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Title

Addressing safety for patients in need of specialized home healthcare - an interview study with multidisciplinary teams and clinical managers

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ABSTRACT

Objective Home healthcare is the fastest growing arena in the healthcare system but patient safety research in this context is limited. The aim was to explore patient safety in specialized home healthcare from multidisciplinary teams' and clinical managers' perspective.

Design An explorative qualitative study.

Setting Healthcare professionals and clinical managers were recruited from three specialized home healthcare organizations in Sweden.

Methods Nine focus group interviews with multidisciplinary teams and six individual interviews with clinical managers were conducted, in total 51 participants. The data were transcribed verbatim and analyzed using qualitative content analysis.

Results Patient safety was inherent in the palliative care ideology and shaped a common mind-set between members in the multidisciplinary team and clinical managers, which grounded their decision on performance of care. The multiple guidelines and quality assessments, aimed to promote patient safety from a macro-perspective, constrained the professionals' freedom to adapt to challenges and provide safe care based on the shared care ideology. Safety work was characterized by co-creation of care in a challenging care environment; a striving to be up to date in the information flow and maintaining high competence levels in emerging complexity. Engineering patient safety was a continuous work at all levels of the system whilst keeping the patient's perspective in mind.

Conclusion Patient safety in home healthcare is dependent on adaptability at the management level; the professionals' ability to adapt to the varying conditions and on patients being capable of adjusting their homes and behaviours to reduce safety risks. A strong culture related to a patient's value as a person where patients' and families' active participation and preferences guides the decisions, could be both a facilitator and a barrier to patient safety, depending on which value is given highest priority.

Strengths and limitations of this study

- Trustworthiness have been strengthened by; research triangulation; setting triangulation and participant triangulation.
- We have less number of participants than expected in each focus group due to the high workload.
- The selection of settings, situated in the same urban area of Sweden, may limit the extent to which our findings may be transferred to rural settings or other regions.

BACKGROUND

Patient safety is a requirement in all healthcare organizations regardless of where care is provided. Still, every year, people worldwide are harmed or even die while receiving healthcare. For example, approximately 98,000 hospitalized patients in the US die as a result of patient safety failures each year and one in ten suffers harm.¹ Similar results were found in Sweden, with 8.6% of hospital patients suffering a preventable adverse event.²

Healthcare is becoming more complex and provision of care in people's homes is increasing, both globally¹ and in Sweden,³ driven by medical and technical advances, economic pressures, demographic factors, and patient preferences.⁴ However, most patient safety research is conducted in hospital settings, while home healthcare is largely unexplored.⁵ Thus, evidence from hospital-based research has also been applied to home healthcare. In recent years, this has been criticized based on the knowledge that patient safety is largely context-dependent.^{6,7} The few existing home healthcare-specific studies on patient safety, mainly conducted in Canada, have highlighted unique safety issues and the occurrence of adverse events. The specific patient safety challenges in home healthcare include fragmentation of care, care providers working in isolation and inadequate communication between different care providers.^{8,9} Studies of adverse events in home healthcare have shown a wide variation in the estimations, with 13% in Canada¹⁰⁻¹² and 37.7% in Sweden.¹³ The types of adverse events were similar in both countries – falls, healthcare-associated infections, pressure ulcers – and most were considered to be preventable.

With a few exceptions, e.g., healthcare-associated infections, the patient safety research is increasingly based on the premise that harm is mainly the result of poorly designed systems.¹⁴ As a system approach encompasses the organization's context, processes and structures, which can have a sustainable influence on promoting safe care^{5,15} there is a need to study patient safety in home healthcare in a European setting.

To address the gap in research on home healthcare, the overall aim of this study was to explore patient safety in specialized home healthcare from the perspectives of multidisciplinary teams and clinical managers.

METHODS

Design

This qualitative study, based on semi-structured interviews with multidisciplinary professionals and clinical managers, is part of a larger study on patient safety in home healthcare settings.¹⁶

Setting

Healthcare professionals and clinical managers were recruited from three specialized home healthcare organizations in one regional healthcare authority in Sweden. Home healthcare in Sweden is defined as healthcare that is administered in a patient's home or the equivalent, and that is consistent over time,¹⁷ but does not encompass home care organizations with unlicensed staff administering social care.

The three studied units are tax-funded and cover a limited geographical area. They were selected to capture socio-demographic differences in, e.g., country of birth and income. Each unit consisted of ambulatory multidisciplinary teams, including four to six physicians, 20-30 registered nurses (RNs) and one of each of the associated healthcare staff: physiotherapist, occupational therapist, dietitian and social worker. One unit had a few assistant nurses. The RNs and physicians were available 24 hours a day. Each unit employed one head of department and one or two first-line manager ("clinical managers"). The units provided long- or short-term round-the-clock advanced care and treatment to patients with complex diseases and symptoms.

All units had in the last years expanded from providing traditional palliative home healthcare to providing specialized home healthcare to patients with all kinds of diagnoses, based on changes in national regulations.¹⁸ Many of the healthcare professionals had experience in practicing care under the palliative care ideology. The cornerstones in the care ideology can be summarized as nearness, wholeness, knowledge, and empathy. The approach should

further be based on continuity, good communication and support provided in accordance with patients and relatives' wishes, in so far as possible.¹⁹

Data collection

Nine focus group interviews with multidisciplinary professionals and seven individual interviews with clinical managers were conducted between December 2013 and May 2014, including in total 51 participants (Table 1). The interview method was inspired by Kvale and Brinkmann.²⁰ A convenience sampling approach was used to capture a variety of perspectives on patient safety. The heads of department approved performance of the study at their respective units.

All interviews took place at the workplace at the start or end of a work shift. Focus group interviews included 4-6 professionals and lasted 60-90 minutes. Individual interviews lasted 30-60 minutes. The interviews were audio-recorded and the researcher took notes.

The interviews were conducted by the first and last researcher (ML and ME). A semi-structured interview guide was developed and tested in a pilot interview, after which minor revisions were made. The interview guide consisted of open-ended questions, such as "Tell me what patient safety means to you" and "Tell me about your experiences of what helps or hinders patient safety in your daily work." In addition to questions on patient safety, the clinical management interviews also included general questions on work organization. Both verbal and non-verbal probing techniques were used to increase clarity.

Table 1. Overview of the interviews

Focus group	1	2	3	4	5	6	7	8	9
Profession (n)	RN (4) Allied health staff (1)	RN (3) Allied health staff (1)	RN (5)	Allied health staff (4)	Physician (5)	Allied health staff (4)	Physician (5)	RN (4) assistant nurse (2)	RN (4) assistant nurse (1)
Number code	F1	F2	F3	F4	F5	F6	F7	F8	F9
Individual	1	2	3	4	5	6	7		
Profession (n)	Head of department (1)	Head of department (1)	Head of department (1)	First-line manager (2)	First-line manager (1)	First-line manager (1)	Physician (1)		
Number code	I1	I2	I3	I4	I5	I6	I7		

Data analysis

The data were transcribed verbatim and analysed using qualitative content analysis with an inductive approach.^{21 22} The transcripts were read through several times by the first (ML) and last (ME) researchers, to get a sense of the data. All three researchers (ML, MF, ME) were then involved in analysis, going from a concrete to a more abstract level. This included identification of meaning units, which were condensed, coded, and sorted into 19 subcategories based on differences and similarities. The subcategories were compared, sorted, interpreted and abstracted into one main theme and four categories. All authors discussed the codes, categories and themes in relation to the transcripts until consensus was reached.

RESULTS

The results include one main theme *Keeping patients safe – a never-ending effort at all levels*, constituting the latent content of four categories.

Keeping patients safe – a never-ending effort at all levels

Keeping patients safe was a continuous effort throughout the system. The palliative care ideology formed a common mind-set upon which both clinical managers and professional teams based their care decisions. Patient safety is an inherent part of the palliative care ideology, not a goal in itself.

Patient safety was described as related to a patient's value as a person. Prevention of psychological harm, such as violated autonomy or respect, had the same priority as prevention of physical harm. This view influenced risk management, in that a patient's preferences outweighed risks detected in the home care environment.

The varying work environment, with "patient rooms" of various standards distributed over a large area, was a health and safety risk for both patients and professionals. Arranging meetings with sufficient time to build trustful relationships enabled co-creation of care based on each patient's or family's wishes. This also allowed for including patients and families in active participation according to their abilities. Each team member contributed with their competence.

We've asked our patients how they perceive the care and we get certain value-based words...like security and participation... I think it's good for patient safety, to get

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3 *patients and family involved. It... I can't imagine anything better than them knowing*
4 *what they are putting in their mouth and what pills they are taking. They know who to*
5 *call when they don't recognize the medication or... They ask us if we've sanitized our*
6 *hands, if we're wearing aprons and so on... That...it's an aspect of culture, safety*
7 *culture, both as regards care...here at the unit, and we take it along to our patients,*
8 *since that's our work environment, so the patients become part of the safety culture,*
9 *and they should feel that they...that it's their...I mean, it is their care (F8).*
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16 ***Co-creating safety in the mess on the floor***

17 The teams were united by their care ideology and the strong belief that establishing and
18 maintaining sustainable, trusting relationships was the core of patient safety work. The care
19 ideology was realized through respect for patients' and relatives' values, wishes and lifestyle.
20 The team ensured that there was time for conversation, to listen and take patients' and
21 relatives' knowledge, feelings and thoughts into account in their planning and performance of
22 care. By focusing on what mattered *for* the patient and relatives rather than what the matter
23 was *with* the patient, the teams could respect the patient's values. Based on the ideology, the
24 professionals felt that a patient's wish to stay at home should be fulfilled. To manage this,
25 several actions were taken, such as the delegation of medication administration to unlicensed
26 staff in the home help services, as they could visit the patient several times a day. In some
27 cases, the professionals found themselves caught between the value of preventing a patient
28 from potential harm and the value of respecting the patient's autonomy, especially for people
29 with cognitive impairments who were living alone. Each such case was a balancing act to help
30 the patients stay at home without too much risk to his/her safety.
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41 A prioritized goal to ensure wellbeing was to maintain a home-like atmosphere, though the
42 home was also a place for care. It was a dilemma to provide care in line with aseptic
43 guidelines in a home environment with narrow, unhygienic spaces, lack of clean areas for
44 wound dressing or when pets interfered with the patient during caregiving.
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49 *Sometimes we get care-related injuries, infections in ports and so on. Some patients*
50 *want to touch things and help us when we are working and cleaning and switching*
51 *things, when it can be harmful. And that's not optimal, and when we don't have a*
52 *work area I have to... maybe the only work area we have is the lid on the box that we*
53 *put on the bed where the patient has urinated and defecated and which was last*
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3 *made...the linen was changed maybe seven months ago, literally... Meanwhile, the*
4 *dog or cat shows up and starts licking and you have to... You're literally sitting like*
5 *this (like a hook) (F8).*
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9 ***Striving to be up to date in the information flow***

10 The joint electronic health record (EHR) system implemented among all publicly funded care
11 providers – both in- and outpatient care – in the region, facilitated information transfer
12 between caregivers. However, shortcomings (e.g., lack of user-friendly software design or a
13 system for reminders and alerts) in the system and inconsistent documentation routines made
14 the information fragmented and easily lost. As the EHR was not accessible during home
15 visits, all essential information had to be reviewed beforehand. Anything that team members
16 wanted to report was noted on paper and documented in the EHR when they came back from
17 home visits. As a workaround for the lack of overview in the EHR, a digital list of tasks for
18 each home visit was used. Nurses updated this “to-do list” manually and used it as their
19 primary tool for organizing their day. The tool, intended to make information accessible, also
20 created a risk that the EHR was not read as carefully as the to-do list.
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30 Information related to medication management was identified as the area that generated the
31 most essential information problems. The teams found it difficult to be up-to-date with
32 generic drugs, which were rapidly replaced as prices changed. For patients, this could lead to
33 the intake of double doses, due to interpreting similar medications as different. Such errors
34 were not easily discovered and created a sense of lacking control for professionals and
35 unnecessary suffering for patients and relatives.
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41 *Then they (the pharmacy) can switch medications that have suddenly become cheaper,*
42 *so the name is different... Sometimes they'll get a double dose. So, there's a lot of*
43 *responsibility on us to check that and I think...sometimes we don't have the time...*
44 *Right, because it's hard, since one person will place pills in the box the day before*
45 *and another will hand it out the next day. And then...it's hard to know what's in it...*
46 *(F9).*
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53 Both the managers and teams felt that written information needed to be supplemented with
54 verbal communication both when transferred within their own organization and across
55 institutional borders. Unstructured small talk in the hallways and lunch room, as well as team
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meetings with a set structure for information transfer, enabled creating a common view of the patients' and relatives' needs and giving reminders about potential risks. Information exchange with other care providers involved in a patient's care was described as equally important, but harder to facilitate. This kind of information exchange with unlicensed staff was mostly conducted through notes in patient homes.

The coordinator at each unit was perceived as an effective barrier to information misses and tended to be at the centre of communication. The coordinator was the team's access to the EHR during home visits and a "detective" to find current information and prescriptions from other caregivers.

Maintaining high competence levels in emerging complexity

The broad spectra of diagnoses and rapid development of treatments and related technical devices that patients received during periods of hospitalization made it hard for the teams to stay informed and updated. The managers were worried that the level of competence and quality of care was threatened as the units expanded and new staff was introduced. Management strived to counteract this by scheduling new staff to work alongside experienced staff. Management also organized continuous training at the unit when new medical technology or new policies were introduced.

The team meetings were important for improving patient safety by sharing experiences and learning from each other. The clinical managers tried to create a proactive, learning perspective by highlighting safety issues. These meetings were also essential for getting to know each other, and each other's specific competences, across professional borders. Thus, the team members knew who to turn to when facing a problem in a patient home and they felt comfortable calling each other for advice. This contributed to "a common knowledge base" that was broader than each individual's knowledge. This reduced feeling of vulnerability during the home visits conducted alone, when rapid decisions had to be made.

... We're all alone out there, we really are... The chart system and medication lists and so on can't be accessed there... (F3)... All those assessments that you feel quite alone in making, you can be unsure... That's probably the most important aspect of the team, being based on parts and adding them all on top of each other. Then you usually get some kind of bigger picture regarding the patient (F1) ...you get an enormous strength in the team actually, so if you've been thinking about something there'll be someone...who

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3 *has another view and then you can get a bigger picture, which is very helpful. One plus*
4 *one is three (F5).*
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7 ***Engaging in patient safety at different levels of the system***

9 The quality of care of the home healthcare organizations was evaluated through regular use of
10 about 40 quality indicators, tailored to national and county level demands. The organizations
11 depend on reimbursement, which is based on these indicators. Both team members and
12 managers felt that the quality indicators poorly reflected quality improvement or patient safety
13 in their daily work. The managers had been invited by the county council to participate in the
14 selection of quality indicators, but felt that their perspectives had little impact.
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20 *We are presented with statistics now every quarter for the existing system, and we shake*
21 *our heads every time and we don't feel our work is reflected in the numbers they show us*
22 *from the system we already have. So, can we possibly understand a change? No, it won't*
23 *happen. Not that way (I2).*
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28 The professionals described that patients were overwhelmed by the number of quality
29 indicators, as some were collected biweekly for all patients, regardless of diagnosis. As most
30 of the indicators were general and not adapted to specific patient groups, both managers and
31 teams perceived that little freedom was left to introduce additional measures targeting each
32 individual patient's needs. In cases where the assessments were useful for the patient's care,
33 the teams needed to register the data twice, as the quality indicator registries were not
34 compatible with the EHR.
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41 *And maybe that works really well in the manufacturing industry...but when it's more*
42 *about what the level of quality is, well, that's hard to measure...we're always filling those*
43 *things out. It takes time and it steals time from patient contact and safety. We mustn't*
44 *forget that when we add administrative burdens, they take time from time spent on patient*
45 *safety (F5).*
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51 Both managers and teams described the incident reporting system as an ongoing patient safety
52 effort, for learning about and communicating patient safety issues. The team members
53 described a dilemma in reporting events where colleagues were involved, as they did not want
54 to implicate anyone. Managers prioritized analyses of adverse events and risks. The
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3 communication back to the professionals, intended to improve patient safety, usually
4 consisted of new guidelines. The team members described them as complicated multi-step
5 guidelines and felt it was difficult to stay up-to-date. Trade-offs were common, as the
6 guidelines sometimes contradicted each other and did not fit all the possible situations in
7 patient homes. The clinical managers were aware that trade-offs were inevitable and gave the
8 professionals a high degree of freedom to make decisions to promote patient safety.
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14 *We keep getting guideline after guideline...and you can't know all those guidelines*
15 *and study them all the time... And I guess that's a way to safeguard and say, well...to*
16 *protect themselves. But it's no use if we don't have time to read them all in a sensible*
17 *way. You read through them once and then...well, there you are with piles of*
18 *guidelines on paper (F9).*

19 *A full structure, you need that, and you need a few checklists... But things come up*
20 *every day...and because these are unexpected events, you have to deviate. People*
21 *deviate every day (I5).*
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29 **DISCUSSION**

30 The main results of this explorative study show that engineering safety in specialized home
31 healthcare is a continuous effort at all levels of the system, while keeping the patient
32 perspective in mind. The well-established palliative care ideology in the studied context
33 shaped a common mind-set between members in the multidisciplinary team and clinical
34 managers, which seemed useful for prioritizing goals. Shared values, attitudes, beliefs,
35 behaviours, and practices are features of a workplace culture.²³ In healthcare, a recent review
36 across a variety of settings showed a consistent association between workplace culture and
37 patient outcomes. However, most of the included studies were cross-sectional, using a wide
38 range of different definitions and measurements of culture, environment, and patient
39 outcomes, and most studies were conducted in hospital settings.²⁴ Safety culture in home
40 healthcare has not yet been widely explored.²⁵ In the current study, the palliative care
41 ideology fostered shared values and practices across the professional teams, promoting patient
42 safety by giving the patient's goals and autonomy priority in decisions about care. This care
43 ideology is truly in line with a person-centred perspective, which has been on the political
44 agenda for years, but is still poorly implemented in Sweden.²⁶ In most healthcare
45 environments, there were difficulties associated with involving patients as equal partners in
46 care, due to lack of private rooms or communication, time pressures, a traditional work
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3 structure, and professionals' attitudes, for example.²⁷ By contrast, in the home healthcare
4 environment, patients were in charge of self-care activities around the clock, with assistance
5 from healthcare professionals who carried out treatment that patients couldn't perform
6 themselves. However, the shared values that guided the professionals in their safety work also
7 implied risks. For example, hygiene guidelines did not mesh with the home healthcare
8 environment or patients' preferences and behaviours. Professionals in this study perceived a
9 dilemma in contradicting a patient's will, i.e., going against the ideology, even when patient
10 safety was in danger. A strong ideology could therefore be both a facilitator and a barrier to
11 patient safety, depending on which value was given highest priority.
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19 At the macro-level of the healthcare system, patient safety risks are rarely weighed against
20 ideological values. There is a widely accepted view that care at home is safer than
21 institutional care, due to the risk of infections at hospital. In reality, the work environment in
22 home healthcare is highly unstable, as it is not designed to reduce medical errors and
23 equipment problems or assist infection control. Thus, safe home healthcare is highly
24 dependent on professionals' ability to adapt to the varying conditions and on patients being
25 informed and capable of adjusting their homes and behaviours to reduce safety risks. This
26 study exemplifies how professionals, by building trusting relationships with patients and their
27 families, promoted a care environment in concert with each patient's specific preferences and
28 needs. This is in similar with other studies showing that the relationship with health providers
29 is central for older people feeling supported and cared for at home, and that a tense relation
30 implied a risk of patient harm.²⁸ It is also in line with resilient healthcare, which is defined by
31 its ability to adapt to unpredictable, unstable environments and remain intact and functional
32 despite threats to care performance²⁹ at the sharp end, i.e., the point where the patient meets
33 healthcare. Resilience at the sharp end also depends on adaptability at the management level.
34 As shown in another study, at this level of the system, adaptations involve rapid
35 reorganization of work as a response to disturbances, and providing sufficient supplies and
36 freedom for professionals to prioritize, adapt, and take time to provide the care that a patient
37 needs.³⁰
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51 At the macro-level, the steering mechanisms to promote quality and safety were built around a
52 large number of mandatory quality assessments. These were combined with economic
53 reimbursements or fines, depending on the degree of observance. At both the micro- and
54 meso-levels of the system, these assessments were perceived as stealing valuable time from
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3 'real' quality improvement work. The quality indicators were sparsely used in the daily work
4 as they rarely fit patients' specific needs, and did not align with coordinating effective, safe,
5 and comprehensive home healthcare. ⁴ Incident reporting is another measure for improving
6 safety that has been used with great success in other high-risk organizations (e.g., nuclear,
7 railway and car industry). ³¹ Even if there is limited evidence on how incident reporting
8 actually contributes to safety in healthcare, ³² it is a globally accepted method. A common
9 management reaction to incident reports was to produce new guidelines, although it is well-
10 known that trade-offs are commonplace in daily work. ^{30 33} Strategies and behaviours to work
11 around problematic practical processes have been shown to either promote or hinder patient
12 safety. ³⁴ McDonald et al ³⁵ found that managers believed that adherence to standardized
13 processes promoted patient safety, which contrasts with the findings in this study, where the
14 clinician managers were aware that the teams made trade-offs to promote patient safety.
15 Standardizations assume causality, that care is predictable, and that adverse events can be
16 prevented through rules and guidelines. ³⁶ As the complexity in healthcare systems increases,
17 the usefulness of the incident reporting system in improving patient safety is disputed. The
18 criticism concerns its use for counting incidents instead of effective analysis leading to
19 meaningful changes and organizational learning. ³⁷ To substantially improve patient safety in
20 home healthcare, we need to develop reliable and valuable methods that enable studying the
21 dynamic complexity of the system at different levels. ³⁸ The guidelines and quality
22 assessments, aimed to promote patient safety from a macro-perspective, constrained the
23 professionals' freedom to adapt to challenges and provide safe care based on the shared care
24 ideology. This indicates that if standardization is to be used as a tool to promote patient
25 safety, it must be aligned with a culture based on patient values and goals, where calculated
26 risks are taken into account.

27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 **Conclusion**

44 The dynamic and complex conditions under which home healthcare operate are fundamentally
45 different from hospital care. Patient safety in the home healthcare is grounded in close team
46 collaboration and a care ideology that support patient autonomy, competence and relatedness
47 as active partner in care. Thus, providing care included weighing risks against patients'
48 preferences and will. Professional adaptations and patient behaviours and preferences set the
49 limits for safety. Standardization and quality assessments introduced for improvement of care
50 must therefore take into consideration the professional ethos that puts patient values at the
51 centre of care.
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List of abbreviations

EHR	Electronic health record
RN	Registered nurse

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Competing interests None declared

Contributors ML and ME designed and conducted the study. All authors jointly contributed with their expertise in methodology, patient safety and home healthcare. All authors were part of the analysis process, drafted the manuscript and agreed to the final version of the manuscript before submission.

Ethics approval This study was approved by the Regional Ethical Review Committee in Sweden, Stockholm (DNr: 2012/1384:31).

Data sharing statement

Supplementary and raw data available upon request.

Patient and Public Involvement statement

Patients were not involved in this study.

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Exploring patient safety in Swedish specialized home healthcare - an interview study with multidisciplinary teams and clinical managers

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Exploring patient safety in Swedish specialized home healthcare - an interview study with multidisciplinary teams and clinical managers

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3 33 **ABSTRACT**

4 34 **Objective** Home healthcare is the fastest growing arena in the healthcare system but patient
5 35 safety research in this context is limited. The aim was to explore patient safety in Swedish
6 36 specialized home healthcare from multidisciplinary teams' and clinical managers'
7 37 perspectives.

8 38 **Design** An explorative qualitative study.

9 39 **Setting** Multidisciplinary teams' and clinical managers were recruited from three specialized
10 40 home healthcare organizations in Sweden.

11 41 **Methods** Nine focus group interviews with multidisciplinary teams and six individual
12 42 interviews with clinical managers were conducted, in total 51 participants. The data were
13 43 transcribed verbatim and analyzed using qualitative content analysis.

14 44 **Results** Patient safety was inherent in the well-established care ideology which shaped a
15 45 common mind-set between members in the multidisciplinary teams and clinical managers.
16 46 This patient safety culture was challenged by the emerging complexity in which priority had
17 47 to be given to standardised guidelines, quality assessments and management of information in
18 48 maladapted communication systems and demands for required competence and skills. The
19 49 multiple guidelines and quality assessments that aimed to promote patient safety from a
20 50 macro-perspective, constrained the freedom, on a meso- and micro-level, to adapt to
21 51 challenges based on the care ideology.

22 52 **Conclusion** Patient safety in home healthcare is dependent on adaptability at the management
23 53 level; the team members' ability to adapt to the varying conditions and on patients being
24 54 capable of adjusting their homes and behaviours to reduce safety risks. A strong culture
25 55 related to a patient's value as a person where patients' and families' active participation and
26 56 preferences guides the decisions, could be both a facilitator and a barrier to patient safety,
27 57 depending on which value is given highest priority.

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Strengths and limitations of this study

- Trustworthiness have been strengthened by research triangulation, setting triangulation, and participant triangulation.
- We have lower numbers of participants than expected in each focus group due to the high workload.
- The selection of settings, situated in the same urban area of Sweden, may limit the extent to which our findings can be transferred to rural settings or other regions.

BACKGROUND

Healthcare is becoming more complex and provision of care in people's homes is increasing, both globally¹ and in Sweden,² driven by medical and technical advances, economic pressures, demographic factors, and patient preferences.³ However, most patient safety research is conducted in hospital settings, while home healthcare is largely unexplored.⁴ Thus, evidence from hospital-based research has also been applied to home healthcare. In recent years, this has been criticized based on the knowledge that patient safety is largely context-dependent.^{5,6}

The few existing home healthcare-specific studies on patient safety, have highlighted unique safety issues and the occurrence of adverse events. The specific patient safety challenges in home healthcare include fragmentation of care, care providers working in isolation and inadequate communication between different care providers.^{7,8} A recent interview study found that the perspectives of patients and their carers on patient safety contributed to safe home healthcare and were equally important as those of healthcare professionals for improving patient safety.⁵ Studies of adverse events in home healthcare have shown a wide variation in the estimations, with 13% in Canada⁹⁻¹¹ and 37.7% in Sweden.¹² The types of adverse events were similar in both countries – falls, healthcare-associated infections, pressure ulcers – and most were considered to be preventable.

With a few exceptions, e.g., healthcare-associated infections, the patient safety research is increasingly based on the premise that harm is mainly the result of poorly designed systems.¹³ As a system safety approach encompasses the organization's context, processes and structures, which can have a sustainable influence on promoting safe care^{4,14} there is a need to study patient safety in the home healthcare setting.

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3 102 Hence, the overall aim of this study was to explore how patient safety is described and
4 103 addressed in specialized home healthcare from the perspectives of multidisciplinary teams and
5 104 clinical managers.
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9 106 **METHODS**

10 107 *Design*

11 108 This qualitative study, based on semi-structured interviews with multidisciplinary
12 109 professionals and clinical managers, is part of a larger study on patient safety in home
13 110 healthcare settings.⁸
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18 112 *Setting*

19 113 Multidisciplinary teams and clinical managers were recruited from three specialized home
20 114 healthcare organizations in one regional healthcare authority in Sweden. Home healthcare in
21 115 Sweden is defined as healthcare that is administered in a patient's home or the equivalent, and
22 116 that is consistent over time,¹⁵ but does not encompass home care organizations with
23 117 unlicensed staff administering social care.
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30 119 The three studied units are tax-funded and cover a limited geographical area. They were
31 120 selected to capture socio-demographic differences in, e.g., country of birth and income. Each
32 121 unit consisted of ambulatory multidisciplinary teams, including four to six physicians, 20-30
33 122 registered nurses (RNs) and one of each of the allied healthcare staff: physiotherapist,
34 123 occupational therapist, dietitian and social worker. One unit had a few assistant nurses. The
35 124 RNs and physicians were available 24 hours a day. Each unit employed one head of
36 125 department and one or two first-line manager ("clinical managers"). The units provided long-
37 126 or short-term round-the-clock advanced care and treatment to patients with complex diseases
38 127 and symptoms.
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46 129 All units had in the last years expanded from providing traditional palliative home healthcare
47 130 to patients with a cancer diagnosis to providing specialized home healthcare to patients with
48 131 all kinds of diagnoses, based on changes in national regulations.¹⁶ The palliative care
49 132 ideology in this study is referred to as 'the care ideology' on the basis that it was applied to all
50 133 patients regardless of diagnosis. The cornerstones in the care ideology, can be summarized as
51 134 nearness, wholeness, knowledge, and empathy. The approach should further be based on
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135 continuity, good communication and support provided in accordance with patients and
136 relatives' wishes, in so far as possible.¹⁷

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138 **Data collection**

139 Nine focus group interviews with team members and seven individual interviews with clinical
140 managers were conducted between December 2013 and May 2014, including in total 51
141 participants (Table 1). The interview method was inspired by Kvale and Brinkmann.¹⁸ All
142 team members were invited to participate in a focus group interview. The groups were
143 deliberately composed so that the participants would feel comfortable discussing issues
144 relevant to their discipline and to capture a variety of perspectives on patient safety. The
145 heads of department approved performance of the study at their respective units.

146

147 All interviews took place at the workplace at the start or end of a work shift. Focus group
148 interviews included 4-6 team members and lasted 60-90 minutes. Individual interviews lasted
149 30-60 minutes. The interviews were audio-recorded and the researcher took notes.

150

151 The interviews were conducted by the first and last researcher (ML and ME). A semi-
152 structured interview guide was developed and tested in a pilot interview, after which minor
153 revisions were made. The interview guide consisted of open-ended questions, such as "Tell
154 me what patient safety means to you" and "Tell me about your experiences of what helps or
155 hinders patient safety in your daily work." In addition to questions on patient safety, the
156 clinical management interviews also included general questions on work organization. Both
157 verbal and non-verbal probing techniques were used to increase clarity.

158

159 **Table 1. Overview of the interviews**

	Unit A	Unit B	Unit C
Focus group interviews	RNs (4 women) and Allied health staff (1 woman)	RNs (5 women)	Allied health staff (4 women)
	RNs (3 women) and Allied health staff (1 woman)	Allied health staff (4 women)	Physicians (3 men and 2 women)
		Physicians (3 men and 2 women)	RNs (4 women) and Assistant nurses (2 women)

			RNs (4 women) and Assistant nurse (1 woman)
Individual interviews	Head of department (1 man)	Head of department (1 man)	Head of department (1 man)
	First-line manager (1 man)	2 First-line managers (2 women)	First-line manager (1 woman)
			Physician (1 woman)
Total	11 (9 women, 2 men)	17 (13 women, 4 men)	23 (19 women, 4 men)

160 Registered nurse=RN

161

162 **Data analysis**

163 The data were transcribed verbatim and analysed using qualitative content analysis with an
 164 inductive approach.^{19,20} The transcripts were read through several times by all researchers, to
 165 get a sense of the data. All three researchers were involved in analysis, going from a concrete
 166 to a more abstract level. This included identification of meaning units, which were condensed,
 167 coded, and sorted into 19 subcategories based on differences and similarities. The
 168 subcategories were compared, sorted, interpreted and abstracted into one main theme and four
 169 categories. All researchers discussed the codes, categories and themes in relation to the
 170 transcripts until consensus was reached. The researchers ML and ME are registered nurses,
 171 MF is a social worker. All researchers have clinical experience from different settings. This
 172 manuscript does not contain personal medical information about an identifiable person.

173

174 **RESULTS**

175 The results include one main theme *Keeping patients safe – a never-ending effort at all levels*,
 176 constituting the latent content of four categories: 1) Co-creating safety between patients and
 177 multidisciplinary teams in the mess on the floor; 2) Using complementary communication
 178 paths – an asset and a risk for patient safety; 3) High competence level and learning across
 179 disciplines – requirements for patient safety; 4) Macro-level system for patient safety not in
 180 alignment with meso- and micro-level goals. In general, there was a high level of consistency
 181 between respondents' opinions in the interviews, regardless of unit, clinical manager, or team
 182 members, unless otherwise stated.

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184 ***Keeping patients safe – a never-ending effort at all levels***

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3 185 The established care ideology formed a mind-set common to both multidisciplinary teams
4 186 (micro-level) and clinical managers (meso-level) on how to provide patient safety. Patient
5 187 safety was described by both multidisciplinary teams and clinical managers as related to a
6 188 patient's value as a person. Prevention of psychological harm, such as violated autonomy or
7 189 integrity, had the same priority as prevention of physical harm. This view influenced risk
8 190 management, in that a patient's preferences outweighed risks detected in the home care
9 191 environment. The care ideology was challenged by the emerging complexity in which priority
10 192 had to be given to standardised guidelines, quality assessments, management of information
11 193 flow in maladapted communication systems, and demands for certain competencies and skills.
12 194 Patient safety was an inherent part of the care ideology, not a goal in itself, and not always in
13 195 agreement with the regional county council (macro-level) directives.
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23 197 *I think it's good for patient safety, to get patients and family involved. It... I can't*
24 198 *imagine anything better than them knowing what they are putting in their mouth and*
25 199 *what pills they are taking. They know who to call when they don't recognize the*
26 200 *medication or... They ask us if we've sanitized our hands, if we're wearing aprons and*
27 201 *so on... That...it's an aspect of culture, safety culture, both as regards care...here at*
28 202 *the unit, and we take it along to our patients, since that's our work environment, so*
29 203 *the patients become part of the safety culture, and they should feel that they...that it's*
30 204 *their...I mean, it is their care (RN, unit C).*
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37 206 ***Co-creating safety between patients and multidisciplinary teams in the mess on the floor***
38 207 The multidisciplinary teams were united by their care ideology and the strong belief that
39 208 establishing and maintaining sustainable, trusting relationships was the core of patient safety
40 209 work. The multidisciplinary teams showed respect for patients' and relatives' values, wishes,
41 210 and lifestyle through ensuring that there was time for conversation, to listen and take patients'
42 211 and relatives' knowledge, feelings and thoughts into account in their planning and
43 212 performance of care. By focusing on what mattered *for* the patient and relatives rather than
44 213 what the matter was *with* the patient, the multidisciplinary teams could respect the patient's
45 214 values. To fulfil the patient's wish to stay at home, the multidisciplinary teams undertook
46 215 several actions that might entail a patient safety risk. An example of such an action was to
47 216 delegate the medication administration to unlicensed staff in social care, as they could visit
48 217 the patient several times a day. In some cases, the team members found themselves caught
49 218 between the value of preventing a patient from potential harm and the value of respecting the
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3 219 patient's autonomy, especially for people with cognitive impairments who were living alone.
4 220 Each such case was a balancing act to help the patients stay at home without too much risk to
5 221 his/her safety.
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9 223 The varied work environment, with "patient rooms" of various standards distributed over a
10 224 large area, was a health and safety risk for both patients and professionals. A prioritized goal
11 225 to ensure wellbeing was to maintain a home-like atmosphere, though the home was also a
12 226 place for care. It was a dilemma to provide care in line with aseptic guidelines in a home
13 227 environment with narrow, unhygienic spaces, lack of clean areas for wound dressing or when
14 228 pets interfered with the patient during caregiving. Arranging meetings with sufficient time to
15 229 build trustful relationships enabled co-creation of care based on each patient's or family's
16 230 wishes. This also allowed for including patients and families in active participation in
17 231 accordance with their abilities. Each team member contributed with their competence.
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25 233 *Sometimes we get care-related injuries, infections in ports and so on. Some patients*
26 234 *want to touch things and help us when we are working and cleaning and switching*
27 235 *things, when it can be harmful. And that's not optimal, and when we don't have a*
28 236 *work area I have to... maybe the only work area we have is the lid on the box that we*
29 237 *put on the bed where the patient has urinated and defecated and which was last*
30 238 *made...the linen was changed maybe seven months ago, literally... Meanwhile, the*
31 239 *dog or cat shows up and starts licking and you have to... You're literally sitting like*
32 240 *this (like a hook) (RN, unit C).*
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242 **Using complementary communication paths – an asset and a risk for patient safety**

243 Both the clinical managers and multidisciplinary teams felt that written information needed to
244 be supplemented with verbal communication both when transferred within their own
245 organization and across institutional borders. Unstructured small talk in the hallways and
246 lunch room, as well as team meetings with a set structure for information transfer, enabled
247 creating a common view of the patients' and relatives' needs and giving reminders about
248 potential risks. Information exchange with other care providers involved in a patient's care
249 was described as equally important, but harder to facilitate. This kind of information exchange
250 with unlicensed staff was mostly conducted through notes in patient homes.

251 The coordinator at each unit was perceived as an effective barrier to information misses and
252 tended to be at the centre of communication. The coordinator was the team's access to the

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3 253 EHR during home visits and a “detective” to find current information and prescriptions from
4 254 other caregivers.
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8 256 *When it's that complicated, the meetings are great, when we have them. People meet*
9 257 *and check in with each other. It's really good; you have your computer to hand and*
10 258 *can look at the parameters, so to speak, that we are discussing. So that's the best*
11 259 *thing, you know, when we can communicate (first-line manager, unit A).*
12 260

13 261 The joint electronic health record (EHR) system implemented among all publicly funded care
14 262 providers – both in- and outpatient care – in the region, facilitated information transfer
15 263 between caregivers. However, shortcomings (e.g., lack of user-friendly software design or a
16 264 system for reminders and alerts) in the system and inconsistent documentation routines made
17 265 the information fragmented and easily lost. As the EHR was not accessible during home
18 266 visits, all essential information had to be reviewed beforehand. Team members noted
19 267 everything that they wanted to report on paper and documented in the EHR when they came
20 268 back from home visits. To compensate for the lack of overview in the EHR, a digital list of
21 269 tasks for each home visit was used. Nurses updated this “to-do list” manually and used it as
22 270 their primary tool for organizing their day. The tool, intended to make information accessible,
23 271 also created a risk that the EHR was not read as carefully as the to-do list.
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26 273 Information related to medication management was identified as the area that generated the
27 274 highest risk for information misses. The team members found it difficult to be up-to-date with
28 275 generic drugs, which were rapidly replaced as prices changed. For patients, this could lead to
29 276 the intake of double doses, due to interpreting similar medications as different. Such errors
30 277 were not easily discovered and created a sense of lacking control for team members and
31 278 unnecessary suffering for patients and relatives.
32 279

33 280 **High competence level and learning across disciplines – requirements for patient safety**

34 281 The team meetings were important for improving patient safety by sharing experiences and
35 282 learning from each other. The clinical managers tried to create a proactive, learning
36 283 environment by highlighting safety issues. These meetings were also essential for getting to
37 284 know each other, and each other's specific competences, across disciplinary borders. Thus,
38 285 the team members knew who to turn to when facing a problem in a patient home and they felt
39 286 comfortable calling each other for advice. This contributed to “a complementary knowledge
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3 287 base” that was broader than each individual’s knowledge. This reduced feeling of
4 288 vulnerability during the home visits conducted alone, when rapid decisions had to be made.
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8 290 *... We’re all alone out there, we really are... The chart system and medication lists and so*
9 291 *on can’t be accessed there... (RN, unit B)... All those assessments that you feel quite alone*
10 292 *in making, you can be unsure... That’s probably the most important aspect of the team,*
11 293 *being based on parts and adding them all on top of each other. Then you usually get*
12 294 *some kind of bigger picture regarding the patient (RN, unit A) ... You get an enormous*
13 295 *strength in the team actually, so if you’ve been thinking about something there’ll be*
14 296 *someone... who has another view and then you can get a bigger picture, which is very*
15 297 *helpful. One plus one is three (physician, unit B).*
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22 299 The broad spectra of diagnoses and rapid development of treatments and related technical
23 300 devices that patients received during periods of hospitalization made it hard for the
24 301 multidisciplinary teams to stay informed and updated. The clinical managers were worried
25 302 that the level of competence and quality of care was threatened as the units expanded and new
26 303 staff was introduced. Clinical managers strived to counteract this by scheduling new staff to
27 304 work alongside experienced staff and organized training when new medical technology or
28 305 new policies were introduced. The multidisciplinary teams, in turn, felt that the training
29 306 lagged behind the rapid implementation of new technology.
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308 **Macro-level system for patient safety not in alignment with meso- and micro-level goals**

309 The quality of care of the home healthcare organizations was evaluated through regular use of
310 about 40 quality indicators, tailored to the county level demands. The organizations depend on
311 reimbursement, which is based on these indicators. Both the multidisciplinary teams and
312 clinical managers felt that the quality indicators poorly reflected quality improvement or
313 patient safety in their daily work. The clinical managers had been invited by the county
314 council to participate in the selection of quality indicators, but felt that their perspectives had
315 little impact.
316

317 *We are presented with statistics now every quarter for the existing system, and we shake*
318 *our heads every time and we don’t feel our work is reflected in the numbers they show us*
319 *from the system we already have. So, can we possibly understand a change? No, it won’t*
320 *happen. Not that way (head of department, unit A).*

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4 322 The multidisciplinary teams described that patients were overwhelmed by the number of
5 323 quality indicators, as some were collected biweekly for all patients, regardless of diagnosis.
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7 324 As most of the indicators were general and not adapted to specific patient groups, both
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9 325 managers and teams perceived that little freedom was left to introduce additional measures
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11 326 targeting each individual patient's needs. In cases where the assessments were useful for the
12
13 327 patient's care, the teams needed to register the data twice, as the quality indicator registries
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15 328 were not compatible with the EHR.
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17 329
18 330 Both clinical managers and the multidisciplinary teams described the incident reporting
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20 331 system as an ongoing patient safety effort, for learning about and communicating patient
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22 332 safety issues. The team members described a dilemma in reporting events where colleagues
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24 333 were involved, as they did not want to implicate anyone. Managers prioritized analyses of
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26 334 adverse events and risks. The communication back to the team members, intended to improve
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28 335 patient safety, usually consisted of new guidelines. The team members described them as
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30 336 complicated multi-step guidelines and felt it was difficult to stay up-to-date. Trade-offs were
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32 337 common, as the guidelines sometimes contradicted each other and did not fit all the possible
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34 338 situations in patient homes. The clinical managers were aware that trade-offs were inevitable
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36 339 and gave the professionals a high degree of freedom to make decisions to promote patient
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38 340 safety.
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41 342 **DISCUSSION**

42 343 The main results of this explorative study show that patient safety in specialized home
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44 344 healthcare is a continuous effort at all levels of the system, while keeping the patient
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46 345 perspective in mind. The well-established care ideology in the studied context shaped a
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48 346 common mind-set between members in the multidisciplinary teams and clinical managers,
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50 347 which seemed to form a patient safety culture. Shared values, attitudes, beliefs, behaviours,
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52 348 and practices are features of a workplace culture.²¹ In healthcare, a recent review across a
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54 349 variety of settings showed a consistent association between workplace culture and patient
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56 350 outcomes. However, most of the included studies were cross-sectional, using a wide range of
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58 351 different definitions and measurements of culture, environment, and patient outcomes, and
59
60 352 most studies were conducted in hospital settings.²² Safety culture in home healthcare has not
61
62 353 yet been widely explored.²³ In the current study, the care ideology fostered shared values and
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64 354 practices across the multidisciplinary teams, promoting patient safety by giving the patient's

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3 355 goals and autonomy priority in decisions about care. Such a person-centred perspective, has
4 356 been on the political agenda for years, but is still poorly implemented in Sweden.²⁴ In most
5 357 healthcare environments, there have been difficulties associated with involving patients as
6 358 equal partners in care, due to lack of private rooms or communication, time pressures, a
7 359 traditional work structure, and professionals' attitudes, for example.²⁵ By contrast in this
8 360 study, in the home healthcare environment, patients were in charge of self-care activities
9 361 around the clock, with assistance from team members who carried out treatment that patients
10 362 couldn't perform themselves. However, the shared values that guided the team members in
11 363 their safety work also implied risks. For example, hygiene guidelines did not mesh with the
12 364 home healthcare environment or patients' preferences and behaviours. The Multidisciplinary
13 365 teams in this study perceived a dilemma in contradicting a patient's will, i.e., going against
14 366 the ideology, even when patient safety was in danger. A strong ideology could therefore be
15 367 both a facilitator and a barrier to patient safety, depending on which value was given highest
16 368 priority.

369

17 370 There is a widely accepted view that care at home is safer than institutional care, including to
18 371 the risk of infections at hospital.²⁶ In this study, the work environment in home healthcare
19 372 was highly unstable, as it is not designed to reduce medical errors and equipment problems or
20 373 assist infection control. Thus, safe home healthcare is highly dependent on team members
21 374 ability to adapt to the varying conditions and on patients being informed and capable of
22 375 adjusting their homes and behaviours to reduce safety risks. This study exemplifies how the
23 376 multidisciplinary teams, by building trusting relationships with patients and their relatives,
24 377 promoted a care environment in concert with each patient's specific preferences and needs.
25 378 This is in line with other studies showing that the relationship with health providers is central
26 379 for older people feeling supported and cared for at home, and that a tense relation implied a
27 380 risk of patient harm.²⁷ It is also in line with resilient healthcare, which is defined by its ability
28 381 to adapt to unpredictable, unstable environments and remain intact and functional despite
29 382 threats to care performance²⁸ at the sharp end, i.e., the point where the patient meets
30 383 healthcare. Resilience at the sharp end also depends on adaptability at the management level.
31 384 As shown in another study, at this level of the system, adaptations involve rapid
32 385 reorganization of work as a response to disturbances, providing sufficient supplies and
33 386 freedom for professionals to prioritize, adapt and take time to provide the care that patient
34 387 needs.²⁹

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3 389 In the current study, at the macro-level, the steering mechanisms to promote quality and
4 390 safety were built around a large number of mandatory quality assessments. These were
5 391 combined with economic reimbursements or fines, depending on the degree of observance. At
6 392 both the micro- and meso-levels of the system, these assessments were perceived as stealing
7 393 valuable time from 'real' quality improvement work from there's point of view. The quality
8 394 indicators were sparsely used in the daily work as they rarely fit patients' specific needs, and
9 395 did not align with coordinating effective, safe, and comprehensive home healthcare.³ Incident
10 396 reporting is another measure for improving safety that has been used with great success in
11 397 other high-risk organizations (e.g., nuclear, railway and car industry).³⁰ Even if there is
12 398 limited evidence on how incident reporting actually contributes to safety in healthcare,³¹ it is
13 399 a globally accepted method. A common clinical management reaction to incident reports was
14 400 to produce new guidelines, although it is well-known that trade-offs are commonplace in daily
15 401 work.^{29 32} Strategies and behaviours to work around problematic practical processes have
16 402 been shown to either promote or hinder patient safety.³³ McDonald et al³⁴ found that
17 403 managers believed that adherence to standardized processes promoted patient safety, which
18 404 contrasts with the findings in this study, where the clinician managers were aware that the
19 405 multidisciplinary teams made trade-offs to promote patient safety. Standardizations assume
20 406 causality, that care is predictable, and that adverse events can be prevented through rules and
21 407 guidelines.³⁵ As the complexity in healthcare systems increases, the usefulness of the incident
22 408 reporting system in improving patient safety is disputed. The criticism concerns its use for
23 409 counting incidents instead of effective analysis leading to meaningful changes and
24 410 organizational learning.³⁶ To substantially improve patient safety in home healthcare, we
25 411 need to develop reliable and valuable methods that enable studying the dynamic complexity
26 412 of the system at different levels.³⁷ The guidelines and quality assessments, aimed to promote
27 413 patient safety from a macro-perspective, constrained the team members freedom to adapt to
28 414 challenges and provide safe care based on the shared care ideology. This indicates that if
29 415 standardization is to be used as a tool to promote patient safety, it must be aligned with a
30 416 culture based on patient values and goals, where calculated risks are taken into account.

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49 418 This research has some limitations to consider. The selection of settings, situated in the same
50 419 urban area of Sweden, may limit the extent to which our findings can be transferred to rural
51 420 settings or other regions. The number of participants was lower than expected in some focus
52 421 groups, due to the high workload, which may have limited the dynamics of the discussions.
53 422 However, a strength of the study is that all professions in the multidisciplinary teams from

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3 423 different settings were represented, and the interviews were characterized by rich variations
4 424 and deep descriptions of patient safety in specialized home healthcare.³⁸ To further broaden
5 425 the understanding of patient safety in home healthcare, patients, and their relatives could be
6 426 involved. To make us aware of biases and preconceptions, we adopted a self-critical attitude
7
8 427 and constantly reflected on our own thoughts and mind-sets, so as to strengthen the
9
10 428 trustworthiness of data.^{20 38} To reduce bias, we used research triangulation in all analyses and
11 429 interpretations of data.³⁸ Finally, interpretation of the results should be made with the delay
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13 430 between data collection and publication kept in mind.
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16 431

17 432 **Conclusion**

18
19 433 The dynamic and complex conditions under which home healthcare operate are fundamentally
20 434 different from hospital care. Patient safety in the home healthcare is grounded in close
21
22 435 multidisciplinary team collaboration based on a care ideology enhancing co-creation of care
23
24 436 through patient autonomy, competence and relatedness. Thus, providing care included
25 437 weighing risks against patients' preferences and will. Standardization and quality assessments
26
27 438 introduced for improvement of care are contrasted against team members adaptations and
28
29 439 patient behaviours and preferences, that set the limits for safety.
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31 440

32 441 **List of abbreviations**

33 442 EHR Electronic health record

34 443 RN Registered nurse

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42 448 publication.
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46 450 **Competing interests** None declared

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49 452 **Contributors** ML and ME designed and conducted the study. All authors (ML, MF, ME)
50 453 jointly contributed with their expertise in methodology, patient safety and home healthcare.
51
52 454 All authors were part of the analysis process, drafted the manuscript and agreed to the final
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54 455 version of the manuscript before submission.
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3 457 **Ethics approval** This study was approved by the Regional Ethical Review Committee in
4 458 Sweden, Stockholm (DNr: 2012/1384:31).

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8 460 **Data sharing statement**

9 461 Supplementary and raw data available upon request.

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12 463 **Patient and Public Involvement statement**

13 464 Patients were not involved in this study.

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19 468

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21 469 **REFERENCES**

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Standards for Reporting Qualitative Research (SRQR)*

<http://www.equator-network.org/reporting-guidelines/srqr/>

Page/line no(s).

Title and abstract

<p>Title - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended</p>	Page 1, line 2
<p>Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions</p>	Page 2

Introduction

<p>Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement</p>	Page 3, line 85
<p>Purpose or research question - Purpose of the study and specific objectives or questions</p>	Page 4, line 102

Methods

<p>Qualitative approach and research paradigm - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**</p>	Page 3, line 107
<p>Researcher characteristics and reflexivity - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability</p>	Page 6, line 170 Page 14, line 426
<p>Context - Setting/site and salient contextual factors; rationale**</p>	Page 4, line 112
<p>Sampling strategy - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**</p>	Page 5, line 141
<p>Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues</p>	Page 14, line 457 and page 6, line 171
<p>Data collection methods - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**</p>	Page 5, line 138

1 2 3 4 5	Data collection instruments and technologies - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	Page 5, line 151
6 7 8	Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	Page 4, line 119 and Page 5, table 1
9 10 11 12	Data processing - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	Page 5, line 147 and Page 6, line 162
13 14 15 16	Data analysis - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	Page 6, line 162
17 18 19 20	Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	Page 14, line 426

Results/findings

23 24 25 26	Synthesis and interpretation - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	Page 6, line 175
27 28 29 30 31 32	Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	Page 7, line 197. Page 8, line 233. Page 9, line 256. Page 10 line 290 and 317.

Discussion

35 36 37 38 39 40 41	Integration with prior work, implications, transferability, and contribution(s) to the field - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	Page 11, line 343
42 43	Limitations - Trustworthiness and limitations of findings	Page 13, line 418

Other

46 47 48	Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	Page 14, line 450
49 50	Funding - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	Page 14, line 445

*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

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3 **The rationale should briefly discuss the justification for choosing that theory, approach,
4 method, or technique rather than other options available, the assumptions and limitations
5 implicit in those choices, and how those choices influence study conclusions and
6 transferability. As appropriate, the rationale for several items might be discussed together.
7

8 **Reference:**

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For peer review only

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3 1 **Title**

4 2 **Exploring patient safety in Swedish** specialized home healthcare - an interview study with
5 3 multidisciplinary teams and clinical managers
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3 33 **ABSTRACT**

4 34 **Objective** Home healthcare is the fastest growing arena in the healthcare system but patient
5 35 safety research in this context is limited. The aim was to explore patient safety in Swedish
6 36 specialized home healthcare from multidisciplinary teams' and clinical managers'
7 37 perspectives.

8 38 **Design** An explorative qualitative study.

9 39 **Setting** Multidisciplinary teams' and clinical managers were recruited from three specialized
10 40 home healthcare organizations in Sweden.

11 41 **Methods** Nine focus group interviews with multidisciplinary teams and six individual
12 42 interviews with clinical managers were conducted, in total 51 participants. The data were
13 43 transcribed verbatim and analyzed using qualitative content analysis.

14 44 **Results** Patient safety was inherent in the well-established care ideology which shaped a
15 45 common mind-set between members in the multidisciplinary teams and clinical managers.
16 46 This patient safety culture was challenged by the emerging complexity in which priority had
17 47 to be given to standardised guidelines, quality assessments and management of information in
18 48 maladapted communication systems and demands for required competence and skills. The
19 49 multiple guidelines and quality assessments that aimed to promote patient safety from a
20 50 macro-perspective, constrained the freedom, on a meso- and micro-level, to adapt to
21 51 challenges based on the care ideology.

22 52 **Conclusion** Patient safety in home healthcare is dependent on adaptability at the management
23 53 level; the team members' ability to adapt to the varying conditions and on patients being
24 54 capable of adjusting their homes and behaviours to reduce safety risks. A strong culture
25 55 related to a patient's value as a person where patients' and families' active participation and
26 56 preferences guides the decisions, could be both a facilitator and a barrier to patient safety,
27 57 depending on which value is given highest priority.

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Strengths and limitations of this study

- Trustworthiness have been strengthened by research triangulation, setting triangulation, and participant triangulation.
- We have lower numbers of participants than expected in each focus group due to the high workload.
- The selection of settings, situated in the same urban area of Sweden, may limit the extent to which our findings can be transferred to rural settings or other regions.

BACKGROUND

Healthcare is becoming more complex and provision of care in people's homes is increasing, both globally¹ and in Sweden,² driven by medical and technical advances, economic pressures, demographic factors, and patient preferences.³ However, most patient safety research is conducted in hospital settings, while home healthcare is largely unexplored.⁴ Thus, evidence from hospital-based research has also been applied to home healthcare. In recent years, this has been criticized based on the knowledge that patient safety is largely context-dependent.^{5,6}

The few existing home healthcare-specific studies on patient safety, have highlighted unique safety issues and the occurrence of adverse events. The specific patient safety challenges in home healthcare include fragmentation of care, care providers working in isolation and inadequate communication between different care providers.^{7,8} A recent interview study found that the perspectives of patients and their carers on patient safety contributed to safe home healthcare and were equally important as those of healthcare professionals for improving patient safety.⁵ Studies of adverse events in home healthcare have shown a wide variation in the estimations, with 13% in Canada⁹⁻¹¹ and 37.7% in Sweden.¹² The types of adverse events were similar in both countries – falls, healthcare-associated infections, pressure ulcers – and most were considered to be preventable.

With a few exceptions, e.g., healthcare-associated infections, the patient safety research is increasingly based on the premise that harm is mainly the result of poorly designed systems.¹³ As a system safety approach encompasses the organization's context, processes and structures, which can have a sustainable influence on promoting safe care^{4,14} there is a need to study patient safety in the home healthcare setting.

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3 102 Hence, the overall aim of this study was to explore how patient safety is described and
4 103 addressed in specialized home healthcare from the perspectives of multidisciplinary teams and
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6 104 clinical managers.
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9 106 **METHODS**

10 107 *Design*

11 108 This qualitative study, based on semi-structured interviews with multidisciplinary
12 109 professionals and clinical managers, is part of a larger study on patient safety in home
13 110 healthcare settings.⁸
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16 112 *Setting*

17 113 Multidisciplinary teams and clinical managers were recruited from three specialized home
18 114 healthcare organizations in one regional healthcare authority in Sweden. Home healthcare in
19 115 Sweden is defined as healthcare that is administered in a patient's home or the equivalent, and
20 116 that is consistent over time,¹⁵ but does not encompass home care organizations with
21 117 unlicensed staff administering social care.
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24 119 The three studied units are tax-funded and cover a limited geographical area. They were
25 120 selected to capture socio-demographic differences in, e.g., country of birth and income. Each
26 121 unit consisted of ambulatory multidisciplinary teams, including four to six physicians, 20-30
27 122 registered nurses (RNs) and one of each of the allied healthcare staff: physiotherapist,
28 123 occupational therapist, dietitian and social worker. One unit had a few assistant nurses. The
29 124 RNs and physicians were available 24 hours a day. Each unit employed one head of
30 125 department and one or two first-line manager ("clinical managers"). The units provided long-
31 126 or short-term round-the-clock advanced care and treatment to patients with complex diseases
32 127 and symptoms.
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35 129 All units had in the last years expanded from providing traditional palliative home healthcare
36 130 to patients with a cancer diagnosis to providing specialized home healthcare to patients with
37 131 all kinds of diagnoses, based on changes in national regulations.¹⁶ The palliative care
38 132 ideology in this study is referred to as 'the care ideology' on the basis that it was applied to all
39 133 patients regardless of diagnosis. The cornerstones in the care ideology, can be summarized as
40 134 nearness, wholeness, knowledge, and empathy. The approach should further be based on
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135 continuity, good communication and support provided in accordance with patients and
136 relatives' wishes, in so far as possible.¹⁷

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138 **Data collection**

139 Nine focus group interviews with team members and seven individual interviews with clinical
140 managers were conducted between December 2013 and May 2014, including in total 51
141 participants (Table 1). The interview method was inspired by Kvale and Brinkmann.¹⁸ All
142 team members were invited to participate in a focus group interview. The groups were
143 deliberately composed so that the participants would feel comfortable discussing issues
144 relevant to their discipline and to capture a variety of perspectives on patient safety. The
145 heads of department approved performance of the study at their respective units.

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147 All interviews took place at the workplace at the start or end of a work shift. Focus group
148 interviews included 4-6 team members and lasted 60-90 minutes. Individual interviews lasted
149 30-60 minutes. The interviews were audio-recorded and the researcher took notes.

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151 The interviews were conducted by the first and last researcher (ML and ME). A semi-
152 structured interview guide was developed and tested in a pilot interview, after which minor
153 revisions were made. The interview guide consisted of open-ended questions, such as "Tell
154 me what patient safety means to you" and "Tell me about your experiences of what helps or
155 hinders patient safety in your daily work." In addition to questions on patient safety, the
156 clinical management interviews also included general questions on work organization. Both
157 verbal and non-verbal probing techniques were used to increase clarity.

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159 **Table 1. Overview of the interviews**

	Unit A	Unit B	Unit C
Focus group interviews	RNs (4 women) and Allied health staff (1 woman)	RNs (5 women)	Allied health staff (4 women)
	RNs (3 women) and Allied health staff (1 woman)	Allied health staff (4 women)	Physicians (3 men and 2 women)
		Physicians (3 men and 2 women)	RNs (4 women) and Assistant nurses (2 women)

			RNs (4 women) and Assistant nurse (1 woman)
Individual interviews	Head of department (1 man)	Head of department (1 man)	Head of department (1 man)
	First-line manager (1 man)	2 First-line managers (2 women)	First-line manager (1 woman)
			Physician (1 woman)
Total	11 (9 women, 2 men)	17 (13 women, 4 men)	23 (19 women, 4 men)

Registered nurse=RN

Data analysis

The data were transcribed verbatim and analysed using qualitative content analysis with an inductive approach.^{19,20} The transcripts were read through several times by all researchers, to get a sense of the data. All three researchers were involved in analysis, going from a concrete to a more abstract level. This included identification of meaning units, which were condensed, coded, and sorted into 19 subcategories based on differences and similarities. The subcategories were compared, sorted, interpreted and abstracted into one main theme and four categories. All researchers discussed the codes, categories and themes in relation to the transcripts until consensus was reached. The researchers ML and ME are registered nurses, MF is a social worker. All researchers have clinical experience from different settings. This manuscript does not contain personal medical information about an identifiable person

RESULTS

The results include one main theme *Keeping patients safe – a never-ending effort at all levels*, constituting the latent content of four categories: 1) Co-creating safety between patients and multidisciplinary teams in the mess on the floor; 2) Using complementary communication paths – an asset and a risk for patient safety; 3) High competence level and learning across disciplines – requirements for patient safety; 4) Macro-level system for patient safety not in alignment with meso- and micro-level goals. In general, there was a high level of consistency between respondents' opinions in the interviews, regardless of unit, clinical manager, or team members, unless otherwise stated.

Keeping patients safe – a never-ending effort at all levels

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3 185 The established care ideology formed a mind-set common to both multidisciplinary teams
4 186 (micro-level) and clinical managers (meso-level) on how to provide patient safety. Patient
5 187 safety was described by both multidisciplinary teams and clinical managers as related to a
6 188 patient's value as a person. Prevention of psychological harm, such as violated autonomy or
7 189 integrity, had the same priority as prevention of physical harm. This view influenced risk
8 190 management, in that a patient's preferences outweighed risks detected in the home care
9 191 environment. The care ideology was challenged by the emerging complexity in which priority
10 192 had to be given to standardised guidelines, quality assessments, management of information
11 193 flow in maladapted communication systems, and demands for certain competencies and skills.
12 194 Patient safety was an inherent part of the care ideology, not a goal in itself, and not always in
13 195 agreement with the regional county council (macro-level) directives.
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22 197 *I think it's good for patient safety, to get patients and family involved. It... I can't*
23 198 *imagine anything better than them knowing what they are putting in their mouth and*
24 199 *what pills they are taking. They know who to call when they don't recognize the*
25 200 *medication or... They ask us if we've sanitized our hands, if we're wearing aprons and*
26 201 *so on... That...it's an aspect of culture, safety culture, both as regards care...here at*
27 202 *the unit, and we take it along to our patients, since that's our work environment, so*
28 203 *the patients become part of the safety culture, and they should feel that they...that it's*
29 204 *their...I mean, it is their care (RN, unit C).*
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37 206 **Co-creating safety between patients and multidisciplinary teams in the mess on the floor**
38 207 The multidisciplinary teams were united by their care ideology and the strong belief that
39 208 establishing and maintaining sustainable, trusting relationships was the core of patient safety
40 209 work. The multidisciplinary teams showed respect for patients' and relatives' values, wishes,
41 210 and lifestyle through ensuring that there was time for conversation, to listen and take patients'
42 211 and relatives' knowledge, feelings and thoughts into account in their planning and
43 212 performance of care. By focusing on what mattered *for* the patient and relatives rather than
44 213 what the matter was *with* the patient, the multidisciplinary teams could respect the patient's
45 214 values. To fulfil the patient's wish to stay at home, the multidisciplinary teams undertook
46 215 several actions that might entail a patient safety risk. An example of such an action was to
47 216 delegate the medication administration to unlicensed staff in social care, as they could visit
48 217 the patient several times a day. In some cases, the team members found themselves caught
49 218 between the value of preventing a patient from potential harm and the value of respecting the
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3 219 patient's autonomy, especially for people with cognitive impairments who were living alone.
4 220 Each such case was a balancing act to help the patients stay at home without too much risk to
5 221 his/her safety.
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10 223 **The varied work environment, with "patient rooms" of various standards distributed over a**
11 224 **large area, was a health and safety risk for both patients and professionals.** A prioritized goal
12 225 to ensure wellbeing was to maintain a home-like atmosphere, though the home was also a
13 226 place for care. It was a dilemma to provide care in line with aseptic guidelines in a home
14 227 environment with narrow, unhygienic spaces, lack of clean areas for wound dressing or when
15 228 pets interfered with the patient during caregiving. **Arranging meetings with sufficient time to**
16 229 **build trustful relationships enabled co-creation of care based on each patient's or family's**
17 230 **wishes. This also allowed for including patients and families in active participation in**
18 231 **accordance with their abilities. Each team member contributed with their competence.**
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25 233 *Sometimes we get care-related injuries, infections in ports and so on. Some patients*
26 234 *want to touch things and help us when we are working and cleaning and switching*
27 235 *things, when it can be harmful. And that's not optimal, and when we don't have a*
28 236 *work area I have to... maybe the only work area we have is the lid on the box that we*
29 237 *put on the bed where the patient has urinated and defecated and which was last*
30 238 *made...the linen was changed maybe seven months ago, literally... Meanwhile, the*
31 239 *dog or cat shows up and starts licking and you have to... You're literally sitting like*
32 240 *this (like a hook) (RN, unit C).*
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40 242 **Using complementary communication paths – an asset and a risk for patient safety**
41 243 Both the clinical managers and multidisciplinary teams felt that written information needed to
42 244 be supplemented with verbal communication both when transferred within their own
43 245 organization and across institutional borders. Unstructured small talk in the hallways and
44 246 lunch room, as well as team meetings with a set structure for information transfer, enabled
45 247 creating a common view of the patients' and relatives' needs and giving reminders about
46 248 potential risks. Information exchange with other care providers involved in a patient's care
47 249 was described as equally important, but harder to facilitate. This kind of information exchange
48 250 with unlicensed staff was mostly conducted through notes in patient homes.
49 251 The coordinator at each unit was perceived as an effective barrier to information misses and
50 252 tended to be at the centre of communication. The coordinator was the team's access to the
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253 EHR during home visits and a “detective” to find current information and prescriptions from
254 other caregivers.

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256 *When it's that complicated, the meetings are great, when we have them. People meet*
257 *and check in with each other. It's really good; you have your computer to hand and*
258 *can look at the parameters, so to speak, that we are discussing. So that's the best*
259 *thing, you know, when we can communicate (first-line manager, unit A).*

260

261 The joint electronic health record (EHR) system implemented among all publicly funded care
262 providers – both in- and outpatient care – in the region, facilitated information transfer
263 between caregivers. However, shortcomings (e.g., lack of user-friendly software design or a
264 system for reminders and alerts) in the system and inconsistent documentation routines made
265 the information fragmented and easily lost. As the EHR was not accessible during home
266 visits, all essential information had to be reviewed beforehand. Team members noted
267 everything that they wanted to report on paper and documented in the EHR when they came
268 back from home visits. To compensate for the lack of overview in the EHR, a digital list of
269 tasks for each home visit was used. Nurses updated this “to-do list” manually and used it as
270 their primary tool for organizing their day. The tool, intended to make information accessible,
271 also created a risk that the EHR was not read as carefully as the to-do list.

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273 Information related to medication management was identified as the area that generated the
274 highest risk for information misses. The team members found it difficult to be up-to-date with
275 generic drugs, which were rapidly replaced as prices changed. For patients, this could lead to
276 the intake of double doses, due to interpreting similar medications as different. Such errors
277 were not easily discovered and created a sense of lacking control for team members and
278 unnecessary suffering for patients and relatives.

279

280 **High competence level and learning across disciplines – requirements for patient safety**

281 The team meetings were important for improving patient safety by sharing experiences and
282 learning from each other. The clinical managers tried to create a proactive, learning
283 environment by highlighting safety issues. These meetings were also essential for getting to
284 know each other, and each other's specific competences, across disciplinary borders. Thus,
285 the team members knew who to turn to when facing a problem in a patient home and they felt
286 comfortable calling each other for advice. This contributed to “a complementary knowledge

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3 287 base” that was broader than each individual’s knowledge. This reduced feeling of
4 288 vulnerability during the home visits conducted alone, when rapid decisions had to be made.
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8 290 *... We’re all alone out there, we really are... The chart system and medication lists and so*
9 291 *on can’t be accessed there... (RN, unit B)... All those assessments that you feel quite alone*
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11 292 *in making, you can be unsure... That’s probably the most important aspect of the team,*
12 293 *being based on parts and adding them all on top of each other. Then you usually get*
13 294 *some kind of bigger picture regarding the patient (RN, unit A) ... You get an enormous*
14 295 *strength in the team actually, so if you’ve been thinking about something there’ll be*
15 296 *someone... who has another view and then you can get a bigger picture, which is very*
16 297 *helpful. One plus one is three (physician, unit B).*
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22 299 The broad spectra of diagnoses and rapid development of treatments and related technical
23 300 devices that patients received during periods of hospitalization made it hard for the
24 301 multidisciplinary teams to stay informed and updated. The clinical managers were worried
25 302 that the level of competence and quality of care was threatened as the units expanded and new
26 303 staff was introduced. Clinical managers strived to counteract this by scheduling new staff to
27 304 work alongside experienced staff and organized training when new medical technology or
28 305 new policies were introduced. The multidisciplinary teams, in turn, felt that the training
29 306 lagged behind the rapid implementation of new technology.
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36 308 **Macro-level system for patient safety not in alignment with meso- and micro-level goals**
37 309 The quality of care of the home healthcare organizations was evaluated through regular use of
38 310 about 40 quality indicators, tailored to the county level demands. The organizations depend on
39 311 reimbursement, which is based on these indicators. Both the multidisciplinary teams and
40 312 clinical managers felt that the quality indicators poorly reflected quality improvement or
41 313 patient safety in their daily work. The clinical managers had been invited by the county
42 314 council to participate in the selection of quality indicators, but felt that their perspectives had
43 315 little impact.
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50 317 *We are presented with statistics now every quarter for the existing system, and we shake*
51 318 *our heads every time and we don’t feel our work is reflected in the numbers they show us*
52 319 *from the system we already have. So, can we possibly understand a change? No, it won’t*
53 320 *happen. Not that way (head of department, unit A).*
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4 322 The multidisciplinary teams described that patients were overwhelmed by the number of
5 323 quality indicators, as some were collected biweekly for all patients, regardless of diagnosis.
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7 324 As most of the indicators were general and not adapted to specific patient groups, both
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9 325 managers and teams perceived that little freedom was left to introduce additional measures
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11 326 targeting each individual patient's needs. In cases where the assessments were useful for the
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13 327 patient's care, the teams needed to register the data twice, as the quality indicator registries
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15 328 were not compatible with the EHR.
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18 330 Both clinical managers and the multidisciplinary teams described the incident reporting
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20 331 system as an ongoing patient safety effort, for learning about and communicating patient
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22 332 safety issues. The team members described a dilemma in reporting events where colleagues
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24 333 were involved, as they did not want to implicate anyone. Managers prioritized analyses of
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26 334 adverse events and risks. The communication back to the team members, intended to improve
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28 335 patient safety, usually consisted of new guidelines. The team members described them as
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30 336 complicated multi-step guidelines and felt it was difficult to stay up-to-date. Trade-offs were
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32 337 common, as the guidelines sometimes contradicted each other and did not fit all the possible
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34 338 situations in patient homes. The clinical managers were aware that trade-offs were inevitable
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36 339 and gave the professionals a high degree of freedom to make decisions to promote patient
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38 340 safety.
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41 342 **DISCUSSION**

42 343 The main results of this explorative study show that patient safety in specialized home
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44 344 healthcare is a continuous effort at all levels of the system, while keeping the patient
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46 345 perspective in mind. The well-established care ideology in the studied context shaped a
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48 346 common mind-set between members in the multidisciplinary teams and clinical managers,
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50 347 which seemed to form a patient safety culture. Shared values, attitudes, beliefs, behaviours,
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52 348 and practices are features of a workplace culture.²¹ In healthcare, a recent review across a
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54 349 variety of settings showed a consistent association between workplace culture and patient
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56 350 outcomes. However, most of the included studies were cross-sectional, using a wide range of
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58 351 different definitions and measurements of culture, environment, and patient outcomes, and
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60 352 most studies were conducted in hospital settings.²² Safety culture in home healthcare has not
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62 353 yet been widely explored.²³ In the current study, the care ideology fostered shared values and
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64 354 practices across the multidisciplinary teams, promoting patient safety by giving the patient's

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3 355 goals and autonomy priority in decisions about care. Such a person-centred perspective, has
4 356 been on the political agenda for years, but is still poorly implemented in Sweden.²⁴ In most
5 357 healthcare environments, there have been difficulties associated with involving patients as
6 358 equal partners in care, due to lack of private rooms or communication, time pressures, a
7 359 traditional work structure, and professionals' attitudes, for example.²⁵ By contrast in this
8 360 study, in the home healthcare environment, patients were in charge of self-care activities
9 361 around the clock, with assistance from team members who carried out treatment that patients
10 362 couldn't perform themselves. However, the shared values that guided the team members in
11 363 their safety work also implied risks. For example, hygiene guidelines did not mesh with the
12 364 home healthcare environment or patients' preferences and behaviours. The Multidisciplinary
13 365 teams in this study perceived a dilemma in contradicting a patient's will, i.e., going against
14 366 the ideology, even when patient safety was in danger. A strong ideology could therefore be
15 367 both a facilitator and a barrier to patient safety, depending on which value was given highest
16 368 priority.
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18 370 There is a widely accepted view that care at home is safer than institutional care, including to
19 371 the risk of infections at hospital.²⁶ In this study, the work environment in home healthcare
20 372 was highly unstable, as it is not designed to reduce medical errors and equipment problems or
21 373 assist infection control. Thus, safe home healthcare is highly dependent on team members
22 374 ability to adapt to the varying conditions and on patients being informed and capable of
23 375 adjusting their homes and behaviours to reduce safety risks. This study exemplifies how the
24 376 multidisciplinary teams, by building trusting relationships with patients and their relatives,
25 377 promoted a care environment in concert with each patient's specific preferences and needs.
26 378 This is in line with other studies showing that the relationship with health providers is central
27 379 for older people feeling supported and cared for at home, and that a tense relation implied a
28 380 risk of patient harm.²⁷ It is also in line with resilient healthcare, which is defined by its ability
29 381 to adapt to unpredictable, unstable environments and remain intact and functional despite
30 382 threats to care performance²⁸ at the sharp end, i.e., the point where the patient meets
31 383 healthcare. Resilience at the sharp end also depends on adaptability at the management level.
32 384 As shown in another study, at this level of the system, adaptations involve rapid
33 385 reorganization of work as a response to disturbances, providing sufficient supplies and
34 386 freedom for professionals to prioritize, adapt and take time to provide the care that patient
35 387 needs.²⁹
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3 389 **In the current study,** at the macro-level, the steering mechanisms to promote quality and
4 390 safety were built around a large number of mandatory quality assessments. These were
5 391 combined with economic reimbursements or fines, depending on the degree of observance. At
6 392 both the micro- and meso-levels of the system, these assessments were perceived as stealing
7 393 valuable time from 'real' quality improvement work from there's point of view. The quality
8 394 indicators were sparsely used in the daily work as they rarely fit patients' specific needs, and
9 395 did not align with coordinating effective, safe, and comprehensive home healthcare.³ Incident
10 396 reporting is another measure for improving safety that has been used with great success in
11 397 other high-risk organizations (e.g., nuclear, railway and car industry).³⁰ Even if there is
12 398 limited evidence on how incident reporting actually contributes to safety in healthcare,³¹ it is
13 399 a globally accepted method. A common clinical management reaction to incident reports was
14 400 to produce new guidelines, although it is well-known that trade-offs are commonplace in daily
15 401 work.^{29 32} Strategies and behaviours to work around problematic practical processes have
16 402 been shown to either promote or hinder patient safety.³³ McDonald et al³⁴ found that
17 403 managers believed that adherence to standardized processes promoted patient safety, which
18 404 contrasts with the findings in this study, where the clinician managers were aware that the
19 405 multidisciplinary teams made trade-offs to promote patient safety. Standardizations assume
20 406 causality, that care is predictable, and that adverse events can be prevented through rules and
21 407 guidelines.³⁵ As the complexity in healthcare systems increases, the usefulness of the incident
22 408 reporting system in improving patient safety is disputed. The criticism concerns its use for
23 409 counting incidents instead of effective analysis leading to meaningful changes and
24 410 organizational learning.³⁶ To substantially improve patient safety in home healthcare, we
25 411 need to develop reliable and valuable methods that enable studying the dynamic complexity
26 412 of the system at different levels.³⁷ The guidelines and quality assessments, aimed to promote
27 413 patient safety from a macro-perspective, constrained the team members freedom to adapt to
28 414 challenges and provide safe care based on the shared care ideology. This indicates that if
29 415 standardization is to be used as a tool to promote patient safety, it must be aligned with a
30 416 culture based on patient values and goals, where calculated risks are taken into account.

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50 418 **This research has some limitations to consider. The selection of settings, situated in the same**
51 419 **urban area of Sweden, may limit the extent to which our findings can be transferred to rural**
52 420 **settings or other regions. The number of participants was lower than expected in some focus**
53 421 **groups, due to the high workload, which may have limited the dynamics of the discussions.**
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56 422 **However, a strength of the study is that all professions in the multidisciplinary teams from**
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3 423 different settings were represented, and the interviews were characterized by rich variations
4 424 and deep descriptions of patient safety in specialized home healthcare.³⁸ To further broaden
5 425 the understanding of patient safety in home healthcare, patients, and their relatives could be
6 426 involved. To make us aware of biases and preconceptions, we adopted a self-critical attitude
7 427 and constantly reflected on our own thoughts and mind-sets, so as to strengthen the
8 428 trustworthiness of data.^{20 38} To reduce bias, we used research triangulation in all analyses and
9 429 interpretations of data.³⁸ Finally, interpretation of the results should be made with the delay
10 430 between data collection and publication kept in mind.
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432 **Conclusion**

433 The dynamic and complex conditions under which home healthcare operate are fundamentally
434 different from hospital care. Patient safety in the home healthcare is grounded in close
435 multidisciplinary team collaboration based on a care ideology enhancing co-creation of care
436 through patient autonomy, competence and relatedness. Thus, providing care included
437 weighing risks against patients' preferences and will. Standardization and quality assessments
438 introduced for improvement of care are contrasted against team members adaptations and
439 patient behaviours and preferences, that set the limits for safety.
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441 **List of abbreviations**

442 EHR Electronic health record

443 RN Registered nurse

444

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448 publication.
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450 **Competing interests** None declared

451

452 **Contributors** ML and ME designed and conducted the study. All authors (ML, MF, ME)
453 jointly contributed with their expertise in methodology, patient safety and home healthcare.
454 All authors were part of the analysis process, drafted the manuscript and agreed to the final
455 version of the manuscript before submission.
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3 457 **Ethics approval** This study was approved by the Regional Ethical Review Committee in
4 458 Sweden, Stockholm (DNr: 2012/1384:31).

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6 460 **Data sharing statement**

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8 461 Supplementary and raw data available upon request.

9 462

10 463 **Patient and Public Involvement statement**

11 464 Patients were not involved in this study.

12 465

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14 467 managers at the three specialized home healthcare units.

15 468

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Exploring patient safety in Swedish specialized home healthcare - an interview study with multidisciplinary teams and clinical managers

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Exploring patient safety in Swedish specialized home healthcare - an interview study with multidisciplinary teams and clinical managers

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10 33 **ABSTRACT**

11 34 **Objective** Home healthcare is the fastest growing arena in the healthcare system but patient
12 35 safety research in this context is limited. The aim was to explore patient safety in Swedish
13 36 specialized home healthcare from multidisciplinary teams' and clinical managers' perspectives.

14 37 **Design** An explorative qualitative study.

15 38 **Setting** Multidisciplinary teams' and clinical managers were recruited from three specialized
16 39 home healthcare organizations in Sweden.

17 40 **Methods** Nine focus group interviews with multidisciplinary teams and six individual interviews
18 41 with clinical managers were conducted, in total 51 participants. The data were transcribed
19 42 verbatim and analyzed using qualitative content analysis.

20 43 **Results** Patient safety was inherent in the well-established care ideology which shaped a common
21 44 mind-set between members in the multidisciplinary teams and clinical managers. This patient
22 45 safety culture was challenged by the emerging complexity in which priority had to be given to
23 46 standardised guidelines, quality assessments and management of information in maladapted
24 47 communication systems and demands for required competence and skills. The multiple
25 48 guidelines and quality assessments that aimed to promote patient safety from a macro-
26 49 perspective, constrained the freedom, on a meso- and micro-level, to adapt to challenges based on
27 50 the care ideology.

28 51 **Conclusion** Patient safety in home healthcare is dependent on adaptability at the management
29 52 level; the team members' ability to adapt to the varying conditions and on patients being capable
30 53 of adjusting their homes and behaviours to reduce safety risks. A strong culture related to a
31 54 patient's value as a person where patients' and families' active participation and preferences
32 55 guides the decisions, could be both a facilitator and a barrier to patient safety, depending on
33 56 which value is given highest priority.

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Strengths and limitations of this study

- Trustworthiness have been strengthened by research triangulation, setting triangulation, and participant triangulation.
- We have lower numbers of participants than expected in each focus group due to the high workload.
- The selection of settings, situated in the same urban area of Sweden, may limit the extent to which our findings can be transferred to rural settings or other regions.

BACKGROUND

Healthcare is becoming more complex and provision of care in people's homes is increasing, both globally¹ and in Sweden,² driven by medical and technical advances, economic pressures, demographic factors, and patient preferences.³ However, most patient safety research is conducted in hospital settings, while home healthcare is largely unexplored.⁴ Thus, evidence from hospital-based research has also been applied to home healthcare. In recent years, this has been criticized based on the knowledge that patient safety is largely context-dependent.^{5,6}

The few existing home healthcare-specific studies on patient safety, have highlighted unique safety issues and the occurrence of adverse events. The specific patient safety challenges in home healthcare include fragmentation of care, care providers working in isolation and inadequate communication between different care providers.^{7,8} A recent interview study found that the perspectives of patients and their carers on patient safety contributed to safe home healthcare and were equally important as those of healthcare professionals for improving patient safety.⁵ Studies of adverse events in home healthcare have shown a wide variation in the estimations, with 13% in Canada⁹⁻¹¹ and 37.7% in Sweden.¹² The types of adverse events were similar in both countries – falls, healthcare-associated infections, pressure ulcers – and most were considered to be preventable. I en intervjustudie framkom det att patienter och närståendes perspektiv på patientsäkerhet bidrar till säker vård lika mycket som vårdpersonalens (Jones 2016).

94
95 With a few exceptions, e.g., healthcare-associated infections, the patient safety research is
96 increasingly based on the premise that harm is mainly the result of poorly designed systems.¹³ As
97 a system safety approach encompasses the organization's context, processes and structures,
98 which can have a sustainable influence on promoting safe care^{4 14} there is a need to study patient
99 safety in the home healthcare setting.

100
101 Hence, the overall aim of this study was to explore how patient safety is described and addressed
102 in specialized home healthcare from the perspectives of multidisciplinary teams and clinical
103 managers.

104 105 **METHODS**

106 *Design*

107 This qualitative study, based on semi-structured interviews with multidisciplinary professionals
108 and clinical managers, is part of a larger study on patient safety in home healthcare settings.⁸

109 110 *Setting*

111 Multidisciplinary teams and clinical managers were recruited from three specialized home
112 healthcare organizations in one regional healthcare authority in Sweden. Home healthcare in
113 Sweden is defined as healthcare that is administered in a patient's home or the equivalent, and
114 that is consistent over time,¹⁵ but does not encompass home care organizations with unlicensed
115 staff administering social care.

116
117 The three studied units are tax-funded and cover a limited geographical area. They were selected
118 to capture socio-demographic differences in, e.g., country of birth and income. Each unit
119 consisted of ambulatory multidisciplinary teams, including four to six physicians, 20-30
120 registered nurses (RNs) and one of each of the allied healthcare staff: physiotherapist,
121 occupational therapist, dietitian and social worker. One unit had a few assistant nurses. The RNs
122 and physicians were available 24 hours a day. Each unit employed one head of department and
123 one or two first-line manager ("clinical managers"). The units provided long- or short-term
124 round-the-clock advanced care and treatment to patients with complex diseases and symptoms.

1
2
3 125
4
5 126 All units had in the last years expanded from providing traditional palliative home healthcare to
6 127 patients with a cancer diagnosis to providing specialized home healthcare to patients with all
7
8 128 kinds of diagnoses, based on changes in national regulations.¹⁶ The palliative care ideology in
9
10 129 this study is referred to as ‘the care ideology’ on the basis that it was applied to all patients
11
12 130 regardless of diagnosis. The cornerstones in the care ideology, can be summarized as nearness,
13 131 wholeness, knowledge, and empathy. The approach should further be based on continuity, good
14
15 132 communication and support provided in accordance with patients and relatives’ wishes, in so far
16
17 133 as possible.¹⁷

18 134

20 135 **Data collection**

21
22 136 Nine focus group interviews with team members and seven individual interviews with clinical
23
24 137 managers were conducted between December 2013 and May 2014, including in total 51
25
26 138 participants (Table 1). The interview method was inspired by Kvale and Brinkmann.¹⁸ All team
27
28 139 members were invited to participate in a focus group interview. The groups were deliberately
29
30 140 composed so that the participants would feel comfortable discussing issues relevant to their
31
32 141 discipline and to capture a variety of perspectives on patient safety. The heads of department
33
34 142 approved performance of the study at their respective units.

35 143
36 144 All interviews took place at the workplace at the start or end of a work shift. Focus group
37
38 145 interviews included 4-6 team members and lasted 60-90 minutes. Individual interviews lasted 30-
39
40 146 60 minutes. The interviews were audio-recorded and the researcher took notes.

41 147
42
43 148 The interviews were conducted by the first and last researcher (ML and ME). A semi-structured
44
45 149 interview guide was developed and tested in a pilot interview, after which minor revisions were
46
47 150 made. The interview guide consisted of open-ended questions, such as “Tell me what patient
48
49 151 safety means to you” and “Tell me about your experiences of what helps or hinders patient safety
50
51 152 in your daily work.” In addition to questions on patient safety, the clinical management
52
53 153 interviews also included general questions on work organization. Both verbal and non-verbal
54
55 154 probing techniques were used to increase clarity.

56 155

156 **Table 1. Overview of the interviews**

	Unit A	Unit B	Unit C
Focus group interviews	RNs (4 women) and Allied health staff (1 woman)	RNs (5 women)	Allied health staff (4 women)
	RNs (3 women) and Allied health staff (1 woman)	Allied health staff (4 women)	Physicians (3 men and 2 women)
		Physicians (3 men and 2 women)	RNs (4 women) and Assistant nurses (2 women)
			RNs (4 women) and Assistant nurse (1 woman)
Individual interviews	Head of department (1 man)	Head of department (1 man)	Head of department (1 man)
	First-line manager (1 man)	2 First-line managers (2 women)	First-line manager (1 woman)
			Physician (1 woman)
Total	11 (9 women, 2 men)	17 (13 women, 4 men)	23 (19 women, 4 men)

157 Registered nurse=RN
 158

159 **Data analysis**

160 The data were transcribed verbatim and analysed using qualitative content analysis with an
 161 inductive approach.^{19 20} The transcripts were read through several times by all researchers, to get
 162 a sense of the data. All three researchers were involved in analysis, going from a concrete to a
 163 more abstract level. This included identification of meaning units, which were condensed, coded,
 164 and sorted into 19 subcategories based on differences and similarities. The subcategories were
 165 compared, sorted, interpreted and abstracted into one main theme and four categories. All
 166 researchers discussed the codes, categories and themes in relation to the transcripts until
 167 consensus was reached. The researchers ML and ME are registered nurses, MF is a social worker.
 168 All researchers have clinical experience from different settings. This manuscript does not contain
 169 personal medical information about an identifiable person.

171 **Patient and Public Involvement statement**

1
2
3 172 Patients were not involved in this study.
4
5 173

6
7 174 **RESULTS**

8 175 The results include one main theme *Keeping patients safe – a never-ending effort at all levels*,
9
10 176 constituting the latent content of four categories: 1) Co-creating safety between patients and
11
12 177 multidisciplinary teams in the mess on the floor; 2) Using complementary communication paths –
13
14 178 an asset and a risk for patient safety; 3) High competence level and learning across disciplines –
15
16 179 requirements for patient safety; 4) Macro-level system for patient safety not in alignment with
17
18 180 meso- and micro-level goals. In general, there was a high level of consistency between
19
20 181 respondents' opinions in the interviews, regardless of unit, clinical manager, or team members,
21
22 182 unless otherwise stated.
23

24 184 ***Keeping patients safe – a never-ending effort at all levels***

25 185 The established care ideology formed a mind-set common to both multidisciplinary teams
26
27 186 (micro-level) and clinical managers (meso-level) on how to provide patient safety. Patient safety
28
29 187 was described by both multidisciplinary teams and clinical managers as related to a patient's
30
31 188 value as a person. Prevention of psychological harm, such as violated autonomy or integrity, had
32
33 189 the same priority as prevention of physical harm. This view influenced risk management, in that a
34
35 190 patient's preferences outweighed risks detected in the home care environment. The care ideology
36
37 191 was challenged by the emerging complexity in which priority had to be given to standardised
38
39 192 guidelines, quality assessments, management of information flow in maladapted communication
40
41 193 systems, and demands for certain competencies and skills. Patient safety was an inherent part of
42
43 194 the care ideology, not a goal in itself, and not always in agreement with the regional county
44
45 195 council (macro-level) directives.
46

46 197 *I think it's good for patient safety, to get patients and family involved. It... I can't imagine*
47
48 198 *anything better than them knowing what they are putting in their mouth and what pills*
49
50 199 *they are taking. They know who to call when they don't recognize the medication or...*
51
52 200 *They ask us if we've sanitized our hands, if we're wearing aprons and so on... That...it's*
53
54 201 *an aspect of culture, safety culture, both as regards care...here at the unit, and we take it*
55
56 202 *along to our patients, since that's our work environment, so the patients become part of*

203 *the safety culture, and they should feel that they...that it's their...I mean, it is their care*
204 *(RN, unit C).*

206 ***Co-creating safety between patients and multidisciplinary teams in the mess on the floor***

207 The multidisciplinary teams were united by their care ideology and the strong belief that
208 establishing and maintaining sustainable, trusting relationships was the core of patient safety
209 work. The multidisciplinary teams showed respect for patients' and relatives' values, wishes, and
210 lifestyle through ensuring that there was time for conversation, to listen and take patients' and
211 relatives' knowledge, feelings and thoughts into account in their planning and performance of
212 care. By focusing on what mattered *for* the patient and relatives rather than what the matter was
213 *with* the patient, the multidisciplinary teams could respect the patient's values. To fulfil the
214 patient's wish to stay at home, the multidisciplinary teams undertook several actions that might
215 entail a patient safety risk. An example of such an action was to delegate the medication
216 administration to unlicensed staff in social care, as they could visit the patient several times a
217 day. In some cases, the team members found themselves caught between the value of preventing
218 a patient from potential harm and the value of respecting the patient's autonomy, especially for
219 people with cognitive impairments who were living alone. Each such case was a balancing act to
220 help the patients stay at home without too much risk to his/her safety.

222 The varied work environment, with "patient rooms" of various standards distributed over a large
223 area, was a health and safety risk for both patients and professionals. A prioritized goal to ensure
224 wellbeing was to maintain a home-like atmosphere, though the home was also a place for care. It
225 was a dilemma to provide care in line with aseptic guidelines in a home environment with
226 narrow, unhygienic spaces, lack of clean areas for wound dressing or when pets interfered with
227 the patient during caregiving. Arranging meetings with sufficient time to build trustful
228 relationships enabled co-creation of care based on each patient's or family's wishes. This also
229 allowed for including patients and families in active participation in accordance with their
230 abilities. Each team member contributed with their competence.

232 *Sometimes we get care-related injuries, infections in ports and so on. Some patients want*
233 *to touch things and help us when we are working and cleaning and switching things,*

1
2
3 234 *when it can be harmful. And that's not optimal, and when we don't have a work area I*
4 *have to... maybe the only work area we have is the lid on the box that we put on the bed*
5 235 *where the patient has urinated and defecated and which was last made...the linen was*
6 236 *changed maybe seven months ago, literally... Meanwhile, the dog or cat shows up and*
7 *starts licking and you have to... You're literally sitting like this (like a hook) (RN, unit C).*
8
9
10 238
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12 239

13 240 **Using complementary communication paths – an asset and a risk for patient safety**

14 241 Both the clinical managers and multidisciplinary teams felt that written information needed to be
15
16 242 supplemented with verbal communication both when transferred within their own organization
17
18 243 and across institutional borders. Unstructured small talk in the hallways and lunch room, as well
19
20 244 as team meetings with a set structure for information transfer, enabled creating a common view
21
22 245 of the patients' and relatives' needs and giving reminders about potential risks. Information
23
24 246 exchange with other care providers involved in a patient's care was described as equally
25
26 247 important, but harder to facilitate. This kind of information exchange with unlicensed staff was
27
28 248 mostly conducted through notes in patient homes.

29 249 The coordinator at each unit was perceived as an effective barrier to information misses and
30
31 250 tended to be at the centre of communication. The coordinator was the team's access to the
32
33 251 electronic health record (EHR) during home visits and a "detective" to find current information
34
35 252 and prescriptions from other caregivers.

36 253
37 254 *When it's that complicated, the meetings are great, when we have them. People meet and*
38 255 *check in with each other. It's really good; you have your computer to hand and can look*
39 256 *at the parameters, so to speak, that we are discussing. So that's the best thing, you know,*
40 257 *when we can communicate (first-line manager, unit A).*
41
42 258

43 259 The joint EHR system implemented among all publicly funded care providers – both in- and
44
45 260 outpatient care – in the region, facilitated information transfer between caregivers. However,
46
47 261 shortcomings (e.g., lack of user-friendly software design or a system for reminders and alerts) in
48
49 262 the system and inconsistent documentation routines made the information fragmented and easily
50
51 263 lost. As the EHR was not accessible during home visits, all essential information had to be
52
53 264 reviewed beforehand. Team members noted everything that they wanted to report on paper and
54
55 265 documented in the EHR when they came back from home visits. To compensate for the lack of
56
57 266 overview in the EHR, a digital list of tasks for each home visit was used. Nurses updated this "to-

267 do list” manually and used it as their primary tool for organizing their day. The tool, intended to
268 make information accessible, also created a risk that the EHR was not read as carefully as the to-
269 do list.

270
271 Information related to medication management was identified as the area that generated the
272 highest risk for information misses. The team members found it difficult to be up-to-date with
273 generic drugs, which were rapidly replaced as prices changed. For patients, this could lead to the
274 intake of double doses, due to interpreting similar medications as different. Such errors were not
275 easily discovered and created a sense of lacking control for team members and unnecessary
276 suffering for patients and relatives.

277
278 **High competence level and learning across disciplines – requirements for patient safety**
279 The team meetings were important for improving patient safety by sharing experiences and
280 learning from each other. The clinical managers tried to create a proactive, learning environment
281 by highlighting safety issues. These meetings were also essential for getting to know each other,
282 and each other’s specific competences, across disciplinary borders. Thus, the team members
283 knew who to turn to when facing a problem in a patient home and they felt comfortable calling
284 each other for advice. This contributed to “a complementary knowledge base” that was broader
285 than each individual’s knowledge. This reduced feeling of vulnerability during the home visits
286 conducted alone, when rapid decisions had to be made.

287
288 *...We’re all alone out there, we really are...The chart system and medication lists and so on*
289 *can’t be accessed there... (RN, unit B)...All those assessments that you feel quite alone in*
290 *making, you can be unsure... That’s probably the most important aspect of the team, being*
291 *based on parts and adding them all on top of each other. Then you usually get some kind of*
292 *bigger picture regarding the patient (RN, unit A) ...You get an enormous strength in the team*
293 *actually, so if you’ve been thinking about something there’ll be someone...who has another*
294 *view and then you can get a bigger picture, which is very helpful. One plus one is three*
295 *(physician, unit B).*

296

1
2
3 297 The broad spectra of diagnoses and rapid development of treatments and related technical devices
4
5 298 that patients received during periods of hospitalization made it hard for the multidisciplinary
6
7 299 teams to stay informed and updated. The clinical managers were worried that the level of
8
9 300 competence and quality of care was threatened as the units expanded and new staff was
10
11 301 introduced. Clinical managers strived to counteract this by scheduling new staff to work
12
13 302 alongside experienced staff and organized training when new medical technology or new policies
14
15 303 were introduced. The multidisciplinary teams, in turn, felt that the training lagged behind the
16
17 304 rapid implementation of new technology.

305 **Macro-level system for patient safety not in alignment with meso- and micro-level goals**

18 306 The quality of care of the home healthcare organizations was evaluated through regular use of
19
20 307 about 40 quality indicators, tailored to the county level demands. The organizations depend on
21
22 308 reimbursement, which is based on these indicators. Both the multidisciplinary teams and clinical
23
24 309 managers felt that the quality indicators poorly reflected quality improvement or patient safety in
25
26 310 their daily work. The clinical managers had been invited by the county council to participate in
27
28 311 the selection of quality indicators, but felt that their perspectives had little impact.
29
30 312

31 313
32 314 *We are presented with statistics now every quarter for the existing system, and we shake our*
33 315 *heads every time and we don't feel our work is reflected in the numbers they show us from the*
34 316 *system we already have. So, can we possibly understand a change? No, it won't happen. Not*
35 317 *that way (head of department, unit A).*
36
37 318

38
39 319 The multidisciplinary teams described that patients were overwhelmed by the number of quality
40
41 320 indicators, as some were collected biweekly for all patients, regardless of diagnosis. As most of
42
43 321 the indicators were general and not adapted to specific patient groups, both managers and teams
44
45 322 perceived that little freedom was left to introduce additional measures targeting each individual
46
47 323 patient's needs. In cases where the assessments were useful for the patient's care, the teams
48
49 324 needed to register the data twice, as the quality indicator registries were not compatible with the
50
51 325 EHR.

52 326
53
54 327 Both clinical managers and the multidisciplinary teams described the incident reporting system as
55
56 328 an ongoing patient safety effort, for learning about and communicating patient safety issues. The

1
2
3 329 team members described a dilemma in reporting events where colleagues were involved, as they
4
5 330 did not want to implicate anyone. Managers prioritized analyses of adverse events and risks. The
6
7 331 communication back to the team members, intended to improve patient safety, usually consisted
8
9 332 of new guidelines. The team members described them as complicated multi-step guidelines and
10
11 333 felt it was difficult to stay up-to-date. Trade-offs were common, as the guidelines sometimes
12
13 334 contradicted each other and did not fit all the possible situations in patient homes. The clinical
14
15 335 managers were aware that trade-offs were inevitable and gave the professionals a high degree of
16
17 336 freedom to make decisions to promote patient safety.

18 337 19 338 **DISCUSSION**

20 339 The main results of this explorative study show that patient safety in specialized home healthcare
21
22 340 is a continuous effort at all levels of the system, while keeping the patient perspective in mind.
23
24 341 The well-established care ideology in the studied context shaped a common mind-set between
25
26 342 members in the multidisciplinary teams and clinical managers, which seemed to form a patient
27
28 343 safety culture. Shared values, attitudes, beliefs, behaviours, and practices are features of a
29
30 344 workplace culture. ²¹ In healthcare, a recent review across a variety of settings showed a
31
32 345 consistent association between workplace culture and patient outcomes. However, most of the
33
34 346 included studies were cross-sectional, using a wide range of different definitions and
35
36 347 measurements of culture, environment, and patient outcomes, and most studies were conducted in
37
38 348 hospital settings. ²² Safety culture in home healthcare has not yet been widely explored. ²³ In the
39
40 349 current study, the care ideology fostered shared values and practices across the multidisciplinary
41
42 350 teams, promoting patient safety by giving the patient's goals and autonomy priority in decisions
43
44 351 about care. Such a person-centred perspective, has been on the political agenda for years, but is
45
46 352 still poorly implemented in Sweden. ²⁴ In most healthcare environments, there have been
47
48 353 difficulties associated with involving patients as equal partners in care, due to lack of private
49
50 354 rooms or communication, time pressures, a traditional work structure, and professionals'
51
52 355 attitudes, for example. ²⁵ By contrast in this study, in the home healthcare environment, patients
53
54 356 were in charge of self-care activities around the clock, with assistance from team members who
55
56 357 carried out treatment that patients couldn't perform themselves. However, the shared values that
57
58 358 guided the team members in their safety work also implied risks. For example, hygiene
59
60 359 guidelines did not mesh with the home healthcare environment or patients' preferences and

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3 360 behaviours. The Multidisciplinary teams in this study perceived a dilemma in contradicting a
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5 361 patient's will, i.e., going against the ideology, even when patient safety was in danger. A strong
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7 362 ideology could therefore be both a facilitator and a barrier to patient safety, depending on which
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9 363 value was given highest priority.

10 364
11 365 There is a widely accepted view that care at home is safer than institutional care, including to the
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13 366 risk of infections at hospital.²⁶ In this study, the work environment in home healthcare was
14
15 367 highly unstable, as it is not designed to reduce medical errors and equipment problems or assist
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17 368 infection control. Thus, safe home healthcare is highly dependent on team members ability to
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19 369 adapt to the varying conditions and on patients being informed and capable of adjusting their
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21 370 homes and behaviours to reduce safety risks. This study exemplifies how the multidisciplinary
22
23 371 teams, by building trusting relationships with patients and their relatives, promoted a care
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25 372 environment in concert with each patient's specific preferences and needs. This is in line with
26
27 373 other studies showing that the relationship with health providers is central for older people
28
29 374 feeling supported and cared for at home, and that a tense relation implied a risk of patient harm.
30
31 375 ²⁷ It is also in line with resilient healthcare, which is defined by its ability to adapt to
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33 376 unpredictable, unstable environments and remain intact and functional despite threats to care
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35 377 performance²⁸ at the sharp end, i.e., the point where the patient meets healthcare. Resilience at
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37 378 the sharp end also depends on adaptability at the management level. As shown in another study,
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39 379 at this level of the system, adaptations involve rapid reorganization of work as a response to
40
41 380 disturbances, providing sufficient supplies and freedom for professionals to prioritize, adapt and
42
43 381 take time to provide the care that patient needs.²⁹

44 382
45 383 In the current study, at the macro-level, the steering mechanisms to promote quality and safety
46
47 384 were built around a large number of mandatory quality assessments. These were combined with
48
49 385 economic reimbursements or fines, depending on the degree of observance. At both the micro-
50
51 386 and meso-levels of the system, these assessments were perceived as stealing valuable time from
52
53 387 'real' quality improvement work from their point of view. The quality indicators were sparsely
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55 388 used in the daily work as they rarely fit patients' specific needs, and did not align with
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57 389 coordinating effective, safe, and comprehensive home healthcare.³ Incident reporting is another
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59 390 measure for improving safety that has been used with great success in other high-risk

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3 391 organizations (e.g., nuclear, railway and car industry).³⁰ Even if there is limited evidence on how
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5 392 incident reporting actually contributes to safety in healthcare,³¹ it is a globally accepted method.
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7 393 A common clinical management reaction to incident reports was to produce new guidelines,
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9 394 although it is well-known that trade-offs are commonplace in daily work.^{29 32} Strategies and
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11 395 behaviours to work around problematic practical processes have been shown to either promote or
12
13 396 hinder patient safety.³³ McDonald et al³⁴ found that managers believed that adherence to
14
15 397 standardized processes promoted patient safety, which contrasts with the findings in this study,
16
17 398 where the clinical managers were aware that the multidisciplinary teams made trade-offs to
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19 400 promote patient safety. Standardizations assume causality, that care is predictable, and that
20
21 401 adverse events can be prevented through rules and guidelines.³⁵ As the complexity in healthcare
22
23 402 systems increases, the usefulness of the incident reporting system in improving patient safety is
24
25 403 disputed. The criticism concerns its use for counting incidents instead of effective analysis
26
27 404 leading to meaningful changes and organizational learning.³⁶ To substantially improve patient
28
29 405 safety in home healthcare, we need to develop reliable and valuable methods that enable studying
30
31 406 the dynamic complexity of the system at different levels.³⁷ The guidelines and quality
32
33 407 assessments, aimed to promote patient safety from a macro-perspective, constrained the team
34
35 408 members freedom to adapt to challenges and provide safe care based on the shared care ideology.
36
37 409 This indicates that if standardization is to be used as a tool to promote patient safety, it must be
38
39 410 aligned with a culture based on patient values and goals, where calculated risks are taken into
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41 411 account.

412 ***Strengths and limitations***

413 This research has some limitations to consider. The selection of settings, situated in the same
414
415 urban area of Sweden, may limit the extent to which our findings can be transferred to rural
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417 settings or other regions. The number of participants was lower than expected in some focus
418
419 groups, due to the high workload, which may have limited the dynamics of the discussions.
420
421 However, a strength of the study is that all professions in the multidisciplinary teams from
422
423 different settings were represented, and the interviews were characterized by rich variations and
424
425 deep descriptions of patient safety in specialized home healthcare.³⁸ To further broaden the
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427 understanding of patient safety in home healthcare, patients, and their relatives could be involved.
428
429 To make us aware of our preconceptions, we adopted a self-critical attitude and constantly

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3 422 reflected on our own thoughts and mind-sets, so as to strengthen the trustworthiness of data.^{20 38}
4
5 423 To further address trustworthiness, we used research triangulation in all analyses and
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7 424 interpretations of data, as the researchers' interpretative repertoires may vary depending on
8
9 425 background and preunderstanding.³⁸ Finally, interpretation of the results should be made with the
10
11 426 delay between data collection and publication kept in mind.
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13

14 428 **Conclusion**

15 429 The dynamic and complex conditions under which home healthcare operate are fundamentally
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17 430 different from hospital care. Patient safety in the home healthcare is grounded in close
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19 431 multidisciplinary team collaboration based on a care ideology enhancing co-creation of care
20
21 432 through patient autonomy, competence and relatedness. Thus, providing care included weighing
22
23 433 risks against patients' preferences and will. Standardization and quality assessments introduced
24
25 434 for improvement of care are contrasted against team members adaptations and patient behaviours
26
27 435 and preferences, that set the limits for safety.
28

29 437 **List of abbreviations**

30
31 438 EHR Electronic health record

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33 439 RN Registered nurse
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35 440

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37
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39
40 443 of the study, in writing the manuscript or the decision to submit the manuscript for publication.
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42 444

43 445 **Competing interests** None declared
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45 446

46 447 **Contributors** ML and ME designed and conducted the study. All authors (ML, MF, ME) jointly
47
48 448 contributed with their expertise in methodology, patient safety and home healthcare. All authors
49
50 449 were part of the analysis process, drafted the manuscript and agreed to the final version of the
51
52 450 manuscript before submission.
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3 452 **Ethics approval** This study was approved by the Regional Ethical Review Committee in
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5 453 Sweden, Stockholm (DNr: 2012/1384:31).
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8 455 **Data sharing statement**

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10 456 Supplementary and raw data available upon request.
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12 457

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15 459 managers at the three specialized home healthcare units.
16
17 460

18 461 **REFERENCES**

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Standards for Reporting Qualitative Research (SRQR)*

<http://www.equator-network.org/reporting-guidelines/srqr/>

Page/line no(s).

Title and abstract

<p>Title - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended</p>	Page 1, line 2
<p>Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions</p>	Page 2

Introduction

<p>Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement</p>	Page 3, line 85
<p>Purpose or research question - Purpose of the study and specific objectives or questions</p>	Page 4, line 102

Methods

<p>Qualitative approach and research paradigm - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**</p>	Page 3, line 107
<p>Researcher characteristics and reflexivity - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability</p>	Page 6, line 170 Page 14, line 426
<p>Context - Setting/site and salient contextual factors; rationale**</p>	Page 4, line 112
<p>Sampling strategy - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**</p>	Page 5, line 141
<p>Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues</p>	Page 14, line 457 and page 6, line 171
<p>Data collection methods - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**</p>	Page 5, line 138

1 2 3 4 5	Data collection instruments and technologies - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	Page 5, line 151
6 7 8	Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	Page 4, line 119 and Page 5, table 1
9 10 11 12	Data processing - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	Page 5, line 147 and Page 6, line 162
13 14 15 16	Data analysis - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	Page 6, line 162
17 18 19 20	Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	Page 14, line 426

Results/findings

23 24 25 26	Synthesis and interpretation - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	Page 6, line 175
27 28 29 30 31 32	Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	Page 7, line 197. Page 8, line 233. Page 9, line 256. Page 10 line 290 and 317.

Discussion

35 36 37 38 39 40 41	Integration with prior work, implications, transferability, and contribution(s) to the field - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	Page 11, line 343
42 43	Limitations - Trustworthiness and limitations of findings	Page 13, line 418

Other

46 47 48	Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	Page 14, line 450
49 50	Funding - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	Page 14, line 445

*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

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**The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

Reference:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014
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