Reports on serious incidents in Norwegian municipal health and care services in the first four years following extension of the national reporting scheme as of 1 July 2019

Contents

1 Summary

Until 1 July 2019, the duty to report serious incidents to the Norwegian Board of Health Supervision only applied to the specialist health service. After this date, a similar duty to report was imposed on the municipal health and care services, and patients, service users and next of kin were also given the right to report serious incidents. During the first four years after the reporting scheme was extended, the Norwegian Board of Health Supervision received reports of 873 incidents involving municipal health and care services that met the criteria set out in the reporting scheme. The reports were mainly received from managers of organisations within the municipal health and care services.

The incidents reported most frequently concerned clinical assessments/diagnostics (17 per cent), falls (13 per cent) and use of medication (9 per cent). Most incidents occurred in nursing homes or other institutions (310 incidents) and in connection with home-based health and care services (180 incidents), out-of-hours medical centres/EMS communications centres (152 incidents) and general practitioner services (100 incidents). In 529 of the cases (61 per cent), the patient died.

We conducted 16 incident-based inspections following reports concerning municipal health and care services. The inspections identified several risks and areas for improvement, including the following:

- **Care coordination** is particularly important for patients/service users who are followed up in multiple settings in the municipal health and care services, in the specialist health service and in emergency situations. This requires improvements with regard to clear lines of responsibility, care coordination and expertise within the various services. We saw that there were issues concerning cooperation agreements between employees, departments and hospitals and between the different levels of the health and care services. Structures must be in place that facilitate proper communication and information flows among employees, between different administrative levels and with relatives.
- We found that the **out-of-hours medical centres and municipal acute inpatient units** had inadequate systems for ensuring medical attendance to patients during busy periods and for detecting changes in the patient's condition post-admission in order for any acute deterioration to be adequately managed.
- **Lack of overview of risk areas** in connection with reorganisation/operational changes.
- **Lack of risk assessments** before the introduction of technological solutions, for example in the use of welfare technology and digital solutions for coordination between employees and between different units/organisations.
- **Lessons learned**: several incident-based inspection cases reported that previously reported nonconformities, acknowledged risk factors and incident-based inspections have not been used to any great extent in subsequent improvement efforts. Nonconformity cases and incident-based inspection reports had not been communicated to employees to any great extent.
- **Procedures** for e.g. the use of medical devices. We saw that procedures were either not in place, were unknown or had not been applied correctly. We also found organisations that lacked systems to ensure that employees were familiar with and able to use devices and that any training received was not systematic and documented.
- With regard **to medication management**, we found problems related to the fact that support systems for medication management existed at the unit but were not applied; there was a lack of internal control concerning medication management; or no assessments had been made concerning the risk of drug interactions.

The purpose of the reporting scheme is to identify incidents and service delivery failures more quickly, so that these can be corrected and patient safety can be improved. In our incident-based regulatory

inspections and the resulting reports, we aim to evaluate incidents and recommend measures for improvement from a systemic perspective. We believe that incident-based inspection reports can be important sources for the municipalities' approach to improving patient safety and for further learning and improvement.

2 Introduction

In the present report, we summarise the reports received by the Norwegian Board of Health Supervision concerning municipal health and care services over the first four years of this reporting scheme. Among other things, we present summaries of the number of reports submitted, the types of incidents the reports concerned and how we have followed up on these reports. In addition, we present more detailed content for the cases we have followed up for regulatory purposes.

Our aim in doing so is to summarise a number of experiences from the commencement of the extended reporting scheme and to describe risk and improvement areas that we have identified. This is to be regarded as a status report, and we have not consulted research literature in our assessments of the topics described. We have also not looked at whether differences exist between municipalities, counties or county governor offices.

3 History

3.1 Legislative amendment in 2019

The statutory scheme for reporting serious incidents to the Norwegian Board of Health Supervision was established in 2010. Until 1 July 2019, the duty to report serious incidents to the Norwegian Board of Health Supervision only applied to the specialist health service. After this date, a corresponding reporting duty was imposed on municipal health and care services. The reporting duty is set out in Section 6 of the Health Supervision Act, Section 3-3 a of the Specialist Health Services Act and Section 12-3 a of the Health and Care Services Act. We refer to reports made under these statutes as *organisation reports*.

From the same date, patients, users and relatives were accorded the right to report serious incidents, pursuant to Section 7-6 of the Patient and User Rights Act. We refer to reports made by patients, users and next of kin collectively as *individual reports*.

3.2 Digital solutions adopted gradually

The duty to report incidents to the Norwegian Board of Health Supervision rests with the organisation and not with individual health professionals.
Individual health professionals can submit reports on behalf of the organisation. By *informant* we mean the person who submitted the report.

Organisations submit reports via melde.no, while individuals use helsenorge.no. Digital solutions for submitting reports were implemented gradually in late 2019. Since 2021, we have received almost all reports digitally. The solution requires the informant to log in with their personal bank ID and complete relevant information, including:

- The patient's or the informant's own name or national identity number
- Next of kin

- The informant's contact details
- Description of the incident

The information contains personally identifiable and sensitive information and is received via a secure solution provided by Norsk helsenett (the national service provider of e-health solutions) directly into the Norwegian Board of Health Supervision's supervisory system. Reply documents are sent out via the Norwegian Board of Health Supervision's archival system. These reply documents have been transmitted digitally since May 2023.

4 Total number of reports received

As shown in Figure 1, we received a total of 5,960 reports in the period 1 July 2019 to 30 June 2023. The majority of individual reports were from patients/users, and the majority of organisational reports were were from the specialist health service.

In the present report, our focus is on the 873 incidents that met the reporting scheme's criteria and which *concerned* municipal health and care services, regardless of whether they were reported by the specialist health service, municipal health and care services or by individuals. The numbers presented in Figure 1 are discussed in various sections of this report.

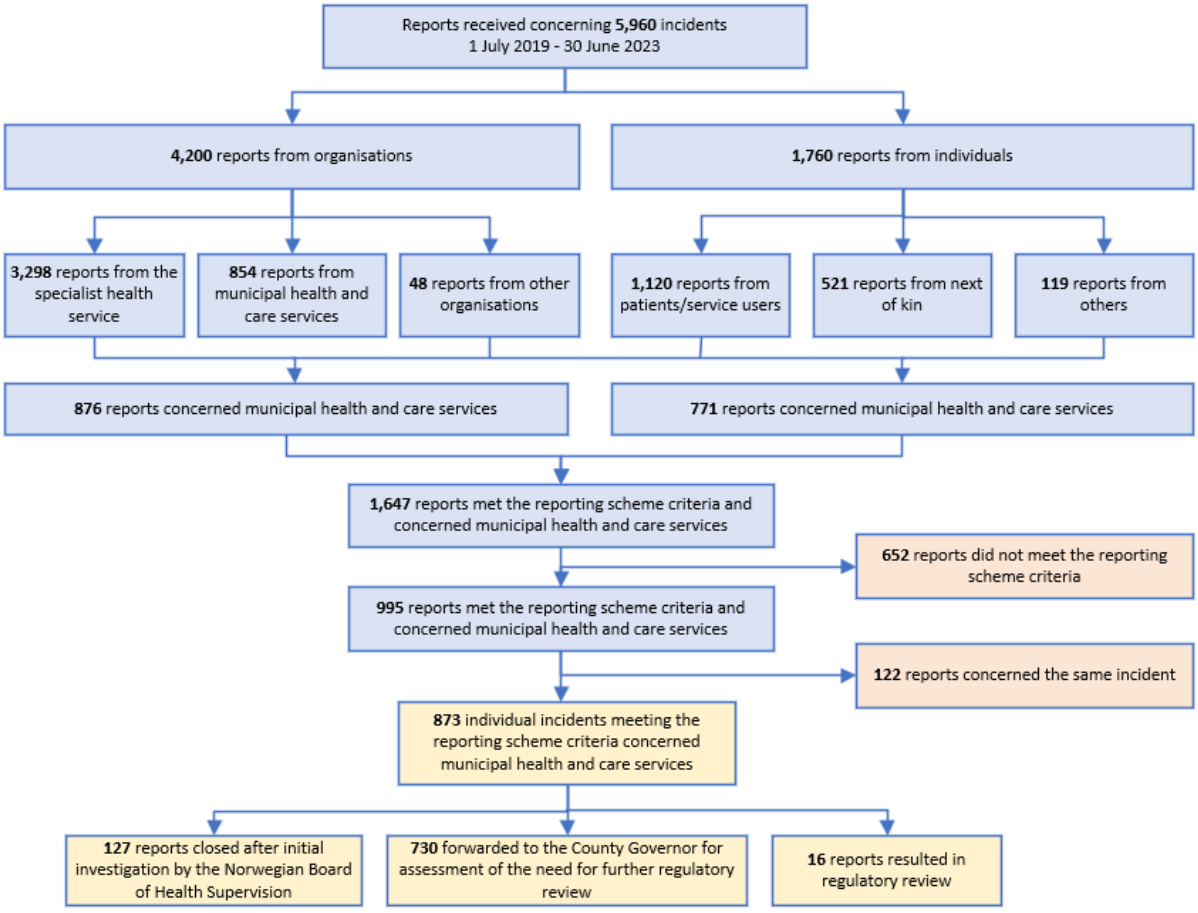

Figure 1: Overview of received reports and how the Norwegian Board of Health Supervision followed them up.

Figure 1 shows that we received 4,200 reports from organisations. These broke down into 3,298 from the specialist health service, 854 from the municipal health and care service and 48 from other organisations. From individuals, we received 1,760 reports; 1,120 from patients/users, 521 from next of kin, and 119 from others. Of these, 1,647 reports concerned municipal health and care services, but since 652 of these did not meet the reporting scheme criteria and 122 of them were submitted more than once, 873 single incidents remain. We closed 127 cases following preliminary investigations, forwarded 730 to the County Governor for assessment of the need for further regulatory investigation, and we conducted 16 inspections.

5 Who submitted the reports?

According to Section 12-3 a of the Health and Care Services Act, "an organisation that provides health and care services shall immediately report to the Norwegian Board of Health Supervision any death or severe harm to a patient or user as a result of the service provided or by a patient or user harming another patient or user. The reporting duty applies if the outcome is unexpected based on foreseeable risk."

In the digital registration form for organisations at melde.no, we ask the informant to state their "role" in the incident as a manager, healthcare provider or other employee. On the form for individuals at helsenorge.no, informants record their relationship with the patient/user if their report concerns someone other than themselves.

Of the 854 reports submitted from municipal health and care services, 823 reports concerned those services. As shown in Table 1, these reports were mainly made by managers. In addition, we received 52 reports from the specialist health service and one report from private-sector municipal health services that also concerned municipal health and care services; i.e. a total of 876 reports from organisations concerning municipal health and care services.

In total, we received 73 reports from "other employee". The majority of these were various types of health and care workers as well as a few quality management employees. For 87 reports, we lack information about the informant's role because this was not recorded before we implemented digital reporting.

Of the individual reports, the majority were from patients/users (59 per cent) (Table 2). Of the individual reports, 33 per cent were submitted by next of kin. Of all the 1,647 reports concerning municipal health and care services, 47 per cent were from individuals.

The reports came from and concerned many municipalities. We have not analysed whether any differences exist between districts, counties or county governor offices.

Table 1: Overview of report submitters from organisations in reports concerning municipal health and care services.

REPORT SUBMITTER	Number	Percentage (within each group)	Total number
Specialist health service			**52**
Treatment provider	18	33.3	
Manager	26	50.0	
Other employee	8	16.6	
Municipal health and care service			**823**
Treatment provider	105	8.7	
Manager	569	74.2	
Other employee	65	6.9	
Information missing	84	10.0	
Health and care service generally			1
Manager	1	100	
Total			**876**

Table 2: Overview of report submitters from individuals in reports concerning municipal health and care services.

REPORT SUBMITTER	Percentage	Number
Patient/user	456	59.1
Next of kin	251	32.6
Others (such as friends, neighbours, or acquaintances)	61	7.9
Information missing	3	0.4
Total	**100**	**771**

A total of 122 incidents were reported by more than one person/entity, for example, by both an individual and an organisation or by two different organisations. In the following, we present the number of incidents, not the number of reports. The 1,647 reports presented in Table 1 thus concerned 873 individual incidents that met the reporting scheme criteria and concerned municipal health and care services.

6 What was reported?

To be reportable, an incident must meet these three criteria:

- * death or severe harm to patient or user
- as a result of the provision of health and care services or the patient or user harming another patient or user AND
- the outcome is unexpected based on foreseeable risk.

There is *no* reporting duty for incidents that *could potentially* have resulted in death or severe harm.

While the scope of what falls within and outside the reporting scheme may be discretionary, we assess all reports in relation to these criteria. As Figure 1 shows, we concluded that 652 reports (40 per cent) did not meet the reporting criteria. These are discussed in more detail in Chapter 5.4.

All reports are considered from an interdisciplinary perspective and are categorised according to incident type and severity of harm to the patient/user before we draw a conclusion on the action to be taken. In the following, we present incidents within the municipal health and care services that fell within the reporting scheme criteria.

6.1 Incident types

The incident descriptions in the reports generally provide a description of what happened, and we have relatively little information about risk factors and improvement potentials. Incidents are categorised based on what we believe was the main concern or issue reported. We select one incident type per incident. However, any given incident may involve multiple factors or issues. An overview of incident types is provided in Table 3. A description and examples of what the incident types involve are presented in Appendix 1

Table 3: Types of incidents in reports concerning municipal health and care services.

INCIDENT TYPES	Percentage	Number
Medical examination/diagnostics	16.8	147
Fall	13.3	116
Unknown/undetermined cause of death	12.0	105
Medication use	9.3	81
Suicide	8.4	73
Acute life-saving intervention	5.4	47
Medical care	5.4	47
Physical assault	5.0	44
Infection	3.3	29
Other	2.4	21
Use of medical devices	2.3	20
Burns/scalds	2.2	19
Complaint regarding service/rights/treatment offered	2.1	18
Overdose/intox	2.1	18
Complication related to feeding/ingestion	1.7	15
Suicide attempt/self-inflicted harm	1.6	14
Nursing, personal care or observation	1.4	12
Disappearance/abscondment	1.3	11
Homicide	1.0	9
Suspected/alleged sexual assault by employee	0.8	7
Surgical intervention/operation	0.7	6
Patient/home care safety alarm	0.7	6
Fall/jump from height	0.5	5
Use of force (physical, mechanical or chemical restraint)	0.3	3
Total	**100**	**873**

6.2 Where in the health and care services did the incident occur?

Unwanted serious patient incidents often occur in a setting where more than one healthcare agency is involved. Therefore, when classifying where the incident occurred, we apply more than one value. Thus, the sum of the numbers in Table 4 exceeds the total number of incidents. Here we see that the majority of incidents involved nursing homes or other institutions, home-based health and care services, local out-of-hours medical centre/EMS communications centres and general practitioner services. Some of the options in this classification system are specialist health care. These are incidents where both the specialist health service and the municipal health and care service were involved.

Table 4: Distribution of care settings involved in the incidents.

CARE SETTING	Number
Nursing home or other institution (not municipal/emergency in-patient care)	310
Home-based health/care services (not practical assistance)	180
Local out-of-hours medical centre/EMS communications centres	152
General practitioner services (not out-of-hours medical centre)	131
Other municipal health and care service	100
Health trust	55
Habilitation/rehabilitation	47
Practical assistance	19
Other	15
Municipal/emergency in-patient care	14
Municipal mental health/SUD service	13
Maternity and child healthcare centre	4
Private hospital or unit in private specialist health services	3
Private practice specialist	3

Prisons health service	3
Other 1st line private health service	2
Public health service/environmental health service	1

6.3 Age distribution

The age distribution among patients/users in the 873 incidents is shown in Figure 2 and Table 5. Here we see that the majority of reports concerned individuals aged 65+; 427 concerned individuals aged 65+ (49 per cent). We lack age data in 78 of the reports. This is because age data was not systematically recorded before we started using digital reports.

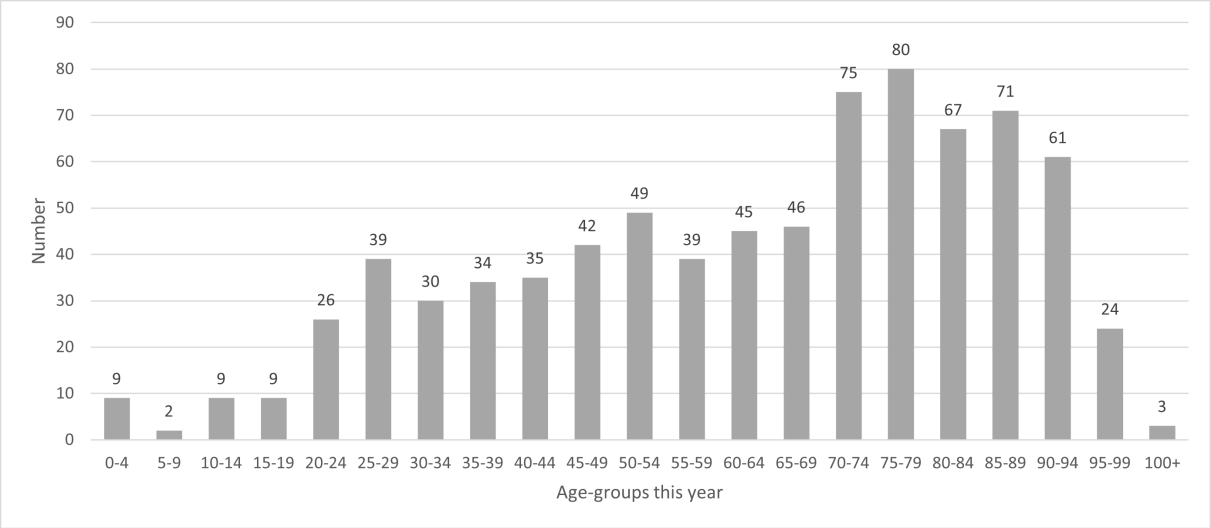

Figure 2: Age distribution of patients/users across the incident reports received

Table 5: Age distribution of patients/users across the incident reports received

AGE GROUP	Number
0-4 years	9
5-9 years	2
10-14 years	9
15-19 years	9
20-24 years	26
25-29 years	39
30-34 years	30
35-39 years	34
40-44 years	35
45-49 years	42
50-54 years	49
55-59 years	39
60-64 years	45
65-69 years	46
70-74 years	75
75-79 years	80
80-84 years	67
85-89 years	71
90-94 years	61
95-99 years	24
99 years+	3
Missing age data	78
Total	873

6.4 Gender distribution

For the 873 incidents reported, gender data was missing in 78 cases.. Of the remaining 795, 377 were women/girls (47 per cent) and 418 were men/boys (53 per cent).

6.5 Degree of harm to patient/user

By *degree of harm*, we mean the severity of the adverse effect or actual impact on a patient/user caused by a given incident. What constitutes *Severe harm* is a matter of discretionary judgement.

For the majority of incidents, we have no information about how the patient's condition progressed after we received information about the incident. This is why the degree of harm is graded as Uncertain/other in around one-fifth of the incidents.

The degree of harm is shown in Table 6.

Table 6: Degree of harm in incidents in municipal health and care service.

DEGREE OF HARM IMPACTING/CAUSED BY PATIENT/USER	Percentage	Number
Death	60.6	529
Severe harm	15.1	147
Death of someone else caused by patient/user	0.6	5
Severe harm caused to someone else by patient/user	1.4	12
Uncertain/other	20.6	180
Total	**100**	**873**

In incidents reported by organisations, the proportion of deaths was somewhat higher than in those reported by individuals (66 versus 41 per cent).

7 Responding to reports

We respond to reports differently depending on incident severity, complexity and the assumed risk of (similar) incident recurrence. In some cases, we obtain more detailed information about the incident from the organisation and from the patient and/or next of kin before deciding how to respond to the report. Table 7 shows our conclusion concerning the reports we rated as meeting the reporting criteria.

Table 7: Conclusion concerning incidents involving municipal health and care services.

NORWEGIAN BOARD OF HEALTH SUPERVISION CONCLUSION REGARDING RESPONSE	Percentage	Number
Closed following preliminary investigation	14.6	127
Forwarded to the County Governor for assessment of supervisory response	83.6	730
Supervisory response	1.8	16
Total	**100**	873

7.1 Closed within Norwegian Board of Health Supervision following preliminary investigations

When assessing whether there is a basis for following up on a report, we look not only at the outcome for the patient, but also at the risk of a similar incident impacting other patients. In cases closed after preliminary investigations by us, our opinion is that the organisation's internal review and actions are the most appropriate means of improving service safety and quality standards. These may be incidents

that have had severe outcomes for the patient/user, but where we still believe that any further action on the part of the supervisory authorities is unwarranted.

7.2 Forwarded to the County Governor

As shown in Table 6, approximately 84 per cent of cases were forwarded to the County Governor for assessment of the need for a supervisory response. These are cases for which we consider that there is a need to conduct a more detailed investigation of the incident and in which the County Governor's local insights may be important for correct understanding of the incident.

The Office of the County Governor has its own methods for incident assessment. The processing and conclusions of the County Governors are not presented in this document.

7.3 Supervisory response

Figure 1 shows that the Norwegian Board of Health Supervision took supervisory action in a total of 16 cases, or on 1.8 percent of reports concerning municipal health and care services. We investigate the most complicated incidents where it may be difficult to ascertain the course of events, when multiple services and employees are involved, if severe failure/omission is suspected and/or if the incident exemplifies a particularly important topic in patient safety and quality of care.

In total, we conducted 14 incident-based regulatory inspections[1]. In some instances, we visit involved organisations to talk to managers and healthcare staff who were involved in care provision and we offer patients/next of kin an interview. Thorough investigation and analysis of these cases is necessary in order to gain an accurate picture of the incident and ascertain whether the incident is indicative of a failure in the organisation's risk management. This forms the basis for assessments of the responsibilities of the organisation's management and involved healthcare staff, and the organisation's regulatory compliance. The inspection identifies and investigates organisational factors that contributed to the failure of risk management and healthcare.

In two cases, we asked the organisation to self-report in writing their assessment of the incident. The organisations set out improvement proposals that are planned to be implemented as a result of the reported incident. We focus on the organisation's active commitment to quality improvement and patient safety in order to prevent future failures as well as on management's responsibility for establishing effective management systems.

The purpose is to identify risk areas, which risk mitigation and harm reduction actions have been undertaken or are needed in order for our supervision to raise standards of care and trust in the services. Before we close an incident-based inspection we consider whether the case can be closed or whether it warrants further action.

7.3.1 Post-inspection reports

After conducting our inspection, we compile and issue our report to the organisation and to the patient/user or next of kin. The Norwegian Board of Health Supervision monitors the case, jointly with

[1] *Two cases were inspected as one because the two incidents were indicative of similar issues a few days apart.*

the County Governor if necessary, until the organisations have rectified any regulatory non-compliance/unsafe circumstances.

As a general rule, all reports are published in an anonymised version on the Norwegian Board of Health Supervision website. Our incident-based inspection reports are intended to contribute to learning and improvement beyond the particular incident and organisation(s) involved, by communicating the findings to other organisations that also stand to learn from the incident in terms of improvements in quality standards and patient safety.

In the following, we present the themes in these cases and some common features of risk reduction and quality improvement measures.

7.3.2 Themes in regulatory inspection cases

1. High-risk pregnancy follow-up
2. Medication monitoring for at-home patients
3. Transportation and healthcare in an emergency
4. Healthcare for a patient in acute mental health crisis
5. Follow-up of patient in a case of acute exacerbation during a stay in a municipal acute inpatient unit
6. Care coordination in follow-up of a patient in a state of confusion (delirium)
7. Healthcare for agitated users in need of round-the-clock supervision
8. Clinician attendance at out-of-hours medical centre for acute chest pain
9. Pregnancy management at out-of-hours medical centre
10. Use of welfare technology (GPS tracker) by nursing home resident with dementia
11. Follow-up of sick child at refugee reception centre
12. Medication management during transition between hospital and nursing home
13. Communication and information flow in medication management in homecare
14. Follow-up care at home following short-stay hospitalisation
15. Mix-up of two patients in medication management
16. Use of medical devices in health care delivery

We concluded that there were nonconformities with best practice in all cases except one (case no. 11 in the list above). We present these cases in Appendix 2.

7.4 Reports that did not meet reporting scheme criteria

The Norwegian Board of Health Supervision also receives reports on incidents that do not indicate that serious harm or death occurred, or that there was any connection between the healthcare and the outcome for the patient/user. As shown in Figure 1, we considered that 652 of the reports concerning municipal health and care services did not meet the reporting scheme criteria (were non-reportable) (40 per cent).

Of the individual reports concerning municipal health and care services, 530 out of 771 – that is, more than 80 per cent – did not meet the reporting scheme criteria. The fact that this proportion is so large may indicate that it is unclear what is reportable to which entity. The individuals who submitted these reports were most likely in a difficult situation, and perceived the incidents they reported as extremely serious. Our assessments that these incidents were non-reportable rely on the wording of Norwegian

law: that for such incidents to be reportable, severe harm or death is caused *as a result of* healthcare. In most of these cases, we concluded that this causal connection was not sufficiently likely to be present. Many of these reports appear to be complaints concerning healthcare or rights. Examples of reports that did not meet the criteria are presented in Appendix 3.

In our response to the person submitting the report, we describe alternative recipients such as the County Governor or the organisation involved. We also refer people to one of the local branches of the Health and Social Services Ombudsman who can assist in directing them to the right recipient.

For reports submitted by municipal health and care services, we cannot tell whether we have received a report concerning the "right" incidents or to what extent all reportable incidents are actually reported. Of the incidents that both were reported by a municipal health and care service and which concerned that healthcare setting, 118 did not meet the criteria (14 per cent).

The reporting scheme is still relatively new. Local authorities may not be fully familiar with what the reporting duty entails, and there may be uncertainty regarding who can submit a report. Information about the reporting duty for municipal health and care services can be provided both through local initiatives and by the Norwegian Board of Health Supervision actively informing them of this.

7.5 Specific risk and improvement areas in inspected incident settings

We will now be discussing some of the risk and improvement areas identified in connection with the completed inspections. Some incidents include several of the described risk and improvement areas. A summary of the inspection reports is provided in Appendix 2. More detailed descriptions can be found in the incident-based inspection reports published (on the Norwegian Board of Health Supervision website).

Here we pay particular attention to problems and deficiencies that were described at the systemic level, and less on the professional practice of the individual health and care worker.

7.5.1 Medication management

Regarding medication management, we saw problems concerning:

- non-use of the existing support tools for medicines administration. In one incident, we saw that both hospitals and nursing homes had support tools for detecting and assessing the risk of interactions, but had not put in place well-defined routines and common practices for use of the tool. One patient received too much blood thinning medication and died.
- deficiencies in internal control systems for medication management. For example, this was described when a homecare user was discharged following a short stay in hospital. There were deficiencies in medicines receipt, dispensing to the user and documentation of healthcare delivery. The user did not receive the prescribed anticoagulant therapy and suffered a massive stroke.

7.5.2 Care coordination

Care coordination is particularly important for patients/users who are followed up at multiple service locations within the municipality, in the specialist health service and in emergency situations. This imposes greater requirements as regards clear lines of responsibility, coordination and expertise within the various services. We identified issues concerning collaboration agreements between employees,

between departments, with next of kin, with hospitals or between the different levels of the health and care services. This resulted in, for example, medication errors, delayed clinician attendance in the transition from hospital to nursing home and a lack of follow-up of the user following transfer to another service location.

In two incidents where seriously ill patients needed rapid transportation to hospital, we identified issues relating to decision-making when a helicopter ambulance was requested, including deficient decision support for staff in prioritising and fulfilling airlift missions. There was a risk of failure because the same individual in the organisation had to fill different roles in the process. There was no system to avert the risk of decision-making failures in situations involving conflicting considerations such as infection control considerations versus emergency preparedness

7.5.3 Out-of-hours medical care centre or municipal acute inpatient unit

At out-of-hours medical care centres or municipal acute inpatient units, we saw that systems were not in place to:

- ensure medical supervision during busy periods
- detect a change in the patient's condition after admission so that acute deterioration could be adequately managed

Among incidents at out-of-hours medical centres, patients were reported as having to wait longer than recommended and dying before they were seen by a doctor. High operating levels were described in both of these events.

The patient in the municipal inpatient unit suffered acute deterioration in their condition. Overall, the municipality was failing to ensure proper healthcare for patients admitted to a municipal acute inpatient unit with somatic disease and at risk of acute deterioration. National and relevant guidelines exist to guarantee proper healthcare for patients admitted to a municipal acute inpatient unit, but the organisation had not ensured familiarity and compliance with these guidelines among the healthcare professionals responsible for care delivery. The organisation had not provided adequate training on procedures and the use of ICT systems to ensure safe practices and nurse-physician coordination.

7.5.4 Risk assessment in the event of reorganisation and prior to the introduction of technological solutions

In connection with reorganisations or operational changes, it is important to perform risk assessments. We saw that this was not done, for example, before the introduction of welfare technology. This applied to a nursing home resident who was issued with a GPS tracking device. The necessary assessment of hazards and risks had not been adequately ensured before the tracker was worn by the resident. When the resident disappeared, managers and staff were unsure of how the device actually worked. In addition, the battery charge in the tracker had not been checked before use. The resident was found dead. There had also been no official decision on use of a GPS tracker as required by law.

In several inspections, we found that departments and units had reorganised their homecare services, but without fully assessing how they would need to ensure that users were not accidentally excluded from the care management system. One service user was not relisted in the new system and was found dead in their home after some time.
For another service user, a decision was made to reduce their follow-up care due to the pandemic. Daily home visits to ensure that the service user was taking vital medication were replaced by

telephone calls, but the service had not established routines for what to do if patients did not respond to scheduled telephone consultations. The service user died a few days after their last contact with the homecare service.

7.5.5 Failure to learn from mistakes

Several reports described that previously reported nonconformities, acknowledged risk factors and regulatory inspections/audits were not put to use in improvement efforts. Nonconformity cases and audit reports had not been communicated to employees to any great extent.

7.5.6 Procedures

We saw that procedures were missing, not known or not carried out correctly, for example for the use of medical devices. One patient did not receive professionally responsible healthcare because the medical device had been incorrectly connected. The patient did not receive the respiratory assistance they needed and died.

It is the responsibility of the organisations to ensure that the users of medical devices are trained so that they have the necessary skills and knowledge of correct and safe use at all times. Training must be systematic and documented.

8 Experiences from the digital reporting system

8.1 Digitalisation involved a new enrolment system

Before we had digital systems for submitting reports to the Norwegian Board of Health Supervision, the information was obtained orally by a case officer within the Board and entered in our case processing system. This resulted in many manual processes for collecting and recording information from organisations and from patients and next of kin. This was time-consuming and also a potential source of inaccurate entries.

With digital reports submitted by the organisations, we receive a description of incidents from the perspective of the organisation directly into our case processing system. There is still, however, often a need to request supplementary information after the initial report has been submitted. This means that a new report must be submitted through melde.no. We note that it would save time if organisations were able to submit reports directly from their quality management systems.

8.2 Login using informant's personal ID

As mentioned in Chapter 1.2, incident reporting may be delegated by an organisation to an individual healthcare professional. Digital reporting currently requires the informant to login with their personal ID. This can be undesirable, since the digital interaction is then via the person submitting the report and the case officer at the Norwegian Board of Health Supervision, instead between the *organisation* and the Board.

9 Have the incident-based inspections had an effect?

The purpose of the reporting scheme as regards the most serious incidents is to identify unsafe circumstances more rapidly, so that they can be rectified and patient safety brought up to standard. This begs the question of whether reports submitted from the municipal health and care services have actually served to improve patient safety. Based on the statistics so far it is not possible to quantify the effect of improvement measures locally or nationally. This is due in part to the relatively limited number of incidents reported and the wide-ranging of those incidents. For the same reason, it is also not possible to quantify the trends in terms of numbers.

Nonetheless, in our experience, the organisations find that incident-based inspections help them to identify risk areas and quality improvement measures, and also support them in carrying out those measures.

In our regulatory inspections and reports, we aim to evaluate incidents and recommend measures for improvement from a systemic perspective. Our aim is for risk areas and improvement measures to be described so generally that they can be applicable to organisations beyond those actually involved. The majority of incident-based inspection reports are published in a redacted version on the Norwegian Board of Health Supervision website. We believe that our inspection reports can serve as important sources for guiding the active commitment to patient safety and efforts to realise lessons learned and improvements.

In addition, we have found that information sharing is achieved by municipalities that have undergone an inspection being contacted to share their experience of improvement projects after the inspection. We are also increasingly being contacted to give talks and communicate our regulatory findings in various forums within the municipal health and care services.

10 Summary

Organisations are responsible for the safety of their services. The purpose of regulatory supervision, including the reporting scheme, is to contribute to patient safety, care quality, and trust in health and care services. While we cannot measure the effect of the incident-based inspections we conduct, our experience of improvement efforts made locally following an inspection tells us that regulatory supervision has a positive effect. Now, following the first four years of the extended incident reporting scheme, we find that there is a lack of familiarity with the scheme in the municipal health and care services. We believe that there is immense transfer value in the incident-based inspections conducted, and it is gratifying that the organisations are actively using their experiences of undergoing regulatory inspection in their training and improvement programmes.

11 Appendices

11.1 Appendix 1 – Description and examples of categories of incident types

- **Medical examination/diagnostics**: this includes incidents concerning all types of somatic examinations and diagnostic procedures. Patients/service users and next of kin accounted for the highest percentage of incident reports in this category. Examples of incidents: possible delayed diagnosis of serious illness; death shortly after physical or telephone contact with a healthcare professional.
- **Fall**s includes different types of falls in own home or institution.
- **Unknown/undetermined cause of death** generally denotes incidents where the patient/user was unexpectedly found dead, and where the cause of death was not known when the organisation reported the incident. In some of these incidents, suicide was suspected.
- **Medication use**: this includes any incidents involving the use of medication, ranging from prescribing, preparing, administering and effect to observed adverse reactions.
- **Suicide** among patients/users who received services in municipal health and care services.
- **Acute life-saving interventions** are incidents in which a patient/user died suddenly and unexpectedly while under medical care, typically without known risk factors. These are also incidents where patients died or were seriously injured after being found in poor condition and despite initiation of a life-saving intervention.
- **Medical care** was mainly reported by employees in organisations and by next of kin and concerned, for example, injury following surgical intervention or catheterisation, injury in connection with personal care or moving and handling and possible delayed initiation of relevant therapeutic interventions.
- **Physical assault** includes incidents in which physical harm was inflicted on fellow patients/residents or on next of kin or friends.
- **Infection**: many of these incidents concerned COVID-19 related factors. These incidents generally concerned, for example, non-compliance with infection control rules resulting in infection or concerns about treatment for suspected or test-positive infection
- **Other** denotes incidents not otherwise classified under one of the options available. Examples of such incidents included harm caused by structural factors on the premises, accidents during transportation between organisations, fire in the home of a user of a municipal health and care service, allegations of medical record errors, a report of potentially ongoing risks and unsafe circumstances in the services.
- **Use of medical devices** includes any incident involving the use of medical devices, including apparatus for moving and handling, prosthetic devices and the use of tubes and catheters.
- **Burns/scalds:** the majority of these incidents involved patients/users injured during bathing in a bathtub, shower or handbasin because the water was too hot. This also includes burn injuries from use of a hot water bottle placed on a person with paralysis. Most of these incidents were reported by municipal health and care services.
- **Complaint regarding service/rights/treatment offered**: Most of these reports were from individuals. They included a complaint from next of kin concerning the type or standard of care offered, a complaint concerning lack of access to medical care and a complaint regarding the child welfare services.
- **Overdose/intox**: Many incident reports concerned overdose of illicit drugs by users/patients undergoing treatment. There were also a few reports concerning overdosing of prescribed therapeutic drugs.
- **Complications related to feeding/ingestion**: these incidents concern patients who got food in their airways either because they were given the wrong type of food (for example, not mashed food where this had been determined) or where patients suffered blocked airways when being fed/eating.
- **Suicide attempt/self-inflicted harm**: all these incident reports were from organisations. Many incidents concerned jumps from a height.

- **Nursing, personal care or observation** include incidents related to wound care, personal care/hygiene assistance, follow-up of basic needs of a user with a mental disability, nutritional follow-up of long-stay inpatient and procedures for issuing advice in connection with discharge from an institution to own home.
- **Disappearance/abscondment** concerns incidents where the patient/use went missing from their home or institution and were subsequently found dead or in poor condition.
- **Homicide**: mainly includes patients/users under a mental health order who commit homicide.
- **Suspicion/alleged sexual assault by employee** was reported both by patients/users, next of kin and both the patient/user, relatives and managers at municipal activities. These alerts relate to suspected/alleged sexual assault of a patient/user by an employee.
- **Surgical procedure/operation**: includes surgery-related complications and/or deaths.
- **Patient/home care safety alarm** includes both technical failure of the alarm system and lack of staff response to sounding of an alarm.
- **Fall/jump from height**: many of the reports described that it was unclear whether the incident was an accident or suicide. The incidents occurred both inside an institution and outdoors.
- **Use of force (physical, mechanical or chemical restraint)** includes harm caused by restraints to prevent, restrict or subdue movement for behavioural control and complaints about the use of force.

11.2 Appendix 2 – The incident-based inspection cases

In the following, we present a summary of the 16 incidents for which we conducted a regulatory inspection; first with a brief description of the incident, followed by the theme for our inspection, our assessments and conclusion, including suggestions for quality improvement measures. The dates and organisations involved have been anonymised.

11.2.1 High-risk pregnancy follow-up

Incident
A pregnant woman received antenatal care from her GP and midwife. There were language problems, and an interpreter was used. Foetal intrauterine growth restriction (IUGR) was detected (based on low symphysis fundal height (SFH). The woman was not referred to the specialist health service, but she was subsequently hospitalised due to an infection. The IUGR was not mentioned in her admission record. Later in the pregnancy, the midwife also measured a low SFH, but did not arrange for a foetal growth checkup appointment. The foetus was dead by the time the woman consulted the obstetrics department when she was about one week over term.

Regulatory topic
Our focus was to investigate how actors in the municipality and at the hospital arranged for women with high-risk pregnancies to receive the necessary antenatal follow-up.

Assessment
We concluded failure to refer the pregnant woman directly to hospital care as soon as the midwife had measured SFH as being under the 2.5 percentile was not in line with best practice. There was no record of the anomalous SFH measurement. This was information that should have been recorded and which should also have been stated in the hospital discharge notes sent to the midwife and GP. The Norwegian Board of Health Supervision also finds that the discharge notes should have provided specific advice on further follow-up concerning the low SFH. Not offering the woman a new consultation was not in line with best practice.

The woman received clinically responsible healthcare while she was hospitalised. The hospital had procedures in place to ensure that women referred due to low SFH were assured of medical follow-up.

Conclusion
Overall, the deviation from best practice was so severe that the woman received sub-standard healthcare.

Post-incident quality improvement
Following the incident, the municipality has worked systematically on quality improvement and patient safety.

11.2.2 Follow-up of medication use by homecare patient

Incident
A patient with a chronic disease was supposed to receive homecare service visits in the morning and evening to check that they were taking their medication. The homecare service was reduced to evening visits only. During the pandemic, the service was further reduced to an evening phone call from a healthcare professional.

Two months after the last service reduction, the patient was found unconscious in their home by relatives, by which time they were in severe decline. The patient brought to hospital where they died. It was discovered that the homecare service had not been in contact with the patient for three days. The homecare service had phoned the patient but had failed to reach them.

Regulatory topic
Had the municipality made a comprehensive assessment of the patient's needs and facilitated that the user received correct drugs?

Assessment
No plans were made for how the patient should be followed up or for how the homecare service should liaise with other services in healthcare delivery to this patient. The homecare service had reduced its follow-up of the patient's care without involving a GP or the specialist health service. When the pandemic took hold, the homecare service decided that daily home visits should be replaced by a telephone call to the patient, despite the fact that it was not possible to check that the patient was correctly medicated over the phone.

The municipality did not have procedures for what to do if the patient did not answer the call, and it was up to the individual healthcare professional to decide what to do when they were unable to make contact. During the inspection, it emerged that the municipality had not established adequate procedures and practices for how homecare patients/users should be followed up.

The municipal services did not ensure that important messages and information about the patients/users were transferred between healthcare professionals. The healthcare was provided mainly on the basis of the individual healthcare professional's best judgement there and then without having any guidelines for decision-support or colleagues or managers to consult.

The municipal services had had a similar incident two years previously concerning non-response to a service user sounding a personal safety alarm at night. The user had been found dead in their home the following day. The County Governor's conclusion was negligence in duty of care. This ruling was unknown to most of the homecare service and to senior municipal management.

Norwegian Board of Health Supervision opinion
The municipal services had not fulfilled their duty of care towards patients/users with complex needs who receive homecare services. We also concluded that the municipal services did not provide the patient with professionally responsible healthcare.

Post-incident quality improvement
The Norwegian Board of Health Supervision concluded that the municipal services have worked systematically on quality improvement and patient and user safety after the incident and have implemented measures to reduce the risk of incident recurrence.

11.2.3 Transportation and healthcare in an emergency

Incident
We received two reports of patient incidents where seriously ill patients were transported by road ambulance instead of the air ambulance requested. In both cases, road transportation would take about

three hours. The two serious incidents involved patients presenting at the out-of-hours medical centre with symptoms of severe infection. The condition of both patients deteriorated during road ambulance transportation, with one patient suffering cardiac arrest and dying in transit. The incidents occurred only four days apart during the summer holiday period and during the ongoing pandemic. In accordance with the organisation's own practice, both patients should have been transported by helicopter. The patients' treatment from the specialist health service was delayed by the decision to transport them by road ambulance.

Theme
Care of sepsis patients in need of rapid transportation to the specialist health service for treatment. We investigated whether the patients received professionally responsible healthcare and whether the organisation ensures professionally responsible care for patients affected by time-critical medical conditions and who need transportation.

Conclusion
For one patient, an alternative plan was made to reverse the original decision and instead transport the patient by air ambulance helicopter in case of deterioration in their condition. We therefore concluded that transportation by road ambulance was not clinically responsible. For the other patient, we concluded that the patient was not transported to the right place in time, and that the healthcare was not clinically responsible.

For both patient incidents, we concluded that failures were revealed that indicated lack of organisation, management and supervision of the service. The review revealed issues related to decision-making when requesting an air ambulance helicopter, including inadequate decision support for staff in prioritising and fulfilling air ambulance helicopter transportation. There was a risk of failure in that the same individual in the organisation has a dual role in the process (doubling as Air Ambulance doctor and Emergency Medical Coordination Centre (EMCC) doctor), and there was no system in place to avert the risk of decision-making failures in situations where the need for infection control had to be weighed up against the need for rapid transportation. The investigation also revealed deficient record-keeping practices concerning medical assessments versus resource and stand-by status in assigning a mode of ambulance transportation.

The organisation had thus not ensured the patients of clinically responsible services in the event of serious illness and the need for transportation by air ambulance helicopter.

11.2.4 Healthcare for a patient in acute mental crisis

Incident
The patient was receiving follow-up care for severe mental illness. In the hours leading up to the incident, the patient and neighbours had repeatedly contacted the out-of-hours medical centre due to a deterioration in the patient's condition. The patient died in an incident in which the patient was perceived to pose a threat.

Regulatory topic
Whether the specialist health service and the municipal health and care service had jointly arranged for patients with serious mental illness who are followed up by Flexible Assertive Community Treatment (FACT) to receive clinically responsible healthcare in response to a deterioration in their condition.

The opinion of the Norwegian Board of Health Supervision
The patient was followed up at several different service locations within municipal services and the specialist health service. This requires clearer lines of responsibility, coordination and expertise within the various organisations. The combined services were deficient in that they failed to facilitate systematic observation, diagnosis and assessment of changes in the patient's condition, including familiarising themselves the patient's psychiatric history. This includes the Board's conclusion that the manner in which telephone calls to the out-of-hours medical service were dealt with was sub-standard. Furthermore, no essential measures were taken or arrangements made to facilitate the necessary coordination between the various service locations.

Conclusion
The specialist health service and the municipal health and care service as a whole did not provide the patient with clinically responsible healthcare during the time period in question.

Post-incident quality improvement
The Norwegian Board of Health Supervision has concluded that the municipality and the specialist health service have jointly worked on systematic quality improvement and patient safety after the incident to reduce the risk of failure in healthcare following a deterioration in the condition of patients with serious mental illness. We have nevertheless asked the municipal services to report in more detail on their quality improvement efforts as regards their out-of-hours medical centre.

11.2.5 Care coordination in follow-up of a patient in a state of confusion (delirium)

Incident
The incident report concerned an elderly patient in a state of confusion (delirium). The patient was first attended to in hospital and was then transferred to primary care for further care in the short-stay unit of a nursing home.

Regulatory topic
We investigated whether the patient had received clinically responsible healthcare and whether the organisations had facilitated their services so that staff are in a position to deliver clinically responsible healthcare. Our main concern was whether the organisations have arrangements in place for clinically responsible assessment, treatment and care management for patients with delirium.

Assessment
A cooperation agreement exists between hospitals and the municipal services in question to ensure care continuity and clinically responsible patient care in transfers from hospital to further follow-up in primary care. The focus here is on reliable hospital discharge procedure and information transmission. The hospital and municipal services have committed to making the care coordination agreement known to their own staff and service users. At the incident-based inspection, it emerged that there was little familiarity with the agreement within the organisations, and that it was not fulfilled in this specific case. This may have compromised the care management of a seriously ill and highly vulnerable patient.

The hospital had not arranged for reliable clinically responsible assessment and treatment of patients with delirium. The municipal service had not ensured that national guidelines for the assessment and management of patients with delirium were understood and followed. The municipal service had also not ensured that healthcare professionals were aware of, had understood or fulfilled the existing

cooperation agreement between the hospital and the municipality for the transfer of patients to primary care.

In communication with the hospital concerning the transfer of the patient to primary care, based on the information available, no further assessment of the patient's need for clinical assessment, treatment and follow-up was made. Further, other competent healthcare professionals within primary care were not consulted in assessing the information available. The municipal services did not discover that the hospital had notified the patient as ready to be discharged to their care without having been sufficiently assessed with a plan for their care.

The nursing home doctor was not summoned by the healthcare professional after the patient had been transferred to the short-stay unit at the nursing home. No other attempts were made to obtain more information about the patient, including about the patient's care plan. There was no concern that that the medication initiated by the hospital was contrary to standard guidelines. When the patient was attended to by the nursing home doctor a day later, the patient was severely reduced, and an overdose of the given drugs was suspected. While the patient was staying in the short-stay unit, no observations regarding the effect of the medication/adverse drug reactions were recorded, and records of the patient's condition were deficient.

Conclusion
The Norwegian Board of Health Supervision concluded that the municipal health service had not facilitated clinically responsible management and care for patients with delirium. The municipal health and care service had not ensured that a healthcare professional on their staff had the requisite competence concerning clinical assessment and treatment of delirium, or that existing guidelines for monitoring inpatients were followed. The municipal health and care service also failed to ensure that healthcare professionals in the organisation were aware of and complying with the existing cooperation agreement between hospital and municipality.

11.2.6 Healthcare for agitated users in need of round-the-clock supervision

This review case had not been closed at the time of writing. We therefore describe the main features of the incident and our assessments and conclusions only to a limited extent.

Incident
A user in a short-stay unit at a health centre jumped out from a second-floor balcony and sustained serious fractures.

Regulatory topic
We investigated whether the municipal health and care service facilitates clinically responsible healthcare for agitated users in need of round-the-clock supervision, including attending to an agitated user unwilling to receive healthcare and who had acted in a manner posing a risk to their own health and safety. We also investigated how the municipal health and care service has ensured effective communication and information flow concerning this type of user.

Assessments
Deficient measures for ensuring the physical safety of users is an area in the health service that poses a high risk of failure and where such failure could potentially have serious consequences for users. Falling from a height is one such risk. It is therefore especially important to implement safeguards

understood by all staff. Management must facilitate the implementation of safeguards by staff. Structures must be in place to ensure communication and information flows among staff, between different administrative levels and with relatives.

The municipal health and care service described its own assessment of the incident and both planned and implemented improvement measures.

11.2.7 Clinician attendance at out-of-hours medical centre for acute chest pain

Incident
A patient with chest pain was brought to the out-of-hours medical centre by ambulance. The patient was assessed as requiring clinical attendance within 10-20 minutes, but was found dead about an hour after arrival, and without having been examined by a clinician.

Regulatory topic
We investigated whether the patient had received clinically responsible healthcare and whether the municipal health and care service ensures that patients with chest pain and other acute conditions receive clinically responsible, reliable quality care so that care delivery is compliant. We also investigated whether the organisation had an adequate overview of and ability to manage risk areas related to waiting times for patients at the out-of-hours medical centre.

Assessment
The organisation had not established procedures to ensure that patients presenting with chest pain and other acute conditions received clinically responsible healthcare in situations of high-volume attendance. The reason for this is that the out-of-hours medical centre did not have sufficient systems or arrangements to ensure clinical attendance within the expected time in the presence of high-volume patient attendance. The Norwegian Board of Health Supervision considers that the time elapsing between triage and clinical attendance entails an increased risk that patients with chest pain and other acute conditions will not receive the necessary healthcare during peak periods.

The organisation did not have a sufficient overview of risk areas in its service provision, and no targeted measures had been put in place for implementation in reduced capacity situations.

Conclusion
The patient did not receive clinically responsible healthcare because they waited too long in the out-of-hours medical centre with chest pain without receiving clinical attendance and without a pull cord for summoning emergency assistance.

11.2.8 Pregnancy management at out-of-hours medical centre

Incident
Just over a month before her due date, a pregnant woman attended a municipal out-of-hours medical centre feeling unwell. The woman was unable to walk, had a sore throat and was short of breath. There were some communication issues. Her symptoms had been ongoing for six days and she attended the out-of-hours medical centre because her condition had deteriorated in the last 24 hours. She had recently moved to the municipality.

At the centre, the receiving nurse recorded the patient's temperature, blood pressure, pulse and blood oxygen saturation. In addition, a blood test was done for signs of infection. Her pulse was rapid. The other vital signs were normal, and the woman was judged to be in good general condition. The woman was not tested for Covid-19. She was asked to wait for a doctor, and she was told she was a priority patient as she was pregnant. After waiting for nearly three hours, the patient went home at her own risk. This was before she had been seen by a doctor.

During the waiting time, the patient had tried to summon the duty room using the call bell several times but with no response. She had pain in her back and was unable to wait any longer. Her husband, who had to remain outside the building due to the centre's infection control rules during the pandemic, called the reception desk to explain this, and was informed that that the patient had to wait until the doctor was available. The man then asked if they could go home as the wait was so long. According to the man, the reception desk staff stated that if they wished, they could go home and call their GP next day. A few days later, the woman went into labour and the term infant was discovered to have died in utero. Afterwards, the patients were informed that Covid-19 infection was the probable cause of death.

Regulatory topic
Whether the patient had received clinically responsible healthcare, and whether the municipal health and care service had ensured that pregnant women attending the centre with severe symptoms receive clinically responsible and reliable care.

Assessment
This case demonstrated the necessity of good communication and triage of pregnant women attending an out-of-hours medical centre. The case also demonstrates the principles of general prenatal care for pregnant women moving to a new municipality, and the barriers to navigating the health service. Furthermore, it is important to ensure prompt and effective maternity care for new members of the community who make contact with the maternity care service.

Conclusion
The out-of-hours medical centre did not provide the patient with clinically responsible healthcare because it failed to ensure that she was examined by a clinician within a reasonable time. We concluded that the centre had not put procedures in place to ensure that expectant mothers presenting with severe symptoms were given priority and examined by a doctor. The Norwegian Board of Health Supervision considers that the waiting time at an out-of-hours medical centre poses an increased risk of pregnant patients with malaise not receiving essential healthcare during busy periods.

Post-incident quality improvement
The organisation has stated that it plans to increase its capacity by having a doctor in reception for ambulant patients (doctor in reception) and a doctor who receives patients together with a nurse in the ambulance reception (team triage). As of today, a pilot scheme has been started and the plan is to implement the new structure over the year. The Norwegian Board of Health Supervision finds this measure to be appropriate and has inquired into the further processes of this improvement programme and whether the new structure is working as intended.

11.2.9 Use of welfare technology (GPS) by nursing home resident with dementia

Incident

A nursing home resident with dementia enjoyed walking and was capable of taking brisk, long walks. The resident was issued with a GPS tracker so that the nursing home could locate the resident if they left the premises undetected. One afternoon the resident went missing. When the healthcare professional attempted to trace the resident, the GPS tracker could not be contracted. The resident was found dead that night.

Regulatory topic
Whether the municipal health and care services had ensured professionally responsible use of GPS tracking for nursing home residents with dementia and whether the service user had received clinically responsible healthcare.

Assessment
The municipal health and care service had adopted welfare technology, but had not adequately ensured the necessary assessment of hazards and risks before implementing GPS tracking, or made a formal decision regarding the use of GPS tracking, as required by law. Management and staff were unsure of how the GPS tracker worked and the GPS tracker battery charge was not checked before use. Furthermore, no arrangements were made to ensure that managers and healthcare professionals at the nursing home had received sufficient training in use of GPS tracking.

Conclusion
The municipal health and care service had not facilitated professionally responsible healthcare concerning use of a GPS tracker for nursing home residents with dementia, and the user did not therefore receive clinically responsible health care. We concluded that after the incident, the municipal health and care service has worked systematically on quality improvement and user safety.

11.2.10 Follow-up of sick child at refugee reception centre

Incident
A child with a chronic illness staying at a refugee reception centre became acutely ill. The acute illness resulted in the child being hospitalised. The child died shortly after admission.

Regulatory topic
We examined the healthcare received by the child and how the municipal services facilitated healthcare for children with complex care needs staying at a refugee reception centre. We focused on the healthcare the child received in the primary care setting from arrival at the reception centre through to the healthcare provided when the acute illness occurred and until the child died.

Assessment
Despite the fatal outcome, the Norwegian Board of Health Supervision concluded that the clinical examinations and assessments made on the day before the child's death were in line with the requirements for clinically responsible healthcare. We found no indications to account for emergency hospitalisation, and the out-of-hours doctor had consulted the paediatrician at the nearest paediatric care department. Care management when the child's condition deteriorated on the next day when they were taken to hospital by ambulance personnel was considered to be in line with clinically responsible healthcare. By that stage, the child was febrile, had increasing abdominal pain and the abdomen was distended and non-palpable.

Conclusion

The municipal services provided the child with clinically responsible healthcare for the child's chronic condition. The municipal services also provided clinically responsible healthcare following onset of the abdominal pain/acute illness while the child was at the refugee reception centre.

The municipal service's facilitation of healthcare for a child with special needs at the refugee reception centre was clinically responsible. Various relevant measures were implemented to facilitate clinically responsible healthcare for a child in need of healthcare. Coordinated healthcare had been arranged for the child both when the interventions were provided within primary care and within the specialist health service habilitation service.

11.2.11 Medication management at hospitals and nursing homes

Incident
An elderly patient living in their own home died following mismedication in hospital and in a nursing home. The patient was taking blood thinning tablets for heart disease. While the patient was hospitalised, the tablets were replaced for a time by blood thinning injections. When tablet therapy was to be resumed, it was forgotten to withdraw administration by injection. As a result, the patient was mistakenly treated with a double dose of blood-thinners for nine days The mismedication took place during a stay in hospital and during two stays in a nursing home short-stay unit.

Regulatory topic
We investigated whether the patient received clinically responsible healthcare, and whether the organisations had ensured that medication was administered in accordance with legal requirements, ensuring that patients receive clinically responsible, reliable and quality care.

Assessment
Both the hospital and the nursing home had procedures and routines in place for medication management, but these were not sufficient to guarantee clinically responsible medication of the patient. The organisations had not put in place adequate safeguards to ensure that healthcare professionals practised clinically responsible medication management in line with their own procedures and routines. Both the hospital and the nursing home used support tools to detect and assess the risk of drug interactions, when therapies were added that should not be given in combination, without ensuring well-defined routines and common practices for use of the tool.

Conclusion
Neither the hospital nor the nursing home had sufficiently reviewed and assessed the patient's medication despite the fact that the patient's condition was deteriorating. Discharge notes containing records of mismedication were repeatedly transferred between the nursing home and hospital without the mismedication being discovered. On this basis, the Norwegian Board of Health Supervision concluded that neither the hospital trust nor the municipal health and care service provided the patient with clinically responsible inpatient medication management.

Post-incident quality improvement
The organisations have initiated efforts to introduce measures to rectify the sub-standard conditions. The Norwegian Board of Health Supervision will be following up on the organisations' implementation of improvement measures to ensure that they have the intended effect.

11.2.12 Communication and information flow in medication management in homecare

Incident
The incident reported by next of kin concerned failure to refill an essential blood-thinning medication prescription for the homecare service user The user was covered by an agreement on medication assistance. This was not followed up and the user was thus not dispensed the essential medication. This failure occurred despite fact that healthcare professionals and management in the organisation had been made aware that the user had no medication by the user, next of kin and homecare staff visiting the user in the time period in question. The medication was ordered for delivery to the organisation, but was not brought out to the user for several days. On the day the user received the medication, the user suffered a massive stroke and was hospitalised.

Regulatory topic
Whether the municipal health and care service has ensured reliable communication and information flow in the homecare services concerning medication management assistance.

Assessment
The homecare service was run at too high a risk of failures in medication management. We believe that the failure of the service could occur due to the lack of management and facilitation of communication and information flow in the unit. There were various formal and informal structures to communicate and manage medication management information to persons receiving homecare services. The systems for internal checks of medication management were deficient both at the time of receipt of drugs in the unit and dispensing to users and in records of healthcare delivery.

The fact that the organisation was unable to verify if users had been dispensed medication supports the conclusion that deficient organisation and management posed a risk of failures in homecare delivery. Previous reports of similar irregularities in the service stating that users had not received medication as agreed had not resulted in measures to reduce the risk of recurrence. The majority of nonconformity cases reported were closed without information about the corrective actions taken.

In the weeks leading up to the incident in question, there had been a reorganisation of homecare services in the municipality. No additional resources or measures were put in place to reduce the risk of failure in performance when the unit acquired a great many new service users, while they had to transfer service users to other units. This additional load on the unit created an additional risk that had not been adequately planned for. No risk assessment of the reorganisation was carried out in advance.

Conclusion
The user did not receive clinically responsible healthcare from the municipal health and care service. For a service user covered by an agreement on medication assistance, it is absolutely essential that the service ensures that necessary medication is made available for the service user to take.

11.2.13 Follow-up of patient in a case of acute exacerbation during a stay in a municipal acute inpatient unit

Incident
Follow-up and management of an elderly patient affected by acute deterioration during a stay in a municipal acute inpatient unit after multiple falls. The patient died the day after admission to the municipal acute inpatient unit, after being transferred to hospital.

Regulatory topic
We investigated how the municipal health and care service facilitates clinically responsible care at its out-of-hours medical centre and municipal acute inpatient unit. In addition, we investigated and assessed whether the patient received clinically responsible healthcare, and whether relevant actions have been taken to reduce future risk based on this incident.

One main focus was on management of patients affected by acute deterioration post-admission. We also examined admission procedure, staff training and competences, observation and management of patients, coordination procedures, documentation procedure and management of record-keeping systems.

Assessment
Overall, the municipal health and care service did not ensure clinically responsible healthcare for patients admitted to municipal acute inpatient units with somatic disease and at risk of acute deterioration. Relevant national guidelines have been established to ensure clinically responsible healthcare for patients admitted to a municipal acute inpatient unit. However, the organisation has not ensured that healthcare staff attending to the patients are familiar with the guidelines and understand and comply with them. The organisation has not provided adequate staff training in procedures and use of ICT systems to ensure patient safety and reliable nurse-physician coordination.

Conclusion
The overall healthcare received by the patient at the municipal acute inpatient unit was sub-standard. There were failures in examination and management of the patient in ambulance triage at the out-of-hours medical centre and on transfer of the patient to the municipal acute inpatient unit. Further, the unit failed in its observation/monitoring duty in the ward and in its management of the acute deterioration in the patient's condition.

Post-incident quality improvement
After the incident, the municipal health and care service implemented and planned additional relevant measures to reduce the risk of any recurrence or similar incident. We have requested that the service reports on and submits a copy of relevant records that the measures have duly been implemented. We have also requested a description of how the organisation monitors whether the measures are instrumental in achieving the necessary and lasting adjustment to practices.

11.2.14 Follow-up by homecare service following discharge from short-stay hospitalisation

Incident
A user was found dead in their home, after they had been left unsupervised for an extended period by homecare staff. In advance of the serious incident, the user had returned from a short stay in hospital, and for this reason the homecare had been put on hold.

Regulatory topic
Whether the municipal health and care service has ensured proper communication and information flow in its homecare services.

Assessment
The user was served under a daily attendance order, but was not attended for a period of almost two weeks. This happened despite the fact that a record had been made that the user had been discharged to

their home following a short stay in hospital, and that the homecare for the user was to be initiated. The user was attended on two consecutive evenings after returning home and it was reported that at these visits the user's general condition had deteriorated. Information about the user was reported orally and in writing, but was not followed up in the days that followed, and among other things, the user was not placed on task lists for further follow-up. Lack of attendance by the homecare service was not discovered until the homecare service received medication the pharmacy prescribed for the user. When staff then visited the user's home, they user was found dead

The department was run with a high risk of failure in connection with the resumption of homecare after returning from a temporary stay at an institution. In order for a user under a homecare order to receive professionally responsible homecare, it is absolutely essential that the homecare service has procedures in place to ensure that staff actually visit the home of those requiring attendance.

We believe that the failure of the service stemmed from a lack of management and facilitation of communication and information flow in the department. There was a high risk that important information did not reach the staff concerned, or that messages about needs were not forwarded and assessed. There were no procedures and agreed practices to ensure reliable management of information that the service to the user was to be resumed after the user was discharged from a stay at an institution. There were a number of different formal and informal structures, both for the receipt and use of such information. There was also a lack of a clear division of tasks and responsibilities. Training and ongoing improvement activities had been underprioritised for some time. Previous reports of similar nonconformities in the service, where users had not been attended as agreed, had not resulted in actions to reduce the risk of further failures.

Conclusion
The user did not receive clinically responsible healthcare service from the municipal services.

11.2.15 Mix-up of patients in medicines dispensing in the homecare service

This review case had not been closed at the time of writing. We therefore describe the main features of the incident and our assessments and conclusions only to a limited extent.

Incident
A user under a home assistance order ("User 1"), including assistance for medication management, was dispensed medication prescribed for another service user ("User 2"). User 1 was taken to hospital. Several hours passed before the hospital was alerted by the municipal health and care service that User 1 had been taking User 2's medication.

User 1 activated their personal safety alarm. When homecare reached User 1, they were lethargic, had speech difficulties and dozed off during their conversation. The health and care assistant called for a nurse. On arriving at the home of User 1, the nurse called for an ambulance. EMCC asked if User 1 had taken any medications or was over-medicated. The staff present in the home of User 1 believed that this could not be the case, as User 1 would not have been dispensed medication.

In the hospital, User 1 was initially treated for suspected stroke, and next of kin had been informed that only palliative treatment could be offered, and that they believed that User 1 was likely to die. After the hospital received information about the misdispensing of medication, targeted therapy was

initiated with good effect. User 1 was discharged to their home, but next of kin describe that the patient suffered physical and mental effects from the care received.

Regulatory topic
Whether the municipal health and care service facilitated and ensured safe medication dispensing in the homecare service. Medication management is an area of the health service with a high risk of failure, and where failure can have severe adverse consequences for the user. This makes it imperative to establish structures for communication on medication management, and the area requires special facilitation and checks.

Assessment
We have requested a written statement from the organisation. The purpose of preparing the written feedback for us is to shed light on the incident and ensure that the organisation has commitment to making improvements in the aftermath of this serious incident.

11.2.16 Use of medical devices in delivery of healthcare

Incident
The incident involved a patient in a nursing home. The patient did not receive the breathing aid needed. The patient died. The municipal health and care service asserted that the incident was related to lack of experience and training in use of medical devices in the nursing home.

Regulatory topic
Whether the municipal health and care service had ensured that healthcare involving medical devices was legally compliant to ensure that patients receive safe and effective care, and whether this patient received clinically responsible healthcare.

Assessments and conclusions
The municipal health and care service had not ensured that expectations and guidelines were understood, and there were no systems to monitor compliance with guidelines. The municipal health and care service did not have systems in place to ensure that staff had received adequate training and expertise in using medical devices and thus in providing clinically responsible healthcare to patients requiring medical devices.

Conclusion
The patient did not receive clinically responsible healthcare at the nursing home. A review of the medical device would have detected that it had been connected incorrectly with the result that the patient failed to receive essential supplemental oxygen. This regulatory case demonstrates the importance of organisations' responsibility for ensuring that the users of medical devices are trained to give them the necessary skills and knowledge of correct and safe use at all times. The training must be systematic and documented.

The municipal health and care service has not sufficiently implemented measures to reduce future risk of events caused by a lack of skills in the use of medical devices.

We will therefore be following up with the service to ensure that they implement such measures, and verify that the measures have duly been implemented.

11.3 Appendix 3 – Content of non-reportable incidents

There was very varying content in the incident reports that did not meet reporting scheme criteria. Those that occurred most frequently concerned:

- **Medication:** Two-thirds of these reports were from individuals. Many of them were complaints that they were not prescribed the medication they wanted. There were also incident reports concerning vaccination logistics
- **Documentation/record-keeping/privacy:** The vast majority of incident reports were submitted by individuals and concerned errors in care records, access to records and unlawful records access.
- **Complaints concerning the child welfare service** by next of kin: lack of service, unwelcome interventions or a complaint against an expert.
- **Complaints concerning rights:** Many patients or relatives submitted reports describing their general frustration with the healthcare or care services they received or did not receive.
- **Complaints concerning staff conduct or service delivery** by individuals concerned, for example, allegations of substandard care by a general practice clinic and improper conduct by healthcare/care staff.
- **Complaints concerning treatment offered** from individuals concerned, for example, dissatisfaction with a clinical assessment and treatment, long waiting times for a medical appointment, long waiting times for enrolling with a new GP, complaint concerning care provision within 24-hour care services.
- **Description of problematic communication between a patient and healthcare professional** was described by individuals. This mainly concerned doctor-patient communication.
- **"Frustration statements"** made by individuals concerning cases already assessed by the County Governor or the Norwegian Board of Health Supervision. This mainly concerned a request to have a reassessment of a closed or ongoing review case.