Title

Patient safety threats in information management using HIT in ambulatory cancer care: an exploratory, prospective study

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Title

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1 **ABSTRACT**

2 *Background.* Cancer care is complex, involving highly toxic drugs, critically ill patients and various

3 different care providers. As it is important for clinicians to have the latest and complete information

4 about the patient available, this study focused on patient safety issues in information management

5 developing from Health Information Technology use (HIT) use in oncology ambulatory infusion

6 centers.

7 *Objectives.* The aim was to exploratively and prospectively assess patient safety risks from an expert

8 perspective: instead of retrospectively analyzing safety events, we assessed the information

9 management hazards inherent to the daily work processes; instead of asking healthcare workers at the

10 front-line, we used them as information sources to construct our patient safety expert view on the

11 hazards.

12 *Methods.* The work processes of clinicians in three ambulatory infusion centers were assessed and

13 evaluated based on interviews and observations with a nurse and a physician of each unit. The 125

14 identified patient safety issues were described and sorted into thematic groups.

15 *Results.* A broad range of patient safety issues was identified, such as data fragmentation, or

16 information islands, meaning that patient data is stored across different cases or software and that

17 different professional groups do not use the same set of information.

18 *Conclusions*. The current design and implementation of HIT-systems does not support adequate

19 information management: clinicians needed to play very close attention and improvise to avoid errors

20 in using HIT and treat cancer patients safely. It is important to take the clinical front-end practice into

21 account when evaluating or planning further HIT improvements.

INTRODUCTION

Cancer care in an ambulatory infusion unit of a hospital involves the administration of toxic drugs to critically ill patients, the cooperation of various care providers, and often of different units within a hospital, or different hospitals, and primary care providers. In these high-risk and complex work environments, addressing error rates is object of various approaches and studies [1–3] into the safety of cancer care. The use of health information technology, for example electronic health records or computerized physician order entry, is common in Swiss hospitals and is changing the way work is carried out in many ways.

Positive effects in managing the complexity of cancer care are expected from Health Information Technology (HIT) use [4], such as more comprehensive patient data, or a better management of the chemotherapy treatment regimens. As Adelson et al.[5] illustrated, the patient safety of cancer care can be improved in using electronic prescription software for example. The Institute of Medicine recommended in their 2013 report [6] to develop HIT for achieving high-quality cancer care: electronic charts should not be a digitalized version of the paper-based charts, but be a real-time, comprehensive patient-centered representation of information, e.g., patient's history, allergies, lab results. Despite the hope for a safer and more efficient oncology care process using HIT[5,7], there is growing evidence that the use of HIT bears risks for patient safety [8–11]. The term e-iatrogenesis has been coined to describe patient harm coming from HIT use [12]. Analyzing *retrospectively* patient safety event reports to investigate the negative impact of HIT use on patient safety[13,14] identified important HIT-related risks, such as poor user interface design leading to selecting the wrong tests or medication. However, from a patient safety perspective, the range and potential variety of risks remains unknown, as events may go unreported or not may not have manifested as safety threat. Therefore, it is important to *prospectively* identify unsafe working conditions that are related to patient safety hazards.

A review showed that mainly single HIT-softwares were investigated for their effect on patient outomes [15] while the influence of simultaneously using multiple HIT-systems was studied less. Therefore, it is important to study the actual "HIT-in-use" [11] in real work environments, in which usually different HIT-systems are simultaneously in place for different purposes. A recent study illustrates that different local customizations of the same software for electronic health records

52 resulted in differences in the actual HIT use, with task durations, clicks and error rates varying [16].

53 Thus, it is important to take into account the interactions between HIT design, HIT-in-use, the social

54 system and the work processes, as well as the technical infrastructure [11] from a system perspective [17,18].

55 Clinicians need to develop an accurate mental model about the patient's state and treatment, as an

56 accurate mental model allows for mindful action and decision-making [17]. For clinicians to develop and

57 update their mental model about a patient, it is essential that information is stored and accessible in a

58 timely way. Ash et al. [19] have shown that often the retrieval of information is hard because of the

59 design of the HIT system. Inadequate information management can result from HIT use and may

60 hinder the development of an accurate mental model and lead to treatment errors.

61 The aim of our study was to assess instances of unsafe information management related to work

62 practices involving HIT use, or simply to bad HIT design. In exploratively and prospectively

63 investigating HIT-related information management hazards, we assessed a broad range of possible

64 patient safety issues. The patient safety issues were analyzed for higher-order topics in order to better

65 understand the involved system-level risks. Based on this analysis, we wanted to define areas for

66 future action and potential improvements.

67 As the infusion centers treat many patients per day using complex treatment regimens and high risk

68 drugs, with prescription orders that may be changed even after the drug has been produced by

69 pharmacy, the potential benefits of using HIT are particularly are particularly relevant in this context.

70 The analysis focus was on normal, everyday operations, patient safety threats relating to a potential

71 system failure were not considered.

72 **METHODS**

73 **Research Design**

74 We applied a patient safety expert's lens on HIT use in information management, i.e., instead of

75 assessing the practitioners' opinions on patient safety issues, we assessed thoroughly their work

76 processes in order to identify patient safety issues (PSI, in the following). We used different data

77 sources (interview, observation) in order to capture all HIT-related work practices and to understand

78 how they are embedded in the overall work organization of the center. As data assessment was

79 centered on understanding the work organization, we applied an iterative procedure in asking specific

80 questions after the first step of analysis identifying the patient safety issues. This led to some

81 specifications and changes of the identified PSIs. The evaluation of the risk inherent to the identified

82 patient safety issues was part of the analysis and identification of thematic groups and was carried out

83 by three researchers (the authors), two of which were experts in patient safety (YP, DS) and one of

84 which was a nurse trained in qualitative research (CZ), all with prior research experience in the

85 ambulatory cancer care setting.

86 Instead of retrospectively looking for unsafe events related to HIT use, the study was designed to

87 prospectively assess the patient safety issues that evolve from information management-related

88 hazards. Thus, the identified issues may or may not lead to a real error in everyday work; however,

89 from our patient safety expert judgment these issues carry a heightened risk for the occurrence of an

90 unsafe event.

91 **Participants**

92 The ambulatory infusion centers of three large Swiss hospitals took part in the study. In order to gain a

93 good understanding of the HIT setup and the work processes, there were two introductory interviews

94 at each site with a physician and a nurse each, in which they described and showed their use of HIT. In

95 each center, a physician and a nurse were interviewed and observed. They had all more than five years

96 of professional experience. Each participant was interviewed for 1.5h, and was observed during their

97 patient-related activities during one working day. The clinicians needed to be the same for the

98 interview and observation only the introductory interview could be done by a different person. At the

99 end of each observation day, the observers had the opportunity to ask questions. Interviews were

100 confidential and participation was voluntary.

101 The study was considered exempt from ethical approval from the Cantonal Ethics Committee Zurich

102 (BASEC-Nr. Req-2017-00622) on the basis of the Swiss Legislation (Human Research Act, HRA), as

103 data assessment was anonymous and no patient-related data was gathered.

104 **Data assessment and analysis**

105 Data assessment and analysis were interwoven and conducted in five steps (see figure 1):

106   ----

107   *Insert figure 1 about here*

108   ----

109   First, we gained a good understanding of the work processes and the HIT use involved in the

110   introductory interviews. Based on this understanding, we developed a scheme for the assessment

111   interviews of step 2. It differentiated eight patient information management-related tasks clinicians

112   have to do before, during or after the visit of a patient in the infusion center.

113   –   prepare for patient visit: gather information (nurse and physician);

114   –   initiating treatment: measuring vital signs, potentially taking blood samples (nurse);

115   –   diagnostic and monitoring: consult health record, lab results, ask patient (physician);

116   –   prescribing: evaluate general condition, use treatment regimen or prior prescription

117   (physician);

118   –   handover to pharmacy for production and to nursing for administration (physician);

119   –   administer premedication, taking e.g., patient record, personal information from physician and

120   guidelines into account (nurse);

121   –   administer chemotherapy along prescription, guidelines, treatment regimen (nurse);

122   –   documentation of patient condition, potential reactions to administered drugs, and for billing

123   (nurse and physician).

124   The development of order forms for chemotherapy treatment regimens is a specific task which is

125   not carried out daily. As it is relevant how the regimens are developed, how they are stored and

126   managed for the safety of their use, we assessed the information-management related safety issues

127   that are involved in treatment regimen development and –management.

128   Thus, in step 2, we assessed the informational in- and output for each task. All tasks related to initial

129   diagnosis were excluded in our analysis.

130   In a third step, we extracted PSIs from the transcribed interviews. For this purpose, we developed

131   short descriptions of PSIs containing the: a) aim of the work step, b) procedure, how the aim is

132   attained, c) the problem regarding patient safety involved. Each PSI description developed by one

133 researcher was checked and validated by the second researcher; disagreements were solved in

134 discussion with the third researcher.

135 The fourth step consisted in validating our identified PSI-descriptions in observing a nurse and a

136 physician each in each ambulatory infusion center. Therefore, we prepared in working through all the

137 identified PSIs, listing remaining open questions. We improved and completed the PSI-descriptions if

138 necessary after the observation day. Any change of a PSI description had to be checked and validated

139 by a second researcher.

140 In the fifth step, we analyzed the PSIs in order to identify higher-order topics, i.e., risks involved in the

141 described patient safety issues from a systemic perspective. Therefore, we discussed the PSIs and

142 identified thematic groups to describe the identified issues. A stable set of thematic groups was

143 developed iteratively in testing the application of thematic groups and discussing them and then testing

144 again. This stable set of thematic groups was then used to categorize all PSI descriptions. Finally, each

145 PSI description was coded by one researcher and checked by a second researcher. Disagreements were

146 solved in discussion with the third researcher. Each PSI could be sorted to more than one group. The

147 aim of this sorting process was not to count the number of PSIs in one group, but to find a set of

148 categories sufficient to thematically cover all identified PSIs.

149 **RESULTS**

150 In all studied centers, there was not one single electronic health record per patient which all involved

151 care providers fed their information to or from which they retrieved all information. Rather, multiple

152 information systems were in use and in addition paper-based information management persisted for

153 certain purposes. Furthermore, only one hospital used software to prescribe chemotherapy that directly

154 communicated with pharmacy. The other hospitals either used word or excel files containing the

155 chemotherapy regimens; they needed to be manually transferred to the pharmacy IT-system before

156 chemotherapy production.

157 We found 125 threats to patient safety involving information management and HIT design and

158 identified eleven thematic groups describing patient safety hazards involving HIT use on a systemic

159 level (see table 1 for examples):

6

1) *The **organization of the daily tasks** is only deficiently or not at all supported by or represented in HIT design*. PSIs were sorted to one of the subgroups: 1a) PSIs regarding the planning of a clinician's work during a work day involving patient care; 1b) PSIs regarding the work organization of the whole infusion center during one day; 1c) PSIs relating to tasks that have to be done for patients independently from their visit.

2) *'**Information islands**' exist despite HIT use*. Two modes of information islands were differentiated: 2a) different groups (e.g., nurses and physicians or hospital units) have separate information sets even though the same IT-system is in use, instead of managing a common set of information; 2b) information islands stem from HIT-systems not communicating between different care institutions.

3) ***Technological bridges** between HIT-systems are lacking.* Non-communicating HIT-systems lead to manual information transfers that are usually error-prone. Additionally, the lack of communication between measuring devices such as a clinical thermometer and HIT involved unsafe practices to document patient parameters.

4) ***Information flood***, because HIT use allows for more comprehensive documentation, e.g., in using predefined phrases, more information is documented. The amount of information often hinders an easy and targeted retrieval of information.

5) ***Fragmentation** of patient-related information*, i.e., the information regarding one patient is often stored in several systems, or in different "places" within one system. Fragmentation can lead to "patient data forking" in which patient data is for example copied from the patient chart of a hospital unit to the chart of the ambulatory unit, and from then on, the patient chart is used in the ambulatory unit without updating it if the patient goes back to the hospital unit. We identified two specific forms of fragmentation: 5a) Electronic health records are saved as 'cases' that are used for billing or that are related to the physician in charge, meaning that the case is closed as soon as the treatment hast been billed or the physician in charge changes; 5b) patient information is documented in different HIT systems, for example in the software used for prescribing chemotherapy and in the electronic health record.

186 6) **_Inadequate usability_** _of the HIT systems_ leads to information management issues. The following

187 subgroups were differentiated: 6a) data storage and retrieval is cumbersome and not well adapted to

188 work requirements; 6b) HIT design fosters confusion errors; 6c) HIT does not work properly, for

189 example it does not reliably display all the ordered drugs ; 6d) HIT does not offer a user-friendly

190 "roadmap", i.e. an overview of a chemotherapy in its course; 6e) changes in information are not easy

191 to perceive or to be traced; 6f) information from physical sources is digitalized slowly, so that the

192 patient chart is not up-to-date when the patient is visiting.

193 7) **_informational structures_** supposed to support either decisions (7a), or actions (7b) **_are missing or_**

194 **_inadequately represented_** in HIT: 7a) for example, no drug interaction warning was integrated in the

195 chemotherapy prescribing tool in any of the hospitals; 7b) procedures, guidelines or information on

196 how to handle for example certain ports were not easily accessible in the HIT system; printing

197 guidelines was discouraged in the hospitals.

198 8) _HIT systems are_ **_not used for communicating information that is time-relevant_**, i.e., entering

199 information into a HIT system is not equivalent to real-time communicating certain information:

200 personal communication was used to make aware of a certain information, e.g., a fax is sent to the

201 physician with the lab results, in addition to loading them up in the electronic health record.

202 9) _Inadequate HIT design can lead to_ **_workarounds_** _involving a substantial amount of additional work._

203 This category is ambiguous, as every activity going back to bad HIT design can be considered a

204 workaround. Therefore, we defined workaround here as involving a substantial amount of additional

205 work that would be unnecessary with better HIT design.

206 10) _The_ **_concurrent use of paper documentation_** _in addition to HIT- based documentation enlarges_

207 _the possibilities for data entry, storage and retrieval errors to occur_. Paper documentation prevailed in

208 all investigated units.

209 11) **_Lacking access_** _to HIT may lead to unsafe practices_. For example, we observed nurses preparing

210 medication (not chemotherapy) without the prescription at hand, because there were no computers in

211 the drug preparation room.

DISCUSSION

The identified groups of patient safety issues show that the introduction of HIT use leads to new patient safety hazards that are currently underestimated in their importance (from our experience in the field). They also show that the opportunities offered by HIT use to improve organizational effectiveness and safety in cancer care are not benefitted from in many cases, e.g., using electronic prescription tools that do not check for drug interactions or allergies.

The studied units are far from fulfilling the recommendation of the 2013 IOM-report [6]: Instead of maintaining one comprehensive record per patient, multiple HIT systems and also paper-based documentation forms co-existed. The resulting fragmentation of data storage made finding information harder, and some information was inaccessible for some care providers [20], or it existed in multiple systems (data forking). Missing technological bridges between the concurrently used information management systems lead to manual information transfers. Data is either entered manually or copied and pasted. Both practices are highly error-prone because the same patient has different records of varying degrees of completeness, accurateness or actuality. Clinicians may not be aware of using outdated or inaccurate information while more up-to-date information may exist in their own unit. Information about prior or other concurrent care providers are often not available or need to be organized specifically, which leads to 'information islands' that the clinicians are on, using and generating data that they do not share with other providers for the same patient. The electronic health record that will be introduced in Switzerland soon, may help with this information exchange.

With the fragmentation (see also [20]), the information flood, the concurrent use of paper-based documentation, and the deficient usability [13] of the HIT systems, it becomes hard for a clinician to develop an accurate mental model of the patient's situation and treatment. Too many different information sources need to be considered: it is easy to forget or to not consult one due to time pressure. Even if they are all considered, the information may still be outdated. Thus, valuable information about the patient's history or current condition may not be taken into account in deciding about and carrying out a treatment.

If a clinician cannot find information fast enough, the patient is often asked, e.g., whether their weight has changed. This may lead to unreliable information, and additionally, from a patient perspective, being asked basic information by different care providers multiple times may lead to mistrust.

The existence of information islands even in using the same HIT system is surprising for nurses and physicians of an ambulatory infusion center caring for the same cancer patient. From a work psychological viewpoint, HIT may be ideal for developing boundary objects [21], i.e. information sets that are managed by both groups. This was only the case for the chemotherapy prescriptions in the hospital using a prescription and production software for chemotherapy. Using HIT deliberately as a boundary object for collaboration between different professional groups could help make the caregivers to be better informed.

The fact that information may be entered more quickly in a HIT system than in a paper-based documentation may lead to procedures that require a lot of information to be documented and thus to information flood in documenting [10] and retrieving information[19]. It is harder to make sense from predefined phrases describing a patient's past condition than from a well-thought evaluation of the prior caregiver [10,19].

Prior research highlighted the design of the human-computer interface as an important contributing factor to errors[13,19,22–24]. Our identified themes within the group of inadequate usability support these findings and illustrate areas for future improvements. Designing better HIT needs requirement-based development and testing of HIT[22], as well as regulatory guidelines for testing the safety and usability of implemented HIT[16].

In all three participating hospitals, we assessed the current state of HIT use, while there were changes and new developments planned. Although it is evident that complex systems develop constantly [11], it is very important to move away from this stage of "constant improvisation" in information management towards a stage in which the basic needs of safe information management are met and supported by the implemented HIT system. In the studied centers, work was organized around inadequate HIT systems rather than HIT systems being designed around the requirements of the work tasks.

265   The explorative and prospective nature of the study allowed for identifying a broad range of safety

266   issues. These insights are important for hospital decision makers, regulators, and vendors in improving

267   clinical practice involving HIT use.

268   This study has several limitations. The collection of PSIs may not be exhaustive, integrating other

269   professional groups and units such as office staff doing work planning or pharmacy would have

270   identified more PSIs. Additionally, the PSIs identified cannot be used to determine the frequency of

271   HIT-related errors or problems. Broader studies need to be conducted to determine the frequency of

272   the identified risks. Furthermore, we did not use any indicators of severity of potential errors. Whether

273   a certain PSI may result in a major error is multifactorial and was not in the scope of this study.

5 CONCLUSIONS

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275   Healthcare workers need to use cognitive resources in paying close attention and improvisation in

276   order to enter, understand and manage information in the HIT systems we studied. We conclude that

277   the complexity and timely dynamic of care was not supported by the HIT systems in use. However,

278   some of the hazards we identified from our analysis were not common knowledge with the

279   practitioners who were our information sources. So, practitioners may be unaware of patient safety

280   threats related to their current HIT use. Therefore, it is very important to measure and evaluate the

281   safety of clinical practice: HIT needs to be developed and tested along the requirements of the actual

282   work done by clinicians. Guidelines and tools for evaluating the safety of HIT design and the actual

283   HIT-in-use need to be developed. Furthermore, safety needs to be built into the design of HIT [26] and

284   hospitals should make HIT use a part of the hospital's overall process improvement activities.

285   Moreover, rapidly communicating and addressing the safety issues emerging in the local work context

286   within the hospital, but also with the vendors [26] will be paramount in improving HIT use to improve

287   patient safety.

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FIGURE LEGEND

Figure 1. Five steps of data assessment and analysis

Table 1: Overview of thematic groups of patient safety issues with examples

Thematic group	Subgroup	Example
1) Organization of daily tasks not supported	1a) planning of a single clinician's work during a work day involving patient care	Nurse uses a print from the planning software to know when they treat which patient and also notes questions or specific to do's on it. As the staff responsible for planning does not have exact information on treatments, information about chemotherapy may be wrong on this print. When for example the wrong chemotherapy is delivered or in stressful situations, this wrong information may lead to errors.
	1b) work organization of the whole infusion center during one day	The physician writes a note for the planning person for the next visit. In the planning tool, patients either get treatment or come for control. On the physician's note, the administration of a drug was noted, but the box "treatment" was not checked. So, the planning person only planned to have a control visit and the patient almost did not get his or her drug.
	1c) tasks to be done for patients independently from their visit	In order to remember that for a certain patient there is something to do like ordering results from other care providers, the physician leaves the health record open in the HIT. If the system is updated, the record closes ad the reminding function of the open record does not work anymore.
2) Information islands exist despite HIT use	groups have separate information sets despite the same IT-system is in use	If a patient has been consulted by another physician within the same hospital, the responsible physician at the ambulatory infusion center will only know of this consultation if the other physician has written a formal report about it. Otherwise he or she will not be informed about it from the HIT-system.
	non-communicating HIT systems between different care institutions	For new patients, information usually is missing, for example prior health records from the primary care provider, or diagnoses. If they exist, they are stored as paper and are not accessible in the electronic health record.
3) Lack of technological bridges between HIT-systems		Pharmacy uses different software than the physicians for chemotherapy orders. Thus, the chemotherapy orders are issued using Word and sent via fax to the pharmacy, where they are transferred manually into the pharmacy chemotherapy production software. Thus, the risk of transfer errors is present.
4) Information flood		In this hospital, one patient's information may be stored in different "cases" that are related to billing. If a patient was treated in other hospital units and is now back in the ambulatory infusion center, the list of medications needs to be imported to the current "case", this means that all medications are displayed concurrently, the ones saved in the ambulatory case and in the other case, and one needs to sort them out in a laborious and error-prone process.
5) Fragmentation of patient-related information	5a) electronic health records saved as different 'cases'	Electronic health records in the nursing software are related to a certain physician in charge. If the physician changes, a new case is opened for the patient and all prior information are lost, and need to be imported from the former case in a complicated process. Thus, it is possible that not all information is imported or that information is missing that has not yet been imported.

	5b) documentation of patient information in different HIT systems	Two different electronic health records are being used concurrently for every patient (one containing the chemotherapy-related information communicating directly to the pharmacy, and another IT system containing all other medications). The vital signs are documented depending on the kind of therapy administered in the one or other HIT-system. Thus, a quick overview of the patient's state is more complicated with such a form of documentation.
6) Inadequate usability	6a) data storage and retrieval is cumbersome	There is no overview about weight development over several months in the patient chart software possible. Therefore it is hard for the clinician to develop an adequate mental model about the patient's history and condition. If the patient is asked, this information can be unreliable and inaccurate.
	6b) HIT design fosters confusion errors	Nurse can easily order a wrong carrier solution from a long drop-down list with a small font.
	6c) HIT does not work properly	If a physician is on-call duty at home, he or she needs to connect to the electronic health record from home. Loading takes several minutes. Thus, in urgent situations, physicians often prescribe based on their prior knowledge about a patient without consulting the current list of medications in the electronic health record.
	6d) no or not user-friendly representation of a chemotherapy "roadmap"	In the software used for chemotherapy prescription, there is no useful visualization of the long-term perspective on the chemotherapy. Thus, it is not easy to assess the chemotherapy as a whole (e.g., dosage adaptations or administrations that have been postponed). However, this is important information for decision-making about therapy or assessing the patient's state.
	6e) changes in information are not easy to perceive or to be traced	In this hospital, nurses have no access to former prescriptions. For the nurse to realize whether a treatment has changed from last time, he or she notes each treatment in their documentation and compares it then next time to the current treatment.
	6f) slow digitalization of information from physical sources	Reports from external care providers come into the infusion center as physical letters. They are read and signed by the physician and then scanned by the administrative staff. Scanning takes time, thus the letter is neither in the paper-based health record, nor in the electronic health record during the time it is in the administrative office to be scanned. Important information may not be taken into account if the letter is in the administrative office and the physician does not remember it exists.
7) Missing or inadequate informational structures	7a) to support decisions	The chemotherapy prescription software does not give an alert for inadvertent overdoses.
	7b) to support actions, i.e., procedures or protocols	In order to avoid outdated nursing guidelines, printing them is discouraged. Yet, nursing guidelines, e.g., how to handle an extravasation, are not easily found in HIT. Thus, finding takes time, but the nurse staff needs to take action quickly.
8) No real-time communication within HIT		For urgent cases, lab results are not only visible in the electronic health record, but also sent by fax from the laboratory. This avoids that the physician needs to look up potentially several times to see whether the results are available. This makes processes more complicated and a fax print exists that may be outdated but still used.

9) Workarounds	For the nurses to know the reason for admission of a patient, they copy it from the last physician report into their documentation system. This copied information may be outdated or wrong if the patient gets readmitted.
10) Concurrent use of paper documentation increases opportunities for errors	As the information about the patient's general state is noted by the physician on paper (e.g., whether the patient has fever), and this paper documentation is stays with the physician, the nurse does not know the current state of the patient when he or she comes for treatment. The patient is often asked for this information again or the nurse is not informed that a patient has a different medication because of fever, she needs to find that out by herself.
11) Lacking access to HIT leads to unsafe practices	As there is no computer in the medication preparation room, medication is prepared either from remembering or from hand-written notes. The risk for medication preparation errors is increased.