Report of a peer evaluation of The Norwegian Board of Health Supervision (Statens helsetilsyn)

Performed by a delegation of the European Partnership of Supervisory Organisations in Health Services and Social Care (July 2011 – January 2012).

March 2012

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Foreword

We are pleased to introduce this report of the peer evaluation of the Norwegian Board of Health Supervision, Statens helsetilsyn (in this report is used the short name Helsetilsynet) which looks at how Helsetilsynet delivers its supervisory functions. The review is the first of its kind to be undertaken by the European Partnership of Supervisory Organisations in Health Services and Social Care (EPSO).

We hope that Helsetilsynet will find this report useful in helping it to take its supervisory functions forward and that stakeholders will be assured by the report that Helsetilsynet is a professional, open and learning organisation that clearly understands the need for a supervisory body to be open to such external scrutiny by its peers. We also hope that all EPSO members will use this report to evaluate and benchmark their own practices. Certainly, those EPSO member organisations who formed part of the peer evaluation team have already benefited and have started on the journey of self-assessment and improvement.

We are very grateful to the management and staff of Helsetilsynet and members of its stakeholder bodies who gave their time and the benefit of their knowledge and expertise to the evaluation team. They provided us with insight in to the workings of Helsetilsynet, answered our questions and responded to our queries in ways that demonstrated that they wanted to learn from the process and improve.

Chapter 1: Introduction and background to the peer evaluation of the Norwegian Board of Health Supervision

1.1 In March 2011, the Director General and Deputy Director General of the Norwegian Board of Health Supervision (Helsetilsynet) wrote to the European Partnership of Supervisory Organisations in Health Services and Social Care (EPSO) requesting that members organise a peer evaluation of Helsetilsynet. Details of EPSO's role and purpose together with the details of the peer review team can be found at **Appendices 1** and **2**. A copy of the invitation letter is provided at **Appendix 3**.

1.2 The letter sets out Helsetilsynet's wish for the peer evaluation to focus on:

- Determining if Helsetilsynet works in a way that could be acknowledged as good supervisory practice.
- Evaluating the methods Helsetilsynet uses and the documentation and traceability of results from supervisory activities.
- Pointing out possible areas for improvement and areas where further standard setting should be sought.

Background to Helsetilsynet

1.3 Helsetilsynet is a national organisation that falls under the oversight of the Ministry of Health and Care Services. It became a purely supervisory body in 2002 when the functions that it had previously held responsibility for (professional development, regulatory development and policy performance) were transferred to other public bodies including the Norwegian Directorate of Health.

1.4 In 2009, Helsetilsynet took on responsibility for the supervision of medical and health related research and in 2010 it became responsible for child welfare services, social assistance in the Nav (Norwegian Labour and Welfare Administration) and health services for the Norwegian Armed Forces' foreign operations.

1.5 In Norway, supervision is carried out at both the national and county level and the supervision authorities are the:

- Norwegian Board of Health Supervision (Statens helsetilsyn);
- Norwegian Board of Health Supervision in the Counties (health service and health care personnel) (integrated into the County Governors as of 1 January 2012); and
- Offices of the County Governors (child protection services and social services).

1.6 Working together the supervision authorities contribute to ensuring that:

- the child welfare, health, care and social services needs of the Norwegian population are met;
- the child welfare services are to the best of the children;
- Norwegian health and social services are run in accordance with acts, regulations and professional standards;
- deficiencies in the provision of health and social services are prevented; and
- health and social service resources are utilised effectively and efficiently.

1.7 Helsetilsynet directs and oversees the supervision authorities that operate at the county level. This includes the offices of the county governors, which have responsibility for the supervision of social services in the Nav (Norwegian Labour and Welfare Administration), child welfare, health and care services and health care personnel.

Scope and approach of the peer evaluation

1.8 In developing the scope and approach for this review careful consideration was given to the standards that other organisations have developed for supervisory and audit bodies including those set by the International Society for Quality in

Healthcare (ISQua) and ISO/IEC standard 1720:1998[1]. We (the peer evaluation team) identified 13 key areas that we considered required examination and evaluation.

1.9 We examined and evaluated the arrangements that Helsetilsynet had in place to ensure that its statutory basis and functions were clearly set out and that it had satisfactory arrangements in place in relation to:

- statutory basis clear and functions clearly defined;
- independence, impartiality and integrity;
- confidentiality and safeguarding of information;
- organisation and management;
- quality systems;
- personnel;
- facilities and equipment;
- inspection methods and procedures;
- engagement and communication with the organisation or individual subject to review;
- openness and transparency;
- disciplinary sanctions;
- impact assessments; and
- co-operation and engagement with other stakeholders including other supervisory bodies.

1.10 The supervision of medical and health related research and supervision of the health services for the Norwegian Armed Forces' foreign operation were not included in the scope of this peer review.

1.11 To enable us to form an opinion on the adequacy or otherwise of Helsetilsynet's arrangements we:

- reviewed key strategic and operational documents;
- observed senior management meeting(s);

[1] General criteria for the operation of various types of bodies performing inspection

- interviewed key members of management, staff and stakeholders;
- held group discussions with members of staff; and
- reviewed samples of work taken forward by Helsetilsynet in relation to:
  - incident investigations;
  - planned inspections; and
  - themed inspections e.g. ICT, maternity and blood services.

1.12 A summary of the documents reviewed and a list of the individuals who took part in this review are provided at **Appendices 4 and 5**.

1.13 For ease of reference, our findings are set out in the remainder of this report under the key questions that we set out to answer. The key standards that we used to assess Helsetilsynet against are set out in the blue boxes under each of these questions.

Chapter 2: Is the statutory basis of Helsetilsynet clear and has its functions been clearly defined?

The supervisory body or the organisation of which it forms part should:

- be legally identifiable;
- have a documented function defined by legislation and its area of competence shall be clearly defined; and
- have documentation describing the goals and responsibility of the inspection body.

Helsetilsynet's legislative basis

2.1 The powers and remit of Helsetilsynet are set out in Acts and Regulations. The requirements for the supervision of health services and health care personnel were until 1 January 2012 set out in the Health Services Supervision Act [Act of 30 March 1984 No.15] and the supervision of social services by the Social Services Act [Act of 13 December 1991 No. 81 relating to social services]. On 1 January 2012 a number of Acts came into force which impacted on the role and relationships of Helsetilsynet.

The Health and Care Services Act

2.2 This Act which came into force on 1 January 2012 replacing the *Municipal Health Services Act* and the *Social Services Act*, modified the role and function of Helsetilsynet and in particular its relationship with the County Governors and County Medical Officers. It introduced a much clearer separation between the County Governors as the local supervisors of child welfare, health and social care and Helsetilsynet as the national, overarching professional supervisory body. Paragraph 12.3 makes it clear that the County Governor shall supervise the way in which the municipality fulfils its duties as set out in Chapters 3 to 10 of the Act and paragraphs 11.2, 11.3 and 11.4.

2.3 The *Health and Care Services Act* does not set out any role or requirements for Helsetilsynet and makes it clear that at the municipal level the role of supervision is to be performed by the County Governor. Therefore, as of 1 January 2012 the role and responsibilities of Helsetilsynet are set out in five acts, the key aspects of which are summarised below.

The Health Services Supervision Act

2.4 The Act of 30 March 1984 No.15 (Helsetilsynsloven) is central to the Norwegian systems of supervision for health and social care services. It establishes that:

> *'The Norwegian Board of Health Supervision has responsibility for the general supervision of health services in the country and shall exercise authority in accordance with that which is laid down in laws and regulations'.*

2.5 It also makes it clear that Helsetilsynet is to be led by a Director General who will be appointed by the King for a fixed term and that there is to be a county medical officer, who is a representative of Helsetilsynet in each county. County medical officers are also appointed by the King. The Act establishes that county medical officers are directly delegated authority as "the Norwegian Board of Health Supervision in the County" in laws and regulations and is thus directly responsible to Helsetilsynet for the supervision of health and care services. As highlighted above, a change in legislation has meant that as of 1 January 2012 responsibility for supervision at the county level is at the county governor's office (Filkesmannen) and not with the county medical officers (Filkeslege) who now report to the county governor and not to Helsetilsynet. The County Governor reports directly to Helsetilsynet.

2.6 The Act sets out some of the tasks of Helsetilsynet and those working at County level. In particular it states that Helsetilsynet shall:

- issue administrative reactions to health care personnel pursuant to the provisions set out in Chapter 11 of the Health Personnel Act;

- register warning and revocation, voluntary renouncement, or suspension of authorisation, licence, certificate of completion of specialist training or the right to prescribe medicinal products or limitation of authorization pursuant to Chapter 11 of the Health Personnel Act;
- inform the employer of health care personnel of warning, revocation, voluntary renouncement, or suspension of authorization, licence, certificate of completion of specialist training or the right to prescribe medicinal products and limitation of authorization pursuant to Chapter 11 of the Health Personnel Act; and
- if an activity in the health services is run in a way that may have adverse effects for patients or other people or in any other way is unfavourable or unacceptable, issue instructions to rectify the conditions.

At the county level

- carry out all supervision of health services and all health care personnel in the county and in connection with supervision give advice, guidance and information that contribute to the needs of the population for health services being met;
- keep Helsetilsynet informed of the health conditions in the county and about conditions that influence these;
- inform Helsetilsynet about conditions that require a warning or revocation, voluntary renouncement, or suspension of authorization, licence, certificate of completion of specialist training or the right to prescribe medicinal products or limitation of authorisation; and
- ensure that everyone who provides health services has established an internal control system and carries out control with their own activity in such a way that failure in the health services may be prevented.

The Public Health Act (Folkehelseloven)

2.7 *The Public Health Act (Folkehelseloven)* is of particular note as it makes it clear that overall professional responsibility for supervision across Norway rests with Helsetilsynet. However, Sections 4 to 9, 20, 21 and 27 to 30 of this Act assign, under powers set out in Section 10 of the Local Government Act, County Governors the authority and responsibility to supervise all municipal and county level activities.

The Child Welfare Act (Barnevernloven)

2.8 This Act gives Helsetilsynet responsibility for the overall supervision of child welfare services in individual municipalities, institutions, centres for parents and children and care centres for unaccompanied minor asylum seekers.

The Social Services in the Nav Act (Act of 18 December 2009 No. 131.

2.9 This Act relates to social services in the Labour and Welfare Administration. It states that Helsetilsynet has general supervision of social services in the Labour and Welfare Administration. It also establishes that the County Governor is responsible for supervising the way in which municipalities fulfil their duties according to the requirements set out in chapters 4 and 16.

The Health Personnel Act (Helsepersonelloven) (Act of 2 July 1999 No. 64 relating to Health Personnel)

2.10 This Act is the central act for handling of incident cases, regulates also the action to be taken should there be a breach of the provisions of this Act. It establishes the authority of Helsetilsynet to issue a warning, to revoke, suspend, or limit an authorisation, licence, or certificate of completion of specialist training.

Specific Powers

2.11 In addition to the Acts referred to above several of Helsetilsynet's specific powers are delegated to it through a number of other, including:

- *The Health Research Act (Helseforskningsloven):* this gives Helsetilsynet powers to oversee all medical and health research and the management of research biobanks.

- *The Communicable Diseases Act (Smittevernloven):* which gives Helsetilsynet overall general responsibility for supervision of the requirements set out in the Act.

- *The Personal Health Data Filing System Act (Helseregisterloven):* which states that the responsibility for supervision of the requirements set out in the Act is to be shared between the Data Inspectorate, Helsetilsynet and the County Governor.

- *The Alternative Treatment Act:*, that describes the penalties that will be issued for endangering life or health. It delegates the powers to issue petition for public prosecution to Helsetilsynet.

- *The Treatment Biobank Act:* through which Helsetilsynet is given the powers to supervise the biobank and its material and to ensure that the provisions of the law are met;

- *The Specialized Health Services Act:* in which a duty to notify Helsetilsynet and the County Governors of any prescribed incidents; and

- *The Dental Health Services Act:* which gives Helsetilsynet the powers to keep oversight of, control and supervise dental health services across Norway.

Documentation of goals and responsibilities

2.12 A strategic plan for the period 2010-2012 was agreed and approved by the Director General in December 2010; this sets out Helsetilsynet's aims and objectives for the three years ahead and also provides some detail in relation to how these will

be met. It was confirmed that plans are in place for the development of the next strategic plan which will cover the period 2013-2015.

2.13 A lot of useful information on Helsetilsynet's roles, responsibilities and activities is provided on its website, www.helsetilsynet.no/no/Norwegian-Board-of-Health-Supervision. The website includes copies of relevant legislation that is available in various languages and formats.

2.14 Helsetilsynet also publishes an Annual Supervision Report that details the supervisory work undertaken in the previous 12-months. The Annual Supervision Reports are detailed, giving a clear account of the work undertaken by Helsetilsynet but providing little information about Helsetilsynet itself. For example, the Annual Report for 2010 included summaries of:

- thematic work carried out by Helsetilsynet – Municipal Services for Frail and Elderly People;
- outcomes of its supervisory work in relation to specialised health services;
- details of the number of health professionals who had had their authorisation to practice removed or limited;
- medicine management concerns highlighted by Helsetilsynet's work;
- Helsetilsynet's responsibilities and findings in relation to unnatural deaths or serious injuries;
- Helsetilsynet's plans for countrywide supervision in 2011; and
- facts and figures in relation to the supervisory activities undertaken in 2010.

Conclusions and Recommendations of the peer evaluation team

2.15 We were satisfied that there was a clear legal basis for Helsetilsynet's supervisory functions and that its direction, objectives and work programme are clearly set out in its Strategic Plan. The aims and objectives set out in the Strategic Plan and reported upon in Helsetilsynet's Annual Supervision Report were in line with

the powers and remit set in legislation. The possible impact of the new legislation that came into force in January 2012, on Helsetilsynet's independence is discussed further in **Chapter 3**.

2.16 We were particularly impressed by Helsetilsynet's website which was user friendly and informative. However, we do consider that Helsetilsynet needs to communicate the goals it has set itself to the public in a more focused and cohesive way. It should also give consideration to expanding its annual supervision reports to include information about how it operates and in particular its long term vision, staff, roles, values and future developments.

2.17 We noted that the planning process for the development of the Strategic Plan for the period 2013-2015 was due to start in February 2012. We have made comments and recommendation in Chapter 13 in relation to the need for Helsetilsynet to reflect on the way it engages with stakeholders and in particular patients and the wider public. These recommendations should be considered by Helsetilsynet when developing its next Strategic Plan.

We recommend that:

1. Helsetilsynet gives consideration to how it may better communicate its goals to the public.

2. Helsetilsynet expands its annual supervision reports to include information about how it operates and in particular its vision, staff, role, values and developmental work.

Chapter 3: Is Helsetilsynet independent, objective, impartial and does it act with integrity?

The supervisory body should have processes and systems in place that ensure that:

- its independence is safeguarded to the extent that is required with regard to the conditions under which it performs its services. As a supervisory body, its dependence or independence of the political system should be defined;
- it remains impartial to the influence of key stakeholders (umbrella organisations, press);
- its personnel understand what is required of them to ensure that they act with integrity; and
- personnel do not have a conflict of interest in relation to the area of work that they are required to perform. Procedures should be implemented to ensure that experts assisting the inspection body in specific cases declare a statement about conflicts of interest, for example political, commercial, financial pressure.

Independence

3.1 The King's appointment of Helsetilsynet's Director General, Deputy Director General and County Medical Officers ensures Helsetilsynet's political autonomy. While the Minister for Health and Care Services is responsible to Parliament for any decision or failure of Helsetilsynet the annual letter from the Ministry of Health and Care Services (the Ministry) states:

'the Norwegian Board of Health Supervision is a professionally independent body.....'

3.2 While the Ministry can request that Helsetilsynet considers areas of additional work to that contained in its proposed forward work programme, it does not influence Helsetilsynet's approach to supervision or its judgements.

3.3 Generally, the representatives of stakeholder organisations and staff we interviewed considered Helsetilsynet to be independent and that it managed this independence well. However, we were advised that as of 1 January 2012 the reporting arrangements for the County Medical Officers who currently report direct to

Helsetilsynet will change, requiring them to report directly to the County Governor. It was clear that the current Director General is well respected by politicians and healthcare leaders and that he has developed strong working relationships with County Governors. We consider that much of the tension that could arise from the current and future County level structures are managed due to the significant amount of time invested by the Director General in developing and maintaining these relationships.

3.4 At the time of our review, Helsetilsynet had responsibility for MedEvent – the reporting system for adverse events in specialised health services. This system collects reports of incidents that have occurred in specialised health services that have led to, or could have led to, serious injury to patients. Hospitals have a statutory duty to report such events. However, we understand that from 1 July 2012 all incidents to MedEvent will be reported to a new system in The Norwegian Knowledge Centre for the Health Services and not to Helsetilsynet. Helsetilsynet will according to an agreement with the Centre be provided with information of cases relevant for the supervisory authorities, and general information of relevance to plan, scope and focus its work. From 2010 hospitals are obliged to report all serious injuries on patients that have taken place directly to Statens helsetilsyn. This new system is legally based from 1 January 2012, on the Specialized Health Services Act section 3-3a.

Objectivity

3.5 Our review of a sample of supervisory reports highlighted that Helsetilsynet is competent in the handling of difficult messages and where it considers issues to be important to patient safety will ensure that its voice and recommendations are heard and taken forward. This was illustrated by a case study of recommendations made to the Ministry of Health and Care Services which highlighted systemic deficiencies in patient administration systems and electronic patient records at several health trusts across Norway.

3.6 Ensuring the integrity and objectivity of a supervisory body very much relies on the values of the organisation that are set by its leaders. The peer evaluation team

noted that the Director General and that the Deputy Director General may be leaving the organisation within the next strategic planning period and it was not clear to the team as to what succession planning arrangements were in place to ensure continuity of culture and strategic direction.

Management of Conflict of interests

3.7 All staff and stakeholders interviewed advised us that they did not feel that conflict of interest was an issue. In general, they considered the integrity of Helsetilsynet to be high, although reference was made by one individual to a greater number of cases being referred for appeal due to a perceived lack of impartiality.

Conclusions and Recommendations of the peer evaluation team

3.8 We believe that Helsetilsynet manages its independence well, but have some concerns that planned changes in respect of the reporting arrangements of the County Medical Officers may impact on Helsetilsynet's independence. We consider that Helsetilsynet should give careful consideration in consultation with staff at the County level as to how this change will be managed. Arrangements between Helsetilsynet and the Counties should be strengthened by the development and implementation of an operational protocol that clearly sets out roles, responsibilities, working relationships and escalation procedures where concerns are identified in relation to a County's ability to deliver the remit set for it by Helsetilsynet. We also recommend that Helsetilsynet give consideration to the use of videoconferencing as a way of improving communication with the Counties.

3.9 Another area of concern and possible impact on the independence of Helsetilsynet, is its relationship with the Norwegian Knowledge Centre for Health Services (the Centre). If this relationship is to work well and not have an adverse impact on the independence of Helsetilsynet it is important that Helsetilsynet is allowed to commission the information that it requires from the Centre; both in terms of content and frequency.

3.10 The current Director General plays a pivotal role in the maintenance of Helsetilsynet's credibility and independence. Much of Helsetilsynet's independence is delivered and maintained as a result of the networks and relationships that he has built; we are concerned that, unless adequate consideration is given to succession planning at this stage, the Director General's retirement in 2013 will have a major impact.

3.11 While all those we spoke to did not feel that conflicts of interest was an issue for Helsetilsynet, and that it delivered its supervisory functions with objectivity and integrity, we consider that Helsetilsynet should introduce a formal system for the recording of possible conflicts of interests. Individuals, teams and experts brought in from external organisations should be asked to declare whether or not they may have a conflict of interest (perceived or real) in relation to the supervisory work to which they have been assigned. Such declarations should cover whether an individual has worked with or for an individual or organisation subject to supervision. This is particularly important given that some of the personnel working for Helsetilsynet still practice in a health professional role on a part-time basis.

We recommend that:

3. Helsetilsynet develops operational protocols and memoranda of understanding with County Governors and the Norwegian Knowledge Centre for Health Services.

4. Helsetilsynet uses videoconferencing as a tool to improve communication with the counties.

5. Helsetilsynet starts to put arrangements in place to ensure that:
   - the corporate knowledge and memory held by the current Director General is not lost on his retirement;
   - the networking arrangements and relationships built up by the current Director General are sustained following his retirement.

6. Helsetilsynet introduces a conflicts of interest register and procedures that require members of staff to declare whether they have a possible conflict of interest in relation to the supervisory work they have been allocated.

Chapter 4: Does Helsetilsynet have the necessary arrangements in place to safeguard the data and information it holds and to ensure its confidentiality?

The supervisory body should:

- ensure the confidentiality of information according to national legislation;
- have policy and procedures in place to safeguard its data and information; and
- ensure that personnel can only access sensitive data that is relevant to their job function.

4.1 All those we questioned about the way in which Helsetilsynet safeguarded information and managed confidentiality considered that Helsetilsynet managed these issues competently.

Staff Awareness

4.2 All staff upon appointment are required to sign a confidentiality statement confirming that they are aware of what is required of them in relation to ensuring the confidentiality of information. Those staff that we spoke to clearly understood their role in ensuring that information and data is properly safeguarded and were able to describe Helsetilsynet's systems and procedures for ensuring the confidentiality of data.

Electronic System

4.3 Helsetilsynet's electronic information system (ePhorte) had the capability to restrict and manage access to information and ensure that individuals only had access to the information that they needed to fulfil their role. The system was easy to use and it was clear that access could be restricted so that information was shared on a 'need to know basis'. During the period of our fieldwork, procedures were further enhanced by the introduction of procedures and guidance that ensured that information was restricted to only the team working on a particular incident. Any emails from patients setting out a complaint about a particular service or individual

are not forwarded via the email system but scanned into the secure archive. Staff at the County level cannot access the central filing system.

4.4 In 2004-2005 Helsetilsynet commissioned an extensive testing of its security systems. This review, undertaken by an external expert body, found the systems to be secure and appropriate for the security and confidentiality levels of the data and information stored and accessed by Helsetilsynet. An assessment of the threats to Helsetilsynet's data systems is undertaken every 2-3 years; the last assessment was undertaken in 2010. The report identifies and evaluates possible threats such as system failure, adverse events and criminal acts involving data; it also contains information on how these threats will be mitigated against and actions that should be taken by Helsetilsynet.

Non electronic systems

4.5 Having identified possible issues in relation to the printing of information, Helsetilsynet has introduced a system whereby staff can send information to a printer but it is held in a queue until they scan their identity card into the printer confirming that they are at the printer and ready to supervise its printing. We considered this to be noteworthy practice.

4.6 Procedures are in place that encourage and support the reporting of any incidents of non-compliance with the procedures; including those where information has not been properly safeguarded or there has been a breach of confidentiality. There is an escalation procedure in place and the level of escalation depends on the severity and seriousness of the incident.

Conclusions and Recommendations of peer evaluation team

4.7 Based on the evidence reviewed and testing of the electronic system undertaken, we are confident that Helsetilsynet manages the data and information it holds competently. Although, given advances in technology and hence the ability of those who wish to do so to hack into electronic systems and databases, we would

recommend that Helsetilsynet commissions a further security testing of its system similar to that undertaken in 2004-2005.

4.8 We are pleased to acknowledge the responsiveness of Helsetilsynet and its readiness to learn and improve as evidenced by the improvements it made to its processes during the period of our fieldwork by the introduction of procedures and guidance that ensured that information was restricted to only the team working on a particular incident.

We recommend that:

7. Helsetilsynet retests the security of its electronic information system by undertaking an exercise similar to that undertaken in 2004-05.

Chapter 5: Does Helsetilsynet have the necessary organisational and managerial arrangements in place?

The supervisory body should:

- have well defined relationships with the Department of Health, umbrella organisations, patient organisations;
- have well defined relationships with the regional offices of the inspection body;
- have a well described and documented organisational and management structure;
- define and document the responsibilities of its personnel and the reporting structure of the organisation;
- have procedures in place to prioritise its activities and is transparent about that prioritisation;
- ensure its inspection activities are carried out in accordance with legislation and the defined standards;
- ensure the effective supervision of all personnel; and
- have procedures in place that ensure the coordination of the various supervisory activities.

Relationships

5.1 The Director General meets with the Secretary General for the Ministry of Health and Care Services on a weekly basis together with the Directors of the Directorate of Health and the Public Health Institute. These regular meeting appear to be key to maintaining a dialogue between the Ministry and Helsetilsynet.

5.2 An annual letter is sent by the Director General to the County Governor (and, until 2012, the Chief Medical Officer) setting out their work programme for the year ahead. The Director General meets with senior individuals at the County level on a regular basis. In addition to these formal meetings, there is extensive interaction between the counties and Helsetilsynet. These activities include:

- the referral to Helsetilsynet of complaints cases;
- informal contact and scheduled meetings eg, teleconferences; and
- discussion and quality assurance of supervisory reports.

5.3 While staff from Helsetilsynet visited the counties and offered professional advice on cases, there is no formal process for the secondment of staff between the counties and Helsetilsynet to facilitate the exchange of learning and experiences. However, each year some recently recruited personnel from the County Governors have a stay in Statens helsetilsyn to learn how the organization on central level works.

5.4 Despite there being evidence of regular communication between Helsetilsynet and the counties, a consistent theme arising from interviews was concern in relation to Helsetilsynet's relationship with the Counties. It appears that these relationships can sometimes be difficult, and that due to the number of counties inconsistent. There is also a view that Helsetilsynet should be doing more to direct and manage the work of the counties to ensure that they are applying best practice and consistent approaches to their work. Funding was also highlighted as an issue as Helsetilsynet is dependent on the funding that goes to the counties to deliver part of its work programme.

5.5 While we were provided with evidence of Helsetilsynet having engaged with a variety of stakeholder organisations including those that represent patients, for example the Cancer Association; it was not clear how systematic or sustained this engagement was. Those we spoke to felt that Helsetilsynet should engage with stakeholders and in particular patients and patient representative groups in a more meaningful and effective way.

Organisational and Management Structure

5.6 The structure of Helsetilsynet is documented and the staff we spoke to were aware of its governance framework, roles and accountabilities. Helsetilsynet is divided into to three departments:

- **Department I** deals with legal safeguarding. This department is staffed by lawyers and health professionals, mainly medical doctors with different specialities and general nurses with different specialities. We were told that the work of this department is very much focused on checking compliance with the law and includes incidence investigation and disciplinary cases. The Department can initiate warnings, revocations, voluntary renouncement's, or suspension of authorisations and licences.
- **Department II** focuses on planned system supervisory inspections. This department is staffed primarily by individuals who have previously held roles as clinicians, health care practitioners or social workers, and lawyers.
- **Department for Administration** operates the governance and administrative framework for Helsetilsynet.

5.7 Those we spoke to told us of the different cultures and approaches operating within Departments I and II and attributed these to the different types of work undertaken by each. Department I was generally considered to be too bureaucratic in their approach.

5.8 While there was evidence of the Departments sharing information for example, in relation to the development of Helsetilsynet's forward work programme, there was some evidence that these Departments could do more to share experiences and expertise. Certainly those we spoke to commented on the need to improve communications between the two departments.

Prioritisation

5.9 Ideas for Helsetilsynet's forward work programme[2] are sought from a number of sources; these include the counties, ministries and the analysis of information held by the Helsetilsynet from its analysis of incidents. Although it was not fully clear how the thematic analysis of incidents shaped supervisory activity. There was little evidence of direct involvement of patients and the public in shaping Helsetilsynet's programme of work.

[2] A forward work programme sets out the priorities that will be taken forward by an organisation over the next year or next three years.

5.10 The process for the prioritisation of areas and topics is informal and based on an evaluation of the suggested areas using the following criteria:

- actions that could lead to major patient safety issues and serious consequences for patients;
- Risk – probability and consequence;
- vulnerable people in certain situations such as those subject to compulsory treatments; and
- children and people without autonomy for example adults with dementia.

5.11 The final decision in relation to priorities is made by the management group who take a pragmatic approach by considering the risks (probability and consequences), whether there has been recent supervisory activity in relation to the area/topic, whether another body has undertaken or is likely to take forward similar work. The forward work streams are then grouped into three broad categories; tasks that Helsetilsynet:

- is required to do by law;
- is expected to do and where it may be the only body that can undertake them; and
- chooses to do after consideration of risk and vulnerability.

Supervision and Coordination

5.12 It is clear that Helsetilsynet, and in particular the Director General, put a lot of time and effort into communicating and co-ordinating its work with the counties. However, there is some evidence that these arrangements could be strengthened both in terms of ensuring consistency and avoiding duplication. In particular there is some concern that complaints cases referred to Helsetilsynet lead to duplication of work previously undertaken by the County and hence duplication of work. We comment on this issue further in **Chapter 9**.

Conclusions and Recommendations of peer evaluation team

5.13 It is clear that staff at the County level have many calls on their resources and time and that this can lead to tensions and an impact on the supervisory agenda. We have already highlighted our concerns in relation to Helsetilsynet's on-going relationship with the Counties and made recommendations aimed at addressing these issues in **Chapter 3** of this report.

5.14 The approach to the identification and prioritisation of Helsetilsynet's forward work programme is pragmatic and based on risk. However, we would suggest that it better communicates the discussions that take place at management board to agree the final work programme. One way in which this may be done is to include a section in Helsetilsynet's forward work programme that sets out why the various areas/topics were chosen as well as the outline scope of the work. Helsetilsynet should publish its forward work programme on its Internet.

5.15 We would also encourage Helsetilsynet to develop a public and patient engagement strategy to ensure that it benefits from the knowledge and experience of those accessing services when planning, scoping and undertaking its supervisory work.

We recommend that:

8. Helsetilsynet documents the rationale for its forward work programme setting out clearly why the various areas/topics were chosen for inclusion. It should also consider making this available to the public.

9. Helsetilsynet develop a patient and public engagement strategy that sets the framework for its engagement with patients and the public to inform all aspects of its work including forward planning.

Chapter 6: Does Helsetilsynet have an appropriate and well-defined quality system in place?

The supervisory body should:

- define and document its policy and objectives for, and commitment to quality, and shall ensure that this policy is understood, implemented and maintained at all levels of the organisation;
- operate a defined quality system which is fully documented. The system should consist of feedback procedures;
- have a quality system in place that is up to date and accessible to the relevant personnel;
- maintain a system for the control of all documentation relating to its activities. It should ensure that the appropriate documentation is available at all relevant locations and to relevant staff;
- ensure that all actions (documentation and legal actions) are conducted according to national law;
- have documented procedures in place for dealing with feedback and corrective action when discrepancies are detected in the quality system and/or in the performance of inspections; and
- review the quality system at appropriate intervals to ensure its continuing suitability and effectiveness. The results of such reviews should be recorded.

Quality system

6.1 When initially asked to define Helsetilsynet's quality system, staff struggled to describe it. However, when asked about quality assurance procedures, staff talked confidently about how quality checks were undertaken as part of their work (quality assurance arrangements for individual supervisory investigations are discussed further in **Chapter 9**). They also described parts of the process such as the sign off of reports and the documentation held on the Intranet; some staff considered the Intranet to be the repository for the quality system.

6.2 Helsetilsynet provided a number of documents as evidence of how aspects of quality were checked and assured. These included a quality book with flow charts

and standard operating procedures which are also available on the intranet. A further example was a document titled 'Procedure for supervision carried out as a system audit' which referenced ISO 19011:2002. However, there was no overarching document that set out the details of Helsetilsynet's quality system.

6.3 Staff also referred to a system of version control being in place but evidence of a systematic approach to the review and update of documentation was not provided. It was also unclear as to who was responsible for updating the various documents.

Review of quality system

6.4 No evidence of systematic audits of the quality system taking place was identified during our evaluation. However, evidence of notes and minutes of meetings where aspects of quality were discussed, were made available. These included board minutes and senior management meetings where on-going and new concerns were raised.

6.5 Good evidence was provided of external scrutiny taking place to ensure that Helsetilsynet works within national law and a legal framework for example, Helsetilsynet has appointed an external lawyer to undertake audits of their approach.

Conclusions and Recommendations of peer evaluation team

6.6 We concluded that elements of a quality system were embedded in practice and supported by policies and procedures that were on the Intranet. However, it was implicit rather than explicit and hence staff did not always relate the procedures and systems they followed to a quality system and also certain aspects of the quality system were unclear.

We recommend that:

10. Helsetilsynet sets out its quality system in one overarching document that makes all parts of the system clear to staff and stakeholders. This document should be made available on both its Internet and Intranet.

11. Helsetilsynet's quality system should include the requirement for all policies and procedural documentation to have the document owner, date of review and individual responsible for taking the review forward highlighted on its front page.

12. A database of all documents and their review date should be maintained by Helsetilsynet.

13. Helsetilsynet introduce a rolling programme of regular audits to test compliance with its quality system.

Chapter 7: Does Helsetilsynet have the right personnel in place and are they appropriately trained and supported?

The supervisory body should:

- have procedures in place that define an appropriate skill mix of personnel to be able to conduct supervisory activities;
- ensure that all staff have the appropriate qualifications, training, experience and a satisfactory knowledge of the requirements of the functions to be carried out. They should have the ability to make professional judgements as to the conformity with general requirements using inspection results and to report thereon; and
- have in place a documented training system to ensure the relevant training of its personnel, especially the personnel involved in inspection or disciplinary cases. The programme should include introduction, initial training, supervision and continuous education.

Skill Mix

7.1 Helsetilsynet employs approximately 110 members of staff, of which around 30 are lawyers, 15 are medical doctors, 10-15 are other healthcare personnel, about 10 are professionals within the field of social work and about 10 are social scientists.

7.2 There is no systematic system of workforce planning in place and we found no evidence of a recent review of skill mix having been undertaken. Decisions in relation to the skills needed are made by senior management; when a post becomes available the management group discusses whether the post needs to be filled and what type of individual is needed.

Training and continuous professional development

7.3 There was clear evidence that staff were undertaking training and that a number of courses were run by Helsetilsynet on a regular basis that focused on the training of inspectors and those leading supervisions. These included a five day course on how to conduct a systems audit. However, a documented training and development plan was not in place.

7.4 Departments had delegated budgets for the buying of books and journals and there was also a well-stocked library that was open to staff. Training budgets were delegated to departments and managers decide what training is needed by individual staff members on the basis of the work they are taking forward and issues identified as part of their annual performance review.

Conclusions and Recommendations of peer evaluation team

7.5 Helsetilsynet employs a highly skilled workforce and we were told that sometimes it was difficult to get staff with the right skills. While we understand that decisions in relation to workforce are made by the management group we consider that Helsetilsynet needs to have more formal mechanisms in place for workforce planning. It needs to ensure that timely succession planning takes place and that there is the right skill mix in the organisation to deliver Helsetilsynet's forward work programme.

7.6 While all the members of staff we spoke to told us that they felt supported and that they were given opportunities to undertake training and development, we believe that Helsetilsynet needs to put a formal training and development plan in place. This plan should be aligned to the skills needed by staff to undertake their work, fulfil Helsetilsynet's forward work programme and ensure that staff are kept up to date with best practice. In this regard we were pleased to note that Helsetilsynet has plans in place to bring in experts to help it develop a training and development plan for implementation in October 2012.

We recommend that:

14. Helsetilsynet puts formal work force planning arrangements in place.

15. Helsetilsynet develops a training and development strategy and plan.

Chapter 8: Does Helsetilsynet have access to the facilities and equipment that is required to deliver its function?

The supervisory body should:

- have access to suitable and adequate facilities and equipment that support the delivery of its function. This includes IT systems, databases and relevant documentation.

Office accommodation

8.1 We visited Helsetilsynet's offices in Oslo and found them to be spacious and well maintained. A staff restaurant was on site as well as a well-stocked library. Meeting rooms were well equipped with up to date VCR and equipment that allowed for the professional delivery of presentations. The staff we spoke to raised no concerns about the accommodation.

IT systems

8.2 We examined IT systems available to staff and particularly the Intranet called "The Pilot" (Norw. Losen), which can be accessed by regional and central supervisory authorities. There was evidence that the Intranet was widely used and that it was accessible and seen as a knowledge asset by staff. We certainly found the Intranet and Internet facilities to be extremely valuable and an excellent resource for staff.

Documentation

8.3 Standard documentation was in place for much of the functions carried out by Helsetilsynet. Staff told us that the documentation is easy to use and can be easily accessed via the Intranet. Documentation is supported by policies and procedures that explain when the different documents should be used and how they should be completed.

Conclusions and Recommendations of peer evaluation team

8.4 We considered the facilities and equipment available to Helsetilsynet to be suitable and relevant to its needs.

We have made a recommendation in Chapter 4 that Helsetilsynet tests the security of its electronic systems. We have no further recommendation to make here.

Chapter 9: Are Helsetilsynet's inspection methods, procedures and follow-up arrangements appropriate and transparent, and do they achieve the necessary outcomes?

The supervisory body should:

- ensure that the methods and procedures it uses for its planned inspections are those that are defined in legislation or documented in its policies and procedures;
- ensure that the methods and procedures it uses for incident inspections, are those that are defined in legislation or documented in its policies and procedures;
- set out in a way that is transparent and clear the methods and types of inspections in case of supervision of individual health personnel (disciplinary cases);
- have sound inspection planning arrangements in place. Planning and prioritisation processes should be documented;
- set clear terms of reference and objectives for its inspection activities;
- have quality assurance procedure in place that assure the consistency of judgments across teams;
- set standards for the delivery of its supervisory functions. The standards should include standards for the documentation of observations, the results of testing, information and data obtained during the course of inspections to ensure that they are recorded in a timely, consistent and professional manner to prevent the loss of relevant information. All documentation should be appropriately referenced, signed off and cross-referenced;
- use standardised techniques for sampling and inspection. These should be documented in circumstances where the absence of such instructions could jeopardize the efficiency or outcome of the inspection;
- describe in detail the use of unannounced inspections and the legal framework for such visits; and
- have arrangements in place for the follow up of its inspection findings.

Planned Inspections

9.1 Helsetilsynet's planned programme of inspections is focused on the supervision of services and to do this it uses a systems audit approach. Systems inspection involves the examination of documents, interviewing key staff and stakeholders, reviewing the organisation's systems and processes and carrying out sample tests. Guidance note 1/2008 sets out the various stages of a systems inspection including timelines for reporting.

9.2 Approximately 700 and 900 system inspections are carried out each year with about half of all planned supervision activities undertaken on a countrywide basis. Helsetilsynet decides the areas for countrywide supervision. The areas selected for countrywide supervision in 2009, 2010 and 2011 were:

- municipal health services: compulsory treatment in accordance with the Patients' Rights Act chap. 4A (applies to people without the capacity to give consent for treatment);
- municipal social and health services for frail, elderly patients;
- municipal child welfare - examination and evaluation of measures;
- specialist health services' treatment and rehabilitation of elderly stroke patients and patients with hip fracture;
- specialist health services (different subjects selected in the five regions);
- financial support in accordance with the new act on social services in the Norwegian Labour and Welfare Administration (Nav);
- psychiatric specialist health services for adults (district psychiatric centres); and
- municipal social and health services for children in palliative care homes and auxiliary housing.

9.3 To ensure consistency, a guideline for the conduct of the systems inspection is developed by Helsetilsynet for each countrywide themed inspection. These guidelines are published on Helsetilsynet's website upon completion of the inspection.

9.4 The stakeholders we spoke to felt that these planned system inspections were important to quality improvement and considered that Helsetilsynet should give more focus to them.

9.5 Counties choose their sample of organisations to visit as part of these systems inspections on the basis of risk. While the approach taken is in-line with legislative requirements that state that Helsetilsynet should focus on high risk organisations and individuals, we consider that for system inspections there is a danger that the overall view of how for example, specialist psychiatric services are working across Norway, could be skewed with only poor practices being identified.

Incident Investigation

9.6 The Counties receive information about possible deficiencies in the health services from many sources (patients, relatives, employers, the police, and the mass media). Approximately 2500 cases are investigated each year to establish whether there has been a breach of any relevant acts or regulations.

9.7 When non-compliance is identified, Helsetilsynet can issue instructions and requirements to the organisation or health professional. In the case of an individual these include a warning, withdrawal of the right to prescribe addictive drugs, or withdrawal of authorisation to practice as a health professional. As at 2010, there were approximately 390,000 health professionals registered to practice in Norway and each year between 50 and 100 lose their right to practice due to a variety of issues including drug abuse and inappropriate sexual relations with a patient.

9.8 Stakeholders spoke about the large number of lawyers employed by Helsetilsynet and the fact that they considered that the focus on quality of care and learning from incidents had been diluted. We were also told that health professionals are fearful of the process.

Unannounced Inspections

9.9 There was no procedure in place setting out the rationale, legal framework or the management arrangements for an unannounced inspection. While a procedure note had been developed for a specific piece of work in relation to elderly services, it did not cover all the areas that we would expect to see.

Consistency and Quality Assurance

9.10 Training and procedure guidelines are in place and provide the foundations to ensuring consistency in approach. All decisions and judgements are countersigned and cases are discussed at open staff meetings that involve both health professionals and lawyers. However, there was no regular audit of the quality of the work undertaken by Helsetilsynet.

Reporting and Follow-Up

9.11 We were advised that planned supervisory activity is reported on in a timely manner and usually a draft report is issued within two to three weeks of completion of fieldwork. However, incidents were often reported upon in a much longer timeframe and this has been an area of concern and criticism.

9.12 When organisational issues are identified as part of a systems inspection there are clear procedures in place for their follow-up; these procedures are set out in Chapter 5.7 of the guidance note on systems audit (Internal series 1/2008). In addition, follow-up instructions are set out in the annual letter sent by Helsetilsynet to the County Medical Officer. Organisations are required to correct the issues of non-compliance and confirm that they have done so in writing. However, similar arrangements are not in place for the follow-up of individual professionals who are subject to a warning. We discuss this further in **Chapter 12**.

Conclusions and Recommendations of peer evaluation team

9.13 We consider the use of the systems audit approach to be noteworthy practice as such an approach provides a framework that ensures consistency, a backbone of rigour and quality assurance at every stage of the inspection process. We reviewed a sample of supervisory systems inspections and incident investigations and found all working papers to be well organised and completed in line with the procedures set out by Helsetilsynet. We considered the systems inspections to be particularly well planned and consider the requirement for all working papers, decisions and judgements to be countersigned to be noteworthy practice.

9.14 However, we consider that Helsetilsynet should consider selecting the organisations to be reviewed as part of planned countrywide systems inspections on the basis of a stratified sample and so include organisations that range from excellent to poor in its sample of organisations to be visited. By including good and well as poor organisations Helsetilsynet will have the opportunity to identify good practice to enable it to better contribute to the improvement agenda. In addition, we also consider that Helsetilsynet should ensure that all health and social care organisations are visited as a minimum once every three years, as a focus on just poorly performing organisations can lead to 'game playing', the non-reporting of incidents and organisations 'falling off the radar' of supervisory bodies.

9.15 The greatest value is to be achieved from systems inspection when the focus of such reviews is not only on what 'isn't working so well' but also on 'things that are working well' and they are used to facilitate the identification and sharing of good practice. In this respect, we consider that Helsetilsynet's approach is too focused on identifying non-compliance and it is therefore missing opportunities to identify and share good practice. Such an approach also appears to be impacting on the way in which the organisation is perceived, many of those we spoke to from stakeholder organisations considered the organisation to be too focused on legal compliance and less focused on quality. In this respect some of those we spoke to also considered there to be an imbalance in numbers of legally trained staff compared to health professionals. This may only be a perception but the challenge for Helsetilsynet is to work with stakeholder organisations to address this perception.

9.16 The system of incident investigation in place appears very legalistic and could be perceived to be adversarial. While it is clear that Helsetilsynet takes its responsibility in relation to public assurance and ensuring patient safety extremely seriously, a balance needs to be struck between supporting health professionals to 'learn from their mistakes' and making them 'fearful of making a mistake'. While Helsetilsynet works actively to ensure that organisations that provide health and social services use supervision reports when developing management systems and improving the quality of services, it needs to consider how the process of supervision itself can contribute to learning and improvement.

9.17 Follow-up arrangements need to be further strengthened as there is a clear gap in relation to the follow-up of individual health professionals. Such arrangements should ensure that the individual has reflected and learnt from the incident that they were involved in and their practice improved.

We recommend that:

16. Helsetilsynet gives consideration to whether its current risk based approach to planned systems inspections is appropriate and whether it should include those organisations that are performing well in its sample of organisations to visit.

17. Helsetilsynet gives consideration to whether part of its role should be to identify and share good practice and communicates its decision to its stakeholders.

18. Helsetilsynet strengthens its follow-up arrangements and ensures that there is follow-up of individual health practitioners issued with a warning to ensure that they have reflected and learnt from the incident they were involved in and their practice improved.

19. Helsetilsynet introduces a programme of regular audit to ensure that its procedures for planned supervision and incident investigation are being properly followed and judgements made are consistent.

Chapter 10: Does Helsetilsynet communicate the objectives and outcomes of its inspection activity to those subject to inspection in a way that is clear and timely; giving them the opportunity to comment on findings and recommendations?

The supervisory body should:

- clearly communicate the objectives and purpose of its inspections to those subject to inspection.
- clearly set out the consequences of non-compliance with supervisory measurements and requirements and its expectations in terms of response to its recommendations.
- give those subject to inspection the opportunity to comment on the findings, conclusions and recommendations set out in the inspection report.

Objectives and Purpose

10.1 Generally, those we spoke to were satisfied that the procedures in place for planned supervisory activity ensured that those subject to supervision were properly informed of the scope of the work, timelines and reporting arrangements. Details of planned supervisory inspections are set out in letters sent to those organisations involved in the inspection two to three weeks before the planned start date.

10.2 Letters are also sent to health professionals who are the subject of an incident investigation but we question whether the information contained in these letters is sufficient to prepare the individual for the process.

Consequences of non-compliance

10.3 While the consequences of any aspects of non-compliance are discussed at the opening meeting of any supervisory activity we consider that the introductory letters issued to both organisations and individual health professionals should be more explicit in terms of process and consequences.

Opportunity to comment on findings

10.4 In cases of planned supervision, organisations get the opportunity to consider a draft report and check it for factual accuracy. They are also given the opportunity to respond to concerns. However, this is not the case in relation to individual incident investigations. Individual health professionals are not afforded the opportunity to hear the final findings and decisions of the investigator, only the preliminary assessment of the problem. There is therefore no opportunity for the health professional to respond to the findings or provide any evidence of mitigating circumstances or correct any factual inaccuracies. Similarly, hospitals and other health organisations are not routinely given the opportunity to respond to any warnings or criticisms issued against them as a result of an incident investigation.

Conclusions and Recommendations of peer evaluation team

10.5 Professional and system regulators have a clear role to play in public protection by ensuring that individuals and organisations comply with the regulations and requirements that are set for them. However, there is a clear balance to be struck between ensuring non-compliance is addressed and a system that allows for reflection and learning. Sometimes, a process that does not allow for the discussion of issues and concerns to take place in a non-threatening environment, amongst peers and without legal input, has the reverse effect to that which it aims to achieve. It can lead to the under reporting of incidents, the stifling of innovation and an inability or fear to make judgements. Helsetilsynet needs to reflect on whether its incident investigation processes could be enhanced to allow for a greater focus on reflection and learning.

We recommend that:

20. Helsetilsynet ensures that its introductory letters contain sufficient information to enable organisations and individuals to properly prepare themselves for the planned inspection or incident investigation.

21. Helsetilsynet reviews its incident investigation processes to ensure that organisations and individuals subject to investigation are given the opportunity to reflect and learn from the process in an environment that is non-threatening.

22. Helsetilsynet ensures that the incident investigation process allows organisations and individuals the opportunity to respond to the final findings and recommendations.

Chapter 11: Is Helsetilsynet open and transparent and does it make its findings available to stakeholders and the public?

The supervisory body should:

- make details of its processes and the findings of its inspections and activities available to the public and other stakeholders; in so doing it should ensure that its reports are written and published in formats that are user friendly and accessible.
- have a policy and guidelines in place setting out its approach for the publication of the results of its inspections.

11.1 Helsetilsynet's website is very good and contains a lot of useful information which is available in different languages and different formats for those who are visually impaired.

11.2 National reports are sent to the relevant authorities including the municipalities and the Department of Health and a copy is always placed on the website.

11.3 Some of the stakeholders we spoke to felt that reports could be written in a more user friendly format. For example, reports are not published in formats that could be easily understood by young people or mental health service users. We were told that patients and the public would like more information about the inspection process itself and information about the quality of hospitals and other health providers.

Conclusions and Recommendations of peer evaluation team

11.4 Helsetilsynet has taken some important steps in relation to making its reports available to patients and the public. It is open and transparent in terms of making its findings available but there are issues in relation to the format of its reports and whether they are user 'public and patient' friendly.

We recommend that:

23. As part of the planning for each national supervisory inspection and the development of its annual supervision reports consideration is given to who the key audiences for the report will be and hence what format the report should take. Such consideration will also help develop the scope and approach to the review.

Chapter 12: Is Helsetilsynet's approach to issuing of disciplinary sanctions appropriate:

The supervisory body should:

- have appropriate processes in place for the issuing and management of disciplinary sanctions.

12.1 The procedures for issuing a warning or revoking a licence are well set out in guidance notes and are in line with relevant legislation.

12.2 There appears to be a significant gap between the issuing of a warning and the revoking of a health professional's licence as there are no arrangements in place for the follow up of warnings. The placing of limitations on licences seems to be used infrequently. Further, when it comes to the abuse of prescription medicines, alcohol or illegal substances the only disciplinary sanction considered is the revocation of the health professional's licence. There is no avenue by which an individual may be given a second chance and the opportunity to get support to address their addiction before their licence is revoked although they may reapply for their licence to be reinstated at a later date when they are able to provide evidence that they have overcome their addiction. In cases of malpractice where there is no evidence of substance abuse the sanctions on the contrary appear lenient.

12.3 Statens helsetilsyn is aware that the number of licences to practice it revokes annually is much higher than other European professional regulators. In recognition of this, it has commissioned a research study to look at the reasons for such a disparity.

Conclusions and Recommendations of the peer evaluation team*:*

12.4 Many professional regulatory bodies have processes that allow for restrictions or conditions to be placed on an individual's licence for example a suitable condition for someone with a substance misuse problem may be a requirement that the

individual goes into “rehab” and becomes subject to regular drug tests in a period where clinical work is not allowed. In general there seems to be more focus on substance abuse and illness than on severe malpractice. The processes and sanctions in place in relation to the regulation of health professionals appear to be focused on stopping the individual from practicing rather than supporting an individual to learn and improve their behaviour or practice.

We recommend that:

24. Statens helsetilsyn ensures that the research study it has commissioned looks at the appropriateness of the introduction of conditions as an alternative to the immediate revoking of an individual’s licence where issues such as substance misuses are reported for the first time.

Chapter 13: Does Helsetilsynet have the necessary mechanisms in place to enable its impact and contribution to the improvement of the quality of care and patient safety to be measured and assessed?

The supervisory body should:

- have a policy and process in place for measuring the impact of its work
- regularly consider and assess how its inspection activity may contribute to the improvement of quality of care and patient safety.

Impact Assessment

13.1 There is no systematic process in place to enable the assessment of the possible impact of Helsetilsynet's forward work programme on Norwegian child welfare, health, care and social organisations. Impact assessments should be used to identify the potential consequences of a proposed inspection on healthcare organisations and professionals. They are useful in that by assessing the impact you are able to 'maximise the positive benefits of an inspection and minimise the potential adverse effects'.

Contribution to patient safety and quality of care

13.2 Planned supervisory activity appears to be focused on improving patient safety and the quality of care. While it is clear that findings are shared for example, through publications such as 'learn from your mistakes', it is less clear how the findings from these reviews are fed into policy and the development of standards and guidelines.

Conclusions and Recommendations of the peer evaluation team

13.3 As mentioned in earlier chapters many of those we spoke to felt that Helsetilsynet was not maximising the impact it could have on the improvement of quality of care. Generally, there was a perception that the focus on the quality of care agenda has been lost by an over emphasis on compliance and the issuing of sanctions.

13.4 The number of complaints made to Helsetilsynet is rising and this is causing pressure on staff, leading to rising levels of overtime and a drop off in planned supervisions. The development of an outreach team to target particularly high priority cases has been introduced but with insufficient resource. Helsetilsynet needs to assess whether it is putting its resources into the right activities and ensure that it focuses on the activities that best drive improvement and quality of care.

We recommend that:

25. Helsetilsynet undertakes an impact assessment of all new supervisory activity so that it is able to maximise the positive benefits of the activity and minimise any potential adverse effects. Such assessments should take account of for example the resource impact on those subject to review.

26. Helsetilsynet introduces formal systems to enable it to assess the contribution that it's various work streams make to patient safety and quality care. It should use such systems to inform its decisions about the allocation its infinite resources.

Chapter 14: In developing its plans, inspection approaches and findings does Helsetilsynet engage with stakeholders, patients and other review bodies?

The Supervisory body should:

- ensure that in taking forward its role it engages with patients, the public and other stakeholders; seeking their views and experiences.
- work in collaboration with other review bodies to share experiences and identify noteworthy practice.
- share its knowledge in relation to patient safety issues with health organisations.

Patients and Public

14.1 Helsetilsynet recognises that it needs to improve the way it engages with patients and the public and plans are in place to amend regulations to enable greater patient participation in supervisory activities. A white paper on patient participation has been developed by the Ministry of Health.

Collaboration with other review bodies

14.2 Helsetilsynet is a leading light in relation to driving collaboration amongst European supervisory bodies. In 1996, its Director General and Deputy Director General together with the Dutch Inspection for Healthcare (IGZ), started the European Platform of Supervising Organisations, the forerunner of EPSO.

14.3 Helsetilsynet is also a key contributor to the annual Nordic Conference that brings together those who are involved in the supervision of health organisations and regulation of health personnel in the Nordic countries.

Conclusions and Recommendations of the peer evaluation team

14.4 Helsetilsynet is to be commended for the hard work and commitment it gives to driving collaboration amongst European supervisory bodies. It is an exemplar of a

truly learning organisation and takes the lead in striving to develop standards and the sharing of best practice.

We have made a recommendation in Chapter 5 that Helsetilsynet develops a patient and public engagement strategy. We have no further recommendation to make here.

Chapter 15: Conclusions and Next Steps

15.1 We considered Helsetilsynet to have sound frameworks in place that ensure the delivery of supervision to a high professional standard. The organisation is well respected and held in high regard by health professionals and stakeholder organisations. We were impressed by Helsetilsynet's openness and willingness to open itself up to challenge and review. This is the mark of a mature learning organisation and indeed an exemplar supervisory body.

15.2 The challenge for Helsetilsynet as it moves forward is for it to decide whether there is an opportunity for it to further enhance its role to one of providing public assurance and driving improvement and not just regulatory compliance. There is a distinct difference in these roles and both are legitimate roles for a supervisory body; the wider public assurance and improvement role adds value and ensures that the fundamental purpose of supervision i.e., to safeguard the public is not lost and the patient is kept at the centre of decision making. It also facilitates learning and more sustainable change by challenging organisations and individuals to hold the mirror up to themselves and identify where they need to improve.

15.3 We have made 26 recommendations in this report that have been developed with the aim of providing guidance to Helsetilsynet as to where we consider it needs to focus its intention. Many of these recommendations we ourselves need to reflect upon and will be using them as the basis of discussions within our own organisations. For ease of reference a summary of these recommendations is provided below:

We recommend that:

1. Helsetilsynet gives consideration to how it may better communicate its goals to the public.

2. Helsetilsynet expands its annual supervision reports to include information about how it operates and in particular its vision, staff, role, values and developmental work.

3. Helsetilsynet develops operational protocols and memoranda of understanding with County Governors and the Norwegian Knowledge Centre for Health Services.

4. Helsetilsynet uses videoconferencing as a tool to improve communication with the counties.

5. Helsetilsynet starts to put arrangements in place to ensure that:
   - the corporate knowledge and memory held by the current Director General is not lost on his retirement;
   - the networking arrangements and relationships built up by the current Director General are sustained following his retirement.

6. Helsetilsynet introduces a conflicts of interest register and procedures that require members of staff to declare whether they have a possible conflict of interest in relation to the supervisory work they have been allocated.

7. Helsetilsynet retests the security of its electronic information system by undertaking an exercise similar to that undertaken in 2004-05.

8. Helsetilsynet documents the rationale for its forward work programme setting out clearly why the various areas/topics were chosen for inclusion. It should also consider making this available to the public.

9. Helsetilsynet develop a patient and public engagement strategy that sets the framework for its engagement with patients and the public to inform all aspects of its work including forward planning.

10. Helsetilsynet sets out its quality system in one overarching document that makes all parts of the system clear to staff and stakeholders. This document should be made available on both its Internet and Intranet.

11. Helsetilsynet's quality system should include the requirement for all policies and procedural documentation to have the document owner, date of review and individual responsible for taking the review forward highlighted on its front page.

12. A database of all documents and their review date should be maintained by Helsetilsynet.

13. Helsetilsynet introduce a rolling programme of regular audits to test compliance with its quality system.

14. Helsetilsynet puts formal work force planning arrangements in place.

15. Helsetilsynet develops a formal training and development strategy and plan.

16. Helsetilsynet gives consideration to whether its current risk based approach to systems inspections is appropriate and whether it should include those organisations that are performing well in its sample of organisations to visit.

17. Helsetilsynet gives consideration to whether part of its role should be to identify and share good practice.

18. Helsetilsynet strengthens its follow-up arrangements and ensures that there is follow-up of individual health practitioners issued with a warning to ensure that they have reflected and learnt from the incident they were involved in and their practice improved.

19. Helsetilsynet introduces a programme of regular audit to ensure that its procedures for planned supervision and incident investigation are being properly followed and judgements made are consistent.

20. Helsetilsynet ensures that its introductory letters contain sufficient information to enable organisations and individuals to properly prepare themselves for the planned inspection or incident investigation.

21. Helsetilsynet reviews its incident investigation processes to ensure that organisations and individuals subject to investigation are given the opportunity to reflect and learn from the process in an environment that is non-threatening.

22. Helsetilsynet ensures that the incident investigation process allows organisations and individuals the opportunity to respond to the final findings and recommendations.

23. As part of the planning for each national supervisory inspection and the development of its annual supervision reports consideration is given to who the key audiences for the report will be and hence what format the report should take. Such consideration will also help develop the scope and approach to the review.

24. Helsetilsynet ensures that the research study it has commissioned looks at the appropriateness of the introduction of conditions as an alternative to the immediate revoking of an individual's licence where issues such as substance misuses are reported for the first time.

25. Helsetilsynet undertakes an impact assessment of all new supervisory activity so that it is able to maximise the positive benefits of the activity and minimise any potential adverse effects. Such assessments should take account of for example the resource impact on those subject to review.

26. Helsetilsynet introduces formal systems to enable it to assess the contribution that it's various work streams make to patient safety and quality care. It should use such systems to inform its decisions about the allocation its infinite resources.

Appendix 1

EPSO
European Partnership for Supervisory Organizations in Health Services and Social Care

The European Partnership for Supervisory Organizations in Health Services and Social Care (EPSO) is an informal group of governmental and government-related organizations involved in law enforcement, supervisory activities, monitoring and accreditation, related to Health Services and Social Care in European countries or regions, including EFTA (European free trade area) countries.

EPSO aims to:

- improve co-operation amongst supervisory bodies to ensure the quality of inspection, supervision and monitoring of health services and social care;
- improve the exchange of ideas, outcome of research, information and good practice;
- facilitate the exchange of experience between interested organisations including directives, regulations, standards and guidelines;
- promote co-operation on topics such as education and dissemination of knowledge; and
- as a result of these activities EPSO aims to improve the quality of health care and social care in Europe including EFTA countries.

Specifically EPSO is focused on:

- Building up a network by exchange of information and co-operation between European colleagues in supervisory organisations, in order to develop mutual confidence and trust in the resolution of matters of health and social service supervision. In the case of cross border health care of patients as well as health care personnel, the network will facilitate the exchange of information about quality and safety of health care institutions and health care personnel. The members of the network will work together if this is deemed desirable or necessary in the interest of cross-border healthcare.

- Improvement of the quality of supervisory activities in health & social care within the European Community including the European Free Trade Area (EFTA countries) by improving informal and formal exchange of information between European colleagues in supervisory organisations, good and bad practice, outcome of research, promotion of joint co-operation on specific terms of health care, education and dissemination of knowledge and other ways to connect between the supervisory organizations and the organizations involved in quality control on health services as well as connecting individual members in the various countries or regions in order to improve the exchange of ideas and good practice in health & social care in Europe.

- Promotion of the adoption of good practice, in respect of the principle of the European 'home authority'. This involves facilitating the exchange of experience

between interested organisations, for example exchange of directives, regulations, standards and guidelines.

Member Countries:

- Belgium Flanders
- Bulgaria
- Denmark
- Estonia
- Finland
- France
- UK
  - England
  - Northern Ireland
  - Scotland
  - Wales
- Germany (participating without membership)
- Hungary (not participating anymore)
- Portugal
- Republic of Ireland
- Lithuania
- Malta (participating without membership)

- Netherlands
- Norway
- Slovenia (participating without membership)
- Sweden

Participating organisations:

The Celtic Network of Social Care Regulators

Appendix 2

EPSO Peer Evaluation Team

Anne Mette Dons	Head of the Department of Supervision and Patient safety at the Danish National Board of Health, Sundhedsstyrelsen, Denmark
Jan Vesseur	Chief inspector for Patient Safety, Health IT and International Affairs Netherlands
Jooske Vos	Director EURinSPECT /Head EPSO Secretariat
Katia Käyhkö	Senior Medical Officer, National Supervisory Authority for Welfare and Health, Valvira, Finland
Mandy Collins	Deputy Chief Executive, Healthcare Inspectorate Wales, Wales
Neil Prime	Head of Analytics, Care Quality Commission, England

HELSETILSYNET
tilsyn med barnevern, sosial- og helsetenestene

European Partnership for Supervisory Organisations in Health Services and Social Care
c/o EURinSPECT
Benoordenhoutseweg 21-23
2596 BA Den Haag

DYKKAR REF: / YOUR REF:	VÅR REF: / OUR REF:	DATO: / DATE:
Jooske Vos	2011/356 L	16th March 2011

REQUEST FOR A PEER EVALUATION OF NORWEGIAN BOARD OF HEALTH SUPERVISION

Norwegian Board of Health Supervision hereby confirms preliminary contacts requesting EPSO to organise a peer evaluation of our organisation.

As a governmental institution NBHS is regularly audited by the Auditor General. In addition NHBS is under scrutiny by the Ministry of Health and Care as our superior institution. Furthermore specific decisions of NBHS may be reviewed by other independent bodies as the courts, the Parliamentary Ombudsman and the Norwegian Appeal Board for Health Personnel.

Section 16 in regulations on economical governance in the state administration of 12. Dec. 2003 states that every governmental institution is obliged to regularly perform evaluations of their own activities. The task proposed here should be seen as a part of this obligation.

In many fields there are established organised peer evaluations performed across national borders. E.g. this is common related to accreditation and certification of commercial bodies related to inspections of quality systems. But related to supervisory organisations in health services and social care there up to now has been no such arrangements on European level. Further there are no commonly accepted standards for supervision of care providers across national borders.

Observing increasing public expectations on good practice and predictability from supervisory/inspecting organisations, NBHS is interested in stimulation the establishment of a more systematic approach to peer evaluations. This also seems necessary to support the ongoing work on strengthening the possibilities for patients to choose among care providers across national boundaries, and to enhance the effectiveness of supervision of cross-boundaries health care provision and migration of health personnel.

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The role of EPSO

According to our view EPSO seems to be a suitable platform for investigating the possibilities and trying a practical approach to a systematic peer evaluation of a national supervisory institution. The issue has been discussed by EPSO, at the conferences in Cork in 2009 and in London in 2010, and the board of EPSO also has indicated support to the idea.

We therefore ask EPSO to coordinate a peer evaluation of NBHS. It should be up to EPSO to elect participants to the evaluation committee and to elaborate the more detailed approach for the evaluation, including the interpretation of national requirements in a European context.

Below NBHS will outline the aim of the peer evaluation seen from our perspective.

Aim of the peer evaluation

The evaluation should be done respecting the formal conditions (legislation, budgets) under which NHBS works.

The aim of the evaluation is to determine if NHBS works in a way that could be acknowledged as good supervisory practice. We especially would like the auditors to evaluate the methods used by NHBS and the documentation and traceability of results from supervisory activities.

Furthermore the aim is to point out possible areas for improvement, and areas where further standard setting should be sought.

The evaluation process is also intended to make a basis for a standard setting by bringing together peer opinions from professionals from the various national supervisory bodies participating in EPSO.

The evaluation team shall be free to choose the relevant topics for further investigation and also decide which parts of the work of NHBS to be closer investigated.

The process and results of the peer evaluation should be documented by a written report and also presented for NHBS at a meeting.

The normative basis for the evaluation

As a governmental institution the work of NHBS is regulated by legislation and by annual budget frames given by the Parliament through the Ministry. These frames should be observed by the evaluators.

In addition the evaluation could relate the findings to certain suitable, though not formally binding norms, as e.g. NS-EN ISO/IEC 17020 – General criteria for the operation of various types of bodies performing inspection (ISO/IEC 17020:1998).

The norms used by the evaluators should be documented in the report.

Methods of the evaluation

The methods should be defined by the evaluators. Seen from NHBS analysis of documents as well as interviews seems relevant. NHBS will provide necessary translation of documents after further agreement with the evaluators. We hope that EPSO will appoint one auditor with knowledge of Scandinavian languages to be in position to select relevant documents for translation into English.

Proposed time schedule

March 2011	Proposal to be sent to EPSO
April 2011	EPSO to appoint evaluators
May 2011	Discussion at the EPSO-meeting in Tromsø
September 2011	Preparatory meeting of the evaluators (Oslo?)
November 2011	Evaluation period (Oslo)
February 2012	Finishing report (?)

Economic basis

We hope that the institutions willing to participate with evaluators can let relevant persons do that as a part of their ordinary work. NHBS is prepared to cover direct expenses as costs related to travel and accommodation on field visits in Norway.

As a preliminary budget we will suggest an upper limit of NOK 300.000,- Claims for reimbursement of expenses shall be sent to NHBS, and will be dealt with according to Norwegian procedures.

NHBS look forward to further cooperation on this issue, now first at the EPSO-conference in Tromsø.

Lars E. Hanssen
Director General

Terje Jensen
Director

Appendix 4

Details of those interviewed as part of peer evaluation process

Helsetilsynet Staff

Anders Haugland	Assistant Director of Dept. (Department II for Supervision - Planned Supervision)
Anna Stavdal	Senior Advisor (Department I for Supervision - Incident Cases)
Bjørn Jamtli	Senior Advisor (Department I)
Geir Sverre Braut	Deputy Director General
Gorm Grammeltvedt	Director of Department I, dep. Director General
Lars E. Hanssen	Director General, Professor of University of Bergen
Lise Broen	Senior Advisor (Department II)
Liv Turid Lieng	Assistant Director of Dept. (Department I)
Merete Steen	Senior advisor (Department II)
Richard H Knoff	Director (Department II, dep. Director General

County Staff

Helga Arianson	Chief County Medical Officer, Hordaland County Governor
Lise R. Winther	Senior Advisor, Østfold County Governor
Petter Schou	Chief County Medical Officer, Oslo and Akershus County Governor
Siri Baekkevold	Senior Advisor, Østfold County Governor

Representatives of Stakeholder Organisations

Barthold Vonen	Vice CEO Nordlandssykehuset (Nordland Hospital)
Birthe Guttormsen	Social Worker Local Child and Elderly Welfare Worker
Heidi Skaara Brorson	Head of Patient Support, Norwegian Cancer Association
Linn Merethe Nilsen	The Welfare Alliance
Randi Talseth	Secretary General, Adults for Children
Sveinung Homme	Advisor, Former Chief of Healthcare in Ringerike Municipality
Torunn Janbu	former President, Norwegian Medical Association

Appendix 5

Documents Reviewed and Considered by Peer Evaluation Team

Legislation

- Act of 17 July 1992 No. 100 relating to Child Welfare Services (The Child Welfare Act)
- Health Research Act
- Personal Data Filing System Act
- Communicable Diseases Act
- Legislation supervisory authority (different acts)
- The Health Services Supervision Act , the Act of 30 March 1984 No. 15
- The Public Health Act of 2011-06-24 No. 29: (folkehelseloven)
- The Act on Social Services in the Nav Act of 183 December 2009 1991 No. 1381 relating to social services in the Labour and Welfare administration
- Act of 13 December 1991 No. 81 relating to social services etc. Social Services Act (out of force by 31 December 2011).
- The Act of 2 July 1999 No. 64 relating to Health Personnel
- The Alternative Treatment Act 2003
- The Treatment Biobank Act
- The Specialist Health Services Act of 1999-07-02 No. 61
- The Dental Health Services Act

General yearly budget, planning, instruction and reporting documents

- Strategy Plan for 2010-12
- Annual Report for 2010
- Annual plans for 2010 and 2011
- Government's proposal for budget and support letter
- Ministry of Health national budget 2011 letter

- Letter to Norwegian Board of Health in the Counties setting out official assignments for health supervision in 2011
- Management Group Minutes and documents
- Minutes of meetings with Ministry of Health
- Annual statistics on incident Cases and patients' rights Cases

Annual plans for planned supervision, including process for decision on countrywide supervision

- Letter inviting comments and suggestions from counties on 2012 priorities
- Comments and suggestions from counties on 2012 priorities
- Summary of suggested priorities
- Management Board papers setting out suggested priorities
- Ministry of Health topics for supervision in 2012
- Supervision plan for Aust-Agder County 2011

Results of supervision

- Report 31 May 2011 of deficiencies in patient administration systems and electronic patient records at several of the nation's health trusts

Procedure documentation and guidance notes

- Quality system overview
- System audit procedures
- Audit report guidance note
- Instruction manual for unannounced supervision
- Guidance for processing - incident cases, part II for Statens helsetilsyn
- Guidance for the routine distribution of publications
- Safety instructions for home working
- Risk analysis of the IT systems

Internal education

- Documentation to support the basic course for supervisors
- Documentation to support course for leaders of supervision