

The background of the slide is a collage of various healthcare-related images, including hospital rooms, medical equipment, and people in clinical settings, all rendered in a semi-transparent, blue-tinted style.

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

European Partnership for Supervisory Organisations
in health services and social care

A first presentation of the results of the Peer evaluation of The Norwegian Board of Health Supervision (Statens helsetilsyn) by EPISO

Presentation April 29 2012 by Mandy Collins, Anne Mette Dons,
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(Team members Neil Prime and Jan Vesseur are unable to attend
due to illness)

This presentation, in English and Norwegian, is published on www.helsetilsynet.no

Content staff presentation

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Background

Helsetilsynet's letter to EPISO (March 16 2011):

EPISO seems suitable platform for a systematic peer evaluation of a national supervisory institution.

Aim of the peer evaluation (1) from Helsetilsynet's letter

Aim is to determine if NBHS works in a way that can be acknowledged as good supervisory practice.

To evaluate :

- a. The **methods** used by NBHS,
- b. the **documentation** used by NBHS,
- c. **traceability of results from supervisory activities** of NBHS.

Aim of Peer evaluation (2) from Helsetilsynet's letter

Aim is furthermore :

- a. To **point out possible areas for improvement** of NBHS.
- b. Point out areas where **further standard setting** should be sought by NBHS.
- c. To form a basis for **standard setting by EPISO** (bringing together peer opinions from professionals cross- border).

Conditions (1) from Helsetilsynet's letter:

- EPISO selects peers and methods;
- EPISO is free to choose topics;
- EPISO is free to decide on which parts of Helsetilsynet they want to investigate closer.

Conditions (2) from Helsetilsynet's letter:

- EPISO respects formal conditions (legal, budget);
- EPISO 'could' relate findings to norms e.g. NS-EN ISO/IEC 17020 and criteria ISO/IEC 17020:1998
- process and Results should be documented by written report and presented to NBHS in a meeting.

EPISO Peer Evaluation Team (members of the group)

EPISO's selection:

Mandy Collins, Dept. Chief Executive, Wales,

Anne Mette Dons, Head of Department, Denmark,

Katia Käyhkö, Senior Medical Officer, Finland,

Neil Prime, Head of Analytics, England,

Jan Vesseur, Chief inspector, Netherlands,

Jooske Vos, Director EURinSPECT /EPISO

The approach

1. Careful consideration was given to the standards/norms that other organisations developed for supervisory and audit bodies (ISQUA, International Society for Quality in Healthcare and ISO/IEC standard 1720:1998).
2. The peer evaluation team identified 13 key areas that required examination and evaluation and set out a set of norms in these areas.

Scope : Key areas examined (1) :

1. Statutory basis – Helsetilsynet's functions;
2. independence, impartiality and integrity;
3. confidentiality and safeguarding of information;
4. organisation and management;
5. quality systems;
6. personnel;
7. facilities and equipment;

Scope Key areas examined (2) :

8. inspection methods and procedures;
9. engagement and communication with the organisation or individual subject to review;
10. openness and transparency;
11. disciplinary sanctions;
12. impact assessments; and
13. co-operation and engagement with other stakeholders including other supervisory bodies.

The methods used

We:

1. Reviewed key strategic and operational documents
2. observed senior management meetings;
3. interviewed key members of management, staff and stakeholders;
4. held group discussions with members of staff;
5. reviewed work samples (incident investigations; planned inspections, themed inspections e.g. ICT, and maternity services).

Norms – Statutory basis (chapter 2)

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

Findings

- . Purpose clearly set out in Acts and Regulation;
- . Objective, direction and work plan. All in the Strategic Plan.
- . We are impressed by your website!!

Recommendations (chapter 2)

1. Helsetilsynet gives consideration to how it may **communicate its goals to the public better.**
2. Helsetilsynet **expands its annual supervision report** to include information about **how it operates** and in particular, its **vision, staff, role, values and developmental work.**

Norms – Independence (chapter 3)

The supervisory body should have processes/ systems to ensure :

- . Independence to be defined;**
- . impartiality to influence of key stakeholders;**
- . personnel understands to act with integrity;**
- . personnel do not have a conflict of interest;**
- . (experts) assisting about conflicts of interest, political, commercial, financial pressure.**



Findings

- **Autonomy given in legislation.**
- **The MedEvent future transferral to the Knowledge Centre is a concern.**
- **The County Medical Officers future terms of reference is a concern.**
- **The Director General is well respected by all and has strong working relationships.**
- **Helsetilsynet's voice is clearly taken forward! As seen in the case of IT in healthcare.**
- **Generally no conflicts of interest.**

Recommendations (chapter 3)

3. Develop **operational protocols and memoranda of understanding with County Governors** and the **Norwegian Knowledge Centre** for Health Services.
4. **Use videoconferencing to improve communication** with the counties.
5. Put arrangements in place **to sustain the corporate knowledge**, memory and working relationship with stakeholders so that it is not lost, on the retirement of the Dir. General.
6. **Conflicts of interest register and procedures.**

Norms – Safeguard data (chapter 4)

- 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.

Findings

- Safeguard of information is managed competently!
- Electronic systems, information access are limited to relevant staff.
- Security is tested.
- Noteworthy printing practice.
- Incidents are handled.

Recommendations (chapter 4)

7. Retest security of electronic information system by undertaking exercise similar to 2004-05

Norms – Organisation/Management (chapter 5)

- . **Defined relationships** with DoH, umbrella organisations, patient and user organisations; the County Governors;
- . **described/documentated organisational and management structure** (responsibilities personnel, reporting structure);
- . inspection **activities cf. legislation and defined standards**;
- . **procedures to prioritise activities (transparently)**;
- . **effective supervision of all personnel**;
- . **ensure co-ordination of supervisory activities.**

Findings

- **Regular meetings with DoH and PHI (Public Health Inst.).**
- **Annual letter from DoH setting the work programme.**
- **Well documented and known structure of Helsetilsynet.**
- **Engaging with some stakeholders.**
- **Much focus on County-HT relation in interviews.**
- **No formal daily learning between HT and Counties.**
- **Final prioritisation decided in management group.**

Recommendations (chapter 5)

8. **Document rationale for the yearly forward work programme** (set out clearly why the various areas/topics were chosen for inclusion) and consider making this available to the public.
9. Develop a **patient /public engagement strategy** (set a framework for engagement with patients /public to inform them about all aspects of Helsetilsynet's work including the forward planning).

Norms – Quality system (chapter 6)

- **Define and document policy and objectives for and commitment to quality**, ensure that **policy is understood, implemented and maintained at all levels** of organisation; (accessible to relevant personnel);
- **feedback** procedures; procedures for dealing with feedback and corrective action;
- system for **control**; documentation and legal actions according to law;
- **review the quality system** at appropriate intervals.

Findings

- **Quality system on the intranet, but difficult for staff to describe.**
- **Written documentation and procedures for many tasks.**

Recommandations (chapter 6)

- 10. Quality system in one overarching document** (available on internet and intranet).
- 11. Document owner, date of review, individual responsibility for the review**, on front page of documents.
- 12. Database of all documents and review date.**
- 13. Test compliance** with quality system (Regular audits).

Norms – Personnel & Training (chapter 7)

- . Define **appropriate skill mix** of personnel.
- . All staff have **appropriate qualifications, training, experience and satisfactory knowledge** of the requirements of the functions to make professional judgements (conformity with general requirements) using inspection results and report thereon.
- . **Documented training system** (including introduction, initial training, supervision and continuous education).

Findings

- . 110 staff, largest group lawyers.
- . Decisions on skill mix made by senior management.
- . Training primarily for inspectors.
- . Well-stocked library!!

Recommendations (chapter 7)

14. Put formal **work force planning arrangements** in place.
15. Develop a **training and development strategy and plan.**

Norms – Facilities (chapter 8)

The supervisory body should have:

Access to suitable and adequate facilities and equipment that support the delivery of its function (including IT systems, databases and relevant documentation).

Findings

Very suitable facilities.

Intranet excellent!

Standard documentation in place and supported
in policies.

Recommandations (chapter 8)

No further recommendation to make here.

Norms – Inspection methods (a) (chapter 9)

- **Methods and procedures for inspections** (planned and incident) are defined in legislation or documented;
- set out to be **transparent and clear in case of supervision of individual health personnel (disciplinary cases)**;
- **sound inspection planning** (documented planning and prioritisation);
- **clear terms of reference/ objectives** for inspection; and
- **quality assurance to assure consistency of judgments across teams.**

Norms – Procedure (b) (chapter 9)

- . Set of standards to include standards for documentation of observations, the result of testing, handling of information and data recorded in a timely manner;**
- . use standardised techniques for sampling and inspection (and document them);**
- . describe in detail the use of unannounced inspections and the legal framework for such visits; and**
- . have arrangements for the follow up of inspection findings.**

Findings

- Good guidance for planned supervision.
- Stakeholders find the planned inspection very important and they want more.
- Concern raised on the doctor/lawyer ratio in incidence investigation.
- Many procedures in place.

Recommendations (chapter 9)

16. **Consider whether the current risk based approach (planned inspections) is appropriate** and whether it should include those performing well.
17. **Consider whether part of Helsetilsynet's role is to identify and share good practice** and communicate decisions it to stakeholders.
18. **Strengthen the follow-up arrangements**; ensure that individual health practitioners have reflected and learnt from the incident and their practice is improved.
19. Introduce 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.**

Norms – Communication (chapter 10)

- **Clearly communicate objectives and purpose of inspections (to subjects to inspection);**
- **clearly set out consequences of non-compliance;**
- **give subjects to inspection opportunity to comment on the findings, conclusions and recommendations in inspection report.**

Findings

- **Information well received in planned supervision**
- **There is information in incidence investigation also, but...**

Recommendations (chapter 10)

20. Ensure that the **introductory letters contain sufficient information** to enable organisations and individuals **to properly prepare themselves** for the planned inspection or incident investigation.
21. Review the 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. Ensure that incident investigation allows organisations and individuals **the opportunity to respond to the final findings and recommendations.**

Norms – Transparency (chapter 11)

- **Make details of processes and findings of inspections and activities available to the public and other stakeholders;**
- **ensure that reports are written and published in formats that are user friendly and accessible;**
- **have a policy and guidelines for the publication of the results of its inspections.**

Findings

- **Very good website!!**
- **Fine National reports**

Recommendations (chapter 11)

23. **Give** (as part of planning for each national supervisory inspection and annual supervision report) **consideration to who the key audiences for the report will be** and hence what format the report should take.

Norms – Disciplinary sanctions (chapter 12)

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

Findings

**Fine guidance in place, good practice.
Gap between warning and revoking.
A large number of revocations.**

Recommendations (chapter 12)

24. Ensure that research study 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.

Norms – Impact (chapter 13)

Have a policy and process in place for **measuring the impact of its work;**

regularly consider and assess how the inspection activity may contribute to the **improvement of quality of care and patient safety.**

Findings

No systematic process to assess impact.

It is not clear how findings from inspections used in the development of standard and guidelines.

Recommendations (chapter 13)

25. **Undertake impact assessment of all new supervisory activity** (for example the resource impact on those subject to review) to:
 - a. maximise the positive benefits of the activity and
 - b. minimise any potential adverse effects.

26. **Introduce a formal systems to assess the contribution of various work streams to patient safety and quality care.** Use such systems to take informed decisions about the allocation of finite resources.

Norms – Engagement (chapter 14)

- Ensure (by taking forward the supervisory role) to **engage with patients and users, 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 knowledge in relation to patient safety issues** with health organisations.

Findings

Whitepaper from DoH on patient involvement; but stakeholders are not regularly addressed and involved

HT is the leading light in European collaboration and in the Nordic collaboration.

What should we do without you!!!

Recommendations (chapter 14)

See recommendation in Chapter 5:

Helsetilsynet develops a patient and public engagement strategy.

(No further recommendation here).

THANK YOU



We are very grateful to:

- management and staff of Helsetilsynet**
- members of stakeholder bodies**

Report
The Norwegian Board of Health
Supervision (Statens helsetilsyn)

**who gave their time, knowledge and expertise
to our review team and**

**demonstrated that they wanted to learn from the process
and improve.**

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

March 2012

We have learned a lot ourselves.



Further Questions and Discussion ??