

# Memorandum on the Use of Information Technology to Improve Medication Safety

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## Keywords

Drug therapy safety, information technology, medication safety, decision support systems, drug safety, patient safety

## Summary

**Background:** Information technology in health care has a clear potential to improve the quality and efficiency of health care, especially in the area of medication processes. On the other hand, existing studies show

possible adverse effects on patient safety when IT for medication-related processes is developed, introduced or used inappropriately.

**Objectives:** To summarize definitions and observations on IT usage in pharmacotherapy and to derive recommendations and future research priorities for decision makers and domain experts.

**Methods:** This memorandum was developed in a consensus-based iterative process that

included workshops and e-mail discussions among 21 experts coordinated by the Drug Information Systems Working Group of the German Society for Medical Informatics, Biometry and Epidemiology (GMDS).

**Results:** The recommendations address, among other things, a stepwise and comprehensive strategy for IT usage in medication processes, the integration of contextual information for alert generation, the involvement of patients, the semantic integration of information resources, usability and adaptability of IT solutions, and the need for their continuous evaluation.

**Conclusion:** Information technology can help to improve medication safety. However, challenges remain regarding access to information, quality of information, and measurable benefits.

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## 1. Introduction

Information technology in health care (“health IT”) has the potential to support and improve the quality and efficiency of health care and patient safety [1]. At the

same time, critical voices have pointed out the risks and possible limitations of health IT [2, 3]. A matter of particularly intense current debate is the use of **health IT for medication safety**. Above all when it is coupled with a decision support system,

health IT for medication safety can achieve a demonstrable improvement of documentation quality and subsaspects of patient safety [4–8]. At the same time, some studies have pointed out possible complications and a resultant danger to patient

safety when health IT for medication safety is developed, integrated, or used in an inadequate way [9–15].

The **present memorandum** begins with fundamental definitions of health IT for medication safety and describes typical functions thereof. It unites observations on the use of health IT for medication safety upon which to develop basic action recommendations that should find consideration in future developments and which provide indications for further research needs. It is directed at decision makers and experts in health IT for medication safety. As errors are an unavoidable part of human nature, health IT for medication safety strives for the best possible support of all steps of the medication process in order to recognize and reduce the potential medicine safety issues in an essentially fault-tolerant integrated system of health care.

## 2. Methods

This memorandum was developed in a consensus-based iterative process that included workshops and e-mail discussions among 21 experts coordinated by the Drug Information Systems Working Group of the German Society for Medical Informatics, Biometry and Epidemiology (GMDS). The authors, who have years of experience in the field of medication safety and information technology in health care, include researchers and practitioners from various professional groups such as medicine, pharmacy, pharmacology, health informatics, and quality management. The German version of the memorandum was finalized and approved by the authors in June 2013 [16].

## 3. Definitions

The following definitions are based on the “Memorandum zur Entwicklung der Forschung auf dem Gebiet der AMTS” (Memorandum on the development of research in the area of medication safety) [17] and a subsequent publication based on it [18] as well as on current definitions from the European Medicine Agency (EMA) [19], as these were and are being developed in a broad national and inter-

national consensus-based process. It should be noted, however, that several of the terms are still being discussed [20] and, despite all efforts of disambiguation, are thus subject to a certain level of flexibility.

1. **Medication safety:** “The totality of measures to ensure the on-label use of a pharmaceutical drug. The aim is to achieve the best possible organisation of the medication process, with the goal of avoiding adverse drug events in particular through medication errors and thus to minimize the risk for the patient during a drug therapy” [18, p 710].
2. **Medication:** The act or the process in the use of one or more pharmaceutical drugs [21].
3. **Medication process:** Includes all steps of the drug therapy (see Figure 1). Simplified, the medication process includes the following activities: diagnostics, treatment planning prescribing and transcribing dispensing and distributing patient information and motivation use (taking/administering) monitoring of effect and assessment [18, p 710].
4. **Adverse drug event<sup>a</sup>:** A harmful event which coincides with the use of a pharmaceutical drug [18, p. 711].
5. **Side effect (adverse drug reaction):** A harmful and unintentional reaction to a pharmaceutical drug [18, p 711].
6. **On-label use of a drug:** “Use of a pharmaceutical drug in accordance with the authorised product information. The current interpretation of the law also considers on-label use of a pharmaceutical drug to include use that is not or not fully in accordance with the authorised product information (off-label use) if it corresponds to the latest advances in medical science and if a positive benefit/risk ratio can be assumed” [18, p 710].
7. **Medication error<sup>b</sup>:** “Any unintentional error in the prescribing, dispensing or ad-

<sup>a</sup> These definitions reflect the current state of the debate in Austria, Switzerland, and Germany. Ongoing work being conducted by international panels of experts may result in changes, additions, or deletions to these definitions.

<sup>b</sup> This EMA definition is a preliminary definition and remains in discussion, as the criterion for a medication error is not yet clearly defined. Compare also [17] for alternative proposals.

ministration of a medicinal product while in the control of the healthcare professional, patient or consumer” [22, p 7].

8. **Information technology for medication safety:** Any form of computer-supported information and communication system which is used to support and monitor the medication process.

Hereafter the memorandum will focus on health IT for medication safety. A distinction must still be made between health IT for medication safety and the following two terms, which are given no further consideration in this memorandum:

9. **Drug safety:** “The regular and systematic monitoring of the safety of a pharmaceutical drug with the goal of discovering, assessing, and understanding adverse effects occurring under conditions of on-label use in order to be able to take the necessary measures to minimize risk” [18, p 711].
10. **Pharmacovigilance:** “Totality of measures relating to the detection, understanding, assessment, and prevention of adverse drug reactions” [18, p 711].

## 4. Typical Functions and Applications of Health IT for Medication Safety

Numerous systems and functions of health IT for medication safety are capable of supporting the medication process. The systems that are presented may represent autonomous products or they may be embedded in larger clinical systems (e.g. hospital information systems, administration systems for medical practices, or pharmacy systems). The following list ordered according to the steps presented in ► Figure 1 highlights only a selection of systems supporting each step:

- **Diagnostics, treatment planning, and prescribing:** Drug databases and drug information systems with search possibilities; systems for medication prescribing (computerized physician order entry/CPOE) – these software systems are often combined with a decision support system (see below); systems for

cross-sector access to the medication history.

- **Dispensing and distributing:** Automatic dispensing and commissioning systems such as unit-dose systems or medication dispensing cabinets; systems to support the drug logistics (e.g. barcoding/scanner systems, pharmacy systems).
- **Patient information and motivation:** Automatically generated medication and drug-taking schedules; patient websites.
- **Use (taking/administering):** Electronic medication administration record (eMAR); eBlister, barcoding and scanner systems, smart pumps, radio frequency identification (RFID) systems; mHealth systems for adherence management which remind the patients to take their medication and/or give

them the opportunity to document their drug-taking.

- **Monitoring of effect and assessment:** Systems for the software-supported, patient-related, and facility-related assessment of the drug therapy including the prospective identification and standardized documentation and reporting of adverse drug events and/or side effects.

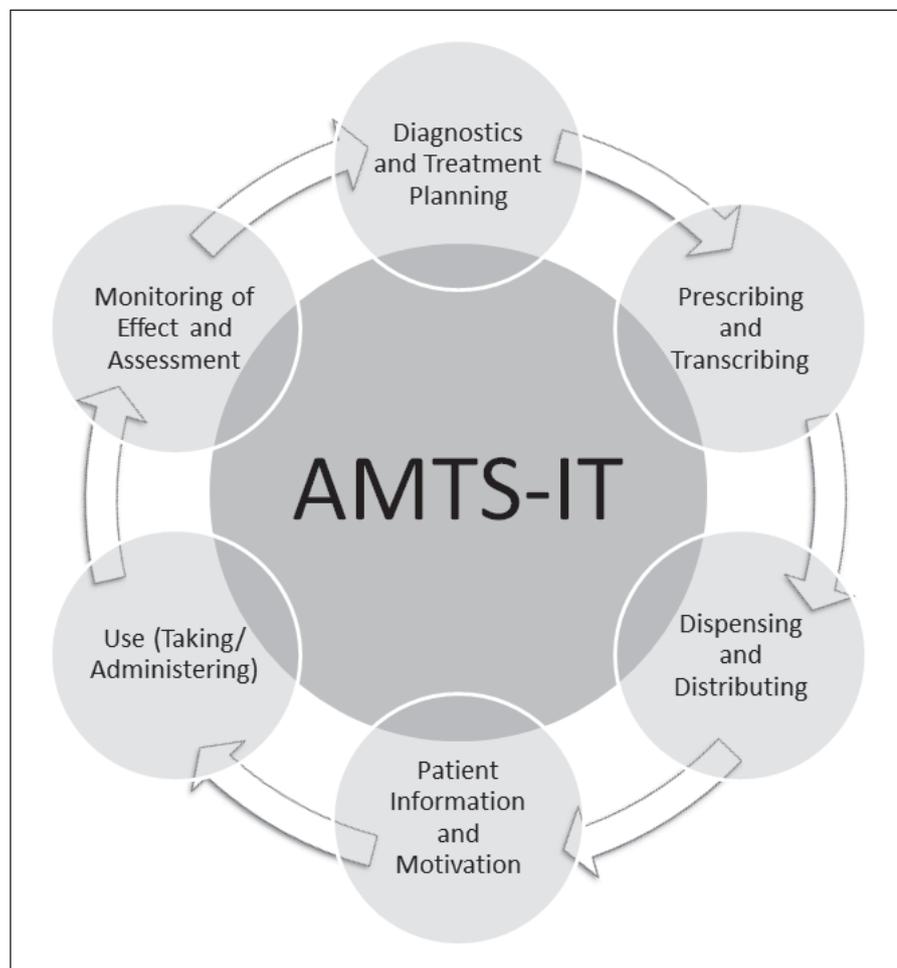
Besides these functions that are directly related to the medication process, also critical incident reporting systems (CIRS) as well as pharmacovigilance systems are used with the purpose to manage structure quality, process quality and outcome quality during treatment with drugs.

Health IT for medication safety can include **decision support functions** for health care professionals, such as drug-allergy checking, basic dosing guidance,

formulary decision support, duplicate therapy checking, drug-drug interaction checking, dosing support for renal insufficiency and geriatric patients, or guidance for medication-related laboratory testing [23].

It is difficult to estimate how **widespread health IT for medication safety** is, as few meaningful studies exist. Most studies in this regard are from the United States, where clinical IT and especially CPOE have for years been subsidized under the American Recovery and Reinvestment Act [24]. In 2008, CPOE systems had already been deployed at 34% of the acute-care hospitals in the United States [24]. In a 2012 survey, this had grown to 54% of all hospitals [25]. In the annual HIMSS Leadership Survey 2012, 16% of 300 IT executives at US hospitals said that installing CPOE was a “primary clinical IT focus” for their hospital, making it the third-most-mentioned focus [26]. The great number of scientific studies on CPOE and medication safety in the US shows that CPOE has also been a scientifically important issue in the United States for years [6, 27].

The **development in the German-speaking world is clearly in the early stages** [28]. In the 2012 IT Report Health Care [29], just 25% of the IT executives at German hospitals polled said that drug-related alert generation systems (e.g. allergies, drug-drug interactions) were in place in at least one organizational facility. 28% of respondents said they offered support in drug therapies (e.g. dosing support) in at least one organizational facility. The 2014 IT Report Health Care that is just being published shows that these numbers did not increase in the last two years. Nevertheless, ambitious projects on various issues related to health IT for medication safety can be found in several hospitals, e.g. Universitätsklinikum Heidelberg [30, 31], Universitätsklinikum Erlangen [32, 33], Universitätsklinikum Genf [34, 35], Spital Thun [36], or Salzburger Landeskliniken [37], just to name a few. Projects in Germany based on health IT and medication safety are enjoying increasing attention thanks to the Federal Ministry for Health's Patient Safety Action Plan which initiated and coordinated a number of activities on medication safety, including the



**Figure 1** Relevant steps of the medication process, presenting starting points for functions of health IT for medication safety

utilisation of health IT for medication safety [38]. Overall, health IT to enable medication safety is an important issue for every hospital in the German-speaking countries. Most, however, are still a long way from having solutions that convincingly support the entire medication process [28]. The most important reasons for this situation are outlined below.

## 5. Observations on Health IT for Medication Safety

1. The **medication process is complex** and requires the coordination of various professional groups (such as physicians, nursing staff, and pharmacists, but also medical assistants, logisticians, computer scientists, administrative staff) and of course patients and care-giving relatives. Also necessary are deep information and communication structures as well as the inclusion of pharmacological and clinical knowledge in line with the latest research findings [39]. Given this situation, the integrated whole of health IT for medication safety can be classified as a socio-technical system.
2. **Medication errors and resultant avoidable adverse drug events are a common occurrence**, with numbers varying depending on the clinical setting, the patient collective studied and the method of data collection (cf. [40–44]). Medication errors are one of the most common causes for alerts in critical incident reporting systems (CIRS) [45, 46].
3. **Good data and information quality** is the basis for successful health IT for medication safety. This means, among other things, complete, understandable, and up-to-date information regarding a patient's current medication and relevant clinical data, but also relevant remarks concerning the characteristics of the pharmaceutical product. It is our opinion that this data quality clearly does not satisfy the requirements for the sensitive and highly specific support of the medication process (e.g. [47, 48]). These shortcomings manifest themselves e.g. as missing or incomplete information as to a patient's current medication, insufficient semantic standardization of clinical data, or a lack of structured, electronically usable specialist information. A systematic and extensive use of common and IT-compatible description standards for data, information, and knowledge in the field of health IT for medication safety does not exist at this time.
4. **Health IT is just one building block in a facility-wide medication safety strategy**: Medication safety comprises the totality of measures to ensure the on-label use of pharmaceutical drugs (cf. chapter "Definitions"). This requires the targeted management of the complex medication process including the people, the organisation, and the technology (cf. "Observations" No. 1) [39]. Health IT is therefore only *one* component of a comprehensive patient safety strategy which is at the beginning of every medication safety related activity.
5. Although health IT for medication safety is generally ascribed the potential of improving information quality and thus contributing to an adequate information supply of the principal actors in the medication process, the **benefits of health IT for medication safety to reduce adverse drug events is not adequately proven** (cf. [5, 27]). Possible causes are that installed health IT systems for medication safety only support individual steps or individual professional groups (cf. chapter "Typical functions"), that the complexity of the medication process is underestimated (cf. "Observations" No. 1), that highly structured patient and drug data necessary for a decision support system are missing (cf. "Observations" No. 3), or that a comprehensive medication safety strategy for the hospital is missing overall (cf. "Observations" No. 4).
6. The use of health IT for medication safety may lead to **negative side effects** that could disturb the medication process and contribute to a worsened state of medication safety. Examples include the extra time spent on having to perform electronic drug documentation [49], the lack of user friendliness of the systems [11], inadequate preparation of the necessary changes to the medication process [9], a flood of clinically meaningless alerts ("alert fatigue") [48], or overly strong trust in the guidance of health IT for medication safety [14].
7. **Health IT for medication safety does not exist as a standard solution off the shelf**: Given the complex and often not very standardized medication processes in the care facility, a careful selection, combination, and adaptation of the available health IT technologies for medication safety (cf. Chapter "Typical functions of health IT for medication safety") are required on a case-by-case basis as part of a superordinated medication safety strategy (cf. Observation No. 4) in order to agree individual components and achieve the desired benefit in the area of medication safety. This requires specialist expertise amongst providers and care facilities.
8. **Medication safety generally is the responsibility of the health professionals involved in the medication process, possibly of the patient as well**. But liability risks may also affect the pharmaceutical company as drug manufacturer, the publisher and/or the publishing house as supplier of the specialist drug information, and the software manufacturer or vendor. Health IT for medication safety always has a support function for the decision-making of the various individuals involved. Not all individuals involved appear to be aware of the limitations and risks of the support service provided by health IT for medication safety (cf. [14, 50, 51]).
9. Special **patient-centred medication safety application systems** in the context of the mobile health (mHealth) trend are currently in an intense discussion phase. A great number of mobile applications ("apps") have appeared with the advent of mobile computing in recent years. Even if initial studies have made apparent the potential for adherence management [52], the long-term benefit of these mobile application systems must first be systematically assessed. Different approaches may be necessary for different target groups, for example in the geriatric context [53].

10. All in all, the **beneficial possibilities of health IT for medication safety do not appear to be exhausted**. The development, installation, integration and operation of health IT for medication safety involve high costs (e.g. system maintenance, staff training) and there are few meaningful benefit-oriented studies (cf. Observation No. 5). Questions as to the long-term benefit and the cost-efficiency must be answered in the future. Moreover, the current investment funds in the health market for IT for medication safety appear too few to be able to tap the recognizable potential of this technology to improve patient safety.

## 6. Recommendations for Health IT for Medication Safety

1. Any installation of health IT for medication safety must be based on an **extensive medication safety strategy** to be developed in advance in relation to the institution (cf. Observation No. 4). Health IT for medication safety is a complex intervention affecting existing, interconnected care processes (cf. Observation No. 1) and must therefore be planned carefully and integrated step by step (**health IT for medication safety step-by-step concept**). Accordingly, a long-term perspective for the support of the entire medication process through health IT for medication safety must be specified and also financed (cf. Observation No. 10). Health IT for medication safety should always be developed on a step-by-step basis in close coordination with the relevant subsystems and in cooperation with the professional groups involved (iterative participatory design) (cf. Observation No. 7). The embedding of health IT for medication safety in the medication process and all necessary accompanying organisational and technical measures must follow the principle of error minimization with the aim of establishing a **fault-tolerant integrated system** [39].
2. Due to the sectoral division of care, the **availability of a complete medication**

**overview** of patient-specific prescriptions and administrations is fundamental for any decision support in health IT for medication safety (cf. Observation No. 3). Any corresponding IT-based infrastructure should follow effective, possibly international description standards in view of completeness and transferability of prescription data (cf. Observation No. 3). Requirements for data protection and data security are to be considered in this process.

3. We see the **integration of health IT for medication safety** (medication lists and accompanying decision-support functions) **in electronic patient, case, or health records** as a pioneering step for an improvement of medication safety. Therefore, application systems in health IT for medication safety must be able to communicate with other existing clinical workplace systems in the facilities or be integrated in them (cf. [38]) to be able to contribute to fault minimization in the integrated system.
4. **Individual medication-related patient data as well as information on the clinical context should be included to the greatest extent possible in every medication safety check**. The necessary information must be structured and standardized so that a computer-supported processing and automated medication safety check is possible (cf. Observation No. 3). This requires the drug-related (indication, contraindications, active ingredient, form of administration, type of application, influence on laboratory parameters, age indications etc.) and patient-related (diagnosis, age, laboratory parameters, life situation, etc.) data and information to be structured and computable. In order to establish the complete exchange of drug and patient data across systems, relevant description standards must be identified for data, information, and knowledge and bindingly established across sectors [54] (cf. Observation No. 3). Quality requirements for health IT for medication safety review systems should also be defined in order to achieve a minimum quality of the review systems (cf. [38]) and to be able to conduct obligate system and specification review.

5. Alerts, when presented to the user, must be as **intelligent, adapted to the specific context, and appropriate to severity** as possible (cf. Observation No. 6). This means that the functions and alerts in health IT for medication safety must be adapted to the clinical context and the respective medication safety goals. Alerts with low relevance should not unnecessarily disturb clinical processes. Health IT for medication safety should be a “learning system” with regard to the alerts, capable of adapting to user wishes and user responses.
6. When **designing the user interfaces** in health IT for medication safety, increased attention must be placed on usability, task relevance, and user friendliness which include physical and logical components. The available design principles in the area of human-machine interactions and software ergonomics (e.g. [55]) must be systematically implemented, and adapted and developed to the specific requirements of health IT for medication safety. Health IT for medication safety should be systematically reviewed for quality of physical and logical components before rollout and usage (cf. Observations Nos. 5 and 6).
7. Health IT for medication safety requires **process-oriented knowledge management**. The individual product characteristics of a drug must be processed, stored, and provided in such a way as to improve the methodological management of this knowledge in the medication processes (cf. Observation No. 3). This requires an understanding of the systematic management of knowledge (create, store, share, use) in software-driven information and communication processes in health care. Pharmaceutical manufacturers and the drug regulatory agencies are the central knowledge carriers and as such are jointly responsible for generating, managing, and providing the available information resources (e.g. prescribing information) in a targeted, structured, and standardized form. For the context-aware semantic structuring of the information resources, suitable, computable data and description standards should be used

as much as possible (cf. Observation No. 3).

8. It is obvious to include **patients in the subject of medication safety** trying to win them as responsible and competent partners (cf. Observations Nos. 8 and 9). Patients should e.g. have the opportunity to check and manage their current medication list at all times. Over-the-counter drugs should also be documented e.g. by means of a health record, and this hereby completed medication list should be subjected to a review by experts or by health IT systems for medication safety (cf. Observation No. 3). The individual collaboration, motivation, and adherence of patients as important pillars of medication safety could thus be strengthened without direct physician influence or to complement the activities of the care-giving health professions.
9. Due to the inherent risks (cf. Observation No. 6), the effectiveness and efficiency (**benefits, risks and costs**) of every health IT for medication safety project should be assessed prospectively and retrospectively (cf. Observation No. 5). There is no universally applicable process model for the rollout of a health IT system for medication safety. Each phase of the rollout process of a health IT system for medication safety (cf. Observation No. 1) must be accompanied by **continuous evaluation** to allow early recognition of possible risks and the intensification of recognizable benefits at an early stage (cf. Observation No. 10). During the subsequent normal operations of health IT for medication safety, the quality of the provided information and of the impact should be constantly safeguarded (e.g. through clinical pharmacists or clinical pharmacologists) and a transparent system of information management be implemented (e.g. through the medical informatics). An adequate budget for these evaluation and quality assurance tasks has to be provided in all health IT for medication safety projects.
10. Health IT for medication safety projects are also always **organisational projects** (cf. Observations No. 1 and 4). Health IT for medication safety can be helpful

to recognize systematic errors and risks and to avoid them as well as to support an organization's individual learning process. This requires a system-oriented approach in contrary to an individual blame or punishment in the **handling of medication errors** [56].

11. The EU's Medical Devices Directive and the corresponding national legislation likewise mention "software" as a medical device. **In principle, every health IT system for medication safety can itself be a medical device** [57, 58]. According to our findings, the transition between health IT for medication safety as a non-medical device and its actual use as a medical device is fluid and should therefore be put in concrete terms in the years to come.

## 7. Discussion and Conclusion

Health IT for medication safety can generally facilitate improved information quality and – as part of a step-oriented medication safety strategy (cf. Recommendations Nos. 1 and 10) and with inclusion of the patient (cf. Recommendation No. 8) – make a contribution to medication safety. The following requirements are therefore to be considered during the development of application systems with respect to health IT for medication safety:

- a) **Information access** at the clinical workplace: secure information access exists with high availability and good user-friendliness (cf. Recommendations Nos. 3, 5, 6)
- b) **Information quality**: the information is up-to-date, complete, correct, integrated, and consistent (cf. Recommendations Nos. 2, 4, 7)
- c) **Information benefit**: the information is of recognizable benefit (cf. Recommendation No. 9)

Inadequate consideration of the recommendations stated above appears to be jointly responsible for the fact that the benefit of health IT for medication safety can currently not be adequately exhausted or proven. Given future consideration of these requirements, health IT for medi-

cation safety will be able to make an important contribution to the adequate information supply of all principal actors in the drug therapy and thus contribute to making a substantial improvement to patient safety.

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