a little more comprehensive (11). These are tools that can be used by physicians, nurses and other therapists. Use of these specific tools is not mandatory; however, the tools that are used must be based on clinical research and must be recognised.

3.2.2 Assessment

The brain and its blood supply

Providing that they are able to go through with the examination, patients arriving at the hospital with symptoms of acute cerebral stroke must immediately be assessed with Computer Tomography (CT) or Magnet Resonance Imaging (MRI). The primary reason for this is to differentiate between an infarction and a haemorrhage. Doing a CT scan can be difficult if the patient is agitated, suffers from claustrophobia or has difficulties lying on their back. Doing an MRI is even more difficult in such circumstances.

The images must be evaluated at once by a radiologist or by a physician with experience in treating stroke patients. This must be done around the clock, throughout the entire week, and also on public holidays and holidays. In some places the evaluation of these images is done via telemedicine. Swiftly and correctly diagnosing cerebral stroke requires close collaboration between the receiving physician, the radiologist and physician

specialised in the treatment of cerebral stroke. Such collaboration requires well-established procedures and/or practice outlining the details in such co-operation.

The heart

An Electrocardiogram (ECG) done shall be done on all patients.

In the initial period, the heart rate of all patients with acute cerebral stroke shall be checked at regular intervals. Assessment needs are defined by the patient's condition and can range from registering the patient's pulse to continuous ECG monitoring. If atrial fibrillation is suspected, the heart rate should be monitored for no less than 24 hours.

Depending on the patient's needs, further cardiovascular examinations may be done.

Swallowing difficulties (dysphagia)

Screening stroke patients for difficulties in swallowing (dysphagia) should be routine procedure, and must always be done prior to giving food or drink by mouth (per-oral food or liquid intake). There are different ways of screening for difficulties in swallowing. However, each hospital/ward must have a standardised and well-established procedure for how this is done, so that deciding this is not up to the personnel in question. Everybody must know who is in charge of such screening, and screening must be performed by healthcare professionals with adequate training for this task. For further follow-up of dysphagia, see Chapter 3.4.2.

Language and speech difficulties

Screening and assessing language and speech function is mostly done after the first 24 hours. However, language and speech issues are so important that they have been included as subjects in this supervision.

Language and speech difficulties are relatively common in patients with cerebral stroke. While some patients experience a spontaneous improvement in the first few days after the stroke, this is not always the case. There are different types of language and speech difficulties, with aphasia and dysarthria being two common types.

Aphasia is impairment in language function that arises after a patient has suffered a brain injury, occurring in approximately 25% of all stroke patients. Aphasia is caused by damage in those areas of the brain that govern language function, and is characterised by difficulties in both understanding and using spoken and written language normally.

Dysarthria is a generic term for speech difficulties caused by paralysis, weakness or lack of co-ordination of the muscles involved in speech production. Patients with dysarthria have trouble articulating words clearly, but are often able to communicate through the use of writing.

All cerebral stroke patients must be screened for language and speech difficulties early on. This can be done by talking with the patient and using an appropriate screening instrument. As mentioned above, tools such as the SSS and the NIHSS can both be used for simple identification of language and speech difficulties. However, use of these specific tools is not mandatory. There is a requirement that each hospital/ward must have a standardised and well-established procedure for how this is done; deciding how to screen patients shall not be left up to the staff member in question. This type of screening establishes whether the patient has any impairment in his or her language and speech

function that was not formerly present. There is no requirement that such screening must be carried out by a speech pathologist; screening can be handled by other professional groups, such as nurses and occupational therapists who have been given appropriate training.

If language and/or speech difficulties lasting beyond the first few days are identified, patients must be referred to a speech pathologist for further assessment of language and speech function. Other staff with special training may handle some parts of this process, but only up to a certain point. A speech pathologist must be involved in this sort of assessment. If the hospital does not have a speech pathologist and is therefore unable to proceed with further assessment of the patient's language and speech difficulties, the service provider that assumes responsibility for the patient after he or she is discharged must be notified of this. This information must be provided in discharge summaries sent by the hospital to the G.P. and other partners the hospital collaborates with.

3.2.3 Treatment

Antithrombotic treatment

Before any antithrombotic treatment is started, it must be established that the cerebral stroke was not caused by a cerebral haemorrhage. This is done on the basis of a CT or MRI scan.

Drugs used in antithrombotic treatment are antiplatelet agents (acetylsalicylic acid – often abbreviated as ASA –, dipyridamole, clopidogrel) or anticoagulants (heparins and warfarin). However, these drugs also entail an increased risk of bleeding. The benefits of antithrombotic therapy must therefore be balanced against the risk of bleeding.

Antiplatelet agents (the most commonly used are ASA) are recommended as initial treatment for acute cerebral stroke. Treatment with ASA within 48 hours reduces the likelihood of a recurrent cerebral infarction by 30%, without any corresponding rise in the risk of haemorrhage (within or outside of the brain).

All patients suffering an acute cerebral infarction shall be treated with a one-off dose of ASA (up to 300 mg), providing there are no contraindications. The treatment should be administered as early as possible, and within the first 48 hours according to the national clinical guidelines. This also applies to patients who used ASA before they had a cerebral stroke. (Also see further details on antithrombotic treatment in the section on measures for secondary prevention, see Chapter 3.4.4 Treatment.)

3.3. Early rehabilitation

3.3.1 General points

Early rehabilitation is a complex process. Multidisciplinary team work is key to a good outcome.

Early mobilisation and rehabilitation have a preventive effect on a number of complications associated with immobility (deep vein thrombosis, pulmonary embolism, pneumonia, bedsores).

Early mobilisation and rehabilitation shall also be provided for elderly patients with cerebral stroke who are not given a place in a stroke unit, but placed in a different ward for shorter or longer periods. The multidisciplinary mobilisation and rehabilitation services provided for these patients shall be on a par with those given to patients in a stroke unit.

This supervision examines early mobilisation and rehabilitation during the initial hospital stay after the patient experienced an acute cerebral stroke. What is done in subsequent rehabilitation is not within the remit of this supervision.

3.3.2 Early mobilisation and rehabilitation

Early mobilisation is a cornerstone in cerebral stroke rehabilitation, and must form part of treatment, regardless of whether the cerebral stroke was caused by a haemorrhage or an infarction (12).

Survival is unambiguously associated with early mobilisation. Patients should therefore be mobilised as soon as they are medically stable, and as a rule within the first 24 hours. If mobilisation is put off until after the first 24 hours, the medical grounds for this must be stated.

When considering patients' mobilisation possibilities, their overall situation must be taken into account. An assessment must be made regarding when mobilisation can be started, and what measures are appropriate for each patient.

Elevated blood pressure or a noticeable drop in blood pressure when the patient is mobilised may be grounds for putting off patient mobilisation. The hospital must have procedures and/or well-established practice for what assessments to make, and what measures to implement based on the patient's situation. There must be no doubt as to who is responsible for making decisions on each patient's mobilisation: whether, and to which extent a patient should be mobilised. Such questions must also be settled for weekends, public holidays and holidays, in order to avoid patients being left lying in bed longer than is necessary. Patients shall not have to await clarification of such issues. Early mobilisation can range from simple movements in bed, sitting on the edge of the bed, or participating in simple day-to-day activities, such as getting washed and dressed.

All members of the multidisciplinary team must do their part in mobilising patients as early and at every possible opportunity.

Early mobilisation is the first step in the patient's rehabilitation process.

In addition to the initial mobilisation activities outlined above, a rehabilitation process containing clearly defined objectives must be embarked on. Early planning of the patient's rehabilitation and defining objectives for rehabilitation are an important element of stroke treatment.

Section 2 of the Regulations on Habilitation and Rehabilitation defines rehabilitation as follows: *Habilitation and rehabilitation are planned processes within defined, limited time frames that have clear objectives and are achieved by clearly understood means. In these processes a number of players collaborate to provide users with the assistance they require in their efforts to achieve optimal functioning ability, mastery, independence and*

social activities as well as participation in society at large.

This is also the definition used in the national clinical guidelines for the treatment and rehabilitation of cerebral stroke.

The objective of post-cerebral stroke rehabilitation is to help patients recover their ability to function or to compensate for their loss of functions, thus improving their quality of life and reducing their need of help from others. The guidelines emphasise that task-related training is of primary importance in the initial phase. In other words, patients must primarily train for the day-to-day tasks they are no longer able to perform themselves, such as personal hygiene, eating and drinking, going to the toilet, language and communication. These everyday, natural situations are therefore key arenas that must form part of patients' post-stroke training. The rehabilitation process must have clearly-defined objectives and measures. The process must be evaluated regularly and goals and measures must be adjusted as required. A co-ordinated approach from a specialised, multidisciplinary team that co-operates with the patient is essential if the patient is to undergo successful rehabilitation.

The multidisciplinary team must have a clear distribution of responsibilities and duties for the tasks involved in the rehabilitation process. Furthermore, the way in which the multidisciplinary team should collaborate must be set out clearly, involving regular meetings and other arenas for collaboration for each patient. Also see Chapter 2.2.

A genuine multidisciplinary effort must be evidenced in multidisciplinary collaboration arenas and documented in patient records, minutes/summaries from multidisciplinary team meetings, as well as the preparation, implementation and evaluation of rehabilitation plans.

Patient participation is of great importance in the rehabilitation process. Section 5 of the Regulations on Habilitation and Rehabilitation establishes that the hospital shall *ensure that each patient is given the opportunity to participate in effecting their own habilitation and rehabilitation services, see Section 1-3 litra b and Section 3-1 of the Patients' Rights Act. Effecting in this context means to plan, frame, perform and evaluate.* Patients and if appropriate the next-of-kin shall therefore be involved throughout the entire rehabilitation process.

The stroke unit or ward must have procedures/measures that ensure genuine user participation. Steps to provide for user participation must be outlined and stated clearly in the preparation, implementation and evaluation of each patient's rehabilitation plan.

Identifying and assessing rehabilitation needs and potential

Functional deficits after acute cerebral stroke vary depending on which area of the brain has been affected, and on how much of the brain has been affected. Deficits can affect either bodily functions (paralysis, sensory disturbances, sensory organ failure, dysphagia, speech impairment, incontinence) or mental function (cognitive problems, mental health symptoms). The need and usefulness of rehabilitation may vary, and must therefore be individually determined based on the needs of each patient. As a rule, all patients who have suffered acute cerebral stroke require rehabilitation. The fact that patients are very old or already live in a nursing home shall not serve as criteria for excluding patients from such rehabilitation. A few patients with extensive neurological deficits and very limited life expectancy, may, however, not be likely to benefit from rehabilitation. These

patients are in need of satisfactory nursing and care (12).

Identifying the patient's rehabilitation potential is necessary in order to assess the extent to which the patient will be able to benefit from rehabilitation. Early identification and assessment of the patient's resources and limitations as regards physical, cognitive and social function is therefore needed, with assessment of patient needs and potential being tailored to the individual patient. There is no single assessment tool that covers all aspects of post-cerebral stroke rehabilitation. The guidelines present some of the instruments that are commonly used in Norway and internationally (see p. 104 of the guidelines). The Norwegian Board of Health Supervision does not require that specific assessment tools are used. However, each hospital must have made a decision as to which tool it wishes to employ, and the tools used must be standardised and based on clinical research. The hospital must also ensure that the professionals who are to use these tools have sufficient training to ensure that they are used professionally and correctly.

At an early point in the patient's treatment pathway, the hospital must gather information on the patient's pre-stroke situation. It may be necessary to learn more about the patient's physical and mental health, living arrangements, social network and possibly their need for assistance and measures related to such needs.

Based on the assessment of the patient's situation and the facts, the patient's rehabilitation needs and potential are assessed. Personal factors, such as the patient's motivation and coping strategies must also input into this type of assessment.

Rehabilitation plan

Once rehabilitation needs and potential have been assessed and evaluated, a rehabilitation plan must be drawn up. This plan must outline the rehabilitation objectives and the specific measures to be implemented. Objectives and measures must be individually adjusted to the situation and wishes of each patient. Furthermore, the plan must be evaluated at regular intervals, and objectives and measures adjusted as required. Rehabilitation plans must be drawn up by the multidisciplinary team in co-operation with the patient and, if applicable, their next-of-kin.

There is no requirement that the rehabilitation plan take the form of a dedicated document. However, the objectives, measures and any adjustments to the plan must be documented in a manner that allows their use in the day-to-day implementation and follow-up of the patient's rehabilitation process.

The rehabilitation plan must be entered in the patient's overall medical records.

Rehabilitation is a process that must take place day and night, on all weekdays, and also on public holidays and during the holidays.

This supervision investigates whether a plan specifying objectives and measures has been drawn up, and whether this plan has been evaluated and, if required, adjusted. This supervision does not include reviewing the clinical content of the objectives, measures and evaluations.

3.4. Preventing complications and secondary cerebral strokes

3.4.1 General points

60-80% of all stroke patients experience complications in the disease's acute phase. Some of these complications can be life-threatening and/or endanger the patient's possibility of improving their functioning ability. However, in many cases complications can be prevented through relatively simple measures.

This supervision examines whether the hospital makes sure that its strategies to prevent complications are medically sound, and whether the hospital implements preventive treatment in order to prevent secondary strokes. In this supervision, we have decided to review two complications that occur quite frequently in connection with acute cerebral stroke, and that can have serious consequences: complications due to swallowing difficulties and bedsores.

3.4.2 Complications due to swallowing difficulties (nutritional problems and aspiration pneumonia)

Swallowing difficulties (dysphagia) are common in the acute phase after a cerebral stroke (13). Such difficulties can lead to the patient not getting enough nourishment through food and drink, and unless appropriate measures are taken, patients are in danger of undernourishment. Swallowing difficulties can also result in food and drink entering the airway instead of the oesophagus. This is known as aspiration and can lead to pneumonia (aspiration pneumonia).

If a patient has been diagnosed as having problems swallowing, the cause of the problem and its severity must be assessed. Swallowing difficulties can range from total pharyngeal paresis to less serious swallowing problems. Next, relevant measures must be considered and started in order to – if possible – train the patient's swallowing function and to ensure that the patient receives adequate nourishment.

If patients only have moderate swallowing problems, adjusting eating or drinking arrangements may be all that is required, alternatively adapting the presentation of food and drink (e.g. consistency and nutritional content of food and drink). Patients with more serious swallowing difficulties may require further assessment, more comprehensive measures and possibly swallowing training. Nurses may carry out patient training during meals or when engaged in basic patient care; speech pathologists or other professionals with relevant qualifications or training can provide patients dedicated training. Patients can also do exercises on their own. All professional groups who play a role in re-training patients' swallowing function must have had training in this.

The supervision does not consider whether the various measures are clinically appropriate, or whether each measure is the "right" one for the patient in question. The supervision reviews the procedures surrounding patient treatment, i.e. the fact that measures are considered, initiated, and, if necessary, adjusted.

If a patient has severe and lasting trouble swallowing, alternative manners of administering nourishment to the patient must be considered and embarked upon. For patients with severe dysphagia lasting more than 24 hours, the national clinical guidelines recommend alternative forms of administering nourishment. Use of a nasogastric tube (a

feeding tube that is passed through the patient's nose and oesophagus into the stomach) is recommended for the initial period. PEG tubes (a feeding tube that is surgically implanted and goes directly from the wall of the abdomen to the stomach) are not recommended in the first three to four weeks.

Aspiration pneumonia

Dysphagia is common in the acute phase after a cerebral stroke, and can lead to a number of complications. Aspiration pneumonia is a type of pneumonia that develops because food or drink enters the airways rather than the oesophagus. The risk of pneumonia rises threefold for patients with swallowing difficulties, and patients who have had aspirated drink or food are eleven times more likely to develop pneumonia (13). Screening for and detecting any swallowing difficulties early on is therefore of great importance.

Aspiration pneumonia usually occurs within the first four days of the cerebral stroke. The clinical guidelines cite dysphagia screening and early mobilisation as measures to prevent aspiration pneumonia. If the patient is shown to have an infection, treatment with antibiotics must be started.

A rise in temperature can be an early sign of infection, and the patients' temperature should be taken several times daily in the acute phase, until their situation has stabilised. See Chapter 3.2.1. However, it is important to remember that elderly persons do not always run a temperature when they have pneumonia; other symptoms such as feeling in poor health may be the most obvious sign of illness. Patients that have a temperature above 38 degrees and/or are feeling unwell must be examined and assessed in order to establish whether they may have (or to rule out) pneumonia. The assessment must include a clinical examination and in some cases a radiological examination, as well as blood tests (to measure infection parameters such as CRP and leukocyte counts). In the event of any positive findings, antibiotics must be administered intravenously without any delay.

3.4.3 Bedsores or pressure ulcers (decubitus ulcers)

If the stroke leads to motor deficits, the patient may become so immobilised that he or she is at risk of further complications, including pressure ulcers or bedsores. The length of time the skin can be exposed to pressure before developing pressure ulcers varies from person to person, but there is an increased risk of tissue damage from as early as two hours. (14) Patients are at particular risk of bedsores during the first ten days of immobility. (15)

Due to common age-related changes, such as reduced blood circulation, thinner epidermis and lower elasticity and sensibility, elderly persons are generally more vulnerable to skin injuries. Moreover, patients that are hospitalised with cerebral stroke may have been bedridden prior to the stroke, for unrelated reasons. Incontinence, reduced general health and poor nutritional status all increase the risk of bedsores. (14)

This supervision assesses whether the hospital has procedures to ensure that steps are taken to prevent pressure sores in patients with acute cerebral stroke. The supervision will not consider whether the measures implemented are the "right" ones from the point of view of each patient's situation. Treatment of pressure sores is not covered by this supervision.

Predicting pressure ulcer risk

Soon after being admitted, patients must be assessed for their risk of developing bedsores, and assessments must be performed at regular intervals throughout their hospital stay. Different instruments have been developed for this, including the Braden scale for predicting pressure ulcer risk. (16) This type of assessment considers the following factors: physical level of activity and the degree of immobility, reduced sensory perception and ability to react to stimuli, nutritional status, cognitive function, and the skin's exposure to moisture, as well as friction and shear. The skin in the areas at risk must be checked regularly in order to check for early signs of bedsores.

The Norwegian Board of Health Supervision does not require use of certain, specific assessment scales, but assessment must be systematic and based on clinical research.

Furthermore, it must be clear who is responsible for assessing patients' risk of pressure sores.

Preventing pressure ulcers

Measures may vary, and must be suited to each patient's situation. The patient records may contain entries regarding measures to prevent bedsores such as the following:

- Relieving pressure on exposed areas,
- Hygiene and care for skin in exposed areas,
- Activity and early mobilisation (see Chapter 3.3).

Relieving pressure

Given that the primary cause of pressure ulcers is persistent pressure on the skin, one of the first steps is to relieve those parts of the body most likely to be subjected to such pressure.

Many places use so-called "turn sheets", indicating times for re-positioning of the body. Staff members tick and sign off on these sheets when the patient has been re-positioned. Other actions to provide pressure relief are pressure-relieving mattresses for the patient's bed/chair, and aids designed to relieve the body areas at risk of pressure sores.

Hygiene and skin care in areas at risk of pressure sores

In order to prevent pressure ulcers, patients' skin must be kept clean, supple and dry. This is done through normal skin hygiene, and by moisturising patient skin with suitable lotions and ointments.

Activity and early mobilisation

Being inactive and immobile leads to reduced blood flow to the skin and subcutaneous tissue. This, in turn, increases the risk of pressure ulcers. Early mobilisation and activation soon after the cerebral stroke helps prevent pressure ulcers (see Chapter 3.3).

3.4.4 Secondary prevention therapy

Patients that have had a cerebral stroke are at significant risk of having a secondary stroke. Patients who have survived a cerebral infarction are also at greater risk of other vascular events, such as heart attacks. Secondary prevention of cerebral stroke has been proven to bring down the risk by 50 to 70%. (9)

Because of the potential benefits resulting from appropriate secondary prevention, all cerebral stroke patients must be assessed with a view to identifying the cause of their

disease, so that their risk profile can be determined.

The scope of the assessment must be tailored to the condition and capacity of each patient, the clinical picture, age and any other diseases. The patient's ability to function prior to the stroke must be considered. However, the chief emphasis must be on identifying those circumstances that are most important for secondary prevention. For stroke patients, this is primarily blood pressure, cholesterol, atrial fibrillation and diabetes.

This supervision is to examine whether the hospital appropriately assesses possibilities for implementing secondary prevention measures, as well as whether such measures are initiated. The supervision does not focus on which specific measures are implemented. In other words, the supervision will not consider whether the measures implemented are the "right" ones from the point of view of each patient's situation. Patients only spend a short period in hospital following an acute cerebral stroke, and measures frequently have to start and/or continue after the patient has been discharged from hospital. If this is the case, it is important that the findings from patient examination and assessment, and any measures that have been started, are communicated to the service provider that will attend the patient after he or she is discharged, where the measures will be started and/or continued. The discharge summaries sent by the hospital to the G.P. and other partners with which the hospital collaborates must contain details on such measures.

Blood pressure

The most important modifiable risk factor for a new stroke is high blood pressure. This applies to both cerebral infarction and brain haemorrhage. Chapter 3.2.1 discusses therapeutic regulation of blood pressure in the initial period following the cerebral stroke. Patients often have elevated blood pressure in the immediate period after an acute cerebral stroke. This is why blood pressure measurements taken somewhat later, once the patient's condition has stabilised, are more important in assessing the need for further drug-based blood pressure treatment. As soon as patients have stabilised, achieving control of the patient's blood pressure is an important treatment objective.

Cholesterol

Cholesterol-lowering treatment with statin drugs has a preventive effect, both against new cerebral infarctions and other arteriosclerotic diseases.

Antithrombotic treatment and atrial fibrillation

All patients with cerebral infarction must be assessed for long-term antithrombotic treatment with anti-platelet agents (ASA, dipyridamole, clopidogrel) or anti-coagulants (warfarin).

The treatment for patients with acute cerebral infarction who also experience atrial fibrillation is ASA initially; this is then changed to anticoagulant treatment (warfarin), providing there are no contraindications.

Diabetes (diabetes mellitus)

Diabetes is a risk factor for second cerebral strokes. Stroke patients who also have diabetes must therefore be given treatment to stabilise their blood sugar levels until these are at a level that is medically sound.

4. Audit criteria

4.1. General points

The supervision shall review whether the specialist health services provide sound treatment to elderly stroke patients.

Chapter 4.2 establishes audit criteria that link the statutory requirements discussed in Chapter 2 (internal control) with those set out in Chapter 3 (treatment of elderly stroke patients). The supervision shall examine whether the service provider's internal control activities ensure:

- Observation, assessment and medical treatment during the first 24 hours after admission to hospital,
- Early rehabilitation,
- Preventing complications and subsequent cerebral strokes.

A visual representation of this is provided in the figure below, with the horizontal line depicting the internal control activities outlined in Chapter 2, and the vertical line depicting the clinical services described in Chapter 3. In practice, this means that all the requirements along the horizontal line must be assessed in relation to the services listed along the vertical line.

Ik Stroke tr.	<u>Chapter 2.1:</u> Organisation and planning	<u>Chapter 2.2:</u> Multidisciplinary treatment teams	<u>Chapter 2.3:</u> Facilitation processing and good practice	<u>Chapter 2.4:</u> Non-conformities processing	<u>Chapter 2.5:</u> The management's review and response [action]
<u>Chapter 3.2:</u> Obs., assessment and med. treatment	Audit criteria				
<u>Chapter 3.3:</u> Early rehabilitation					
<u>Chapter 3.4:</u> Preventing complications and secondary strokes					

Any given criterion

does not necessarily represent a single non-conformity, but may instead indicate a major deficiency or risk of major deficiency. In order to gauge whether treatment is medically sound, the health trust's treatment of elderly stroke patients must be assessed in relation to all the audit criteria. This representation will indicate how the health services are led, organised and managed, and thus also which areas are not adequately ensured through internal control activities.

The non-conformities shall not be described more extensively than what is appropriate, based on the findings. Non-conformities that are identified shall be thoroughly

substantiated, and have legal authority both in Section 2-2 of the Specialist Health Services Act and Section 4 of the Internal Control Regulations, as well as, if applicable, in Section 5 of the Internal Control Regulations. If other statutory authorities shall be referenced in addition, this is specifically indicated under the audit criterion in question.

4.2. Audit criteria

1. Services to elderly stroke patients are organised and planned in a manner that ensures medically sound treatment in the disease's acute phase, and early rehabilitation (see Chapter 2.1).

- The management ensures that the statutory requirements in health legislation are complied with so that the health services given to elderly stroke patients are medically sound. This is ensured through the service provider's internal control system.
- The activities and resources for the treatment and rehabilitation of elderly stroke patients are managed and co-ordinated by the same organisational entity. There is no ambiguity as to the line of responsibility within the organisation.
- Independent of how it is organised and what it is called, the stroke unit shall form an easily recognisable structure with dedicated staff, a clearly identifiable management, established procedures and the necessary expertise and skills.
- The health trust has laid down quality and activity targets for the service provider. The service provider's staff are familiar with these targets and this is reflected in the care given this patient group. An example of a quality target might be that elderly stroke patients are treated by a multidisciplinary team attending to both medical therapy and rehabilitation simultaneously. Activity targets might describe the number of cerebral stroke patients for which the service provider can provide acute therapy (capacity), and how an intake in excess of this level is handled.
- The care given to elderly stroke patients involves acute treatment and early rehabilitation. Both treatment and rehabilitation are provided through multidisciplinary collaboration.

2. Elderly stroke patients are assessed and followed up by a multidisciplinary treatment team in order to ensure medically sound acute treatment and early rehabilitation (see Chapter 2.2).

- The health trust ensures that the necessary personnel is available, and that the personnel has the appropriate expertise and qualifications to ensure medically sound acute treatment and early rehabilitation.
 - Staffing levels, the on-duty staff's capabilities and a multidisciplinary approach to treatment and rehabilitation are adequate and appropriate for the tasks that must be performed day and night, all days of the week, and during holidays and on public holidays.
The treatment team consists of physicians(s), nurse(s), a physiotherapist, an occupational therapist and a speech pathologist. Alternatively, other health personnel have had special training, enabling them to handle some of the tasks of the speech pathologist, the occupational therapist and the physiotherapist.
 - Furthermore, it should be clear who is responsible for ensuring that the staff have the relevant capabilities at all times. The organisation must be aware of any variations in the work load, and such variations must be acted on in planning shift rotas and other necessary activities.
 - The various functions' competency requirements are clearly defined. The staff

- have had specialised training/specialised capabilities in the treatment and rehabilitation of stroke patients.
- The service provider must have a plan for training and follow-up of new employees and substitute staff, and a plan for in-house training and other forms of upskilling. The plans are implemented and facilitate multidisciplinary co-operation.
 - The organisation must have made clear who co-ordinates and follows up staff belonging to a different unit in organisational terms, and there must be clearly-defined criteria for the situations in which additional staff and/or staff with different or higher capabilities must be called in. This is also the case in hospitals where the A&E Department handles some of the stroke treatment.
 - The treatment team has a meeting schedule and co-operation structures that ensure cohesive multidisciplinary co-operation on the objectives, implementation and evaluation of treatment and rehabilitation.
 - Furthermore, it is clear which team member is responsible for and has the authority to decide on, carry out and evaluate treatment, including rehabilitation measures. All team members must know who does what, and when these actions must be performed.
 - Pertinent information and decisions from the multidisciplinary team must be passed on to the appropriate staff members working with the patient in question.
 - Patient handovers are organised so that necessary and relevant information from all staff groups is passed on, and that necessary tasks are carried out by the next shift coming on duty.

3. The service provider facilitates good practice: critical steps have been identified and the necessary measures have been implemented to ensure sound treatment of elderly stroke patients in the acute phase and early rehabilitation (see Chapter 2.3).

- Risk assessments have been performed in order to identify critical steps in the treatment and rehabilitation pathway for elderly stroke patients. Risk assessments are based on issues such as the complexity and degree of urgency of the work process, the personnel's education and experience, in-house training and personnel turnover.
- The health trust makes use of patients' and next-of-kin's experiences in its work to improve services. Systems to obtain such information have been established, such as complaint processing procedures, surveys, and systematic use of proposals for improvement.
- The measures required to minimise any risk of deficiency have been implemented.
 - All personnel are familiar with their duties; their powers are clearly defined, with responsibilities and authorities set out in unambiguous terms. The descriptions of the various functions should be set out in writing. As a minimum, this applies to those tasks considered critical steps in patient treatment and where there is a risk of deficiency.
 - Treatment and rehabilitation of elderly stroke patients is prioritised in line with the health trust's targets for stroke treatment. This includes allocation of resources in evening and night shifts, weekend shifts and shifts on public holidays and in holiday periods.
 - Routines, procedures and other measures required to ensure medically sound services have been established. They are unambiguous and in accordance with the capabilities of the involved staff members. Procedures may or may not be set out in writing. This will depend on the outcomes from risk assessments, and be in line with the service provider's decision. The hospital has written procedures

that ensure the most critical steps in diagnosis, assessment, observation, acute treatment, early rehabilitation and prevention of complications in elderly patients with acute cerebral stroke.

- Routines, procedures and other necessary measures are known to and are adhered to by all staff members involved in treatment and rehabilitation, and work satisfactorily, regardless of who is on duty.

3a The service provider facilitates good practice: the necessary routines, procedures and measures have been established to ensure observation, assessment and medical treatment during the first 24 hours after admission to hospital (see Chapter 3.2).

- The health trust ensures medically sound observation during the first 24 hours after admission to hospital. The following basic functions are observed and assessed at regular intervals: respiration and oxygen saturation, blood pressure and pulse, fluid balance, body temperature, and blood glucose. The patient's neurological status is assessed. The first time this is done is soon after the patient arrives at the hospital. The hospital uses standardised and evidence-based screening and assessment tools.
- The health trust ensures necessary patient assessment during the first 24 hours after admission to hospital.
 - A CT or MRI scan of the brain is done immediately after a patient with symptoms of a cerebral stroke is admitted, providing that the patient is able to undergo the examination. The images must be evaluated at once by a radiologist or a physician with experience in treating stroke patients.
 - All patients undergo a cardiac examination with electrocardiogram (ECG). All patients have their heart rate monitored.
 - All patients with acute cerebral stroke are screened for swallowing difficulties soon after admission. Such screening is performed before patients are given food or drink by mouth. Screening is based on a standardised and well-established method.
 - Any speech and language difficulties are identified at an early point in the patient's hospital stay by means of screening. Such screening is based on standardised and well-established methods.
 - If any language or speech difficulties are detected during screening, patients are referred to a speech pathologist for further assessment.
- The health trust ensures medically sound treatment of patients during the first 24 hours after admission to hospital.
 - Prior to initiating any antithrombotic treatment, a CT or MRI must be done in order to establish that the cerebral stroke was not caused by a cerebral haemorrhage. Providing there are no contraindications, all patients with cerebral infarction are treated with a one-off dose of ASA (up to 300 mg).

3b The service provider facilitates good practice: necessary routines, procedures and measures have been established to ensure early rehabilitation (see Chapter 3.3).

- The health trust ensures that patients are mobilised at an early point, and that rehabilitation is started soon after an acute cerebral stroke.
 - User participation is ensured in all phases of early rehabilitation. Proactive steps are taken to involve patients and, if appropriate, next-of-kin (Section 5 of the Regulations on Habilitation and Rehabilitation, see Section 3-1 of the Patient Rights' Act).
 - All patients are mobilised as early as possible, depending on their

- medical condition, and usually within the first 24 hours.
- Patients' abilities and limitations are assessed using standardised screening and assessment scales that have been developed on the basis of clinical research. Assessment of rehabilitation need and potential is undertaken by a multidisciplinary team.
 - Necessary and relevant information on the patient's situation prior to the cerebral stroke is gathered, concerning aspects such as mental health, requirements for assistance in day-to-day life, living arrangements and social network.
 - The multidisciplinary team in co-operation with the patient and, if applicable, next-of-kin, draws up a plan for rehabilitation, stating the rehabilitation objectives and outlining specific rehabilitation measures (Section 5 of the Regulations on Habilitation and Rehabilitation, see Section 3-1 of the Patient Rights' Act).
 - Rehabilitation plans are assessed by the multidisciplinary team and in co-operation with patients and, if applicable, next-of-kin. Objectives and/or measures are adjusted as required (Section 5 of the Regulations on Habilitation and Rehabilitation, see Section 3-1 of the Patient Rights' Act).

3c The service provider facilitates good practice: necessary routines, procedures and measures have been established to ensure prevention of complications and secondary cerebral stroke (see Chapter 3.4).

- The health trust ensures medically sound preventive measures against complications.
 - If screening reveals swallowing difficulties, further assessment is undertaken. Individual measures to ensure adequate nourishment and training of the swallowing function are considered and started. If patients have severe and ongoing trouble swallowing, alternative manners of administering nourishment are considered and started.
 - Patients with swallowing difficulties are assessed repeatedly and at regular intervals in order to identify any signs of aspiration pneumonia. Patients' temperature is taken several times a day, and their general state of health assessed at regular intervals.
 - The patients are mobilised early on, and usually within the first 24 hours, or as early as is medically advisable (also see early rehabilitation).
 - If there are any signs of aspiration pneumonia, patients are swiftly assessed with further blood tests and radiological examinations. If they are found to be suffering from aspiration pneumonia, intravenous antibiotics treatment is started without any delay.
 - Immobilised patients are assessed soon after admission for their risk of pressure ulcers. This is done regardless of whether their immobility is the result of the cerebral stroke or other conditions.
 - If patients are found to be at risk of bedsores, measures adapted to the needs of the patient in question are implemented.
 - All elderly cerebral stroke patients are assessed so as to identify the cause of their illness, and determine their risk profile. The following shall be given importance: blood pressure, cholesterol, antithrombotic treatment and atrial fibrillation, as well as diabetes. Secondary preventive measures are implemented with a view to preventing secondary cerebral strokes.

4. Measures to detect and correct deficiencies have been implemented in order to ensure the acute treatment and early rehabilitation of elderly patients with stroke (see Chapter 2.4).

- The health trust has a well-functioning non-conformity system in which failings in day-to-day procedures and routine activities are reported and corrected. Non-conformity reports are handled systematically, so that they result in the necessary improvements in patient treatment.
 - The staff are familiar with the non-conformity system, and use it in order to report non-conformities related to the treatment and rehabilitation of elderly patients with acute cerebral stroke.
 - The leaders monitor and act so that the non-conformities are corrected, that the corrective measures have the intended effect and that procedures are amended if required. Non-conformities that are not corrected within an acceptable time frame or that involve more than one department/clinic are moved upwards within the organisation and handled at a higher level.

5. The management reviews, monitors and acts on the day-to-day situation in order to ensure the acute treatment and early rehabilitation of elderly patients with stroke (see Chapter 2.5).

- The managers understand and are in control of actual day-to-day conditions, and implement the required measures if day-to-day activities cannot proceed as planned.
 - The health trust's uppermost management monitors that the overall targets and framework conditions governing the service provider's activities facilitate that elderly stroke patient are attended to in accordance with statutory requirements in the health legislation.
 - Clinic and department heads monitor and maintain overview of the actual day-to-day situation. The management systematically checks that the adopted quality and activity targets are achieved, and that procedures are adhered to, so that elderly patients with cerebral stroke are given medically sound treatment and rehabilitation. Among other things, this is monitored through the use of random checks, evaluations, internal audits, management reviews (strategic meetings) and/or other appropriate ways.
 - Appropriate measures are implemented as required in order to care for this patient group.

5. Planning, preparation and performance of the supervision

5.1. General points

Each health region shall have one audit team undertaking the supervision, and the leader of this audit team shall lead all supervisions within the health region. This does not include the South-Eastern Norway Regional Health Authority, where it is likely that more than one audit team may be required. The supervision requires extensive collaboration among the County Governors, who are the supervisory authorities in the counties. This co-operation involves both preparation and performance of the audits. It is important that this collaboration is viewed as binding by all parties.

The Norwegian Board of Health Supervision expects the County Governors to act in a co-ordinated manner, to familiarise themselves with the supervision guidance document, and ensure that conditions are investigated with the requisite thoroughness.

5.2. Supervision methodology

The supervision is to be conducted as a series of system audits. This means that the audit teams shall investigate whether the various health trusts' internal control activities (quality management systems) ensure medically sound treatment and rehabilitation of frail elderly stroke patients. This shall be done according to the supervision guidance document provided, and in accordance with the procedure for supervisions performed as system audits.

5.3. Audit teams

The audits are carried out by regional teams, usually with three County Governor Offices collaborating in each instance. We recommend at least one representative from each Office of the County Governor. The audit teams must be composed of team members who, overall, bring the following qualifications to the work:

- An experienced audit leader familiar with the applicable procedure for supervisions conducted as system audits, including the key role of internal control systems in this type of audit.
- Qualifications in the medical science and experience from the specialist health services. We recommend including both physicians and nurses on the team, and if possible also a physiotherapist.
- Legal qualifications.
- Knowledge and understanding of the challenges involved in the specialist health services regarding management, organisation and governance.

In terms of legal expertise, the audit team does not necessarily need to have a lawyer, but one of the auditors must have sufficient knowledge of legal methodology to enable the team to analyse and judge the findings, including findings that are in the “grey areas”.

A thorough supervision depends on the auditors relying on each other's capabilities. Getting the audit teams to work well is a key part of the audit leader's responsibilities, requiring co-operation and co-ordination skills, and the ability to get work going. The sum of the audit team's qualifications must be put to productive use throughout the entire audit process, allowing the audits to proceed effectively and determinedly, as well as in a transparent and open manner. Among other things, this means that all auditors must acquaint themselves thoroughly with the supervision guidance document, and concentrate on the audit criteria in Chapter 4, both when preparing for the audit, and while engaged in its performance.

Chapter 5.2.1 of the system audit procedure states that the audit leader shall be involved in selecting the auditors. It is important to put together a group that can work as a team, and that, together, meets the audit team's requirements in terms of qualifications and capabilities. The audit leader is appointed by the county medical officer and is in charge of planning, co-ordination and performance of the audits within each region. Once the final report has been concluded, the audit leader's responsibilities come to an end.

5.4. The time frame and scope of the supervision

The supervision shall be completed and final reports sent to the Norwegian Board of Health Supervision by 15 November 2011. The scope of the supervision indicates that two entire working days must be dedicated to each supervisory visit.

5.5. Selection of service providers

The selection of service providers should be based on an assessment of risk and vulnerability. The requirements regarding scope are listed in the annual letter.

5.6. To whom are the audit notification and the audit report addressed?

The supervision is an audit of the health trusts. This entails that the notification of the audit, the audit report and any request regarding correction of non-conformities shall be addressed to the health trust. The health trusts, represented by their respective managing directors, will (independent of the management model chosen by the health trust) bear overall responsibility for the service providers/services, and thus also responsibility for any non-conformities being followed up on and corrected adequately.

5.7. Preparation and collection of documents

In reviewing this guidance document, the audit teams should evaluate which details and documents they should gather prior to the supervision. Among other things, the audit team should gather information on how stroke treatment is organised in the hospital in question, what actions are taken, where they are performed, and who is responsible for what. This entails that the team needs to obtain information on how the management manages, monitors and acts on stroke treatment, and how the management ensures that there is adequate access to capabilities and sufficient collaboration.

The audit teams should evaluate whether a pre-audit meeting with the health trust is called for as part of the preparation, see Chapter 5.4.1 of the system audit procedure. This may be the case if the documents sent the audit team prior to the audit are unclear, making it difficult to understand how services are led, organised and managed. If so, a pre-audit meeting may be required in order to clear up these issues.

The audit team shall, prior to conducting the audit, familiarise itself with the written documentation on the management, and the documentation relating to results, see Chapter 5.3 of the system audit procedure. These details must be compared with the audit criteria, and the information obtained used in the supervision. The supervisory visit must therefore be planned with a view to supplementing and confirming – or disproving – the information the audit teams received as part of their preparation work.

The audit criteria in Chapter 4 are a good basis for the preparation of checklists which can be used to examine the documentation, interviews and examination of the medical records. The audit team should also try to estimate the amount of time it will require for the review of patient records.

5.8. Persons who were interviewed, interviews and random checks

The interviews are used to elicit missing information; to check that the staff that should be familiar with the documentation that has been sent to the auditors are in fact well acquainted with it; and to verify that the adopted written procedures have been implemented. The interviews shall also establish whether the adopted targets are realised; whether the management checks on the progress of plans; whether any problems in this regard are addressed; whether the service providers learn from their errors, and how this is handled and acted on by the management.

The questions raised during the interviews are dictated by the audit criteria, and shall ascertain whether the treatment and rehabilitation of elderly stroke patients is medically sound. In order to secure a constructive dialogue in the interviews, and seek out information that answers the questions arising during the audit, it is necessary to adjust the language used so that it is in line with the terminology employed in the health trust.

Data from the interviews must be compared with the results of the document review that was undertaken prior to the audit. Some interviews may reveal information which must be investigated further, e.g. by studying documents, recorded results or minutes from meetings. In this connection, auditors may decide to have brief talks with persons who were not on the original list of persons to be interviewed, but who may have pertinent information. It is important that the audit team set aside enough time for such verification, so that the team's conclusions can either be confirmed or corrected. The audit team must also plan for a little time between interviews, to allow them to write down a brief summary after each talk.

During the supervisory visit, the auditors must consult patient records. It is recommended that the auditors review the patient records as early as possible during the supervisory visit. This is because knowledge of the patients' medical records makes it easier to steer the interviews in the right direction. Moreover, the audit teams may decide to look at non-conformity processing, reports from other relevant internal audits, checklists and documentation relating to staff training.

The information in these documents shall help determine whether the service provider is in compliance with the audit criteria.

We recommend requesting medical records for 20 patients above the age of 80 who were alive when discharged following acute admission for cerebral stroke (ICD-10 diagnoses I61, I63 and I64⁴). Over the course of the audit, the audit team may decide that an inspection is appropriate.

5.9. Monitoring and action regarding non-conformities

The responsibility for supervisory response to any non-conformities lies with the Office of the County Governor with supervisory responsibility for the audited health trust. The audit leader should be consulted regarding the supervisory response.

⁴ ICD-10 diagnosis I64 is the code for cerebral strokes where the stroke has not been specified as being caused by either a haemorrhage or an infarction.

In connection with sending the final report, we recommend that the audit team ask the health trust to analyse the cause(s) of their non-conformities, and that the team requests an action plan for how the management plans to ensure that the necessary changes in their procedures and practice are implemented. Such a plan should also detail any changes required in the health trust's internal control system.

It is important that the supervision is not finalised until the service provider's management has checked and documented that the corrective measures implemented have had the intended effect, and that the treatment of elderly patients with cerebral stroke is subject to adequate management, monitoring and response from the health trust. This is with a view to preventing non-conformities from recurring.

6. Audit reports

6.1. The audit report from the respective audit

The audit report shall be in line with the adopted template for system audits, and plainly explain and substantiate any deficiency or risk of deficiency uncovered relating to the treatment and rehabilitation of elderly stroke patients. Where relevant, auditors can make reference to the documents they have examined in their review of audit evidence. The report shall also clearly indicate that the audit has evaluated what part of the health trust's internal control activities has fallen short. The currently applicable template for the audit report is to be used, in accordance with Chapters 5.5.3, 5.5.4 and 5.6 of the system audit procedure.

If the audit teams find that the deficiency/deficiencies indicate general inadequacies in the service provider's internal control activities, they are encouraged to conduct an overall assessment of the management system in Chapter 6 of the audit report. If the audit report includes such an assessment, the summary should also include some observations on the management system. In cases where non-conformities have been discovered, such an assessment will be a very useful way of communicating and highlighting the management's responsibility and the close relation between inadequate governance and the non-conformities that were found.

Moreover, it is important that Chapter 4 of the audit report provides ample information on what the audit investigated, rather than merely reiterating the principal headlines of the subjects included in the supervision. As regards Chapter 2, a brief description of the organisation and size of the treatment of stroke (2010) is recommended.

The audit report is sent to the health trust, and addressed to the managing director.

Copies of the audit report are sent to postmottak@helsetilsynet.no on an ongoing basis. They are published on the website of the Norwegian Board of Health Supervision.

6.2. Regional report summarising findings

The audit teams shall summarise the audits performed within each regional health trust, and send the report summarising these findings to the regional health trust. A copy of the report summarising the findings is sent to postmottak@helsetilsynet.no. They are published on the website of the Norwegian Board of Health Supervision.

6.3. National report summarising the findings

On the basis of the respective audit reports, the Norwegian Board of Health Supervision will prepare a national report summarising the findings from this countrywide supervision.

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