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Adverse events in patients in home health care: a cohort study using trigger tool methodology

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ABSTRACT

Objective: Home health care is increasingly becoming a part of health care. The patients are often aged, frail and have multiple diseases, and multiple caregivers are involved in their treatment and care. This study explores the origin, incidence, pattern and preventability of the adverse events (AEs) that occur in patients admitted to receiving home health care.

Design: A cohort study using retrospective record review and trigger tool methodology.

Setting and methods: Ten teams experienced in home health care from nine regions across Sweden reviewed home health care records in a two-stage procedure using 38 predefined triggers in four modules. A random sample of 600 patients 18 years or older receiving home health care during 2015 was reviewed.

Primary and secondary outcome measures: The primary outcome measure was the cumulative incidence of AEs found in patients receiving home health care; secondary measures were origin, type, severity of harm and preventability of the AEs.

Results: The patients were aged 20–79 years old; 280 men and 320 women. The review teams identified 356 AEs in 226 (37.7%) of the home health care record. Of these, 255 (71.6%) were assessed as being preventable. Most (246, 69.1%) required extra health care visits or led to a prolonged period of health care. Most of the AEs (271, 76.1%) originated in home health care; the rest were detected during home health care but were related to care outside home health care. The most common AEs were health care-associated infections, falls and pressure ulcers.

Conclusions: AEs in patients receiving home health care are common, mostly preventable and often cause temporary harm requiring extra health care resources. The types of AEs that occur or are detected in home health care settings imply that we must address and improve how care is provided. This is an important area for future studies.

Keywords: Home health care, Patients, Adverse events, Patient harm, Patient safety, Trigger tool

Strengths and limitations of the study

- This study included ten teams from different parts of Sweden and a review of 600 records, which provided an overview of adverse events detected in home health care settings.
- The definition based on the National Coordinating Council for Medication Error Reporting and Prevention classification E was expanded to include all adverse events that resulted in temporary harm to the patient, regardless of whether an intervention was documented that could be seen as an improvement from a patient perspective.
- In any study based on record review, only adverse events that are documented in the record can be identified.
- Generalizability may be limited if home health care programs differ from the Swedish context at the sites being investigated.

BACKGROUND

Home health care is increasingly becoming a component of health care as an alternative to hospitalization. It includes a variety of health care interventions. The purpose can be curative, supportive, palliative or rehabilitative. Safe solutions for care outside the hospital are important when planning for the future. The incidence and types of adverse events (AEs) in the acute care hospital setting have been well investigated in many countries and for several medical specialities.[1-7] Despite the challenges related to an aging population and citizens' demands to receive care at home, patient safety in home health care is rarely investigated.[8-12] Incidence rates of AEs of up to 13% have been reported in a Canadian context;[8, 11] falls and drug-related AEs are the most frequent.

Retrospective record review is commonly used to study patient harm using predefined triggers indicating potential AEs. More AEs are found through record review than through incident reporting systems.[13] One of the most frequently used methods for retrospective record review is the Global Trigger Tool,[14] which has been further adapted to suit different areas of health care.

The number of patients who are cared for in their homes is increasing. They are often aged, frail and have multiple diseases. Municipal home services provide assistance with activities of daily life, but medical and technical advances have made it possible for advanced treatment of complex and long-term illness to take place in the patient's home. As the complexity of care increases, interaction between multiple professionals from different health care providers (i.e. home health care, primary care, specialist care and social care) is critical for patient safety. New risks arise if communication and coordination of care is deficient. Thus, there is a need to further explore safety issues for patients admitted to home health care, taking into consideration the complexity of multiple caregivers involved in treatment and care. This study

explores the origin, incidence, pattern and preventability of the AEs that occur in patients admitted to receiving home health care.

METHODS

Study setting

The study was set in Sweden, where assistance with activities of daily living is provided in patients' homes by unlicensed staff (e.g. assistant nurses) organized by the municipal social care service. The municipalities are also most often responsible for providing home health care for older people.[15] Their health care organization includes unlicensed assistant nurses, physiotherapists and occupational therapists, with registered nurses (RNs) providing the highest medical competence. The RNs have the overall responsibility for medication management and delivery of specialized health care in the patient's home and consequently visit each patient less frequently than the unlicensed staff. When physician resources are necessary, this is usually provided by primary care physicians but hospital physicians may also become involved. All physicians are employed by the county councils. Documentation between different caregivers is not always accessible to health care professionals from other settings. As patients receiving home health care may simultaneously be receiving care from different organizations, we found it important to include all documented AEs in the home health care notes, irrespective of origin.

Definitions

In this study, an AE was defined as suffering, physical or psychological harm, illness or death caused by health care or social care that was not an inevitable consequence of the patient's condition or an expected effect of the treatment received by the patient because of her/his condition. A preventable AE was defined as an event that could have been prevented if adequate measures and/or actions had been taken during the patient's contact with health care or social care. This definition is based on the terminology in the Swedish Patient Safety

Act.[16] AEs related to acts of omission and AEs related to acts of commission were included.

Study sample, inclusion and exclusion criteria

Ten review teams from different sites across Sweden were recruited using a convenience sampling strategy. Seven teams were organized in the municipalities and three teams were employed by the county councils. The teams consisted of one to three RNs and one or two physicians. They all had long experience of working as RNs or physicians, and in the home health care context.

A random sample of 600 home health care admissions was reviewed during the period from February to August 2016. In order to collect as rich data as possible, all patients 18 years or older admitted to home health care during 2015 at the review sites were eligible for inclusion. The review included the period from admission (index admission) up to a maximum of 90 days after admission. If a patient was discharged from home health care and was readmitted within the 90-day period, the review of that patient continued. To be included as an AE in the study, one of the following criteria had to be met:

1. The AE or no-harm incident occurred during the index admission, i.e. within 90 days after enrolment in home health care, regardless of caregiver.
2. The AE or no-harm incident derived from caregivers outside home health care (outpatient care, social care or in-hospital care), occurred within 30 days prior to the index admission and was detected during the index admission.

Randomization was performed by one of the authors (MU), using an online randomizer, to ensure it was carried out in the same way for all review teams. Oversampling was carried out with ten records per team. If a patient in the random sample was receiving limited home health care once or twice a week, for example blood pressure measurement or delivery of pre-dispensed drugs, this patient was replaced by another random admission. AEs that gave

symptoms more than 90 days after the start of the index admission or that occurred and were detected and the treatment were completed before the start of the index admission were excluded.

Education of the review teams

To ensure the validity and reliability of the results, the review process was standardized in a written project manual, in which the definitions and the inclusion and exclusion criteria were also included. A trigger manual was used, including trigger definitions and preventability decision support, as well as detailed examples that were discussed by the review teams before the study began. The team members underwent a mandatory one-day education in the trigger tool methodology. Discussions were held to reach consensus about definitions, exclusion and inclusion criteria, interpretation and application of the triggers, judgement of AEs and preventability assessments, as well as how to use the two cases report forms. During the process of familiarization with the methodology, each member of the review team independently reviewed six training records in order to achieve reliable reviews.

Review process

The review was performed in a two-stage procedure. In most teams, the RNs carried out both the primary and secondary reviews and later discussed the findings with the physicians. In some teams, the physicians carried out some of the primary as well as the secondary reviews.

In the primary review stage, the reviewers screened all records for the presence of 38 predefined triggers categorized into four modules (Table 1). A trigger is an indicator suggesting that an AE might have occurred during the inclusion period. For each trigger detected, the reviewer determined whether or not the trigger reflected the presence of a potential AE. Only records with triggers indicating a potential AE went forward to the

secondary review stage. The reviewers also recorded demographic data. Starting from the index admission to home health care, a maximum of 90 days was reviewed. There was no time restriction for the review of each record in this stage. To ensure inter-rater reliability, 10% of the records in the primary review process were reviewed by a secondary reviewer. Concordance was assessed between the reviewers' judgements concerning the presence of AEs in the primary review, and whether the record should be forwarded to the secondary review. Discussions about individual judgements were held and when consensus was reached, the records were ready for the secondary review stage.

Table 1 List of triggers

Care module	Cardiac arrest and/or deterioration in vital signs
	Deep venous thrombosis and/or pulmonary embolus
	Pressure ulcer
	Blood vessel, skin and/or tissue harm
	Neurological impairment and/or harm
	Fall
	Health care-associated infection
	Moderate/severe pain
	Moderate/severe worry, anxiety, suffering, existential pain and/or psychological pain
	Moderate/severe agitation and/or acute confusion/delirium
	Undernutrition
	Insufficient oral health
	Moderate/severe gastrointestinal problem
	Distended urinary bladder
	Deviation from normal course after invasive/surgical treatment
	Treatment
	Advanced medical device
	Threats, violence and/or improper contact
	Self-inflicted harm
	Escape from home/special accommodation

	Documentation of mistake or dissatisfaction with care
	Other
Laboratory module	Abnormal glucose value
	Increasing creatinine value
	Abnormal potassium value
	Abnormal sodium value
	Abnormal calcium value
Medication module	Adverse drug event/adverse drug reaction
	Drug that requires follow-up with blood sampling
	Treatment with at least 10 drugs
	Absence of in-depth drug review
	Treatment with drugs that increase the risk for haemorrhage
	Drug management
Continuity and transition module	Unplanned change of care-providing unit
	Unplanned contact with physician and/or registered nurse
	Absence of and/or deviation from care plan
	Absence of a coordinated individual care plan when care is provided by several caregivers
	Documentation related to insufficient coordination of care, communication and/or information

In the secondary review stage, each potential AE was scrutinized individually. To qualify as an AE, a score of three or higher on a 4-point Likert scale was required (1, the AE was not related to health care/social care; 2, the AE was probably not related to health care/social care; 3, the AE was probably related to health care/social care; 4, the AE was related to health care/social care). The reviewer made a judgement whether or not the event qualified as an AE. If it did, the AE was marked for further assessment. The preventability of an AE was judged on a similar 4-point scale: 1, the AE was not preventable; 2, the AE was probably not preventable; 3, the AE was probably preventable; 4, the AE was preventable.[5] In the following, probably preventable (grade 3) and preventable (grade 4) AEs are referred to as preventable AEs.

The severity of harm was evaluated using two different scales. The first was the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Index (NCC MERP; http://www.nccmerp.org/sites/default/files/indexBW2001-06-12.pdf), which is used in the Global Trigger Tool.[14] NCC MERP Index categories E–I were included, i.e. those relating to harm (grade E, contributed to or resulted in temporary harm; grade F, contributed to or resulted in temporary harm to the patient and required outpatient, home health or hospital care, or prolonged hospitalization or an extended period of home health care; grade G, contributed to or resulted in permanent patient harm; grade H, lifesaving intervention required within 60 minutes; grade I, contributed to the patient's death). The second severity scale was that used in the Harvard Medical Practice Study (HMPS)[17] and subsequently in several nationwide AE studies. It includes seven grades (minimal impairment, recovery within 1 month; moderate impairment, recovery within 1–6 months; moderate impairment, recovery within 6–12 months; permanent impairment, degree of disability ≤50%; permanent impairment, degree of disability >50%; contributed to patient death; unable to determine). All secondary reviewers also documented, e.g., the types of AEs as well as information on the origin of the AE (home health care, inpatient care, outpatient care or social care).

Access to different parts of the patients' medical records differed between the review teams. The municipalities and county councils sometimes have separate medical record systems. Accordingly, some municipal review teams had to request physicians' notes and laboratory values, for example, because these were stored in a county council's record system.

All review teams were supported by record review experts in the research group who could answer questions; one of those (MU) monitored all reviews from the primary and secondary review stages for completeness and adherence to the trigger definitions and project manual. Any questions or discrepancies were referred back to the relevant team for resolution.

Data analysis

Data are presented as median (range), mean (SD) (95% CI) or number (percent). We calculated the cumulative incidence of AEs over the review period. Comparisons between groups were made using the Mann-Whitney U test or the chi-squared test, as appropriate. $p < 0.05$ was considered significant. All statistical calculations were made using Statistica 64 version 13 (StatSoft, Oklahoma, USA).

RESULTS

A total of 600 patient records from home health care were reviewed; 280 of the patients were men, median age 79 years (range, 20–97 years), and 320 were women, median age 82 years (range, 29–99 years). The number of days reviewed days was 40 735 in total, with a median of 90 days per patient. Depending on patient discharge or death, the range of days reviewed varied between 1 and 90. Demographic data are shown in Table 2.

Table 2 Demographic data

Parameter	Value
Men/women, n (%)	280 (46.7) / 320 (53.3)
Age in years, median (range)	80.5 (20–99)
Reviewed days, median (range)	90 (1–90)
Referral to home health care from	
Hospital care, n (%)	300 (50.0)
Outpatient care, n (%)	212 (35.3)
Not possible to determine, n (%)	88 (14.7)
Medical diagnosis at home health care admission*	
Malignancy, n (%)	253 (42.2)
Cardiovascular disease, n (%)	119 (19.8)
Confusion, dementia, n (%)	102 (17.0)
Diabetes, n (%)	51 (8.5)
Skin wound, pressure ulcer, n (%)	38 (6.3)

Stroke, n (%)	36 (6.0)
Pulmonary disease, n (%)	35 (5.8)
Neurological disease, n (%)	33 (5.5)
Medical needs at home health care admission†	
Medication assistance, n (%)	233 (38.8)
Palliative care, n (%)	144 (24.0)
Activities of daily living, n (%)	111 (18.5)
Laboratory sampling, n (%)	88 (14.7)
Wound care, assistance with compression stockings, n (%)	74 (12.3)
Assistance with advanced medical devices, n (%)	62 (10.3)
Rehabilitation, home modifications, means testing, n (%)	51 (8.5)
Pain relief, n (%)	39 (6.5)
Social situation at home health care admission	
Patient's own home, lives alone, n (%)	265 (44.2)
Patient's own home, cohabiting, n (%)	257 (42.8)
Home for medical health care, assistance 24/7, n (%)	50 (8.3)
Not possible to determine, n (%)	28 (4.7)

*Medical diagnosis affecting >5% of patients. The patients could have several diagnoses.

†Medical needs for >5% of patients. The patients could have several medical needs.

The total percentage agreement (range between teams) of the reviewers' judgements concerning the presence of events in the primary review and whether the record should be forwarded to secondary review was 82.9% (46.2–94.7%) and 92.8% (75.0–100%), respectively.

Through the home health care records, 356 AEs were identified affecting 226 patients (37.7 %). This corresponds to a median of 1 (range, 1–7) AE per patient affected (Table 3). Most were considered preventable (255, 71.6 %). There was no difference in the incidence of AEs between men and women (p = 0.72), or between patients aged 80 years or older and those less than 80 years (p = 0.12) (data not shown).

Table 3 Adverse events (AEs) detected in patients receiving home health care according to origin (n = 600)

	Home health care	Care outside home health care	Total
Number of AEs	271	85	356
Number of patients affected by AEs (%)	182 (30.3)	67 (11.2)	226 (37.7)
Median number of AEs per affected patient (range)	1 (1–5)	1 (1–4)	1 (1–7)
Number of preventable AEs	194	61	255
Number of patients affected by preventable AEs (%)	137 (22.8)	50 (8.3)	174 (29.0)
Median number of preventable AEs per affected patient (range)	1 (1–4)	1 (1–4)	1 (1–5)
Number of patients with >1 AE (%)	62 (10.3)	12 (2.0)	83 (13.8)
Number of patients with >1 preventable AE (%)	39 (6.5)	8 (1.3)	54 (9.0)
Number of AEs per 100 patients	45.2	14.2	59.3
Number of preventable AEs per 100 patients	32.3	10.2	42.5
Number of AEs per 1000 patient days	6.7	2.1	8.7
Number of preventable AEs per 1000 patient days	4.8	1.5	6.3

Of the AEs, 271 (76.1 %) were related to home health care, 44 (12.4 %) to in-hospital care, 23 (6.5 %) to social care and 12 (3.4 %) to outpatient care. For the remaining 6 (1.7%) AEs, it was not possible to determine from the documentation where they had originated. There was no difference in preventability (p = 0.97) between AEs originating from home health care or outside home health care.

According to the NCC MERP scale, 102 (28.6%) of all AEs resulted in temporary harm to the patient and 246 (69.1 %) in temporary harm that required extra health care visits or a prolonged care period. The HMPS scale showed that 213 (59.8%) of all AEs were minor with recovery within 1 month (Table 4). When comparing AEs originating from home health care and care given to the patients outside home health care, NCCP MERP revealed no difference in severity (p = 0.64), but the HMPS classification did (p = 0.027). When AEs

where severity could not be determined were excluded, this difference no longer remained (p = 0.07).

Table 4 Severity of adverse events (AEs) detected in patients receiving home health care according to origin

Severity category	In home health care		Care outside home health care		Total	
	AE, n (%)	Preventable AE, n (%)	AE, n (%)	Preventable AE, n (%)	AE, n (%)	Preventable AE, n (%)
Severity category according to NCCP MERP index						
E Contributed to or resulted in temporary harm	78 (28.8)	50 (64.1)	24 (28.2)	14 (58.3)	102 (28.6)	64 (62.7)
F Contributed to or resulted in temporary harm to the patient and required outpatient, home health or hospital care, or prolonged hospitalization or an extended period of home health care	187 (69.0)	142 (75.9)	59 (69.4)	45 (76.3)	246 (69.1)	187 (76.0)
G Contributed to or resulted in permanent patient harm	3 (1.1)	1 (33.3)	2 (2.4)	2 (100)	5 (1.4)	3 (60.0)
H Lifesaving intervention required within 60 minutes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
I Contributed to patient's death	3 (1.1)	1 (33.3)	0 (0)	0 (0)	3 (0.8)	1 (33.3)
Total	271 (100)	194 (71.6)	85 (100)	61 (71.8)	356 (100)	255 (71.6)
Severity category according to HMPS scale						
Minimal impairment, recovery within 1 month	171 (63.1)	118 (69.0)	42 (49.4)	31 (73.8)	213 (59.8)	149 (69.9)
Moderate impairment, recovery within 1–6 months	57 (21.0)	44 (77.2)	26 (30.6)	19 (73.1)	83 (23.3)	63 (75.9)
Moderate impairment, recovery within 6–12 months	14 (5.2)	11 (78.6)	1 (1.2)	0 (0)	15 (4.2)	11 (73.3)
Permanent impairment, degree of disability ≤50%	3 (1.1)	1 (33.3)	2 (2.4)	2 (100)	5 (1.4)	6 (83.3)
Permanent impairment, degree of disability >50%	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Contributed to patient death	3 (1.1)	1 (33.3)	0 (0)	0 (0)	3 (0.8)	1 (33.3)

Unable to determine	23 (8.5)	19 (82.6)	14 (16.5)	9 (64.3)	37 (10.4)	28 (75.7)
Total	271 (100)	194 (71.6)	85 (100)	61 (71.8)	356 (100)	255 (71.6)

NCCP MERP, National Coordinating Council for Medication Error Reporting and Prevention. HMPS, Harvard Medical Practice Study.

Table 5 Types of adverse events (AEs) detected in patients receiving home health care and the origin and proportion of preventable AEs, according to total n (%)

Type of AE	**Home health care, AEs n (%)**	**Preventable AEs in home health care, n (%)**	**Care outside home health care, AEs n (%)**	**Preventable AEs in care outside home health care, n (%)**	**Total AEs, n (%)**	**Total preventable AEs, n (%)**
Health care-associated infections	59 (21.8)	37 (62.7)	13 (15.3)	9 (69.2)	72 (20.2)	46 (63.9)
Oral *Candida*	12 (25.4)	6 (50.0)	1 (7.7)	0 (0.0)	13 (18.1)	6 (46.1)
Urinary tract infection	9 (15.2)	7 (77.8)	2 (15.4)	1 (50.0)	11 (15.3)	8 (72.7)
Pneumonia	10 (16.9)	7 (70.0)	1 (7.7)	1 (100.0)	11 (15.3)	8 (72.7)
Wound infection	9 (15.2)	9 (100.0)	3 (23.1)	3 (100.0)	12 (16.6)	12 (100.0)
Sepsis	5 (8.5)	0 (0.0)	1 (7.7)	1 (100.0)	6 (8.3)	1 (16.7)
Skin *Candida*	5 (8.5)	5 (100.0)	1 (7.7)	1 (100.0)	6 (8.3)	6 (100.0)
Others	9 (15.2)	3 (33.3)	4 (30.8)	2 (50.0)	13 (18.1)	5 (38.5)
Falls	51 (18.8)	22 (43.1)	15 (17.6)	7 (46.7)	66 (18.5)	29 (43.9)

Fracture	7 (13.7)	4 (57.1)	4 (26.7)	2 (50.0)	11 (16.7)	6 (54.5)
Skin wound	33 (64.7)	11 (33.3)	7 (46.7)	3 (42.9)	40 (60.6)	14 (35.0)
Pain	11 (21.6)	7 (63.6)	3 (30.0)	1 (33.3)	14 (21.2)	8 (57.1)
Not specified	0 (0)	–	1 (6.7)	1 (100.0)	1 (1.5)	1 (100.0)
Pressure ulcers	46 (17.0)	38 (82.6)	16 (18.8)	14 (87.5)	62 (17.4)	52 (83.9)
Category 1	20 (43.5)	17 (85.0)	4 (25.0)	4 (100.0)	24 (38.7)	21 (87.5)
Category 2	17 (37.0)	13 (76.5)	8 (50.0)	6 (75.0)	25 (40.3)	19 (76.0)
Category 3	3 (6.5)	2 (66.7)	2 (12.5)	2 (100.0)	5 (8.0)	4 (80.0)
Category 4	2 (4.3)	2 (100.0)	0 (0)	–	2 (3.2)	2 (100.0)
Category unknown	4 (8.7)	4 (100.0)	2 (12.5)	2 (100.0)	6 (9.7)	6 (100.0)
Skin, vessel or tissue harm	25 (9.2)	21 (84.0)	8 (9.4)	6 (75.0)	33 (9.3)	27 (81.8)
Skin harm	18 (72.0)	15 (83.3)	4 (25.0)	3 (75.0)	22 (66.7)	18(81.8)
Vessel harm	4 (16.0)	3 (75.0)	1 (12.5)	0 (0.0)	5 (15.2)	3 (80.0)
Tissue harm	3 (12.0)	3 (100.0)	3 (37.5)	3 (100.0)	6 (18.2)	6 (100.0)
Pain	17 (6.3)	16 (94.1)	6 (7.1)	5 (83.3)	23 (6.5)	21 (91.3)
Psychological harm	12 (4.4)	9 (75.0)	6 (7.1)	5 (83.3)	18 (5.1)	14 (77.8)
Other	10 (3.7)	9 (90.0)	1 (1.2)	1 (100.0)	11 (3.1)	10 (90.1)
Neurological harm	7 (2.6)	6 (85.7)	3 (3.5)	3 (100.0)	10 (2.8)	9 (90.0)
Haemorrhage (not related to surgery)	7 (2.6)	3 (42.9)	3 (3.5)	1 (33.3)	10 (2.8)	4 (40.0)

Failure in vital signs	7 (2.6)	6 (85.7)	3 (3.5)	3 (100.0)	10 (2.8)	9 (90.0)
Weight loss, nutrition-related AE	5 (1.8)	4 (80.0)	3 (3.5)	3 (100.0)	8 (2.2)	7 (87.5)
General deterioration in health status	7 (2.6)	7 (100.0)	0 (0)	–	7 (2.0)	7 (100.0)
Severe constipation	5 (1.8)	5 (100.0)	0 (0)	–	5 (1.4)	5 (100.0)
Severe vomiting	4 (1.5)	3 (75.0)	0 (0)	–	4 (1.1)	3 (75.0)
Affected laboratory values	3 (1.1)	3 (100.0)	1 (1.2)	1 (100.0)	4 (1.1)	4 (100.0)
Allergic reaction	1 (0.4)	0 (0.0)	2 (2.4)	1 (50.0)	3 (0.8)	1 (33.3)
Severe diarrhoea	1 (0.4)	1 (100.0)	2 (2.4)	0 (0.0)	3 (0.8)	1 (33.3)
Distended urinary bladder	2 (0.7)	2 (100.0)	2 (2.4)	2 (100.0)	4 (1.2)	4 (100)
Dehydration	1 (0.4)	1 (100.0)	1 (1.2)	0 (0.0)	2 (0.6)	1 (50.0)
Attempted suicide	1 (0.4)	1 (100.0)	0 (0)	–	1 (0.3)	1 (100.0)
Total	271 (100.0)	194 (71.6)	85 (100.0)	61 (71.8)	356 (100.0)	255 (71.6)

The most common types of AEs were health care-associated infections, falls and pressure ulcers (Table 5). There were no differences in the number of such AEs between men and women or between patients aged 80 years or older and those less than 80 years (data not shown). The probability of falls being preventable was 43.9%, whereas the majority of the other types of AEs were considered preventable to a greater extent. There was no difference in the type of AEs between those originating from home health care and those from care given to patients outside home health care (p = 0.52).

Forty-one (18.1%) of the AEs in the home health care setting required a median of one (range, 1–5) additional physician visit(s) in an outpatient setting, 40 (14.8 %) required a median of 1 (range, 1–9) additional physician visit(s) in the home health care setting and 37 (13.7%) required hospital care for a median of 6 days (range, 1–41 days). There were no significant differences compared with AEs outside home health care: 7 (8.2%) (median, 1; range, 1–2) additional physician visit(s) in an outpatient setting; 11 (12.9%) (median, 1; range, 1–11) additional physician visit(s) in the home health care setting; 13 (15.3%) required hospital care for a median of 7 days (range, 2–10 days).

DISCUSSION

This study is the first to assess AEs in patients receiving home health care across different parts of Sweden through the use of retrospective record review. Our main findings are that AEs affect over a third of these patients, are deemed to be mostly preventable and result in temporary harm to the patient requiring extra health care resources. One fourth of the AEs detected in home health care originated in other health care settings. We found no differences in the types of AEs, the severity or preventability, regardless of the origin.

There are few studies investigating AEs in home health care with which to compare our findings. The incidence of AEs, 37.7%, is much higher than the 4–13% reported by other studies. [8,9,10,11] It is difficult to compare the rates because the differences may be due to

varying services, patient characteristics, and methods of record review, as well as the definition of an AE and the inclusion criteria used. It is also difficult to compare the rates for the home health care setting with in-hospital AE rates, because the home health care provider may not continuously overview the patients and the health care environment.

Patients receiving home health care are often old and vulnerable and frequently have concomitant contact with different caregivers. We have shown that almost 25% of AEs found in patients in home health care originated in care given in other settings. The continued care of a patient with AEs such as pressure ulcers or infections impose an additional burden on the home health care organization with its limited access to RNs and physicians. This finding also highlights the importance of learning about AEs between caregivers. The pattern of AEs originating within or outside home health care is similar and may predominately characterize the risks for this group of elderly fragile patients, irrespective of the health care setting. The findings imply that all sections of health care should be aware of these most common AEs and preventive measures that can be taken along the patients' health care journey.

Almost three out of four AEs were judged preventable by the review teams in our study, regardless of origin. This is higher than the 33–56% previously reported in the home health care setting[8,9,] but is in line with many hospital record reviews.[1, 5, 6, 18] Risk reduction in a patient's home is not directly transferable from hospital care. The possibility of conflict between patient autonomy and safety should be considered in the home care setting. Patients are the hosts of the care environment and supervision by health care personnel is mostly limited to short visits. Preventive safety measures in a patient's home requires true patient involvement, taking the patient's values and integrity into consideration; e.g. removing carpets to prevent falls, one of the AEs with the lowest preventability ratings, must be weighed against a patient's own wishes.

Our findings of health care-associated infections, falls, pressure ulcers and skin breakdown as the most common AEs are largely consistent with a Canadian review of 1200

records during 2009–2010, which reported falls, wound infections, psychosocial, behavioural or mental health problems, or medication-related AEs as the most prominent findings.[9] Other studies also report injurious falls as the most common AE in home health care.[11, 19] Decline in physical function is a prevalent safety risk.[10] Falls are also associated with increased risk of admission to long-term care and of death.[11] This emphasizes the need to find effective strategies for prevention of falls. Preventive strategies for pressure ulcers and skin breakdown[8] also need to be addressed. Patients in home health care may have several well-known risk factors for pressure ulcers. One tenth of AEs in patients receiving home health care was characterized as general decline.[8] The aging patient is at risk for weight loss and malnutrition. Doran et al.[10] noted that unintended weight loss accounted for 10% of the safety problems in home health care. Patients receiving home health care are often affected by cancer, where weight loss is a well-known problem.[10,20] Routines for the prevention of weight loss are important. Interventions can include energy- and protein-rich food, food with a particular texture, artificial nutrition, information about eating habits and checking the patient's weight on a regular basis.[21]

Health care-associated infections are common in both home health care and hospital care.[1, 22] Falls and pressure ulcers are also common in hospitalized patients. However, the pattern of AEs in home health care differs from that in hospital care in other aspects. Surgical/procedural AEs and distended urinary bladder are more common in hospital care.[1, 6, 18, 23, 24]

We found that more than half of the AEs caused minimal impairment, with recovery within 1 month. This is in contrast to the findings of Sears et al.,[8] where one quarter of the AEs caused slight impairment and half resulted in moderate to serious impairment or death. One explanation for the difference could be that we found three times more AEs and probably included less severe AEs. Sears et al.[8] only included AEs that required the use of additional health care resources. Interventions in connection with AEs are a resource-consuming burden

to health care. In order to get a broader and more proactive approach to patient safety, we found it important to include AEs that caused temporary harm without requiring extra visits or a prolonged health care period.

We chose to review a period up to a maximum of 90 days from the start of a randomly chosen home health care period and included all AEs regardless of caregiver. If a patient was hospitalized and returned to home health care during that period, we included the new home health care period(s). The Institute for Healthcare Improvement has developed a trigger tool for skilled nursing facilities recommending that only the first 30 days in an admission are reviewed.[25] Blais et al.[9] included a period of up to 12 months preceding discharge for review and also included a 6-month period after discharge from the index admission. There is no consensus regarding which triggers to use in different kinds of settings.[26] The same applies for reporting of AE rates, as well as characterization of AEs, which makes comparisons difficult. As interest in home health care safety increases, in parallel with the increased demand for the service, reliable and validated safety tools are warranted.

The strengths of this study include having ten teams from different parts of Sweden to review 600 records, which served to give an overview of AEs occurring in home health care settings. In accordance with the Global Trigger Tool methodology and as patients receiving home health care sometimes need parallel interventions from caregivers outside home health care, we chose a broader perspective on patient safety and included all AEs that occurred and/or were detected during the 90-day review period. We modified our definition based on NCC MERP classification E to include all AEs that resulted in temporary harm to the patient, regardless of whether an intervention was documented or not. We regard this as an improvement from a patient perspective. To suit the patients and to visualize the extra resources related to AEs, we also expanded NCC MERP classification F to include extra visits within home health care and outpatient care. This study also has a number of limitations. In any study based on record review, only AEs that are noted in the record can be

found. Generalizability may be limited if home health care programmes differ from the Swedish context at the investigation sites. As this study forms a basis for a national trigger tool for home health care, we aimed for richer review material and limited inclusion by excluding patients receiving infrequent home health care.

CONCLUSIONS

AEs in patients admitted to home health care are common, mostly preventable and often result in temporary harm that requires extra health care resources. As in hospital care, health care-associated infections, falls and pressure ulcers are common AEs. The latter two are even more common in home health care, as is harm to skin, vessels and tissue. This implies that we must address how home health care is provided. This is an important area for future studies.

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Competing interests

The authors declare that they have no competing interests.

Contributors

KS, MU, ME, ML and LN designed and conducted the study. KS, MU and LN undertook the initial interpretation of the data, which was followed by discussions with all the authors. All

authors drafted the manuscript and were part of the revision process. All authors agreed to the final version of the manuscript before submission.

Data sharing statement

No additional data are available.

REFERENCES

1. Soop M, Fryksmark U, Köster M, et al. The incidence of adverse events in Swedish hospitals: a retrospective medical record review study. *Int J Qual Health Care* 2009;21:285–91.

2. von Plessen C, Kodal AM, Anhoj J. Experiences with global trigger tool reviews in five Danish hospitals: an implementation study. *BMJ Open*;2:1–8.

3. Resar RK, Rozich JD, Simmonds T, et al. A trigger tool to identify adverse events in the intensive care unit. *Jt Comm J Qual Patient Saf* 2006;32:585–90.

4. Kaafarani HM, Rosen AK, Nebeker JR, et al. Development of trigger tools for surveillance of adverse events in ambulatory surgery. *Qual Saf Health Care* 2010;19:425–9.

5. Unbeck M, Lindemalm S, Nydert P, et al. Validation of triggers and development of a pediatric trigger tool to identify adverse events. *BMC Health Serv Res* 2014;14:655.

6. Nilsson L, Risberg MB, Montgomery A, et al. Preventable adverse events in surgical care in Sweden: a nationwide review of patient notes. *Medicine (Baltimore)* 2016;95:e3047.

7. Mattsson TO, Knudsen JL, Lauritsen J, et al. Assessment of the global trigger tool to measure, monitor and evaluate patient safety in cancer patients: reliability concerns are raised. *BMJ Qual Saf* 2013;22:571–9.

8. Sears N, Baker GR, Barnsley J, et al. The incidence of adverse events among home care patients. *Int J Qual Health Care* 2013;25:16–28.

9. Blais R, Sears NA, Doran D, et al. Assessing adverse events among home care clients in three Canadian provinces using chart review. *BMJ Qual Saf* 2013;22:989–97.

10. Doran DM, Hirdes JP, Blais R, et al. The nature of safety problems among Canadian homecare clients: evidence from the RAI-HC reporting system. *J Nurs Manage* 2009;17:165–74.

11. Doran DM, Hirdes JP, Blais R, et al. Adverse events among Ontario home care clients associated with emergency room visit or hospitalization: a retrospective cohort study. *BMC Health Serv Res* 2013;13:227.

12. Madigan E. A description of adverse events in home healthcare. *Home Healthc Nurse* 2007;25:191–7.

13. Classen DC, Resar R, Griffin F, et al. Global Trigger Tool' shows that adverse events in hospitals may be ten times greater than previously measured. *Health Affairs* 2011;30:581–9.

14. Griffin F, Resar R. IHI Global Trigger Tool for Measuring Adverse Events. 2nd ed. Cambridge, MA: Institute for Healthcare Improvement; 2009.

15. Anell A, Glenngård AH, Merkur S. Sweden: health system review. *Health Syst Transit* 2012;14:1–159.

16. SFS 2010:659. Patientsäkerhetslagen [Patient Safety Act]. 2010. Stockholm: Riksdagen. https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/patientsakerhetslag-2010659_sfs-2010-659 (accessed Mar 20 2017).

17. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *N Engl J Med* 1991;324:370–6.

18. Kennerly DA, Saldana M, Kudyakov R, et al. Description and evaluation of adaption to the Global Trigger Tool to enhance value to adverse event reduction efforts. *J Patient Saf* 2013;9:87–95.

19. Johnson K. Adverse events among Winnipeg Home Care clients. *Healthc Q* 2006;9 Spec No:127–34.

20. Tisdale MJ. Cachexia in cancer patients. *Nat Rev Cancer* 2002;2:862–71.

21. Alibhai SMH, Greenwood C, Payette H. An approach to the management of unintentional weight loss in elderly people. *CMAJ* 2005;172:773–80.

22. Deilkås ET, Bukholm G, Lindstrom JC, et al. Monitoring adverse events in Norwegian hospitals from 2010 to 2013. *BMJ Open* 2015;5:e008576.

23. Unbeck M, Muren O, Lillkrona U. Identification of adverse events at an orthopedics department in Sweden. *Acta Orthop* 2008;79:396–403.

24. Unbeck M, Dalen N, Muren O, Lillkrona U, Härenstam KP. Healthcare processes must be improved to reduce the occurrence of orthopaedic adverse events. *Scand J Caring Sci* 2010;24(4):671-7. doi: 10.1111/j.1471-6712.2009.00760.x.

25. Adler L, Moore J, Federico F. IHI Skilled Nursing Facility Trigger Tool for Measuring Adverse Events. Cambridge, MA: Institute for Healthcare Improvement; 2015. http://www.ihi.org/resources/Pages/Tools/SkilledNursingFacilityTriggerTool.aspx (accessed Dec 30 2016).

26. Hibbert PD, Molloy CJ, Hooper TD, et al. The application of the Global Trigger Tool: a systematic review. *Int J Qual Health Care* 2016;28:640–9.

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Adverse events in patients in home health care: a cohort study using trigger tool methodology

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ABSTRACT

Objective: Home health care is an increasingly common part of health care. The patients are often aged, frail and have multiple diseases, and multiple caregivers are involved in their treatment. This study explores the origin, incidence, types and preventability of adverse events (AEs) that occur in patients receiving home health care.

Design: A cohort study using retrospective record review and trigger tool methodology.

Setting and methods: Ten teams with experience of home health care from nine regions across Sweden reviewed home health care records in a two-stage procedure using 38 predefined triggers in four modules. A random sample of records from 600 patients (18 years or older) receiving home health care during 2015 were reviewed.

Primary and secondary outcome measures: The cumulative incidence of AEs found in patients receiving home health care; secondary measures were origin, types, severity of harm and preventability of the AEs.

Results: The patients were 20–79 years old, 280 men and 320 women. The review teams identified 356 AEs in 226 (37.7%; 95% CI 33.0−42.8) of the home health care records. Of these, 255 (71.6%; 95% CI 63.2−80.8) were assessed as being preventable, and most (246, 69.1%; 95% CI 60.9-78.2) required extra health care visits or led to a prolonged period of health care. Most of the AEs (271, 76.1%; 95% CI 67.5-85.6) originated in home health care; the rest were detected during home health care but were related to care outside home health care. The most common AEs were health care-associated infections, falls and pressure ulcers.

Conclusions: AEs in patients receiving home health care are common, mostly preventable and often cause temporary harm requiring extra health care resources. The most frequent types of AEs must be addressed and reduced through improvements in inter-professional collaboration. This is an important area for future studies.

Keywords: Home health care, Patients, Adverse events, Patient harm, Patient safety, Trigger tool

Strengths and limitations of the study

- The review process was standardized and included a manual with detailed trigger definitions and preventability decision support.
- The review team members had long experience of home health care.
- Our recruitment of review teams was based on convenience sampling and did not enable review of a stratified sample of patients receiving home health care in Sweden.
- The results can only be generalized to facilities with similar organizations and clinical standards.

BACKGROUND

Home health care is an increasingly common component of health care, as an alternative to hospitalization. It includes a variety of health care interventions. The purpose can be curative, supportive, palliative or rehabilitative. Safe solutions for care outside the hospital are important. The incidence and types of adverse events (AEs) in the acute care hospital setting have been well-investigated in many countries and for several medical specialities.[1-7] Despite the challenges related to an aging population and citizens' demands to receive care at home, patient safety in home health care is rarely investigated.[8-12] Incidence rates of AEs of up to 13% have been reported in a Canadian context;[8, 11] falls and drug-related AEs are the most frequent.

Retrospective record review is commonly used to study patient harm using predefined triggers indicating potential AEs. More AEs are found through record review than through incident reporting systems.[13] One of the most frequently used methods for retrospective record review is the Global Trigger Tool,[14] which has been further adapted to suit different areas of health care.

The number of patients who are cared for in their homes is increasing. They are often aged, frail and have multiple diseases. Municipal home services provide assistance with activities in daily life, but medical and technical advances have also made it possible for advanced treatment of complex and long-term illnesses in patient homes. As the complexity of care increases, interaction between multiple professionals from different health care providers (i.e., home health care, primary care, specialist care and social care) is critical for patient safety. New risks arise if communication and coordination of care is deficient. Thus, there is a need to further explore safety issues for patients receiving home health care, taking into consideration the complexity of having multiple caregivers involved in treatment and care. We have developed and validated a trigger tool intended for this group of patients.[15]

This study explores the origin, incidence, types and preventability of the AEs that occur in patients receiving home health care.

METHODS

Study setting

The study was set in Sweden, where assistance with activities in daily life is provided in patient homes by unlicensed staff (e.g., assistant nurses) on behalf of the municipal social care services. The municipalities are also usually responsible for providing home health care to the elderly.[16] Their health care organizations include unlicensed assistant nurses, physiotherapists and occupational therapists, with registered nurses (RNs) providing the highest medical competence. The RNs have the overall responsibility for medication management and delivery of specialized health care in patient homes and consequently visit each patient less frequently than the unlicensed staff. When physician resources are necessary, they are usually provided by primary care physicians, but hospital physicians may also become involved. All physicians are employed by the county councils.

Home health care records are generally computerized. There are many different journal systems used in home health care in Sweden and the documentation routines, as well as access to these systems (read and write permissions), vary. Documentation from one caregiver, such as home health care, is not always accessible to health care professionals in other settings, such as staff at a hospital. As patients receiving home health care may be receiving care from several organizations simultaneously, we found it important to include all AEs documented in the home health care notes, irrespective of origin.

Definitions

In this study, an AE was defined as suffering, physical or psychological harm, illness or death caused by health care or social care that was not an inevitable consequence of the patient's

condition or an expected effect of the treatment received by the patient because of her/his condition. A preventable AE was defined as an event that could have been prevented if adequate measures and/or actions had been taken during the patient's contact with health care or social care. This definition is based on the terminology in the Swedish Patient Safety Act.[17] AEs related to both acts of omission and acts of commission were included.

Study sample, inclusion and exclusion criteria

Ten review teams from different sites across Sweden were recruited using a convenience sampling strategy, invitations through personal contacts or by e-mail via a national patient safety network. All review teams interested in participation were included. Seven teams were organized within municipalities and three teams were employed by county councils. The teams consisted of one to three RNs and one or two physicians. They all had long experience of working as RNs or physicians, and in the home health care context.

After approval from the regional ethical board, a random sample of 600 home health care records was reviewed during the period February to August 2016. All patients 18 years or older admitted to home health care during 2015 at the review sites were eligible for inclusion. The review included the period from admission (index admission) up to a maximum of 90 days after admission. If a patient was discharged from home health care and was readmitted within the 90-day period, the review of that patient continued. To be included as an AE in the study, one of the following criteria had to be met:

1. The AE occurred during the index admission, that is, within 90 days after admission in home health care, regardless of caregiver.
2. The AE derived from caregivers outside home health care (outpatient care, social care or in-hospital care), occurred within 30 days prior to the index admission and was detected during the index admission.

Randomization of records was performed by one of the authors (MU), using an online randomizer, to ensure it was carried out in the same way for all review teams. Oversampling was carried out with ten records per team. If a patient in the random sample was receiving limited home health care once or twice a week, for example only blood pressure measurement or delivery of pre-dispensed drugs, this patient was replaced by another random admission. AEs that gave symptoms more than 90 days after the index admission or that occurred were detected and for which treatment was completed before the index admission were excluded.

Education of the review teams

To ensure result validity and reliability, the review process was standardized in a written project manual, where the definitions and the inclusion and exclusion criteria were also included. A trigger manual was used, including trigger definitions and preventability decision support, as well as detailed examples that were discussed by the review teams before the study began. The team members underwent a mandatory one-day education in the trigger tool methodology. Discussions were held to reach consensus about definitions, exclusion and inclusion criteria, interpretation and application of the triggers, assessment of AEs and preventability, as well as how to use the two cases report forms. During the process of familiarization with the methodology, each member of the review team independently reviewed six training records in order to achieve reliable reviews. This was followed by a consensus process with all teams including discussions regarding trigger outcome, assessments of AEs and preventability.

Review process

The review was performed in two stages. In most teams, the RNs carried out both primary and secondary reviews and later discussed the findings with the physicians. In some teams, the physicians carried out some of the primary as well as the secondary reviews.

In the primary review stage, the reviewers screened all records for the presence of 38 predefined triggers categorized into four modules (Table 1). A trigger is an indicator suggesting that an AE might have occurred during the inclusion period. For each trigger detected, the reviewer determined whether or not the trigger reflected the presence of a potential AE. Only records with triggers indicating a potential AE went forward to the secondary review stage. The reviewers also recorded demographic data. Starting from the index admission to home health care, a maximum of 90 days was reviewed. There was no time restriction for the review of each record in this stage. To ensure inter-rater reliability, 10% of the records in the primary review process were reviewed by a second reviewer. Inter-rater reliability was assessed based on the reviewers' judgements regarding whether a record should be forwarded to secondary review. Discussions about individual judgements were held and when consensus was reached, the records were ready for the secondary review stage.

Table 1 List of triggers

Care module	Cardiac arrest and/or deterioration in vital signs
	Deep venous thrombosis and/or pulmonary embolus
	Pressure ulcer
	Blood vessel, skin and/or tissue harm
	Neurological impairment and/or harm
	Fall
	Health care-associated infection
	Moderate/severe pain
	Moderate/severe worry, anxiety, suffering, existential pain and/or psychological pain
	Moderate/severe agitation and/or acute confusion/delirium
	Undernutrition
	Insufficient oral health
	Moderate/severe gastrointestinal problem
	Distended urinary bladder
	Deviation from normal course after invasive/surgical treatment
	Treatment
	Advanced medical device
	Threats, violence and/or improper contact
	Self-inflicted harm
	Escape from home/special accommodation
	Documentation of mistake or dissatisfaction with care
	Other
Laboratory module	Abnormal glucose value

	Increasing creatinine value
	Abnormal potassium value
	Abnormal sodium value
	Abnormal calcium value
Medication module	Adverse drug event/adverse drug reaction
	Drug that requires follow-up with blood sampling
	Treatment with at least 10 drugs
	Absence of in-depth drug review
	Treatment with drugs that increase the risk for haemorrhage
	Drug management
Continuity and transition module	Unplanned change of care-providing unit
	Unplanned contact with physician and/or registered nurse
	Absence of and/or deviation from care plan
	Absence of a coordinated individual care plan when care is provided by several caregivers
	Documentation related to insufficient coordination of care, communication and/or information

In the secondary review stage, each potential AE was scrutinized individually. To qualify as an AE, a score of three or higher on a 4-point Likert scale was required (1, the event was not related to health care/social care; 2, the event was probably not related to health care/social care; 3, the event was probably related to health care/social care; 4, the event was related to health care/social care). The reviewer made a judgement whether or not the event qualified as an AE. If it did, the AE was marked for further assessment. The preventability of an AE was judged on a similar 4-point scale: 1, the AE was not preventable; 2, the AE was probably not preventable; 3, the AE was probably preventable; 4, the AE was preventable.[5] In the following, probably preventable (grade 3) and preventable (grade 4) AEs are referred to as preventable AEs.

The severity of harm was evaluated using two different scales. The first was the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Index,[18] which is used in the Global Trigger Tool.[14] NCC MERP Index categories E–I were included, i.e., those relating to harm (grade E, contributed to or resulted in temporary harm; grade F, contributed to or resulted in temporary harm to the patient and required outpatient, home health or hospital care, or prolonged hospitalization or extended the period of home health care; grade G, contributed to or resulted in permanent patient harm; grade H,

lifesaving intervention required within 60 minutes; grade I, contributed to the patient's death). The second severity scale was that used in the Harvard Medical Practice Study (HMPS)[19] and subsequently in several nationwide AE studies. It encompasses seven grades (minimal impairment, recovery within 1 month; moderate impairment, recovery within 1–6 months; moderate impairment, recovery within 6–12 months; permanent impairment, degree of disability ≤ 50%; permanent impairment, degree of disability > 50%; contributed to patient death; unable to determine). All reviewers also documented, e.g., the types of AEs, as well as information on the origin of each AE (home health care, inpatient care, outpatient care or social care).

Access to various parts of the patients' medical records differed between review teams. Municipalities and county councils sometimes have separate medical record systems. Accordingly, some municipal review teams had to request physicians' notes and laboratory values, for example, because these were stored in their county council's record system.

All review teams were supported by record review experts in the research group who could answer questions; one expert (MU) monitored all reviews from the primary and secondary review stages for completeness and adherence to the trigger definitions and project manual. Any questions or discrepancies were referred back to the relevant team for resolution.

Data analysis

Data are presented as median (range), mean (SD) (95% CI) or number (percent). We calculated the cumulative incidence of AEs over the review period. Comparisons between groups were made using the Mann-Whitney U test or the chi-squared test, as appropriate. A p value < 0.05 was considered significant. Agreement between reviewers was analysed using κ statistics. All statistical calculations were performed using Statistica 64 version 13 (StatSoft, Oklahoma, USA).

RESULTS

A total of 600 patient records from home health care were reviewed; 280 of the patients were men, median age 79 years (range, 20−97 years), and 320 were women, median age 82 years (range, 29−99 years). The number of days reviewed was 40,735 in total, with a median of 90 days per patient. Depending on patient discharge or death, the range of days reviewed varied between 1 and 90. Demographic data are shown in Table 2.

Table 2 Demographic data

Parameter	Value
Men/women, n (%)	280 (46.7) / 320 (53.3)
Age in years, median (range)	80.5 (20−99)
Reviewed days, median (range)	90 (1−90)
Referral to home health care from	
Hospital care, n (%)	300 (50.0)
Outpatient care, n (%)	212 (35.3)
Not possible to determine, n (%)	88 (14.7)
Medical diagnosis at home health care admission*	
Malignancy, n (%)	253 (42.2)
Cardiovascular disease, n (%)	119 (19.8)
Confusion, dementia, n (%)	102 (17.0)
Diabetes, n (%)	51 (8.5)
Skin wound, pressure ulcer, n (%)	38 (6.3)
Stroke, n (%)	36 (6.0)
Pulmonary disease, n (%)	35 (5.8)
Neurological disease, n (%)	33 (5.5)
Medical needs at home health care admission†	
Medication assistance, n (%)	233 (38.8)
Palliative care, n (%)	144 (24.0)
Activities of daily living, n (%)	111 (18.5)
Laboratory sampling, n (%)	88 (14.7)
Wound care, assistance with compression stockings, n (%)	74 (12.3)
Assistance with advanced medical devices, n (%)	62 (10.3)
Rehabilitation, home modifications, means testing, n (%)	51 (8.5)
Pain relief, n (%)	39 (6.5)
Social situation at home health care admission	
Patient's own home, lives alone, n (%)	265 (44.2)
Patient's own home, cohabiting, n (%)	257 (42.8)
Home for medical health care, assistance 24/7, n (%)	50 (8.3)
Not possible to determine, n (%)	28 (4.7)

*Medical diagnosis affecting > 5% of patients. A patient could have several diagnoses.

†Medical needs for > 5% of patients. A patient could have several medical needs.

The inter-rater reliability of the reviewers' judgements concerning if a record was to be forwarded to secondary review was $\kappa = 0.801$ (substantial).

Through the home health care records, 356 AEs were identified, affecting 226 patients (37.7 %; 95% CI 33.0−42.8). This corresponds to a median of 1 (range, 1−7) AE per patient affected (Table 3). Most were considered preventable (255, 71.6 %; 95% CI 63.2−80.8). There was no difference in the incidence of AEs between men and women (p = 0.72), or between patients aged 80 years or older and younger patients (p = 0.12) (data not shown).

Table 3 Adverse events (AEs) detected in patients receiving home health care classified by origin (n = 600)

	Home health care	Care outside home health care	Total
Number of AEs	271	85	356
Number of patients affected by AEs (%; 95% CI)	182 (30.3; 26.2−35.0)	67 (11.2; 8.7−14.1)	226 (37.7; 33.0−42.8)
Median number of AEs per affected patient (range)	1 (1−5)	1 (1−4)	1 (1−7)
Number of preventable AEs	194	61	255
Number of patients affected by preventable AEs (%; 95% CI)	137 (22.8; 19.2−26.9)	50 (8.3; 6.3−10.9)	174 (29.0; 24.9−33.6)
Median number of preventable AEs per affected patient (range)	1 (1−4)	1 (1−4)	1 (1−5)
Number of patients with > 1 AE (%; 95% CI)	62 (10.3; 8.0−13.2)	12 (2.0; 1.1−3.4)	83 (13.8; 11.1−17.1)
Number of patients with > 1 preventable AE (%; 95% CI)	39 (6.5; 4.7−8.8)	8 (1.3; 0.6−2.5)	54 (9.0; 6.8−11.6)
Number of AEs per 100 patients	45.2	14.2	59.3
Number of preventable AEs per 100 patients	32.3	10.2	42.5
Number of AEs per 1,000 patient days	6.7	2.1	8.7
Number of preventable AEs per 1,000 patient days	4.8	1.5	6.3

Of the AEs, 271 (76.1 %; 95% CI 67.5−85.6) were related to home health care, 44 (12.4 %; 95% CI 9.1−16.4) to in-hospital care, 23 (6.5 %; 95% CI 4.2−9.5) to social care and 12 (3.4 %; 95% CI 1.8−5.7) to outpatient care. It was not possible to determine from the documentation where the remaining 6 (1.7%; 95% CI 0.7−3.5) AEs had originated. There was no difference in preventability (p = 0.97) between AEs originating in home health care or outside home health care (data not shown).

On the NCC MERP scale, 102 (28.6%; 95% CI 23.5−34.6) of all AEs resulted in temporary harm to the patient and 246 (69.1 %; 95% CI 60.9−78.2) in temporary harm that required extra health care visits or a prolonged care period. The HMPS scale showed that 213 (59.8%; 95% CI 52.2−68.3) of all AEs were minor with recovery within 1 month (Table 4). When comparing AEs originating in home health care and care given to the patients outside

home health care, NCCP MERP revealed no difference in severity ($p = 0.64$), but the HMPS classification did ($p = 0.027$). When AEs for which severity could not be determined were excluded, this difference no longer remained ($p = 0.07$).

Table 4 Severity of adverse events (AEs) detected in patients receiving home health care classified by origin

Severity category	In home health care		Care outside home health care		Total	
	AE, n (%; 95% CI)	Preventable AE, n (%; 95% CI)	AE, n (%; 95% CI)	Preventable AE, n (%; 95% CI)	AE, n (%; 95% CI)	Preventable AE, n (%; 95% CI)
Severity category according to NCCP MERP index						
E Contributed to or resulted in temporary harm	78 (28.8; 22.9−35.7)	50 (64.1; 48.1−83.8)	24 (28.2; 18.5−41.4)	14 (58.3; 33.2−95.6)	102 (28.6; 23.5−34.6)	64 (62.7; 48.7−79.6)
F Contributed to or resulted in temporary harm to the patient and required outpatient, home health or hospital care, or prolonged hospitalization or an extended period of home health care	187 (69.0; 59.6−79.4)	142 (75.9; 64.2−89.2)	59 (69.4; 53.3−88.9)	45 (76.3; 56.3−101.2)	246 (69.1; 60.9−78.2)	187 (76.0; 65.7−87.5)
G Contributed to or resulted in permanent patient harm	3 (1.1; 0.3−3.0)	1 (33.3; 1.7−164.4)	2 (2.4; 3.9−7.8)	2 (100; 167.7−330.4)	5 (1.4; 0.5−3.1)	3 (60.0; 15.3−163.3)
H Lifesaving intervention required within 60 minutes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
I Contributed to patient's death	3 (1.1; 0.3−3.0)	1 (33.3; 1.7−164.4)	0 (0)	0 (0)	3 (0.8; 0.2−2.3)	1 (33.3; 1.7−164.4)
Total	271 (100)	194 (71.6; 62.0−82.2)	85 (100)	61 (71.8; 55.4−91.6)	356 (100)	255 (71.6; 63.2−80.8)
Severity category according to HMPS scale						
Minimal impairment, recovery within 1 month	171 (63.1; 54.2−73.1)	118 (69.0; 57.4−82.3)	42 (49.4; 36.1−66.2)	31 (73.8; 51.0−103.5)	213 (59.8; 52.2−68.3)	149 (69.9; 59.4−81.9)
Moderate impairment, recovery within 1–6 months	57 (21.0; 16.1−27.0)	44 (77.2; 56.8−102.7)	26 (30.6; 20.4−44.2)	19 (73.1; 45.3−112.0)	83 (23.3; 18.7−28.8)	63 (75.9; 58.8−96.5)
Moderate impairment, recovery within 6–12 months	14 (5.2; 2.9−8.5)	11 (78.6; 41.3−136.6)	1 (1.2; 0.1−5.8)	0 (0)	15 (4.2; 2.5−6.8)	11 (73.3; 38.6−127.5)
Permanent impairment, degree of disability ≤ 50%	3 (1.1; 0.3−3.0)	1 (33.3; 1.7−164.4)	2 (2.4; 0.4−7.8)	2 (100; 167.7−330.4)	5 (1.4; 0.5−3.1)	3 (60.0; 15.3−163.3)
Permanent impairment, degree of disability > 50%	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Contributed to patient death	3 (1.1; 0.3−3.0)	1 (33.3; 1.7−164.4)	0 (0)	0 (0)	3 (0.8; 0.2−2.3)	1 (33.3; 1.7−164.4)
Unable to determine	23 (8.5; 5.5−12.5)	19 (82.6; 51.2−126.6)	14 (16.5; 9.4−27.0)	9 (64.3; 31.4−118.0)	37 (10.4; 7.4−14.2)	28 (75.7; 51.3−107.9)
Total	271 (100)	194 (71.6; 62.0−82.2)	85 (100)	61 (71.8; 55.4−91.6)	356 (100)	255 (71.6 ; 63.2−80.8)

NCCP MERP, National Coordinating Council for Medication Error Reporting and Prevention. HMPS, Harvard Medical Practice Study.

Table 5 Types of adverse events (AEs) detected in patients receiving home health care, the origin and the proportion of preventable AEs

Type of AE	Home health care, AEs n (%; 95% CI)	Care outside home health care, AEs n (%; 95% CI)	Total, AEs n (%; 95% CI)	Total preventable AEs, n (%; 95% CI)
Health care-associated infections	59 (21.8; 16.7−27.9)	13 (15.3; 8.5−25.5)	72 (20.2; 15.9−25.3)	46 (63.9; 47.3−84.5)
Oral candida	12 (25.4)	1 (7.7)	13 (18.1)	6 (46.1)
Urinary tract infection	9 (15.2)	2 (15.4)	11 (15.3)	8 (72.7)
Pneumonia	10 (16.9)	1 (7.7)	11 (15.3)	8 (72.7)
Wound infection	9 (15.2)	3 (23.1)	12 (16.6)	12 (100.0)
Sepsis	5 (8.5)	1 (7.7)	6 (8.3)	1 (16.7)
Skin candida	5 (8.5)	1 (7.7)	6 (8.3)	6 (100.0)
Others	9 (15.2)	4 (30.8)	13 (18.1)	5 (38.5)
Falls	51 (18.8; 14.2−24.6)	15 (17.6; 10.2−28.4)	66 (18.5; 14.4−23.4)	29 (43.9; 30.0−62.3)
Fracture	7 (13.7)	4 (26.7)	11 (16.7)	6 (54.5)
Skin wound	33 (64.7)	7 (46.7)	40 (60.6)	14 (35.0)
Pain	11 (21.6)	3 (30.0)	14 (21.2)	8 (57.1)
Not specified	0 (0)	1 (6.7)	1 (1.5)	1 (100.0)
Pressure ulcers	46 (17.0; 12.6−22.4)	16 (18.8; 11.1−29.9)	62 (17.4; 13.5−22.2)	52 (83.9; 63.3−109.1)
Category 1	20 (43.5)	4 (25.0)	24 (38.7)	21 (87.5)
Category 2	17 (37.0)	8 (50.0)	25 (40.3)	19 (76.0)
Category 3	3 (6.5)	2 (12.5)	5 (8.0)	4 (80.0)
Category 4	2 (4.3)	0 (0)	2 (3.2)	2 (100.0)
Category unknown	4 (8.7)	2 (12.5)	6 (9.7)	6 (100.0)
Skin, vessel or tissue harm	25 (9.2; 6.1−13.4)	8 (9.4; 4.4−17.9)	33 (9.3; 6.5−12.9)	27 (81.8; 55.0−117.4)
Skin harm	18 (72.0)	4 (25.0)	22 (66.7)	18(81.8)
Vessel harm	4 (16.0)	1 (12.5)	5 (15.2)	3 (80.0)
Tissue harm	3 (12.0)	3 (37.5)	6 (18.2)	6 (100.0)
Pain	17 (6.3; 3.8−9.8)	6 (7.1; 2.9−14.7)	23 (6.5; 4.2−9.5)	21 (91.3; 58.0−137.2)
Psychological harm	12 (4.4; 2.4−7.5)	6 (7.1; 2.9−14.7)	18 (5.1; 3.1−7.8)	14 (77.8; 44.3−127.4)
Other	10 (3.7; 1.9−6.6)	1 (1.2; 0.1−5.8)	11 (3.1; 1.6−5.4)	10 (90.1; 46.2−162.0)
Neurological harm	7 (2.6; 1.1−5.1)	3 (3.5; 0.9−9.6)	10 (2.8; 1.4−5.0)	9 (90.0; 43.9−165.2)
Haemorrhage (not related to surgery)	7 (2.6; 1.1−5.1)	3 (3.5; 0.9−9.6)	10 (2.8; 1.4−5.0)	4 (40.0; 12.7−96.5)
Failure in vital signs	7 (2.6; 1.1−5.1)	3 (3.5; 0.9−9.6)	10 (2.8; 1.4−5.0)	9 (90.0; 43.9−165.2)
Weight loss, nutrition-related AE	5 (1.8; 0.7−4.1)	3 (3.5; 0.9−9.6)	8 (2.2; 1.0−4.3)	7 (87.5; 38.3−173.1)
General deterioration in health status	7 (2.6; 1.1−5.1)	0 (0)	7 (2.0; 0.9−3.9)	7 (100.0; 43.7−197.8)
Severe constipation	5 (1.8; 0.7−4.1)	0 (0)	5 (1.4; 0.5−3.1)	5 (100.0; 36.6−221.7)
Severe vomiting	4 (1.5; 0.5−3.6)	0 (0)	4 (1.1; 0.4−2.7)	3 (75.0; 19.1−204.1)
Affected laboratory values	3 (1.1; 0.3−3.0)	1 (1.2; 0.1−5.8)	4 (1.1; 0.4−2.7)	4 (100.0; 31.8−241.2)
Allergic reaction	1 (0.4; 0.0−1.8)	2 (2.4; 0.4−7.8)	3 (0.8; 0.2−2.3)	1 (33.3; 1.7−164.4)
Severe diarrhoea	1 (0.4; 0.0−1.8)	2 (2.4; 0.4−7.8)	3 (0.8; 0.2−2.3)	1 (33.3; 1.7−164.4)
Distended urinary bladder	2 (0.7; 0.1−2.4)	2 (2.4; 0.4−7.8)	4 (1.2; 0.4−2.7)	4 (100; 31.8−241.2)
Dehydration	1 (0.4; 0.0−1.8)	1 (1.2; 0.1−5.8)	2 (0.6; 0.1−1.9)	1 (50.0; 2.5−246.6)
Attempted suicide	1 (0.4; 0.0−1.8)	0 (0)	1 (0.3; 0.0−1.4)	1 (100.0; 5.0−493.2)
Total	271 (100.0)	85 (100.0)	356 (100.0)	255 (71.6; 63.2−80.8)

The most common types of AEs were health care-associated infections, falls and pressure ulcers (Table 5). There were no differences in the number of such AEs between men and women or between patients aged 80 years or older and younger patients (data not shown). The

probability of falls being preventable was 43.9%; 95% CI 30.0−62.3, whereas the majority of the other types of AEs were considered preventable to a greater extent. There was no difference in the type of AEs between those originating in home health care and those from care given outside home health care (p = 0.52).

Forty-one (18.1%) of the AEs in the home health care setting required a median of one (range, 1−5) additional physician visit(s) in the outpatient setting, 40 (14.8 %) required a median of 1 (range, 1−9) additional physician visit(s) in the home health care setting and 37 (13.7%) required hospital care for a median of 6 days (range, 1−41 days). There were no significant differences compared with AEs outside home health care: 7 (8.2%) (median, 1; range, 1−2) required additional physician visit(s) in the outpatient setting; 11 (12.9%) (median, 1; range, 1−11) required additional physician visit(s) in the home health care setting; 13 (15.3%) required hospital care for a median of 7 days (range, 2−10 days).

DISCUSSION

This study is the first to assess AEs in patients receiving home health care across different parts of Sweden through the use of retrospective record review. Our main findings are that AEs affect over a third of these patients, are deemed to be mostly preventable and result in temporary harm to the patient requiring extra health care resources. One fourth of the AEs detected in home health care originated in other health care settings. We found no differences in the types of AEs, or their severity or preventability, depending on origin.

There are few studies investigating AEs in home health care with which to compare our findings. The incidence of AEs, 37.7%, is much higher than the 4−13% reported by other studies.[8, 9, 10, 11] It is difficult to compare the rates, as the differences may be due to varying services, patient characteristics, and methods of record review, as well as the definition of an AE and the inclusion criteria used. It is also difficult to compare the rates for the home health care setting with in-hospital AE rates, because the home health care provider

may not continuously observe the patients and the health care environment. The majority of the identified AEs were minor and transient. In a comparison of serious AEs (recovery within 6–12 months, permanent disability or death) by recalculating their respective prevalence, there seem to be no obvious differences between our study and an earlier Swedish in-hospital study or Canadian home health care.[1, 8]

Patients receiving home health care are often old and frail and frequently have concomitant contact with multiple caregivers. We have shown that almost 25% of AEs found in patients in home health care originated in care given in other settings. AEs such as pressure ulcers or infections impose an additional burden on the home health care organization with its limited access to RNs and physicians. This finding also highlights the importance of passing knowledge about AEs between caregivers. The findings imply that all sections of health care should be aware of these most common AEs and preventive measures that can be taken along a patient's health care journey.

Almost three out of four AEs, regardless of origin, were judged by the review teams in our study to be preventable. This is higher than the 33−56% previously reported in the home health care setting,[8, 9] but is in line with many hospital record reviews.[1, 5, 6, 20] Risk reduction in patient homes is not directly transferable from hospital care. The possibility of conflict between patient autonomy and safety should be considered in the home care setting. Patients are the hosts of the care environment and supervision from health care personnel is mostly limited to short visits. Preventive safety measures in a patient's home require true patient involvement, taking the patient's values and integrity into consideration. For instance, removing carpets to prevent falls, one of the AEs with the lowest preventability ratings must be weighed against a patient's own wishes.

Our findings of health care-associated infections, falls, pressure ulcers and skin breakdown as the most common AEs are largely consistent with a Canadian review of 1,200

records from 2009−2010, which reported falls, wound infections, psychosocial, behavioural or mental health problems, or medication-related AEs as the most prominent findings.[9] We chose to not to use "medication-related AEs" as a separate AE group, since we regarded medication as a cause of AEs. Medication-caused AEs can be found among for example falls, severe constipation and oral candida. Other studies also report injurious falls as the most common AE in home health care.[11, 21] Decline in physical function is a prevalent safety risk.[10] Falls are also associated with increased risk of admission to long-term care and death.[11] This emphasizes the need to find effective strategies for prevention of falls. Preventive strategies for pressure ulcers and skin breakdown [8] also need to be identified. Patients in home health care may have several well-known risk factors for pressure ulcers. In one study, one tenth of AEs in patients receiving home health care fell into the category general decline.[8] The aging patient is at risk for weight loss and malnutrition. Doran et al.[10] noted that unintended weight loss accounted for 10% of the safety problems in home health care. Patients receiving home health care are often affected by cancer, where weight loss is a well-known problem.[10,22] Routines for the prevention of weight loss are important. Interventions can include energy- and protein-rich food, food with a particular texture, artificial nutrition, information about eating habits and checking the patient's weight on a regular basis.[23]

Health care-associated infections are common in both home health care and hospital care.[1, 24] Falls and pressure ulcers are also common in hospitalized patients. However, the types of AEs in home health care differ from that in hospital care in other aspects. Surgical/procedural AEs and distended urinary bladder are more common in hospital care.[1, 6, 20, 25, 26]

We found that more than half of the AEs caused minimal impairment, with recovery within 1 month. This is in contrast to the findings of Sears et al.,[8] where one quarter of the AEs caused slight impairment and half resulted in moderate to serious impairment or death.

One explanation for the difference could be that we found three times more AEs and probably included less severe AEs. Sears et al.[8] only included AEs that required the use of additional health care resources. Interventions in connection with AEs are a resource-consuming burden to health care. In order to get a broader and more proactive approach to patient safety, we found it important to include AEs that caused temporary harm without requiring extra visits or a prolonged health care period. The HMPS scale seemed less suitable than the NCC MERP scale in evaluating AE severity. Approximately one in ten AEs could not be characterized using the former scale.

We chose to review a period up to a maximum of 90 days from the start of a randomly chosen home health care period and included all AEs regardless of caregiver. If a patient was hospitalized and returned to home health care during that period, we included the new home health care period(s). The Institute for Healthcare Improvement has developed a trigger tool for skilled nursing facilities recommending that only the first 30 days of an admission are reviewed.[27] Blais et al.[9] included a period of up to 12 months preceding discharge for review and also included a 6-month period after discharge from the index admission. There is no consensus regarding which triggers to use in different settings.[28] The same applies for reporting of AE rates, as well as characterization of AEs, which makes comparisons difficult. As demand for home health care and interest in home health care safety increase, reliable and validated safety tools are warranted.

The strengths of this study include having ten teams from different parts of Sweden to review 600 records, which served to give an overview of AEs occurring in home health care settings. In accordance with the Global Trigger Tool methodology and as patients receiving home health care sometimes need parallel interventions from caregivers outside home health care, we chose a broader perspective on patient safety and included all AEs that occurred and/or were detected during the 90-day review period. We modified our definition based on NCC MERP classification E to include all AEs that resulted in temporary harm to the patient,

regardless of whether an intervention was documented or not. We regard this as an improvement from a patient perspective, as it contributes to the identification of risk areas. To adapt to the patient perspective and visualize the extra resources required due to AEs, we also expanded NCC MERP classification F to include extra visits within home health care and outpatient care. This study also has a number of limitations. We did not use a stratified sample of records for all patients receiving home health care in Sweden. As the review was a part of the development and validation of a trigger tool suited for home health care, we aimed for review teams with an interest in patient safety. The 600 records were randomised from the ten sites and gave an overview of AEs occurring in home health care. As this study forms a basis for a national trigger tool for home health care, we aimed for richer review material and limited inclusion by excluding records from patients receiving very sparse and infrequent home health care. This exclusion criterion was defined using examples only. In any study based on record review, only AEs that are noted in the record can be found. Generalizability may be limited if home health care services have differing clinical standards.

CONCLUSIONS

AEs in patients receiving home health care are common, mostly preventable and often result in temporary harm that requires extra health care resources. As in hospital care, health care-associated infections, falls and pressure ulcers are common AEs. The latter two are even more common in home health care, as is harm to skin, vessels and tissue. This implies that we must address and reduce these AEs through improvements identified in collaborations between professionals. This is an important area for future studies.

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Competing interests

The authors declare that they have no competing interests.

Ethics approval

Ethical permission was obtained from the Regional Ethical Board of Linköping University, Sweden (No 2014/150-31).

Contributors

KS, MU, ME, ML and LN designed and conducted the study. KS, MU and LN undertook the initial interpretation of the data, which was followed by discussions between all the authors. All authors drafted the manuscript and were part of the revision process. All authors agreed to the final version of the manuscript before submission.

Data sharing statement

No additional data are available.

REFERENCES

1. Soop M, Fryksmark U, Köster M, et al. The incidence of adverse events in Swedish hospitals: a retrospective medical record review study. *Int J Qual Health Care* 2009;21:285–91.

2. von Plessen C, Kodal AM, Anhoj J. Experiences with global trigger tool reviews in five Danish hospitals: an implementation study. *BMJ Open*;2:1–8.

3. Resar RK, Rozich JD, Simmonds T, et al. A trigger tool to identify adverse events in the intensive care unit. *Jt Comm J Qual Patient Saf* 2006;32:585–90.

4. Kaafarani HM, Rosen AK, Nebeker JR, et al. Development of trigger tools for surveillance of adverse events in ambulatory surgery. *Qual Saf Health Care* 2010;19:425–9.

5. Unbeck M, Lindemalm S, Nydert P, et al. Validation of triggers and development of a pediatric trigger tool to identify adverse events. *BMC Health Serv Res* 2014;14:655.

6. Nilsson L, Risberg MB, Montgomery A, et al. Preventable adverse events in surgical care in Sweden: a nationwide review of patient notes. *Medicine (Baltimore)* 2016;95:e3047.

7. Mattsson TO, Knudsen JL, Lauritsen J, et al. Assessment of the global trigger tool to measure, monitor and evaluate patient safety in cancer patients: reliability concerns are raised. *BMJ Qual Saf* 2013;22:571–9.

8. Sears N, Baker GR, Barnsley J, et al. The incidence of adverse events among home care patients. *Int J Qual Health Care* 2013;25:16–28.

9. Blais R, Sears NA, Doran D, et al. Assessing adverse events among home care clients in three Canadian provinces using chart review. *BMJ Qual Saf* 2013;22:989–97.

10. Doran DM, Hirdes JP, Blais R, et al. The nature of safety problems among Canadian homecare clients: evidence from the RAI-HC reporting system. *J Nurs Manage* 2009;17:165–74.

11. Doran DM, Hirdes JP, Blais R, et al. Adverse events among Ontario home care clients associated with emergency room visit or hospitalization: a retrospective cohort study. *BMC Health Serv Res* 2013;13:227.

12. Madigan E. A description of adverse events in home healthcare. *Home Healthc Nurse* 2007;25:191–7.

13. Classen DC, Resar R, Griffin F, et al. Global Trigger Tool' shows that adverse events in hospitals may be ten times greater than previously measured. *Health Affairs* 2011;30:581–9.

14. Griffin F, Resar R. IHI Global Trigger Tool for Measuring Adverse Events. 2nd ed. Cambridge, MA: Institute for Healthcare Improvement; 2009.

15. Lindblad M, Schildmeijer K, Nilsson L, et al. Development and validation of a trigger tool to identify adverse events and no-harm incidents that affect patients admitted to home healthcare. BMJ Qual and Saf. Accepted 25 Aug 2017.

16. Anell A, Glenngård AH, Merkur S. Sweden: health system review. *Health Syst Transit* 2012;14:1–159.

17. SFS 2010:659. Patientsäkerhetslagen [Patient Safety Act]. 2010. Stockholm: Riksdagen. https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/patientsakerhetslag-2010659_sfs-2010-659 (accessed Mar 20 2017).

18. NCC MERP; http://www.nccmerp.org/sites/default/files/indexBW2001-06-12.pdf (accessed Sept 26 2017).

19. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *N Engl J Med* 1991;324:370–6.

20. Kennerly DA, Saldana M, Kudyakov R, et al. Description and evaluation of adaption to the Global Trigger Tool to enhance value to adverse event reduction efforts. *J Patient Saf* 2013;9:87–95.

21. Johnson K. Adverse events among Winnipeg Home Care clients. *Healthc Q* 2006;9 Spec No:127–34.

22. Tisdale MJ. Cachexia in cancer patients. *Nat Rev Cancer* 2002;2:862–71.

23. Alibhai SMH, Greenwood C, Payette H. An approach to the management of unintentional weight loss in elderly people. *CMAJ* 2005;172:773–80.

24. Deilkås ET, Bukholm G, Lindstrom JC, et al. Monitoring adverse events in Norwegian hospitals from 2010 to 2013. *BMJ Open* 2015;5:e008576.

25. Unbeck M, Muren O, Lillkrona U. Identification of adverse events at an orthopedics department in Sweden. *Acta Orthop* 2008;79:396–403.

26. Unbeck M, Dalen N, Muren O, Lillkrona U, Härenstam KP. Healthcare processes must be improved to reduce the occurrence of orthopaedic adverse events. *Scand J Caring Sci* 2010;24(4):671-7. doi: 10.1111/j.1471-6712.2009.00760.x.

27. Adler L, Moore J, Federico F. IHI Skilled Nursing Facility Trigger Tool for Measuring Adverse Events. Cambridge, MA: Institute for Healthcare Improvement; 2015. http://www.ihi.org/resources/Pages/Tools/SkilledNursingFacilityTriggerTool.aspx (accessed Dec 30 2016).

28. Hibbert PD, Molloy CJ, Hooper TD, et al. The application of the Global Trigger Tool: a systematic review. *Int J Qual Health Care* 2016;28:640–9.

STROBE Statement

	Page No	Recommendation
Title and abstract	1-2	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	4	Explain the scientific background and rationale for the investigation being reported
Objectives	5	State specific objectives, including any prespecified hypotheses
Methods		
Study design	5	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6-7	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	8-10	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	6	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias		Describe any efforts to address potential sources of bias
Study size	6	Explain how the study size was arrived at
Quantitative variables	10	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	10	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
		(*e*) Describe any sensitivity analyses

Continued on next page

Results		
Participants	11	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	11	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)
Outcome data	12	*Cohort study*—Report numbers of outcome events or summary measures over time
		Case-control study—Report numbers in each exposure category, or summary measures of exposure
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	12-15	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses		Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	16-19	Summarise key results with reference to study objectives
Limitations	20	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	20	Discuss the generalisability (external validity) of the study results
Other information		
Funding	21	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

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Adverse events in patients in home health care: a retrospective record review using trigger tool methodology

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ABSTRACT

Objective: Home health care is an increasingly common part of health care. The patients are often aged, frail and have multiple diseases, and multiple caregivers are involved in their treatment. This study explores the origin, incidence, types and preventability of adverse events (AEs) that occur in patients receiving home health care.

Design: A study using retrospective record review and trigger tool methodology.

Setting and methods: Ten teams with experience of home health care from nine regions across Sweden reviewed home health care records in a two-stage procedure using 38 predefined triggers in four modules. A random sample of records from 600 patients (18 years or older) receiving home health care during 2015were reviewed.

Primary and secondary outcome measures: The cumulative incidence of AEs found in patients receiving home health care; secondary measures were origin, types, severity of harm and preventability of the AEs.

Results: The patients were 20–79 years old, 280 men and 320 women. The review teams identified 356 AEs in 226 (37.7%; 95% CI 33.0−42.8) of the home health care records. Of these, 255 (71.6%; 95% CI 63.2−80.8) were assessed as being preventable, and most (246, 69.1%; 95% CI 60.9-78.2) required extra health care visits or led to a prolonged period of health care. Most of the AEs (271, 76.1%; 95% CI 67.5-85.6) originated in home health care; the rest were detected during home health care but were related to care outside home health care. The most common AEs were health care-associated infections, falls and pressure ulcers.

Conclusions: AEs in patients receiving home health care are common, mostly preventable and often cause temporary harm requiring extra health care resources. The most frequent types of AEs must be addressed and reduced through improvements in inter-professional collaboration. This is an important area for future studies.

Keywords: Home health care, Patients, Adverse events, Patient harm, Patient safety, Trigger tool

Strengths and limitations of the study

- The review process was standardized and included a manual with detailed trigger definitions and preventability decision support.
- The review team members had long experience of home health care.
- Our recruitment of review teams was based on convenience sampling and did not enable review of a stratified sample of patients receiving home health care in Sweden.
- The results can only be generalized to facilities with similar organizations and clinical standards.

BACKGROUND

Home health care is an increasingly common component of health care, as an alternative to hospitalization. It includes a variety of health care interventions. The purpose can be curative, supportive, palliative or rehabilitative. The incidence and types of adverse events (AEs) in the acute care hospital setting have been well-investigated in many countries and for several medical specialities.[1-7] Despite the challenges related to an aging population and citizens' demands to receive care at home, patient safety in home health care is rarely investigated.[8-12] Incidence rates of AEs of up to 13% have been reported in a Canadian context;[8, 11] falls and drug-related AEs are the most frequent.

Retrospective record review is commonly used to study patient harm using predefined triggers indicating potential AEs. More AEs are found through record review than through incident reporting systems.[13] One of the most frequently used methods for retrospective record review is the Global Trigger Tool,[14] which has been further adapted to suit different areas of health care.

The number of patients who are cared for in their homes is increasing. They are often aged, frail and have multiple diseases. Municipal home services provide assistance with activities in daily life, but medical and technical advances have also made it possible for advanced treatment of complex and long-term illnesses in patient homes. As the complexity of care increases, interaction between multiple professionals from different health care providers (i.e., home health care, primary care, specialist care and social care) is critical for patient safety. New risks arise if communication and coordination of care is deficient. Thus, there is a need to further explore safety issues for patients receiving home health care, taking into consideration the complexity of having multiple caregivers involved in treatment and care. We have developed and validated a trigger tool intended for this group of patients.[15]

This study explores the origin, incidence, types and preventability of the AEs that occur in patients receiving home health care.

METHODS

Study design

This study used a retrospective record review design and was part of a validation study to validate the trigger tool for home healthcare settings.[15]

Study setting

The study was set in Sweden, where assistance with activities in daily life is provided in patient homes by unlicensed staff (e.g., assistant nurses) on behalf of the municipal social care services. The municipalities are also usually responsible for providing home health care to the elderly.[16] Their health care organizations include unlicensed assistant nurses, physiotherapists and occupational therapists, with registered nurses (RNs) providing the highest medical competence. The RNs have the overall responsibility for medication management and delivery of specialized health care in patient homes and consequently visit each patient less frequently than the unlicensed staff. When physician resources are necessary, they are usually provided by primary care physicians, but hospital physicians may also become involved. All physicians are employed by the county councils.

Home health care records are generally computerized. There are many different journal systems used in home health care in Sweden and the documentation routines, as well as access to these systems (read and write permissions), vary. Documentation from one caregiver, such as home health care, is not always accessible to health care professionals in other settings, such as staff at a hospital. As patients receiving home health care may be receiving care from several organizations simultaneously, we found it important to include all AEs documented in the home health care notes, irrespective of origin.

Definitions

In this study, an AE was defined as suffering, physical or psychological harm, illness or death caused by health care or social care that was not an inevitable consequence of the patient's condition or an expected effect of the treatment received by the patient because of her/his condition. A preventable AE was defined as an event that could have been prevented if adequate measures and/or actions had been taken during the patient's contact with health care or social care. This definition is based on the terminology in the Swedish Patient Safety Act.[17] AEs related to both acts of omission and acts of commission were included.

Study sample, inclusion and exclusion criteria

Ten review teams from different sites across Sweden were recruited using a convenience sampling strategy, invitations through personal contacts or by e-mail via a national patient safety network. All review teams interested in participation were included. Seven teams were organized within municipalities and three teams were employed by county councils. The teams consisted of one to three RNs and one or two physicians. They all had long experience of working as RNs or physicians, and in the home health care context.

After approval from the regional ethical board, a random sample of 600 home health care records was reviewed during the period February to August 2016. All patients 18 years or older admitted to home health care during 2015 at the review sites were eligible for inclusion. The review included the period from admission (index admission) up to a maximum of 90 days after admission. If a patient was discharged from home health care and was readmitted within the 90-day period, the review of that patient continued. To be included as an AE in the study, one of the following criteria had to be met:

1. The AE occurred during the index admission, that is, within 90 days after admission in home health care, regardless of caregiver.

2. The AE derived from caregivers outside home health care (outpatient care, social care or in-hospital care), occurred within 30 days prior to the index admission and was detected during the index admission.

Randomization of records was performed by one of the authors (MU), using an online randomizer, to ensure it was carried out in the same way for all review teams. Oversampling was carried out with ten records per team. If a patient in the random sample was receiving limited home health care once or twice a week, for example only blood pressure measurement or delivery of pre-dispensed drugs, this patient was replaced by another random admission. AEs that gave symptoms more than 90 days after the index admission or that occurred were detected and for which treatment was completed before the index admission were excluded.

Education of the review teams

To ensure result validity and reliability, the review process was standardized in a written project manual, where the definitions and the inclusion and exclusion criteria were also included. A trigger manual was used, including trigger definitions and preventability decision support, as well as detailed examples that were discussed by the review teams before the study began. The team members underwent a mandatory one-day education in the trigger tool methodology. Discussions were held to reach consensus about definitions, exclusion and inclusion criteria, interpretation and application of the triggers, assessment of AEs and preventability, as well as how to use the two cases report forms. During the process of familiarization with the methodology, each member of the review team independently reviewed six training records in order to achieve reliable reviews. This was followed by a consensus process with all teams including discussions regarding trigger outcome, assessments of AEs and preventability.

Review process

The review was performed in two stages. In most teams, the RNs carried out both primary and secondary reviews and later discussed the findings with the physicians. In some teams, the physicians carried out some of the primary as well as the secondary reviews.

In the primary review stage, the reviewers screened all records from their respective own setting for the presence of 38 predefined triggers categorized into four modules (Table 1). A trigger is an indicator suggesting that an AE might have occurred during the inclusion period. For each trigger detected, the reviewer determined whether or not the trigger reflected the presence of a potential AE. Only records with triggers indicating a potential AE went forward to the secondary review stage. The reviewers also recorded demographic data. Starting from the index admission to home health care, a maximum of 90 days was reviewed. There was no time restriction for the review of each record in this stage. One reviewer carried out the primary review. To test inter-rater reliability, 10% of the records in the primary review process were reviewed by a second reviewer. Inter-rater reliability was assessed based on the reviewers' judgements regarding whether a record should be forwarded to secondary review. Discussions about individual judgements were held and when consensus was reached, the records were ready for the secondary review stage.

Table 1 List of triggers

Care module	Cardiac arrest and/or deterioration in vital signs
	Deep venous thrombosis and/or pulmonary embolus
	Pressure ulcer
	Blood vessel, skin and/or tissue harm
	Neurological impairment and/or harm
	Fall
	Health care-associated infection
	Moderate/severe pain
	Moderate/severe worry, anxiety, suffering, existential pain and/or psychological pain
	Moderate/severe agitation and/or acute confusion/delirium
	Undernutrition
	Insufficient oral health
	Moderate/severe gastrointestinal problem

	Distended urinary bladder
	Deviation from normal course after invasive/surgical treatment
	Treatment
	Advanced medical device
	Threats, violence and/or improper contact
	Self-inflicted harm
	Escape from home/special accommodation
	Documentation of mistake or dissatisfaction with care
	Other
Laboratory module	Abnormal glucose value
	Increasing creatinine value
	Abnormal potassium value
	Abnormal sodium value
	Abnormal calcium value
Medication module	Adverse drug event/adverse drug reaction
	Drug that requires follow-up with blood sampling
	Treatment with at least 10 drugs
	Absence of in-depth drug review
	Treatment with drugs that increase the risk for haemorrhage
	Drug management
Continuity and transition module	Unplanned change of care-providing unit
	Unplanned contact with physician and/or registered nurse
	Absence of and/or deviation from care plan
	Absence of a coordinated individual care plan when care is provided by several caregivers
	Documentation related to insufficient coordination of care, communication and/or information

In the secondary review stage, each potential AE was scrutinized individually by the review team. To qualify as an AE, a score of three or higher on a 4-point Likert scale was required (1, the event was not related to health care/social care; 2, the event was probably not related to health care/social care; 3, the event was probably related to health care/social care; 4, the event was related to health care/social care). The reviewer made a judgement whether or not the event qualified as an AE. If it did, the AE was marked for further assessment. The preventability of an AE was judged on a similar 4-point scale: 1, the AE was not preventable; 2, the AE was probably not preventable; 3, the AE was probably preventable; 4, the AE was preventable.[5] In the following, probably preventable (grade 3) and preventable (grade 4) AEs are referred to as preventable AEs.

The severity of harm was evaluated using two different scales. The first was the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP)

Index,[18] which is used in the Global Trigger Tool.[14] NCC MERP Index categories E–I were included, i.e., those relating to harm (grade E, contributed to or resulted in temporary harm; grade F, contributed to or resulted in temporary harm to the patient and required outpatient, home health or hospital care, or prolonged hospitalization or extended the period of home health care; grade G, contributed to or resulted in permanent patient harm; grade H, lifesaving intervention required within 60 minutes; grade I, contributed to the patient's death). The second severity scale was that used in the Harvard Medical Practice Study (HMPS)[19] and subsequently in several nationwide AE studies. It encompasses seven grades (minimal impairment, recovery within 1 month; moderate impairment, recovery within 1–6 months; moderate impairment, recovery within 6–12 months; permanent impairment, degree of disability ≤ 50%; permanent impairment, degree of disability > 50%; contributed to patient death; unable to determine). All reviewers also documented, e.g., the type of AEs, as well as information on the origin of each AE (home health care, inpatient care, outpatient care or social care).

Access to various parts of the patients' medical records differed between review teams. Municipalities and county councils sometimes have separate medical record systems. Accordingly, some municipal review teams had to request physicians' notes and laboratory values, for example, because these were stored in their county council's record system.

All review teams were supported by record review experts in the research group who could answer questions. To ensure review quality one expert (MU) monitored all reviews from the primary and secondary review stages for completeness and adherence to the trigger and AE definitions, and project manual. Any questions or discrepancies were referred back to the relevant team for resolution to make sure that the AE inclusion followed the project manual.

Data analysis

Data are presented as median (range), mean (SD) (95% CI) or number (percent). We calculated the cumulative incidence of AEs over the review period. Comparisons between groups were made using the Mann-Whitney U test or the chi-squared test, as appropriate. A p value < 0.05 was considered significant. Agreement between reviewers was analysed using κ statistics. All statistical calculations were performed using Statistica 64 version 13 (StatSoft, Oklahoma, USA).

RESULTS

A total of 600 patient records from home health care were reviewed; 280 of the patients were men, median age 79 years (range, 20−97 years), and 320 were women, median age 82 years (range, 29−99 years). The number of days reviewed was 40,735 in total, with a median of 90 days per patient. Depending on patient discharge or death, the range of days reviewed varied between 1 and 90. Demographic data are shown in Table 2.

Table 2 Demographic data

Parameter	Value
Men/women, n (%)	280 (46.7) / 320 (53.3)
Age in years, median (range)	80.5 (20−99)
Reviewed days, median (range)	90 (1−90)
Referral to home health care from	
Hospital care, n (%)	300 (50.0)
Outpatient care, n (%)	212 (35.3)
Not possible to determine, n (%)	88 (14.7)
Medical diagnosis at home health care admission*	
Malignancy, n (%)	253 (42.2)
Cardiovascular disease, n (%)	119 (19.8)
Confusion, dementia, n (%)	102 (17.0)
Diabetes, n (%)	51 (8.5)
Skin wound, pressure ulcer, n (%)	38 (6.3)
Stroke, n (%)	36 (6.0)
Pulmonary disease, n (%)	35 (5.8)
Neurological disease, n (%)	33 (5.5)
Medical needs at home health care admission†	
Medication assistance, n (%)	233 (38.8)
Palliative care, n (%)	144 (24.0)
Activities of daily living, n (%)	111 (18.5)
Laboratory sampling, n (%)	88 (14.7)
Wound care, assistance with compression stockings, n (%)	74 (12.3)
Assistance with advanced medical devices, n (%)	62 (10.3)
Rehabilitation, home modifications, means testing, n (%)	51 (8.5)
Pain relief, n (%)	39 (6.5)
Social situation at home health care admission	
Patient's own home, lives alone, n (%)	265 (44.2)

Patient's own home, cohabiting, n (%)	257 (42.8)
Home for medical health care, assistance 24/7, n (%)	50 (8.3)
Not possible to determine, n (%)	28 (4.7)

*Medical diagnosis affecting > 5% of patients. A patient could have several diagnoses.

†Medical needs for > 5% of patients. A patient could have several medical needs.

The inter-rater reliability of the reviewers' judgements concerning if a record was to be forwarded to secondary review was $\kappa = 0.801$ (substantial).

Through the home health care records, 356 AEs were identified, affecting 226 patients (37.7 %; 95% CI 33.0−42.8). This corresponds to a median of 1 (range, 1−7) AE per patient affected (Table 3). Most were considered preventable (255, 71.6 %; 95% CI 63.2−80.8). There was no difference in the incidence of AEs between men and women (p = 0.72), or between patients aged 80 years or older and younger patients (p = 0.12) (data not shown).

Table 3 Adverse events (AEs) detected in patients receiving home health care classified by origin (n = 600)

	Home health care	Care outside home health care	Total
Number of AEs	271	85	356
Number of patients affected by AEs (%; 95% CI)	182 (30.3; 26.2−35.0)	67 (11.2; 8.7−14.1)	226 (37.7; 33.0−42.8)
Median number of AEs per affected patient (range)	1 (1−5)	1 (1−4)	1 (1−7)
Number of preventable AEs	194	61	255
Number of patients affected by preventable AEs (%; 95% CI)	137 (22.8; 19.2−26.9)	50 (8.3; 6.3−10.9)	174 (29.0; 24.9−33.6)
Median number of preventable AEs per affected patient (range)	1 (1−4)	1 (1−4)	1 (1−5)
Number of patients with > 1 AE (%; 95% CI)	62 (10.3; 8.0−13.2)	12 (2.0; 1.1−3.4)	83 (13.8; 11.1−17.1)
Number of patients with > 1 preventable AE (%; 95% CI)	39 (6.5; 4.7−8.8)	8 (1.3; 0.6−2.5)	54 (9.0; 6.8−11.6)
Number of AEs per 100 patients	45.2	14.2	59.3
Number of preventable AEs per 100 patients	32.3	10.2	42.5
Number of AEs per 1,000 patient days	6.7	2.1	8.7
Number of preventable AEs per 1,000 patient days	4.8	1.5	6.3

Of the AEs, 271 (76.1 %; 95% CI 67.5−85.6) were related to home health care, 44 (12.4 %; 95% CI 9.1−16.4) to in-hospital care, 23 (6.5 %; 95% CI 4.2−9.5) to social care and 12 (3.4 %; 95% CI 1.8−5.7) to outpatient care. It was not possible to determine from the documentation where the remaining 6 (1.7%; 95% CI 0.7−3.5) AEs had originated. There was

no difference in preventability (p = 0.97) between AEs originating in home health care or outside home health care (data not shown).

On the NCC MERP scale, 102 (28.6%; 95% CI 23.5−34.6) of all AEs resulted in temporary harm to the patient and 246 (69.1 %; 95% CI 60.9−78.2) in temporary harm that required extra health care visits or a prolonged care period. The HMPS scale showed that 213 (59.8%; 95% CI 52.2−68.3) of all AEs were minor with recovery within 1 month (Table 4).

Table 4 Severity of adverse events (AEs) detected in patients receiving home health care classified by origin

Severity category	In home health care		Care outside home health care		Total	
	AE, n (%; 95% CI)	Preventable AE, n (%; 95% CI)	AE, n (%; 95% CI)	Preventable AE, n (%; 95% CI)	AE, n (%; 95% CI)	Preventable AE, n (%; 95% CI)
Severity category according to NCCP MERP index						
E Contributed to or resulted in temporary harm	78 (28.8; 22.9−35.7)	50 (64.1; 48.1−83.8)	24 (28.2; 18.5−41.4)	14 (58.3; 33.2−95.6)	102 (28.6; 23.5−34.6)	64 (62.7; 48.7−79.6)
F Contributed to or resulted in temporary harm to the patient and required outpatient, home health or hospital care, or prolonged hospitalization or an extended period of home health care	187 (69.0; 59.6−79.4)	142 (75.9; 64.2−89.2)	59 (69.4; 53.3−88.9)	45 (76.3; 56.3−101.2)	246 (69.1; 60.9−78.2)	187 (76.0; 65.7−87.5)
G Contributed to or resulted in permanent patient harm	3 (1.1; 0.3−3.0)	1 (33.3; 1.7−164.4)	2 (2.4; 3.9−7.8)	2 (100; 167.7−330.4)	5 (1.4; 0.5−3.1)	3 (60.0; 15.3−163.3)
H Lifesaving intervention required within 60 minutes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
I Contributed to patient's death	3 (1.1; 0.3−3.0)	1 (33.3; 1.7−164.4)	0 (0)	0 (0)	3 (0.8; 0.2−2.3)	1 (33.3; 1.7−164.4)
Total	271 (100)	194 (71.6; 62.0−82.2)	85 (100)	61 (71.8; 55.4−91.6)	356 (100)	255 (71.6; 63.2−80.8)
Severity category according to HMPS scale						
Minimal impairment, recovery within 1 month	171 (63.1; 54.2−73.1)	118 (69.0; 57.4−82.3)	42 (49.4; 36.1−66.2)	31 (73.8; 51.0−103.5)	213 (59.8; 52.2−68.3)	149 (69.9; 59.4−81.9)
Moderate impairment, recovery within 1–6 months	57 (21.0; 16.1−27.0)	44 (77.2; 56.8−102.7)	26 (30.6; 20.4−44.2)	19 (73.1; 45.3−112.0)	83 (23.3; 18.7−28.8)	63 (75.9; 58.8−96.5)
Moderate impairment, recovery within 6–12 months	14 (5.2; 2.9−8.5)	11 (78.6; 41.3−136.6)	1 (1.2; 0.1−5.8)	0 (0)	15 (4.2; 2.5−6.8)	11 (73.3; 38.6−127.5)
Permanent impairment, degree of disability ≤ 50%	3 (1.1; 0.3−3.0)	1 (33.3; 1.7−164.4)	2 (2.4; 0.4−7.8)	2 (100; 167.7−330.4)	5 (1.4; 0.5−3.1)	3 (60.0; 15.3−163.3)
Permanent impairment, degree of disability > 50%	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Contributed to patient death	3 (1.1; 0.3−3.0)	1 (33.3; 1.7−164.4)	0 (0)	0 (0)	3 (0.8; 0.2−2.3)	1 (33.3; 1.7−164.4)
Unable to determine	23 (8.5; 5.5−12.5)	19 (82.6; 51.2−126.6)	14 (16.5; 9.4−27.0)	9 (64.3; 31.4−118.0)	37 (10.4; 7.4−14.2)	28 (75.7; 51.3−107.9)
Total	271 (100)	194 (71.6; 62.0−82.2)	85 (100)	61 (71.8; 55.4−91.6)	356 (100)	255 (71.6 ; 63.2−80.8)

NCCP MERP, National Coordinating Council for Medication Error Reporting and Prevention. HMPS, Harvard Medical Practice Study.

Table 5 Types of adverse events (AEs) detected in patients receiving home health care, the origin and the proportion of preventable AEs

Type of AE	Home health care, AEs n (%; 95% CI)	Care outside home health care, AEs n (%; 95% CI)	Total, AEs n (%; 95% CI)	Total preventable AEs, n (%; 95% CI)
Health care-associated infections	59 (21.8; 16.7−27.9)	13 (15.3; 8.5−25.5)	72 (20.2; 15.9−25.3)	46 (63.9; 47.3−84.5)
Oral candida	12 (25.4)	1 (7.7)	13 (18.1)	6 (46.1)
Urinary tract infection	9 (15.2)	2 (15.4)	11 (15.3)	8 (72.7)
Pneumonia	10 (16.9)	1 (7.7)	11 (15.3)	8 (72.7)
Wound infection	9 (15.2)	3 (23.1)	12 (16.6)	12 (100.0)
Sepsis	5 (8.5)	1 (7.7)	6 (8.3)	1 (16.7)
Skin candida	5 (8.5)	1 (7.7)	6 (8.3)	6 (100.0)
Others	9 (15.2)	4 (30.8)	13 (18.1)	5 (38.5)
Falls	51 (18.8; 14.2−24.6)	15 (17.6; 10.2−28.4)	66 (18.5; 14.4−23.4)	29 (43.9; 30.0−62.3)
Fracture	7 (13.7)	4 (26.7)	11 (16.7)	6 (54.5)
Skin wound	33 (64.7)	7 (46.7)	40 (60.6)	14 (35.0)
Pain	11 (21.6)	3 (30.0)	14 (21.2)	8 (57.1)
Not specified	0 (0)	1 (6.7)	1 (1.5)	1 (100.0)
Pressure ulcers	46 (17.0; 12.6−22.4)	16 (18.8; 11.1−29.9)	62 (17.4; 13.5−22.2)	52 (83.9; 63.3−109.1)
Category 1	20 (43.5)	4 (25.0)	24 (38.7)	21 (87.5)
Category 2	17 (37.0)	8 (50.0)	25 (40.3)	19 (76.0)
Category 3	3 (6.5)	2 (12.5)	5 (8.0)	4 (80.0)
Category 4	2 (4.3)	0 (0)	2 (3.2)	2 (100.0)
Category unknown	4 (8.7)	2 (12.5)	6 (9.7)	6 (100.0)
Skin, vessel or tissue harm	25 (9.2; 6.1−13.4)	8 (9.4; 4.4−17.9)	33 (9.3; 6.5−12.9)	27 (81.8; 55.0−117.4)
Skin harm	18 (72.0)	4 (25.0)	22 (66.7)	18(81.8)
Vessel harm	4 (16.0)	1 (12.5)	5 (15.2)	3 (80.0)
Tissue harm	3 (12.0)	3 (37.5)	6 (18.2)	6 (100.0)
Pain	17 (6.3; 3.8−9.8)	6 (7.1; 2.9−14.7)	23 (6.5; 4.2−9.5)	21 (91.3; 58.0−137.2)
Psychological harm	12 (4.4; 2.4−7.5)	6 (7.1; 2.9−14.7)	18 (5.1; 3.1−7.8)	14 (77.8; 44.3−127.4)
Other	10 (3.7; 1.9−6.6)	1 (1.2; 0.1−5.8)	11 (3.1; 1.6−5.4)	10 (90.1; 46.2−162.0)
Neurological harm	7 (2.6; 1.1−5.1)	3 (3.5; 0.9−9.6)	10 (2.8; 1.4−5.0)	9 (90.0; 43.9−165.2)
Haemorrhage (not related to surgery)	7 (2.6; 1.1−5.1)	3 (3.5; 0.9−9.6)	10 (2.8; 1.4−5.0)	4 (40.0; 12.7−96.5)
Failure in vital signs	7 (2.6; 1.1−5.1)	3 (3.5; 0.9−9.6)	10 (2.8; 1.4−5.0)	9 (90.0; 43.9−165.2)
Weight loss, nutrition-related AE	5 (1.8; 0.7−4.1)	3 (3.5; 0.9−9.6)	8 (2.2; 1.0−4.3)	7 (87.5; 38.3−173.1)
General deterioration in health status	7 (2.6; 1.1−5.1)	0 (0)	7 (2.0; 0.9−3.9)	7 (100.0; 43.7−197.8)
Severe constipation	5 (1.8; 0.7−4.1)	0 (0)	5 (1.4; 0.5−3.1)	5 (100.0; 36.6−221.7)
Severe vomiting	4 (1.5; 0.5−3.6)	0 (0)	4 (1.1; 0.4−2.7)	3 (75.0; 19.1−204.1)
Affected laboratory values	3 (1.1; 0.3−3.0)	1 (1.2; 0.1−5.8)	4 (1.1; 0.4−2.7)	4 (100.0; 31.8−241.2)
Allergic reaction	1 (0.4; 0.0−1.8)	2 (2.4; 0.4−7.8)	3 (0.8; 0.2−2.3)	1 (33.3; 1.7−164.4)
Severe diarrhoea	1 (0.4; 0.0−1.8)	2 (2.4; 0.4−7.8)	3 (0.8; 0.2−2.3)	1 (33.3; 1.7−164.4)
Distended urinary bladder	2 (0.7; 0.1−2.4)	2 (2.4; 0.4−7.8)	4 (1.2; 0.4−2.7)	4 (100; 31.8−241.2)
Dehydration	1 (0.4; 0.0−1.8)	1 (1.2; 0.1−5.8)	2 (0.6; 0.1−1.9)	1 (50.0; 2.5−246.6)
Attempted suicide	1 (0.4; 0.0−1.8)	0 (0)	1 (0.3; 0.0−1.4)	1 (100.0; 5.0−493.2)
Total	271 (100.0)	85 (100.0)	356 (100.0)	255 (71.6; 63.2−80.8)

The most common types of AEs were health care-associated infections, falls and pressure ulcers (Table 5). There were no differences in the number of such AEs between men and women or between patients aged 80 years or older and younger patients (data not shown). The

probability of falls being preventable was 43.9%; 95% CI 30.0−62.3, whereas the majority of the other types of AEs were considered preventable to a greater extent. There was no difference in the type of AEs between those originating in home health care and those from care given outside home health care (p = 0.52).

Forty-one (18.1%) of the AEs in the home health care setting required a median of one (range, 1−5) additional physician visit(s) in the outpatient setting, 40 (14.8 %) required a median of 1 (range, 1−9) additional physician visit(s) in the home health care setting and 37 (13.7%) required hospital care for a median of 6 days (range, 1−41 days). There were no significant differences compared with AEs outside home health care: 7 (8.2%) (median, 1; range, 1−2) required additional physician visit(s) in the outpatient setting; 11 (12.9%) (median, 1; range, 1−11) required additional physician visit(s) in the home health care setting; 13 (15.3%) required hospital care for a median of 7 days (range, 2−10 days).

DISCUSSION

This study is the first to assess AEs in patients receiving home health care across different parts of Sweden through the use of retrospective record review. Our main findings are that AEs affect over a third of these patients, are deemed to be mostly preventable and result in temporary harm to the patient requiring extra health care resources. One fourth of the AEs detected in home health care originated in other health care settings. We found no differences in the type of AEs, or their severity or preventability, depending on origin.

There are few studies investigating AEs in home health care with which to compare our findings. The incidence of AEs, 37.7%, is much higher than the 4−13% reported by other studies.[8, 9, 10, 11] It is difficult to compare the rates, as the differences may be due to varying services, patient characteristics, and methods of record review, as well as the definition of an AE and the inclusion criteria used. It is also difficult to compare the rates for the home health care setting with in-hospital AE rates, because the home health care provider

may not continuously observe the patients and the health care environment. The majority of the identified AEs were minor and transient. In a comparison of serious AEs (recovery within 6–12 months, permanent disability or death) by recalculating their respective prevalence, there seem to be no obvious differences between our study and an earlier Swedish in-hospital study or Canadian home health care.[1, 8]

Patients receiving home health care are often old and frail and frequently have concomitant contact with multiple caregivers. We have shown that almost 25% of AEs found in patients in home health care originated in care given in other settings. AEs such as pressure ulcers or infections impose an additional burden on the home health care organization with its limited access to RNs and physicians. This finding also highlights the importance of passing knowledge about AEs between caregivers. The findings imply that all sections of health care should be aware of these most common AEs and preventive measures that can be taken along a patient's health care journey.

Almost three out of four AEs, regardless of origin, were judged by the review teams in our study to be preventable. This is higher than the 33−56% previously reported in the home health care setting,[8, 9] but is in line with many hospital record reviews.[1, 5, 6, 20] Risk reduction in patient homes is not directly transferable from hospital care. The possibility of conflict between patient autonomy and safety should be considered in the home care setting. Patients are the hosts of the care environment and supervision from health care personnel is mostly limited to short visits. Preventive safety measures in a patient's home require true patient involvement, taking the patient's values and integrity into consideration. For instance, removing carpets to prevent falls, one of the AEs with the lowest preventability ratings must be weighed against a patient's own wishes.

Our findings of health care-associated infections, falls, pressure ulcers and skin breakdown as the most common AEs are largely consistent with a Canadian review of 1,200

records from 2009−2010, which reported falls, wound infections, psychosocial, behavioural or mental health problems, or medication-related AEs as the most prominent findings.[9] We chose to not to use "medication-related AEs" as a separate AE group, since we regarded medication as a cause of AEs. Medication-caused AEs can be found among for example falls, severe constipation and oral candida. Other studies also report injurious falls as the most common AE in home health care.[11, 21] Decline in physical function is a prevalent safety risk.[10] Falls are also associated with increased risk of admission to long-term care and death.[11] This emphasizes the need to find effective strategies for prevention of falls. Preventive strategies for pressure ulcers and skin breakdown [8] also need to be identified. Patients in home health care may have several well-known risk factors for pressure ulcers. In one study, one tenth of AEs in patients receiving home health care fell into the category general decline.[8] The aging patient is at risk for weight loss and malnutrition. Doran et al.[10] noted that unintended weight loss accounted for 10% of the safety problems in home health care. Patients receiving home health care are often affected by cancer, where weight loss is a well-known problem.[10,22] Routines for the prevention of weight loss are important. Interventions can include energy- and protein-rich food, food with a particular texture, artificial nutrition, information about eating habits and checking the patient's weight on a regular basis.[23]

Health care-associated infections are common in both home health care and hospital care.[1, 24] Falls and pressure ulcers are also common in hospitalized patients. However, the type of AEs in home health care differ from that in hospital care in other aspects. Surgical/procedural AEs and distended urinary bladder are more common in hospital care.[1, 6, 21, 25, 26]

We found that more than half of the AEs caused minimal impairment, with recovery within 1 month. This is in contrast to the findings of Sears et al.,[8] where one quarter of the AEs caused slight impairment and half resulted in moderate to serious impairment or death.

One explanation for the difference could be that we found three times more AEs and probably included less severe AEs. Sears et al.[8] only included AEs that required the use of additional health care resources. Interventions in connection with AEs are a resource-consuming burden to health care. In order to get a broader and more proactive approach to patient safety, we found it important to include AEs that caused temporary harm without requiring extra visits or a prolonged health care period.

We chose to review a period up to a maximum of 90 days from the start of a randomly chosen home health care period and included all AEs regardless of caregiver. If a patient was hospitalized and returned to home health care during that period, we included the new home health care period(s). The Institute for Healthcare Improvement has developed a trigger tool for skilled nursing facilities recommending that only the first 30 days of an admission are reviewed.[27] Blais et al.[9] included a period of up to 12 months preceding discharge for review and also included a 6-month period after discharge from the index admission. There is no consensus regarding which triggers to use in different settings.[28] The same applies for reporting of AE rates, as well as characterization of AEs, which makes comparisons difficult. As demand for home health care and interest in home health care safety increase, reliable and validated safety tools are warranted.

The strengths of this study include having ten teams from different parts of Sweden to review 600 records, which served to give an overview of AEs occurring in home health care settings. In accordance with the Global Trigger Tool methodology and as patients receiving home health care sometimes need parallel interventions from caregivers outside home health care, we chose a broader perspective on patient safety and included all AEs that occurred and/or were detected during the 90-day review period. We modified our definition based on NCC MERP classification E to include all AEs that resulted in temporary harm to the patient, regardless of whether an intervention was documented or not. We regard this as an improvement from a patient perspective, as it contributes to the identification of risk areas. To

adapt to the patient perspective and visualize the extra resources required due to AEs, we also expanded NCC MERP classification F to include extra visits within home health care and outpatient care. This study also has a number of limitations. We did not use a stratified sample of records for all patients receiving home health care in Sweden. As the review was a part of the development and validation of a trigger tool suited for home health care, we aimed for review teams with an interest in patient safety. The 600 records were randomised from the ten sites and gave an overview of AEs occurring in home health care. As this study was part of a validation study and forms a basis for a national trigger tool for home health care, we aimed for richer review material and limited inclusion by excluding records from patients receiving very sparse and infrequent home health care. This exclusion criterion was defined using examples only. Defining a minimum level of home health care services for inclusion to the study would have been preferable. The review process had only two primary reviewers reviewing the same sample in ten percent of the records. In any study based on record review, only AEs that are noted in the record can be found. There is a risk of underreporting of AEs as the reviewer teams screened records from their own setting. On the other hand, they could have found more AEs as they have context information that is not stated in the record. Finally, generalizability may be limited if home health care services have differing clinical standards.

CONCLUSIONS

AEs in patients receiving home health care are common, mostly preventable and often result in temporary harm that requires extra health care resources. As in hospital care, health care-associated infections, falls and pressure ulcers are common AEs. The latter two are even more common in home health care, as is harm to skin, vessels and tissue. This implies that we must address and reduce these AEs through improvements identified in collaborations between professionals. This is an important area for future studies.

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Competing interests

The authors declare that they have no competing interests.

Ethics approval

Ethical permission was obtained from the Regional Ethical Board of Linköping University, Sweden (No 2014/150-31).

Contributors

KS, MU, ME, ML and LN designed and conducted the study. KS, MU and LN undertook the initial interpretation of the data, which was followed by discussions between all the authors. All authors drafted the manuscript and were part of the revision process. All authors agreed to the final version of the manuscript before submission.

Data sharing statement

No additional data are available.

REFERENCES

1. Soop M, Fryksmark U, Köster M, et al. The incidence of adverse events in Swedish hospitals: a retrospective medical record review study. *Int J Qual Health Care* 2009;21:285–91.

2. von Plessen C, Kodal AM, Anhoj J. Experiences with global trigger tool reviews in five Danish hospitals: an implementation study. *BMJ Open*;2:1–8.

3. Resar RK, Rozich JD, Simmonds T, et al. A trigger tool to identify adverse events in the intensive care unit. *Jt Comm J Qual Patient Saf* 2006;32:585–90.

4. Kaafarani HM, Rosen AK, Nebeker JR, et al. Development of trigger tools for surveillance of adverse events in ambulatory surgery. *Qual Saf Health Care* 2010;19:425–9.

5. Unbeck M, Lindemalm S, Nydert P, et al. Validation of triggers and development of a pediatric trigger tool to identify adverse events. *BMC Health Serv Res* 2014;14:655.

6. Nilsson L, Risberg MB, Montgomery A, et al. Preventable adverse events in surgical care in Sweden: a nationwide review of patient notes. *Medicine (Baltimore)* 2016;95:e3047.

7. Mattsson TO, Knudsen JL, Lauritsen J, et al. Assessment of the global trigger tool to measure, monitor and evaluate patient safety in cancer patients: reliability concerns are raised. *BMJ Qual Saf* 2013;22:571–9.

8. Sears N, Baker GR, Barnsley J, et al. The incidence of adverse events among home care patients. *Int J Qual Health Care* 2013;25:16–28.

9. Blais R, Sears NA, Doran D, et al. Assessing adverse events among home care clients in three Canadian provinces using chart review. *BMJ Qual Saf* 2013;22:989–97.

10. Doran DM, Hirdes JP, Blais R, et al. The nature of safety problems among Canadian homecare clients: evidence from the RAI-HC reporting system. *J Nurs Manage* 2009;17:165–74.

11. Doran DM, Hirdes JP, Blais R, et al. Adverse events among Ontario home care clients associated with emergency room visit or hospitalization: a retrospective cohort study. *BMC Health Serv Res* 2013;13:227.

12. Madigan E. A description of adverse events in home healthcare. *Home Healthc Nurse* 2007;25:191–7.

13. Classen DC, Resar R, Griffin F, et al. Global Trigger Tool' shows that adverse events in hospitals may be ten times greater than previously measured. *Health Affairs* 2011;30:581–9.

14. Griffin F, Resar R. IHI Global Trigger Tool for Measuring Adverse Events. 2nd ed. Cambridge, MA: Institute for Healthcare Improvement; 2009.

15. Lindblad M, Schildmeijer K, Nilsson L, et al. Development and validation of a trigger tool to identify adverse events and no-harm incidents that affect patients admitted to home healthcare. BMJ Qual and Saf. Accepted 25 Aug 2017.

16. Anell A, Glenngård AH, Merkur S. Sweden: health system review. *Health Syst Transit* 2012;14:1–159.

17. SFS 2010:659. Patientsäkerhetslagen [Patient Safety Act]. 2010. Stockholm: Riksdagen. https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/patientsakerhetslag-2010659_sfs-2010-659 (accessed Mar 20 2017).

18. NCC MERP; http://www.nccmerp.org/sites/default/files/indexBW2001-06-12.pdf (accessed Sept 26 2017).

19. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *N Engl J Med* 1991;324:370–6.

20. Kennerly DA, Saldana M, Kudyakov R, et al. Description and evaluation of adaption to the Global Trigger Tool to enhance value to adverse event reduction efforts. *J Patient Saf* 2013;9:87–95.

21. Johnson K. Adverse events among Winnipeg Home Care clients. *Healthc Q* 2006;9 Spec No:127–34.

22. Tisdale MJ. Cachexia in cancer patients. *Nat Rev Cancer* 2002;2:862–71.

23. Alibhai SMH, Greenwood C, Payette H. An approach to the management of unintentional weight loss in elderly people. *CMAJ* 2005;172:773–80.

24. Deilkås ET, Bukholm G, Lindstrom JC, et al. Monitoring adverse events in Norwegian hospitals from 2010 to 2013. *BMJ Open* 2015;5:e008576.

25. Unbeck M, Muren O, Lillkrona U. Identification of adverse events at an orthopedics department in Sweden. *Acta Orthop* 2008;79:396–403.

26. Unbeck M, Dalen N, Muren O, Lillkrona U, Härenstam KP. Healthcare processes must be improved to reduce the occurrence of orthopaedic adverse events. *Scand J Caring Sci* 2010;24(4):671-7. doi: 10.1111/j.1471-6712.2009.00760.x.

27. Adler L, Moore J, Federico F. IHI Skilled Nursing Facility Trigger Tool for Measuring Adverse Events. Cambridge, MA: Institute for Healthcare Improvement; 2015. http://www.ihi.org/resources/Pages/Tools/SkilledNursingFacilityTriggerTool.aspx (accessed Dec 30 2016).

28. Hibbert PD, Molloy CJ, Hooper TD, et al. The application of the Global Trigger Tool: a systematic review. *Int J Qual Health Care* 2016;28:640–9.

STROBE Statement

	Page No	Recommendation
Title and abstract	1-2	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	4	Explain the scientific background and rationale for the investigation being reported
Objectives	5	State specific objectives, including any prespecified hypotheses
Methods		
Study design	5	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6-7	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	8-10	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	6	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias		Describe any efforts to address potential sources of bias
Study size	6	Explain how the study size was arrived at
Quantitative variables	10	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	10	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
		(*e*) Describe any sensitivity analyses

Continued on next page

Results		
Participants	11	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	11	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)
Outcome data	12	*Cohort study*—Report numbers of outcome events or summary measures over time
		Case-control study—Report numbers in each exposure category, or summary measures of exposure
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	12-15	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses		Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	16-19	Summarise key results with reference to study objectives
Limitations	20	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	20	Discuss the generalisability (external validity) of the study results
Other information		
Funding	21	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based