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**A Prospective Risk Assessment of Informal Carers’
Medication Administration Errors within the Domiciliary Setting**

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A Prospective Risk Assessment of Informal Carers’ Medication Administration Errors within the Domiciliary Setting

ABSTRACT

Increasingly, medication is being administered at home by family and friends of the care-recipient. This study aims to identify and analyse risks associated with potential drug administration errors made by informal carers at home. We mapped medication administration at home with a multidisciplinary team that included carers, healthcare professionals and patients. Evidence-based risk-analysis methodologies were applied: Healthcare Failure Modes and Effect Analysis (HFMEA), Systematic Human Error Reduction and Prediction Analysis (SHERPA) and Systems-Theoretic Accident Model and Processes (STAMP). The process of administration comprises seven sub-processes. Thirty four possible failure modes were identified and six of these were rated as high risk. These highlighted that medications may be given with a wrong dose, stored incorrectly, not discontinued as instructed, not recorded, or not ordered on time, and often caused by communication and support problems. Combined risk analyses contributed unique information helpful to better understand the medication administration risks and causes within homecare.

Key Words: Patient safety; Medication Errors; HFMEA, SHERPA, Risk Assessment.

Practitioner Summary

Increasingly, medication is being administered at home by family and friends of the care-recipient. This study identifies risks associated with potential drug administration errors made by informal carers at home through consensus-based quantitative techniques. The different analyses contribute unique information helpful to better understand the administration risks and causes.

Introduction

Home medication administration errors

The home environment is unique and not designed for health care (Lang et al. 2008, McGraw et al. 2008). However, due to over-stretched hospitals, an ageing population and patient preference, more and more patients are requiring care within their own homes. Unfortunately, there is limited research on safety of such patients in the home compared to the hospital setting (Madigan 2007, Lang et al. 2008, Masotti et al. 2010). Recent research has identified a considerable number of adverse events that occur at home (e.g. 13.2 per 100 home care cases) (Sears et al. 2013), and a potential for higher adverse events than in hospitals (Woodward et al. 2002, Masotti et al. 2009). Drug-related adverse events have been reported to be the most common adverse events in the home (Masotti et al. 2010), largely comprising problems associated with polypharmacy (Riker and Setter 2012) and medication administration errors (MAEs).

Aside from patients' own adherence to medication, on which there is a wealth of literature (McDonald et al. 2002, Sokol et al. 2005), those responsible for MAEs may include informal carers who are regularly involved in home medication management. These carers are typically relatives or friends of patients cared for in the home, who help with daily care activities and whose mistakes during administration of medication can result in severe and significant harmful outcomes for the patients (Kaushal et al. 2007, Zandieh et al. 2008).

A recent systematic review of the literature on MAEs caused by carers in patients' own homes has identified errors by informal carers to include wrong dosing of medication, wrong medication, missed administration, wrong time and wrong route of administration (Parand et al. 2016). Contributing factors to these MAEs included individual carer factors such as carer's age, environmental factors such as storage, medication factors including polypharmacy, prescription communication factors and understanding instructions, psychosocial factors including carer-to-carer communication, and the care-recipient's age.

This evidence is almost exclusively retrospective in nature – prospective, structured risk analyses of informal carers' medication administration practices are currently lacking. These would add to the literature by providing structured, quantitative and evidence-based overviews of the processes and carer-related actions involved in home medication administration, where the risks may occur, and suggestions for how they may be prevented.

Structured risk analyses as used in numerous high-risk industries, have the advantage of systematic risk representation and evaluation – in comparison to the subjectivity of self-report. Further, prospective approaches have an advantage over other retrospective investigative approaches such as root cause analysis that suffer from ‘hindsight bias’ (the tendency to exaggerate the extent to which they would have predicted the predictability of event), ‘outcome bias’ (the tendency to use outcome knowledge in evaluations of decision quality) and ‘assimilation to the familiar’ (not searching beyond the most recognised contributory factors) (Henriksen and Kaplan 2003).

Aim

The aim of this study was to apply a combination of evidence-based, structured, quantitative risk analysis methods to identify and analyse the risks associated with informal carers’ MAEs in the home of adult patients and their effects on patient care and safety.

Methods

Prospective Risk Analyses

We applied three evidence-based and well-established risk analyses techniques to MAEs within homecare: Healthcare Failure Mode and Effect Analysis (HFMEATM) is a prospective risk assessment tool that maps out a process of care and identifies potential hazards, their severity, probability and detectability, and their causes and solutions (DeRosier et al. 2002). It was designed by the United States Department of Veterans Affairs’ National Center for Patient Safety (DeRosier et al. 2002), developed from the FMEA NASA (National Aeronautics and Space Administration) tool (National Aeronautic and Space Administration 1966) that was originally implemented within industry (military, automotive and aviation). More recently, HFMEA has been used to inform patient safety, including medication administration failures (Habraken et al. 2009, Yue et al. 2012). Specifically, the HFMEA approach highlights failure modes (different ways that a process or sub-process can fail to provide the anticipated result) (DeRosier et al. 2002) and the effects that these failures may have.

HFMEA has been criticised for its subjectivity and time consuming nature (Franklin et al. 2012, Chadwick and Fallon 2013). A recent validity study that showed HFMEA to raise important hazards also recommended multiple hazard analysis methods to achieve a more

comprehensive assessment (Potts et al. 2014). In consideration of these critiques, we wanted to address some of the criticisms by clearly defining rating scale anchors, and by incorporating additional assessment tools to supplement the HFMEA approach. We therefore also used Systematic Human Error Reduction and Prediction Analysis (SHERPA), as a human error prediction technique (Embrey 1986), and Systems-Theoretic Accident Model and Processes (STAMP), an accident causation model that focuses on failure of control measures (Leveson 2004). These tools have separately shown promise in identifying problem areas in healthcare (Lyons et al. 2004) and combining SHERPA with HFMEA has been previously suggested (Chadwick and Fallon 2013). Additionally, SHERPA in particular and human factor identification in general have been recommended for examining medication errors and MAE (DeRosier et al. 2002) and SHERPA has been previously validated as a reliable tool (Harris et al. 2005, Stanton et al. 2009).

Design

Figure 1 illustrates the main steps of the integrated methodologies. As referenced in the figure, we followed DeRosier et al's five steps for HFMEA (DeRosier et al. 2002): (1) Define the HFMEA topic; (2) Assemble the team; (3) Graphically describe the process; (4) Conduct a hazard analysis; and (5) Identify actions and outcome measures to test the new process. Simultaneously to steps three, four and five, we introduced SHERPA to better understand the sequence of events and to categorise human errors involved in the process, and the STAMP framework to identify control errors and communication flows. The SHERPA and STAMP analysis was performed by two of the authors (GF & AP) and fed back to the team, in accordance with methodological guidelines (Stanton et al. 2014).

[Figure 1 near here]

Team composition

A purposive and snowball sampling strategy was used to identify 14 key stakeholders (12 from England and two from Italy) involved in or knowledgeable about medication administration to adults at home and/or the use of HFMEA (Appendix 1). These comprised pharmacists (BDF, JD, NC, MA), psychologists (AP, NS), patients (FH, MT), an elderly care consultant physician (SL), a community nurse (HD) and a family member carer (MT). In

addition to a team leader (AP), there were three facilitators (PC, MJ, GF) with prior expertise in HFMEA. The team included members who were not familiar with the specific study topic (PC, MJ).

Procedure

Four two-hour team meetings took place between 5 August and 2 September 2014, with additional email correspondence before and after each meeting. Each meeting had 10 team members in attendance for the entire duration of the meeting with a pre-specified mix of representatives with different backgrounds and expertise (e.g. there were at least two informal carers and two pharmacists at each meeting). Prior to the first meeting, the team members were emailed a research information sheet, an accompanying consent form and a PowerPoint presentation explaining the HFMEA stages and meeting arrangements. The four meetings covered the following content: (1) Introduction and graphical representation of process; (2) Failure mode identification and hazard analysis; (3): Cause analysis; and (4) Actions and outcome measures.

At the first meeting, the team defined the scope of the project more precisely, particularly concerning who the target care-recipient might be and the type of medication to focus on. The process starting point was agreed to be the moment the carer receives the medication prescription from a healthcare professional. A further assumption was that the prescription and any accompanying healthcare professionals' instructions were without error, so that the focus remained on possible errors involving the informal carer. The team expanded the original definition of an MAE ('any deviation between the medication as prescribed and that administered' (Barber et al. 2009)) to include deviations from best practice guidelines, so that we could more comprehensively examine failures around the medication administration process.

We asked the team to focus on two exemplar situations, representing a low risk medication (tablets) and a high risk medication (insulin injection), with accompanying scenarios (box 1).

[Box 1 near here]

Based on a systematic review of the literature on carers' MAEs (Parand et al. 2016), and publicly available guides for medication administration (The Regulation and Quality Improvement Authority 2012, Royal Pharmaceutical Society of Great Britain 2014), we identified a list of sub-processes for the process of medication administration, verified by a pharmacist (NC) prior to its presentation to the wider team (see Figure 2). In accordance with DeRosier's step 3, we then graphically presented the sub-processes to the team who were invited to suggest amendments.

Once consensus was agreed, the tasks and their failure modes for each sub-process were identified by the team. The team leader asked general questions to help the group discussion, such as "what could go wrong here?" The team then rated the severity and probability of each failure mode on a rating scale of minor, moderate, major, or catastrophic for severity, and remote, uncommon, occasional, or frequent for probability. Hazard scores were calculated by multiplying the severity and probability (Tables 1a & b). These rating scales and hazard scores were based on HFMEA and SHERPA guidelines (DeRosier et al. 2002, Stanton et al. 2004) and were defined clearly for the team. Team members first provided individual scores by email and then collectively discussed their scores in the meetings.

[Tables 1a & 1b near here]

For failure modes that received a hazard score of 8 or above (referred to as critical failure modes) (DeRosier et al. 2002), a decision tree was used to determine controls (measures for prevention), detectability and criticality (importance of activity/task) (DeRosier et al. 2002). Two members of the team (GF & AP) identified any point whereby if the activity fails, the entire process would fail, referred to as a 'Single Point of Weakness' (SPW) and confirmed these with the team. The analysis of SPW overlaps with SHERPA's criticality analysis that also aims to identify the failures that have critical consequences.

Next, the team brainstormed possible causes of each of these critical failure modes, regardless of whether they had effective control measures or not. The team made

recommendations on the critical failure modes and considered relevant outcomes measures that could be used to assess success of proposed solutions.

Separately, two members of the team (GF & AP) followed SHERPA guidelines (Embrey 1986, Stanton et al. 2004) to identify the hierarchy and sequence of tasks ('hierarchical task analysis') (Stanton 2006) human errors ('human error identification'), consequences of failure modes ('consequence analysis'), any points where the activity can recover from the failure ('recovery analysis'), and proposed error reduction solutions ('remedy analysis', divided into equipment, training, procedures and organisational solutions). The consequence analysis was also used to identify any discrepancies between the SHERPA and HFMEA severity ratings made by the team where the consequence was the same. For example, we found the team had collectively rated the consequence for wrong dose as both a high and low severity consequence, and this was later resolved by the team). The STAMP method additionally provided a tool to examine the controls and communication problems via closer examination of communication networks and measures already in place and to classify causes identified by HFMEA, using an adapted taxonomy. Classifications from STAMP were adapted to the study subject (e.g. the control measures/constraints of the process were defined as supporting material, double checks, utensils, and training.). Double-blind inter-rater reliabilities between two of the authors (GF & AP) were performed using Cohen's Kappa test (Cohen 1968) on the SHERPA hierarchical task analysis and human error identification and remedy analysis classifications and the STAMP causal classifications.

At the end of the process, all data were presented back to the team to verify the findings and an evaluation form was completed by team members. This form included open questions about the advantages and disadvantages of the HFMEA process, suggestions for dissemination, and ratings of importance and difficulty of the different stages involved (Appendix 5). The questions focused on HFMEA. The team members and facilitators were asked extra questions by the team leader about the material and challenges/enablers of facilitating.

Ethical approval was obtained from the Camden and Islington NHS National Research Ethics Service Committee, reference 13/L0/1319.

Results

Processes, failure modes and error types

Figure 2 presents the complete process of medication administration for both high and low risk scenarios. This comprised seven sub-processes: (1) understanding the prescription; (2) storing the medication; (3) pre-monitoring the patient; (4) preparing the medication; (5) giving the medication; (6) (re)storing/discarding the medication; and (7) post-monitoring the patient. There were 23 tasks/activities, one of which (preparing the patient) was not applicable for the low-risk medication and two were not relevant for the high-risk medication (ensuring the medication has been taken/given¹, and putting the medication back in its packaging). Thirty-four failure modes were identified in total, six of which were rated as critical according to the hazard scores, three per medication type (Appendix 2). The critical failure modes for insulin injections were: (4.7i) ‘The medication is measured out incorrectly’, (5.1d) ‘the medication is given with a wrong dose’, and (5.3h) ‘the given/not given medication is not recorded’. For tablets, these were: (2.2c) ‘the medication is stored out of the original container that is dispensed and labelled by the pharmacist’, (7.3c) ‘not discontinuing medication as instructed after starting the next medication’, and (7.4g) ‘the medication in short supply are not ordered’.

Four of these six failure modes represent deviations from prescriptions, and two deviations from best practice: (5.3h) ‘the given/not given medication is not recorded’ and (2.2c) ‘the medication is stored out of the original container’.

The sub-processes with the highest number of possible failures were: (4) preparing the medication, (5) giving the medication, and (7) storing or discarding the medication. However, the sub-processes with the highest number of critical failure modes were giving the medication and storing/discarding the medication. This highlights that acts relating to giving and storing/discarding the medicines are perceived to be most vulnerable. This further varies by type of medication, with failure modes associated with giving the medication more critical for insulin injections and failure modes associated with storing/discarding medication more problematic for tablet medication. As expected, the scores pertaining to administration of insulin injections had higher severity ratings than those for tablets.

¹ This was not relevant because insulin injection devices used by patients and carers do not allow for incomplete administration, and would be administered directly by the carer in this case

Although all of the critical failure modes were either rarely or not at all detectable (Tables 2 & 3), there were 31 recovery points and only two had single points of weakness: the medication is not prepared and the medication is not given (Appendix 2).

The human error identification (SHERPA) revealed that the human errors were mostly retrieval errors (specifically, incomplete information retrieval) at the very start of the process when receiving information about the prescription, and then mostly omission of operation and checking issues, such as not discarding expired medication or omission of checks of medication expiry dates. Also noted was one selection error (selecting medication) and one communication error (notifying health care professionals of any side-effects). The categorised error types are presented by task in Figure 2 and by failure mode in Appendix 2.

The hierarchical task analysis (SHERPA) presents additional information related to the pathway, specifically the order in which tasks are carried out, either in sequence or at the same time, and whether a task is dependent upon another task (Figure 2). For example, if the carer recognises side effects, they can only then conduct the task of informing healthcare professionals accordingly. However, checking the remaining amount of medication and discarding old/expired medication can be conducted at the same time.

Causes and recommendations for critical failure modes

STAMP causal analysis (see Appendix 3 for full results) identified that the most common causes (classified by the HFMEA analysis) were due to inadequate reading, listening or understanding of information provided by control measures (e.g. carers with poor literacy) or inadequate operation by carer (e.g. medication taken out of the original container to keep medications together), followed by inappropriate or ineffective control measures in place to prevent failures. These demonstrate that issues are most likely due to carers' understanding of medication advice, down to their chosen behaviours, and that there is a need for control measures to address such issues. The examination of communication networks additionally revealed problems in the branch of the actuator's (person in control of the system) loop, further highlighting the importance of healthcare professionals' instructions and training on specific topics such as medication identification and storage.

Tables 2 and 3 illustrate the causes, current and proposed solutions by the team, those responsible for their implementation, detectability and outcome measures per critical failure mode. These are summarised in Appendix 4 for both the low and high-risk medications.

Methodological evaluation

The survey evaluation by the 14 team members had a response rate of 100%. It showed that the majority perceived the main aspects of the HFMEA process to be both important and difficult. For example, the majority of respondents found the graphical presentation and identification of failure modes and their causes and solutions to be important (at least 10 of 14 respondents rated each of these to be of high importance on a 1-5 low to high importance scale), with more variance in their agreement on the difficulty of these tasks. The converse was true for scoring the risks; there was more disagreement between team members on the importance of the task of rating (only half of the group rated it as important) and most agreed it to be a difficult process (10/14 rated it as highly difficult). More positively, everyone considered the scenarios to be very useful and almost all responded that the two-hour duration of the meetings were reasonable and felt that the solutions/findings from this study will help inform carers about home MAE. In addition, there were good Cohen's Kappa inter-rater reliability scores for SHERPA hierarchical task analysis classifications ($\kappa=0.875$, $p<0.001$), SHERPA human error identification classifications ($\kappa=0.707$, $p<0.001$), SHERPA solutions ($\kappa=0.838$, $p<0.001$), and STAMP causes ($\kappa=0.721$, $p<0.001$).

[Figure 2 near here]

[Table 2 near here]

[Table 3 near here]

DISCUSSION

This study has revealed potential vulnerabilities in the process of carers administering medication for their adult family or friends at home. The different prospective risk analyses additionally highlight distinct and corresponding areas for improvement, and the results demonstrate variations by medication type for what may go wrong and the likelihood and impact. The majority of risks were perceived to lie in the process of preparing, giving and storing/discarding the medication, with the latter two tasks most susceptible to significant error for insulin injections and tablet medication respectively.

The most common causes of errors revealed communication/comprehension and support problems. Most likely confounding this was an identified reluctance to ask for help. While there has been a recent focus on patient and carer involvement on speaking up for medication safety within the hospital setting, little exists on this in the home (Garfield and Parand 2015). There is however evidence that home carers' poor knowledge and understanding of medication administration can be problematic (Parand et al. 2016). Parents who have some knowledge about medication dosing are more likely to dose appropriately (Li et al. 2000) and yet healthcare providers often fail to provide relevant medication information (Lemer et al. 2009). These findings from the adult-child situation are likely to extrapolate to an adult-adult carer relationship. Other key causes from the present study included impractical medication package designs, and carers' organisational and record-keeping skills.

Implications and recommendations

Recommendations to address the communication and support causes centred around educating pharmacists, GPs and community nurses on provision of guidance to carers on the identified key risks. These include advice to carers about how to recognise medications from their appearance, to store and discard them appropriately, the methods and benefits of recording medication administration, to encourage the carers to speak about any difficulties in medication administration and demonstrating technical aspects of administration to them. These recommendations are aligned with findings that suggest that healthcare professionals should check with informal carers about the details of their medicine administration and imply reduced carer MAE following administration demonstration and guidance (Gribetz and Cronley 1987, Guberman 1990). Successful interventions have comprised of more detailed

initial instructions and provided equipment for medication administration (McMahon et al. 1997) and weekly lessons on home safety (Llewellyn et al. 2003).

On a wider scale, our findings support the need for system changes, such as checks at hospital discharge and alerts to carers to order new medications. These could in turn help carers to communicate, in a timely fashion, with clinicians to ensure medication is procured in good time. A systematic literature review of self and carer-administered medication errors similarly advocated improvement of verbal and written information provided to address communication and information problems (Mira et al. 2015). This review, like other studies before it, further raises the importance of design and technology solutions for MAEs. Our study particularly emphasise the importance of medication package design and IT communication systems.

In addition to practical recommendations, this study provides wider implications. The fact that the critical failure modes were different for tablets and insulin injections shows the importance of a tailored analysis to different medicines and that different solutions should be considered for different types of medication. The combined methodologies further hold implications for theory. Specifically, the individual analyses derive from contrasting assumptions, not least in how systems-focused or reductionist they are in their approach. Directions for future research would be to evaluate, with the use of objective measures, the added benefits of the combined analyses over and above any one singular analysis applied alone. A separate paper by the authors currently under review explores these theoretical advances from this present study and outlines how STAMP and SHERPA address criticisms of HFMEA (e.g. that HFMEA lacks analysis of human errors).

Evidence of reliability and usefulness of the approach can further be sought from application to other medication scenarios and with different participants. A next step to build on the present study results could be to consult human factor engineering experts on the practicality of proposed solutions to improve medication packaging, equipment and storage (e.g. re-designing dosette boxes), and how to use IT systems for monitoring and support amongst carers and healthcare professionals (e.g. with telemonitoring). A focus on how information is currently given could additionally help to tailor feedback.

The study recommendations are to be disseminated to community carer groups across UK cities and London Boroughs, including mental health and black minority ethnic groups via members of the HFMEA team.

Strengths and limitations

We have already outlined limitations of the HFMEA methodology according to the literature and how we have attempted to minimise biases. As found by others evaluating HFMEA, the process was found to be worthwhile in its aim but time consuming and subjective (Nagpal et al. 2010, Chadwick and Fallon 2013). Much of the value of the process was considered to be from mapping out the process, tasks and failure modes with relevant participants offering different perspectives. The prioritisation from hazard scores and recommendations from a small sample should be considered with caution and the recommendations were not evaluated for cost-benefit; the associated financial burden is something that needs to be considered by implementers. Similarly, suggestions based on best practice such as recording the administration of doses should be considered on an individual case basis, so as not to put further strain on the carers' already difficult role. Specific to our study, a higher proportion of informal carers within the team might have enriched the findings further from their perspective, and inter-rater reliability was performed by only two members of the team.

The strengths of this study include its prospective design, mixed-analysis, multi-disciplinary team and comparison by medication type, along with reliability testing of the methods (Stanton and Young 1999), comparable with previous findings (Stanton et al. 2009). This adds to the predominantly retrospective and unstructured nature of the existing evidence. It is the first time that systematic risk assessment has been applied to examine home carers' medication administration and the first time that these three analytical methods have been combined. Together the mixed analysis should provide a more robust analysis of the risks associated with MAE and we found the three methods to be complementary. For example, hierarchical task analysis highlighted errors that may result from the incorrect order of tasks, and as found elsewhere in the hospital setting, human error identification facilitated consideration of how human interaction with tasks of medication administration can result in MAE (Lane et al. 2006).

Conclusion

This prospective study has exposed a number of risks and effects associated with informal carers' potential MAEs for both low and high-risk medications. The most common causes involved communication and support problems. In particular, carers may not be instructed about or understand the purpose of medications and administration technique and they may not be accustomed to record information or use tools to help manage medication. There was also a perceived lack of awareness by carers of the importance of the labels on the packaging as well as reluctance to ask for help or admit to problems. Recommendations centred around educating pharmacists, GPs and community nurses on the most hazardous risks of medication administration, and guidance for carers to help prevent or ameliorate these key risks.

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Caption of Figures

Figure 1. Flowchart of steps of integrated methodologies

Figure 2. Process diagram & SHERPA task classification for home carer medication administration for tablets and insulin injection

Box 1. HFMEA Scenarios

<p>HFMEA Scenario 1: Low Risk Drugs</p> <p>Mrs Agata Nowak is a 64 year old patient who suffers from severe dementia. Agata lives with her daughter Lena who is her informal carer and administers her medications daily. Agata has been taking 5 different drugs (aspirin, omeprazole, amlodipine, simvastatin and paracetamol) at different times of day, for the past 14 months. The drugs have been prescribed and dispensed correctly for her.</p> <p>We need to ascertain what steps are present in this process of medication administration by the informal carer, where they might fail, how badly and how frequently they might fail, and identify preventative actions.</p>	<p>HFMEA Scenario 2: High Risk Drug</p> <p>Mrs Sofia Primo is a 35 year old patient who suffers from blindness due to her type 1 diabetes. Sofia lives with her husband Tom who is her informal carer and administers her insulin injections. Sofia has been using insulin for the past twenty years. She is on combined long and short acting insulin taken twice a day. In the past her compliance with the drug was erratic. The drug has been prescribed and dispensed correctly for her.</p> <p>We need to ascertain what steps are present in this process of medication administration by the informal carer, where they might fail, how badly and how frequently they might fail, and identify preventative actions.</p>
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Table 1a: HFMEA and SHERPA Hazard ratings (DeRosier et al. 2002, Stanton et al. 2004)

Severity ratings			Probability ratings		
HFMEA - Score		SHERPA	HFMEA - Score		SHERPA
Catastrophic	4	High	Frequent	4	High
Major	3	Medium	Occasional	3	Medium
Moderate	2		Uncommon	2	
Minor	1	Low	Remote	1	Low

HFMEA=Human Failure Modes and Effect Analysis; SHERPA=Systematic Human Error Reduction and Prediction Analysis.

Table 1b: HFMEA hazard scoring matrix with SHERPA ratings (Derosier et al. 2002, DeRosier et al. 2002, Stanton et al. 2004)

		HFMEA Severity of Effect			
HFMEA Probability		Catastrophic [rating:4] [SHERPA rating = High (H)]	Major [rating:3] [SHERPA rating = Medium (M)]	Moderate [rating:2] [SHERPA rating = Medium (M)]	Minor [rating:1] [SHERPA rating = Low (L)]
	Frequent [rating:4] [SHERPA rating = High (H)]	(4x4=) 16	(4x3=) 12	(4x2=) 8	(4x1=) 4
	Occasional [rating:3] [SHERPA rating = Medium (M)]	(3x4=) 12	(3x3=) 9	(3x2=) 6	(3x1=) 3
	Uncommon [rating:2] [SHERPA rating = Medium (M)]	(2x4=) 8	(2x3=) 6	(2x2=) 4	(2x1=) 2
	Remote [rating:1] [SHERPA rating = Low (L)]	(1x4=) 4	(1x3=) 3	(1x2=) 2	(1x1=) 1

HFMEA=Human Failure Modes and Effect Analysis; SHERPA=Systematic Human Error Reduction and Prediction Analysis.
Red=high risk, yellow=medium risk, green=low risk.

Table 2. Low-risk scenario causes, solutions and outcome measures for critical failure modes

	The medication is stored out of the original container that is dispensed and labelled by the pharmacist [2.2.c]	Not discontinuing medication as instructed, after starting the next medication [7.3.e]	The medication in short supply are not ordered [7.4.g]			
Present solutions	<ul style="list-style-type: none"> Medication administration aids, e.g. multi-compartment compliance aids (MCCAs), such as Dossette boxes filled by the community pharmacist for one month Information on medication strips 	Medication administration organisers.	Emergency supply bag available in pharmacy			
Detectable?	Rarely detectable by a second carer or healthcare professionals	Rarely detectable by a second carer or healthcare professionals	Rarely detectable by a second carer or healthcare professionals			
Causes (most common underlined)	<ol style="list-style-type: none"> <u>The medication is taken out of the original container in order to keep them all together</u> The medication is stored out of the packaging because of impractical packaging. The medication is stored out of the packaging due to lack of storage space (e.g. the packaging is too big) The medication is preserved in a container that is well-known by the patient to avoid refusal by the patient 	<ol style="list-style-type: none"> <u>The carers do not understand the purpose of a medication or why the GP has changed/stopped it.</u> The Dossette box remains full of the discontinued medication The carers do not know what to do with medications that are no longer needed The IT system does not support the coordination and communication among the carers and GPs/Pharmacists The carers are not informed about the new therapy because the GPs only speak to the patient The GP does not check the carers' comprehension of therapy because of time constraints 	<ol style="list-style-type: none"> <u>The carers have poor organisational skills (e.g. inability to prioritise activities or plan ahead)</u> The carers are busy The carers over rely on emergency supply The carers are not aware that they can request an emergency supply from their pharmacy The carers forget/are forgetful 			
Proposed Solutions	The pharmacists or GPs guide the carers on how to store medications correctly (e.g. reminders about the importance of the labels on container/ blister pack)	T	The pharmacists provide written instructions to explain what to do with old medications	T	The carers note the date of when to order new prescriptions in a part of the house that others use frequently	P
	The carers are instructed to recognise medications from their appearance (e.g. shape, colour)	T	The GPs or the pharmacists highlight the name of the current medication on the prescription	P	The carers communicate the date for ordering new prescriptions to the others outside of the home	O
			IT solutions to be developed and used in order to help share information between GP, pharmacists and carers (e.g. Telemonitoring)	O	The carers are asked to make a plan to order medications (e.g. on a spreadsheets)	T
			Carers periodically check prescriptions to avoid continuing old medication	P	The carer creates personal reminder systems (e.g. alarm, checklist, calendar, text message, chart)	E
			The GPs use a form to notify the carer that their medication has changed	E	Pharmacy alerts carers when it is necessary to order new medications	P
Responsible	<ul style="list-style-type: none"> Carer(s) GP(s) Community Pharmacist(s) Hospital Consultant(s) 	<ul style="list-style-type: none"> Carer(s) GP(s) Community Pharmacist(s) 	<ul style="list-style-type: none"> Carer(s) GP(s) Community Pharmacist(s) 			
Outcome measures	The pharmacists or GPs regularly check the medication storage with questions	<ul style="list-style-type: none"> The pharmacists regularly check the usage of the current medications with questions The carers keep a written record with information about medications and the date that they have been dispensed 	Pharmacy alerts carers when it is necessary to order new medications			

SHERPA Remedy Analysis: *Equipment (E)* = redesign or modification of existing equipment; *Training (T)* = changes in training or informing carer/patient of procedures to follow; *Procedures (P)* = provision of new or redesign of old procedures; *Organisational (O)* = changes in organisational policies or culture. [Numbers in square brackets refer to failure modes in Appendix 2]

Table 3. High-risk scenario causes, solution and outcome measure for critical failure modes

	The medication is measured out wrongly (i.e. the dose is wrong) [4.7.i]	The medication is given with a wrong dose [5.1.d]	The given/not given medication is not recorded [5.3.h]			
Present solutions	<ul style="list-style-type: none"> Some insulin pens have a dial to set the individualised amount of insulin Training and assessment of carers made by community healthcare professionals 	<ul style="list-style-type: none"> The carers write down a list of patient's medications (e.g. My medication passport(Barber et al. 2014)) Information about the doses provided by the community service (i.e. community nurses and clinics) 	None			
Detectable?	Difficult to detect. Particularly for small medication measurement doses; it depends on the design of syringe or insulin pen	No	No			
Causes (most common underlined)	<ol style="list-style-type: none"> <u>The carers do not admit problems with their medication administration because they are worried about being labeled as 'someone that cannot cope'</u> Frequent changes of insulin pens that have different dials, (e.g. unit, half unit, and different system to set the maximum) The carers are rushing due to stress or other reasons The carers have difficulties in reading the dial because of poor eyesight The carers haven't been trained adequately 	<ol style="list-style-type: none"> <u>The carers do not understand the instructions or specific requirements to adjust the dose.</u> The carers do not read the instructions The carers misunderstand the prescriptions The carers have difficulties in using syringes or insulin pens The carers have not been trained adequately in measuring out the doses The carers have difficulties in acquiring information about the dose from the GP Failure mode 5.7 (The medication is measured out wrongly) 	<ol style="list-style-type: none"> <u>The carers do not feel the necessity to record the given/not given medications because it is a part of their daily routine</u> The carers have poor literacy and cannot read or write (e.g. language and cultural barriers) The carers have not been told to record medications The carers do not have the organisational or IT skills (e.g. they do not have the skills to create an Excel spread sheet) The carers assume that they will always be around (e.g. to tell healthcare professionals about medications given) The carers have to manage many medications that change frequently 			
Proposed Solutions	The GPs monitor and support the patients and carers in the measurement of the doses (e.g. emphasising the unit measures on insulin pens or offering psychological support)	P	The GPs or pharmacists reinforce the use of records of patient medications (e.g. My Medication Passport(Barber et al. 2014) for insulin that helps to check the type and the doses of medication actually given)	T	The carers use tools (e.g. Excel spreadsheet) to record medications	P
	The GPs or pharmacists encourage the carers to speak about their difficulties in medication administration	P	The carers are trained to administer medications with courses organised by community clinics	T	The carers are trained to improve their organisational or IT skills (e.g. how to use Excel spreadsheet or Notes application)	T
	The community nurses support the carers in technical medication administration	O/P	Checks at discharge that carers understand instructions	P	The pharmacists promote the use of Medication Administration Record chart	T
Responsible	<ul style="list-style-type: none"> Carer(s) GP(s) Community-District nurse(s) 	<ul style="list-style-type: none"> Carer(s) GP(s) Community pharmacist(s) 	<ul style="list-style-type: none"> Carer(s) GP(s) Community Pharmacist(s) 			
Outcome Measures	Community healthcare professionals organise dummy runs to check carers' technique of measuring out medication doses	<ul style="list-style-type: none"> The carers monitor the effects of therapy (e.g. wrong dose could cause deterioration) Number of hospital admissions for wrong dose errors at home 	Excel spreadsheet with all scheduled medications			

SHERPA Remedy Analysis: **Equipment (E)** = redesign or modification of existing equipment; **Training (T)** = changes in training provided, informing carer/patient of procedures to follow; **Procedures (P)** = provision of new or redesign of old procedures; **Organisational (O)** = changes in organisational policies or culture