

Role of Patient Safety Incident Reporting Systems in Home Hospitalization

*Laura De la Torre-Pérez¹, Carme Hernández-Carcereny², Isabel Fortes-Bazaga¹, Andreu Prat-Marin¹, Maria-Jesus Bertran¹

¹Preventive Medicine and Epidemiology Department. Clínic Institute of Medicine and Dermatology (ICMiD). Hospital Clínic de Barcelona.

²Coordinator of Home Hospitalization unit. Medical and Nursing Direction. Hospital Clinic. University of Barcelona. Barcelona.

ARTICLE INFO	ABSTRACT
<p>Article type: Original Article</p>	<p>Introduction: The present study aimed to assess the effectiveness of the current hospital-based electronic patient safety incident reporting system (IRS) in the improvement of patient safety in home hospitalization (HH).</p>
<p>Article History: Received: 21-Sep-2020 Accepted: 13-Feb-2021</p>	<p>Materials and Methods: Out of 6381 patient safety reports voluntarily presented by healthcare professionals in a tertiary hospital in Barcelona between 2016 and 2019, all those related to HH were analyzed. They were characterized by incident type, description, risk and year, the ways to get notified, patient's age, and the results of the analysis. Moreover, falls were classified depending on circumstances.</p>
<p>Key words: Home care services, Hospital-Based, Patient safety, Risk management.</p>	<p>Results: Based on the results, 68 HH incident reports were related to the following factors: use of medication (n=2), procedures (1), patient's behavior (n=1), and falls (n=64). Regarding the damage degree, the incidents were reported as extreme risk (n=1), high (n=8), moderate (n=27), low (29), and very low risk (n=3). The majority of patients involved in the incidents were more than 60 years old. Out of the reported falls, 8 cases were categorized as high risk, and 32 cases reported health consequences. Moreover, 19 falls from height, 31 cases of falling while sitting or lying, and 30 incidents classified as unknown were identified.</p> <p>Conclusion: Patient safety is a matter of great concern, especially in HH but with some differential features. The IRS can play a peculiar role in minimizing patient safety risks and promoting a safety culture. The results of the present study pointed to some frequent risks and suggested improving opportunities in HH. Nonetheless, further studies are needed to design tailored patient safety interventions in HH, as well as a tailored IRS adapted to this growing setting.</p>
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***Corresponding Author:**

Preventive Medicine and Epidemiology Department. Clínic Institute of Medicine and Dermatology (ICMiD). Hospital Clínic de Barcelona. E-mail: lr.delatorre.prz@gmail.com

Introduction

Nowadays, western societies have modified the health care delivery approach due to economic and demographic situations (1). Hospital-at-home care provides acute hospital-level care in patient's homes as an alternative to conventional inpatient care. Based on observational and randomized clinical trials, this home healthcare service resulted in marked reductions in mortality and iatrogenic complications, better patient and caregiver experience, and reduced costs of care (2–6). Hospital at Home is defined as a service providing acute, home-based, short-term complex interventions aiming at substituting conventional hospitalization fully (Home Hospitalization [HH]) or partially (Early Discharge). During HH, service is delivered by trained hospital healthcare professionals. The assessment of HH deployment over a period of 10 years (2006-2015) at Hospital Clínic has demonstrated safety and effectiveness with high levels of user acceptance(7).

Patient safety refers to the prevention of harms and adverse effects to patients associated with healthcare(8). Patient safety primarily aims to make simple designs that can prevent minor errors and take necessary precautions to determine, report, and rectify the errors before they affect the patient (9). The frequency and consequences of healthcare risks represent a public health problem recognized by health administrations. They have led to the incorporation of Incident Reporting Systems (IRS) in the public healthcare sector to identify adverse events and evaluate patient risks (10–12). The IRS are useful tools in patient safety and safety culture developing (13) aiming at risk identification and implantation of appropriate measures to reduce those risks. Incident and adverse events reporting systems allow us to learn from experiences about clinical safety, clinical good practice, and preventive measures (14).

Unexpected and unwanted events can take place in every setting where healthcare is delivered (8,15); therefore, its occurrence is inevitable in HH (16,17). Nonetheless, there is a dearth of data on the severity of these events outside hospital setting(18).

Home care, especially HH, is probably a care unit with great potential to grow in the years to come (19). It has specific characteristics (20), such as the involvement of patients and caregivers in healthcare (21,22), as well as the presentation of specific challenges to patient safety (23,24). These differential aspects are still not included in most patient safety surveillance tools. To the best of our knowledge, a few studies have so far specifically assessed patient safety in HH. Nevertheless, patient safety in HH has been studied using different methodologies, the most relevant of which is qualitative assessment (23,25). The qualitative assessment aims to identify potential patient safety risks using the perspectives of patients, caregivers, and health professionals. A qualitative explorative study in advanced home care identified risk situations related to neglects in monitoring tasks, as well as communication with patients and between professionals (25). Another methodology used in home care is systematic data processing displayed as a resource for mapping potential safety risks in a specific patient or population according to their characteristics (26). It can be used as a resource to map potential safety risks in a specific area or center. To date, there are no IRS data on HH activities, and no specific IRS has been developed for HH. In light of the aforementioned issues, the present study aimed to describe and analyze the notifications related to HH received in the IRS of a tertiary hospital between 2016 and 2019 to explore how current hospital-based electronic patient safety IRS can be a facilitator for patient safety in HH.

Materials and Methods

Study population and setting

Barcelona is located on the northeast coast of the Iberian peninsula on the coast of the Mediterranean sea. It holds 1,636,762 inhabitants based on the data of the regional statistical institute in 2019. The present study focused on notified incidents in HH activities of Hospital Clínic de Barcelona with an approximate reference population of 524,000 inhabitants (27). Hospital Clínic is one of the three main tertiary hospitals in Barcelona with 728 beds, 44,035 inpatient discharges,

142,823 Emergency Room Visits, and 551,800 ambulatory visits in 2019. Between 2006 and 2015, HH patients (n=2,529) were admitted either for respiratory (n=1,018; 40%), cardiologic (n=367; 15%), post-surgery (n=20;1%), or oncologic conditions (n=260;10%) with a mean of four comorbidities (SD=3). More information about the HH patients and program details were thoroughly described elsewhere (7).

Study period

Notifications were reported between January 2016 and December 2019.

Study procedure

The information was extracted from the Patient Safety Company ® electronic platform used in the Hospital Clínic since 2015 to register and manage adverse events and near misses voluntarily reported

by healthcare professionals. The platform is organized in sections determined by Hospital's divisions call institutes (28). Institutes are groups of clinically related departments. Apart from the 15th institutes, there is another section called Other Areas. There is no section (institute or department) specifically related to HH. The mandatory information to fill a notification in the platform is as follows: the hospitalization area, incident's hour and date, institute and department where the incident happened, people involved in the incident (e.g., patient, nurse, doctor, relative, pharmacist, others), incident's description (free-text entry), patient harm (categories: no harm, physic harm, psychic harm, social, and others), potential harm degree, probability of occurrence, and incident's type. Descriptions of the last three variables are presented in Table 1.

Table 1: IRS Platform variables: potential harm, probability of occurrence, incident's type

Variable	Categories
Potential harm degree	No patient harm 1 An error is possible
	No patient harm 2 An error occurred; nonetheless, it did not affect the patient
	Minimum The error did not produce any lesion
	Minor The error led to patient monitoring but not patient lesions
	Moderate 1 The error led to the patient's lesion and/or treatment
	Moderate 2 The error led to a patient's temporal lesion or a longer hospital stay
	Critic 1 The error produced a permanent lesion
	Critic 2 The error resulted in a life-threatening situation
	Catastrophic Lethal
	Probability of occurrence
Not frequent Could happen once between 2 and 5 years	
Possible Could happen once or twice a year	
Probable Could happen a few times a year	
Frequent Could happen in the next weeks or months	
Incident's type	Medication
	Falls
	Blood products
	Assistive devices
	Healthcare-associated infection
	Nutrition
	Patient's behavior
	Oxygen and other medicinal gases
	Documentation
	Clinic and procedures management
Clinical-administrative management and laboratory	
Infrastructures	

Non-mandatory entries include notifier's identification data (professional category, full name, e-mail, and the ways of getting notified), variables related to patient's identification and characteristics (medical history number, gender, date of birth, age range), contributing factors, measures for improvement, and additional information according to the incident category (for example, *Medication*: Identified problem, stage of the medication circuit in which the

incident occurred [prescription, validation or dispensation], drugs involved, way of administration, doses, and presentation). Some of the introduced variables are processed to generate calculated variables. With the variables of potential harm degree and probability of occurrence, the risk of the incident is assigned to five categories: very low risk, low risk, moderate risk, high risk, and extreme risk. It is calculated from the risk matrix depicted in Figure 1.

	Very infrequent	Not frequent	Possible	Probable	Frequent
No patient harm 1	Very low Risk	Very low Risk	Very low Risk	Low Risk	Low Risk
No patient harm 2	Very low Risk	Very low Risk	Very low Risk	Low Risk	Low Risk
Minimum	Low Risk	Low Risk	Low Risk	Low Risk	Moderate risk
Minor	Low Risk	Low Risk	Moderate risk	Moderate risk	Moderate risk
Moderate 1	Moderate risk	Moderate risk	High risk	High risk	High risk
Moderate 2	Moderate risk	Moderate risk	High risk	High risk	High risk
Critic 1	Moderate risk	High risk	High risk	Extreme risk	Extreme risk
Critic 2	Moderate risk	High risk	High risk	Extreme risk	Extreme risk
Catastrophic	Extreme risk	Extreme risk	Extreme risk	Extreme risk	Extreme risk

Figure 1: Risk Assessment Variable Calculation

In order to identify HH notifications during the study period, among the hospital database of 6381 patient safety reports voluntarily reported by healthcare professionals between January 2016 and December 2019, the research group selected all incidents notified in "Other Areas" and analyzed those related to HH.

In order to characterize the notifications exposed in the current article, the following variables were used: incident type, incidents' description, risk, year of notification, the ways of getting notified, patient's age, and results of the analysis. General incident characterization was performed using the notification form field corresponding to the incident description. Falls were classified in different categories depending on the situation of the fall, following the incident's description, conclusion, and medical history if provided. This classification was performed in order to identify common risks and specific characteristics that could be avoided during HH. If the information was provided, specific

home place and time of the day were collected.

As mentioned earlier, IRS aims to identify risks associated with healthcare provision that can potentially lead to quality improvements in healthcare service. Therefore, the personal information of the notifier and patient in the incident's notification is voluntary and confidential. Moreover, if provided, the patient's identification is only transitorily stored in the database to ensure ulterior anonymity. Consequently, no information was collected about the patient's individual data (such as preexisting conditions or cause of admission to HH).

Results

A total of 111 notifications pertained to patient safety incidents or events of "Other Areas". A number of 68 HH incident reports were related to the following factors: use of medication (n=2), procedures (1), patient's behavior (n=1), and falls (n=64). Out of 38 incidents, 2, 13, 21, and 32 cases were

reported in 2016, 2017, 2018, and 2019, respectively. Moreover, regarding harm degree, the risks were categorized as extreme (n=1), high (n=8), moderate (n=27), low (n=29), very low (n=3). Age range and the way of getting informed were notified in 57 and 65 of the incidents, respectively. Most of the incidents (n=55) were notified by an eye witness, and 10 cases were directly experienced or observed by notifiers. All patients linked to the incidents, except one case, were more than 60 years of age, and 56.14% of the incidents (32 out of 57) were associated with patients older than 80 years. Out of the two incidents related to medication, the first one was notified in December 2018 and categorized as very low risk. The incident was related to the drug distribution circuit in the hospitalization ward and delays in medication deliveries. There were no consequences for the patient since HH has a drug stock of their own management independent from hospitalization ward drug dispensation. However, this incident involved an increase in the cost of healthcare since dispensed antibiotics were not used.

The second incident related to medication notified in 2019 was first identified as a clinic and procedure management and categorized as an extreme Risk. The incident occurred during the home hospitalization of a woman older than 80 years with a known metamizole allergy. In a medical telephone inquiry for painkiller prescription, the patient and relatives received oral consultation. Metamizole was prescribed since allergies were registered in the discharge report but not the electronic medical record allergy section, and the patient and relatives only identify streptomycin allergies. This resulted in patient's death after an anaphylactic shock treated in the hospital's emergency room. A root cause analysis was performed, and some measures were implemented to improve the allergy registration system and promote the development of alert systems in drug prescriptions.

The incident related to patient behavior was defined as moderate risk occurring when a young patient in home hospitalization was aggressive and uncooperative with health professionals. Falls were the most frequent

incidents notified during this period. Furthermore, 54 cases were notified by an eye witness, rather than by direct experience (88.52% of 61 fall notifications with that information are available). Regarding harm degree, the risks were categorized as high (n=8), moderate (n=25), low (n=28), and very low (n=2). After the analysis of fall notifications, 32 cases reported negative consequences: 18 incidents were mild contusions or scratches, and 14 cases required additional medical attention. Just one of 14 falls reported severe health consequences for the patient (hip fracture). In general, out of 64 fall notifications, 4 cases reported that the patient was alone when the incident occurred. Moreover, the following associated factors were identified: patient factors (n=40), environmental factors (n=13), and external factors (n=3).

Besides, 19 falls from height were identified, 18 of which had occurred while walking around the house. Specific causes were loose of balance (n=5), slip (n=5), stumbling (n=7), and loss of consciousness (n=2). Out of those falls from height providing that information (n=12), 11 incidents occurred in the bathroom or on the way to it. The associated factors included the presence of obstacles in the house (related to four cases of stumbling), the absence of a caregiver (related to one case of loss of consciousness), as well as the presence of liquids on the floor and type of flooring (reported in two cases of slip). Out of these 19 falls from height, the two notifications caused by loss of consciousness were categorized as high risk (corresponding to, probability: possible, severity: moderate 1). A number of 32 falls had occurred while sitting or lying down, while 13 cases were unknown or unclear when the notifier did not provide enough information. Those 13 falls were caused by the followings: loose of balance (n=6), lack of strength (n=1), stumbling (n=1), slip (n=1), and unknown (n=4). Out of 32 falls in sitting or lying positions, 13 cases happened when getting up, and 6 incidents were associated with lack of strength.

However, in general, slip (n=10) was the most frequently observed cause of fall in sitting or lying position, followed by lack of strength (n=6) and loss of balance (n=4).

Poor illumination (n=1), patients' agitation (n=1), and failure to apply safety measures (n=1) were the associated factors identified from the descriptions.

Discussion

As evidenced by the results of the present study, falls and medication were the patient safety risks identified in HH.

The HH has progressively been implemented in western healthcare and its activity has received increasing importance in Hospital Clínic since it was first incorporated in 2006. However, only 68 incidents were notified about its activity in IRS since 2015.

Hospital Clínic IRS was piloted in 2013-2014 and started its activity in 2015. Nonetheless, a specific HH safety section was developed neither on the notification form nor the platform. This absence in the recognition of HH activity as a specific area might have contributed to the limited number of notifications. Moreover, the safety culture situation in the HH environment and lack of training on notification tools in HH are other potential contributing factors.

Nevertheless, since HH notifications were not contemplated, and this area was not specifically considered in the platform design, the number of identified notifications is higher than expected. The fact that HH professionals spend some of their workdays in hospital environments could have provided them with general knowledge about the functioning of the platform.

These results point to great opportunities for improvement in incident reporting and can be part of a call to action to increase safety culture in HH. In the Hospital Clínic, a HH-specific safety committee has already been created, and awareness was raised by clinical sessions to improve safety culture in the HH department.

These changes are of paramount importance under the current COVID pandemic when other forms of healthcare based on the HH model have gained relevance for policymakers and healthcare service managers. The small number of reported incidents can also be ascribed to relatives and patients' disengagement. Patients, families, and caregiver's involvement in the health decision-making process has been

associated with the greatest health outcomes in home environments(29). Therefore, due to their key role in HH, their participation in patient safety has also been linked to better outcomes(30–32). Current IRS are digital platforms easily accessible through technological devices, such as computers or tablets. The technological advances already implemented and claimed to be necessary in home care and advanced home care (33) could also apply to patient safety surveillance tools. Health technology has already been applied to reduce patients' risks in home care. One example of this is the use of robots to manage home-care medication (34). The characteristics of HH make electronic tools specifically useful and could increase incident reporting, help to identify risks, thereby improving safety when applied through an easy and point-of-care access incident report system.

The type of identified notifications demonstrates risks similar to those reported after different risk analysis techniques in home healthcare (16,35,36). Nevertheless, we would have expected more medication-related incidents since they are one of the most frequently identified potential risks in home healthcare (36–38). The number of identified notifications does not permit the induction of a prevalence-based incident report. However, the most plausible explanation is that medication-related incidents might have happened but not notified during the study period. The promotion of safety culture and incident reporting system adaptation to HH could increase the notifications and lead to different conclusions about this kind of data.

The analysis of fall-related data was compelling since these incidents can be facilitated by home-related factors. The collected data suggest that some specific safety issues can be considered in patient's homes to increase patient safety in HH. The factors related to home situation (e.g., the presence of obstacles, type of flooring, and poor illumination) and caregiver presence were the most distinctive factors associated with HH fall notifications. The patient's home factors are already contemplated in home adaptation-recommendations (39). However, they assumed greater importance in this environment since in HH, hospitals safeguard patient's safety.

Another frequent characteristic of HH notifications is that most of them are reported by witnesses of the incident (mostly because caregivers communicate it to the professionals). This supports that caregivers' involvement in patient safety is of utmost importance in HH since it has been pointed out by some studies conducted in home care environments (33,40). Caregiver and patient's involvement should be considered in any safety culture intervention and incident reporting tool development, especially in home healthcare-related services. It could increase the reporting rates and facilitate the identification of contributing factors.

To the best of our knowledge, there is a dearth of data on incident reporting system results in HH environment and patient safety in HH. Therefore, the current study can contribute to the improvement of knowledge in this area, displaying the potential benefit of IRS in HH safety. These tools provide the possibility of prompt, systematic risk identification, and therefore, the definition of areas of improvement. The current pandemic situation has highlighted the importance and expected growth of HH since different forms of healthcare are essential to guarantee healthcare delivery in a context of an overburdened traditional healthcare system. The lack of methods considering IRS in this ambit makes this data sample a relevant example of the potential benefits of this device implementation in HH. The current context, therefore, urges to the development of a particular IRS based on point-of-care participatory app systems adapted to HH risks and the characteristics of notifiers (e.g., patients, caregivers, healthcare professionals).

Regarding the limitations of the present study, the results of a case report data must be generalized cautiously. Moreover, since the system was not defined for HH and the used tool consisted of a passive surveillance system, the most important events were merely notified. In addition, no accurate comparisons could be made considering the few published studies on incidents in HH activity reported through IRS. Furthermore, no specific association can be established with patients' comorbidities or cause of admission since the IRS only collect ecological and anonymized data to identify systemic-oriented risks (as opposed to individual-oriented). On the other hand, the

results of the current study can provide valuable insight into potential patient's risk associated with this form of healthcare and contribute to the improvement of HH patient's safety.

Conclusion

Although patients can benefit from HH, patient safety is a daunting challenge in this care setting. The HH is a healthcare model that could improve patient's wellbeing and the health system's affordability; nonetheless, it must deal with specific risks. The findings obtained in the present study demonstrated the potential usefulness of IRS in HH and highlighted the need for a specific IRS notification taxonomy for this modality of healthcare. This need should be fulfilled by patients and caregivers' involvement from its design until implementation. Further research should focus on patient risk management in the HH setting since the COVID-19 pandemic demonstrated that other forms of healthcare provision are necessary to guarantee health care access.

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