VFTH e.V.

smart medication™

Comparison of data security of the electronic patient diary smart medication™ with manual documentation in a paper diary

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Objective:
Comparison of data security of the electronic patient diary smart medication™ with manual documentation in a paper diary. Assurance of market approval and certification of smart medication™ as a medical device according to national and international regulations.

Method:
The risk assessment method PHA (Preliminary Hazard Analysis) based on the risk management standards ISO 14971:2007 and EN ISO 14971:2012 was used to compare risks associated with the electronic documentation platform smart medication™ with the traditional methods of paper documentation. Conceivable scenarios, such as loss of data, incorrect data transmission and possible misuse of data have been analyzed and evaluated using a risk-based approach.

Results:
The risk assessment revealed clear advantages for the electronic patient diary in particular in the following areas:

- no irreversible data loss possible
- error minimization through plausibility checks during the patient's entry and later by the physician or the hemophilia nurses
- seamless traceability of all data inputs and amendments
- highly reduced risk of data misuse due to pseudonymization and access rights control to the electronic diary
- sustainable long-term storage reliability

FIG. 5 PAPER BASED DIARY (RISK ACCEPTANCE MATRIX)

Comparison btw. paper based and electronic diary shows significant risk reduction.
All ALARP (risks as low as reasonably practicable) could be mitigated to acceptable risks.

FIG. 6 ELECTRONIC DIARY (RISK ACCEPTANCE MATRIX)

Summary:
The results show that the electronic patient diary is clearly superior to paper documentation in terms of the confidentiality, security and integrity of the data. The comparison shows significant risk reduction in favor of electronic patient diary smart medication™. However, the selection and implementation of appropriate measures for minimizing risks is decisive. In doing so, product manufacturers must take into account not only the relevant standards, directives and laws, but also technical frameworks such as the recommendations of the Federal Office for Information Security (Bundesamt für Sicherheit in der Informationstechnik, BSI) or standard ISO/IEC 27000 series on information security.

FIG. 1
DEFINITION OF SEVERITY CATEGORIES (ACCORDING TO EN ISO 14971)

Description	Definition
Marginal	No physical harm
Minor	No medical intervention needed. Impairment unlikely.
Major	Medical intervention advisable. Reversible and not life-threatening impairment possible.
Severe	Medical intervention needed. Irreversible harm with a degree of impairment possible.
Catastrophic	Irreversible harm with a degree of impairment likely. One or more deaths.

FIG. 2
DEFINITIONS OF PROBABILITY CATEGORIES (ACCORDING TO EN ISO 14971)

Description	Probability	^ Number of events
Regularly	10^{-2}	1000 - 10000
Frequently	10^{-3}	100 - 1000
Occasionally	10^{-4}	10 - 100
Rarely	10^{-5}	1 - 10
Unlikely	10^{-6}	0,1 - 1
Unthinkable	10^{-7}	0,1

Assumptions:
x = 2000 installations of smart medication™ medical app
y = 5 years usage (product lifetime)
z = 1 patient per year per installation
u = 120 treatments per patient per year (approx. every 3rd day)
v = 1 x (2000 x 5) x 120 = 10^6 uses in total

Note: one event corresponds to one data entry in a patient diary

FIG. 3
PRINCIPLE PHA RISK ACCEPTANCE MATRIX

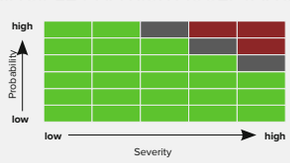

FIG. 4
RISK ASSESSMENT WITH PRELIMINARY HAZARD ANALYSIS (PHA)

#	Category	Misbehavior	Impact	Severity	Probability paper diary	Probability smart medication	Explanation
1	Data Quality / Integrity	Patient forgets to fill in diary (i.e. prophylaxis, bleeding event)	• important bleeding events are not documented and hence not recognized by doctor. Therapy cannot be adjusted as needed. • doctor cannot verify if patient is compliant to therapy schema (prophylaxis, treatment of a bleeding event).	minor	regularly	frequently	• in smart medication patients use smartphones to enter data. Smartphones are normally ubiquitously accessable for patients.
2	Data Quality / Integrity	Patient enters incorrect data in diary (i.e. wrong date/time)	• patient seems to be not compliant to therapy schema, but is. • important events are falsely documented and lead do misinterpretation by doctor.	minor	frequently	occasionally	• smart medication minimizes wrong data entry by prefilled form fields and selections. • smart medication data entries are reviewed by hemophilia nurses on a regular bases. • graphic charts visualize long term data and allow instant plausibility checks by doctors.
3	Data Quality / Integrity	Patient does not fill in diary, because of a longer period of absence from home (i.e. vacation)	• important bleeding events are not documented and are not recognized by doctor. • doctor cannot verify if patient is compliant to therapy schema (prophylaxis, treatment of a bleeding event). • ex post documentation is difficult and unlikely.	major	occasionally	rarely	• smart medication is available on any smartphone, tablet or computer. Devices are ubiquitously available.
4	Data Quality / Integrity	Diary is altered or manipulated by others and manipulations are not identified.	• therapy may be altered based on false data leading to i.e. formation of target joints or waste of factor concentrates.	major	occasionally	unlikely	• smart medication records inputs and all changes in an audit trail log that allows seamless traceability of all data inputs and amendments.
5	Data Quality / Integrity	Diary is not readable by personal in hemophilia center (i.e. nurses, doctor)	• diary information is partially worthless. • important bleeding events are not recognized by doctor	severe	frequently	unthinkable	• smart medication contains always structured and readable information.
6	Data Quality / Integrity	Diary is not available to doctor in case of critical events (i.e. bleeding event, batch recall)	• doctor is not able to react to critical events (i.e. severe or unusual bleeding events, batch recall by pharmaceutical company)	severe	rarely	unthinkable	• smart medication diary data is accessible via a computer, tablet or even smartphone at any time.
7	Data Security	Current diary is lost	• detailed therapy information and bleeding events are irrecoverably lost. • in case of paper diary data of up to one year might be irrecoverably lost.	severe	frequently	unthinkable	• in smart medication diary data is secured by means of higly redundant systems supplemented by georedundant backup of all data.
8	Data Security	Diary is destroyed (i.e. fire, water)	• detailed therapy information and bleeding events are irrecoverably lost. • success of long term treatment to avoid i.e. formation of target joints is in danger.	severe	occasionally	unthinkable	• in case of destruction of smart medications data center, a backup system at another site can be activated instantly. There will be no loss of historic data.
9	Data Security	Diary is not available at next consultation (i.e. patient forgets diary to bring with)	• doctor is not able to review recent history since last visit of patient. • therapy cannot be adopted to recent events (i.e. bleeding events). • success of long term treatment is in danger.	major	regularly	unthinkable	• smart medication diary data is accessible via a computer, tablet or even smartphone at any time.
10	Data Security	Archived diaries are lost (more than one or all diaries)	• because of a total loss of historical bleeding event data long term treatment to avoid i.e. formation of target joints is danger.	severe	occasionally	unthinkable	• encrypted backups of all diary data in smart medication is stored remotely at another site (georedundant data storage).
11	Data Security	Diary is lost because of change of hemophilia center (i.e. patient moves to another city or country)	• loss of historical bleeding event data prevent successful long term therapy.	severe	occasionally	unthinkable	• in smart medication patients can easily be switched to another doctor and/or hemophilia center.
12	Data Security	Diary is mistaken in name (i.e. associated with wrong patient)	• therapy schema is adopted based on false information.	severe	unthinkable	occasionally	• name is written on paper diary and cannot be mistaken. • smart medication uses patient ID's only. ID's maybe mistaken more often compared to patients name.
13	Data Privacy	Diary is accessed by unauthorized persons	• breach of patients data privacy may lead to major violation of privacy.	major	occasionally	unthinkable	• smart medication uses role based access control based on individual users • smart medication uses pseudonymization and does not store personal data of a patients