PEDeus
Pediatric Decision Support

PEDeus is a 100% subsidiary of the University Children's Hospital Zurich.
Our vision is to perfect drug therapy and drug safety in children through «clinical decision support» (CDS).

PEDeDose – challenges for a CDS software

Karin Käser[1], Francine Lorenz[1], Priska Vonbach[1]
[1]PEDeus, a subsidiary of the University Children's Hospital Zurich

Introduction

A recently published review [1] concludes that every seventh prescription in a pediatric intensive care unit is incorrect. Dosage errors lead to the most common and serious complications in drug therapy in children. Computerized physician order entry (CPOE) may reduce medication errors. However, in children it has been demonstrated that CPOE must be implemented with a pediatric CDS tool for patient-specific dosages to increase the medication safety and reduce mortality [2, 3].

In Swiss children's hospitals and clinics, CDS tools for patient-specific dosages are still rarely used. The requirements for such a tool are high and costly, in particular because such software falls under the Medical Device Regulation (MDR) which will replace the Medical Device Directive (MDD) after a transitional period in May 2020.

PEDeDose, a pediatric CDS tool, was developed during 18 months. The PEDeus team, consisting of three hospital pharmacists, had to face great challenges.

Conclusion

PEDeDose is a software as a Medical Device, because the software is performing an action on data different from storage, archival, communication or simple search AND this action is for the benefit of individual patients.

The requirements for a pediatric CDS tool for patient-specific dosages are high and costly: development of a software as a medical device, IT security, validity of data, etc.

In April 2019, PEDeDose was introduced successfully into the Swiss market.

PEDeus will have to face further challenges with PEDeDose, especially meeting the requirements of the MDR.

What is PEDeDose?

PEDeDose consists of a comprehensive database of pediatric drug dosages, drug information, warnings and algorithms for calculating the individual dosages, embedded in a website (www.pededose.ch) in German, French and English, a database which allows a documented and traceable data management and a web service that enables an integration of PEDeDose into clinical information systems (CIS).

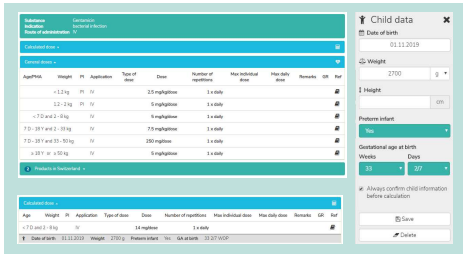

Figure 1: PEDeDose database and algorithms

When is a software a Medical Device?

First, it has to be clarified, whether a specific software falls under the Medical Device Regulation (MDR) [4]. Therefore, the MDR itself and the MDCG Guidance document [5] need to be consulted. Formulated in a few words: a software is a Medical Device if there is an action for the benefit of an individual patient. (see Figure 2)

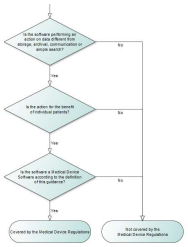

Figure 2: Decision steps to assist qualification of software

Classification of the Medical Device

According to the Medical Device Directive (MDD) PEDeDose was classified in class I. Since the MDD will be replaced by the MDR after a transitional period in May 2020, PEDeDose needs to be up-classified (class IIa or higher).

Clinical Evaluation Report

The Clinical Evaluation Report found that there was sufficient evidence for the safety and performance of PEDeDose.

Instructions for Use

A comprehensive instruction manual is a must for every medical device. For PEDeDose, it can be accessed at the website https://www.pededose.ch/en/info/usage.

Development process and technical file of a Medical Device software

The development process of the software was performed according to the norm IEC 62304 (see Figure 3). The technical file of PEDeDose includes about 40 QM documents, among others the Classification, the Risk Analysis, the Clinical Evaluation Report, the Instructions for Use and Usability tests and protocols.

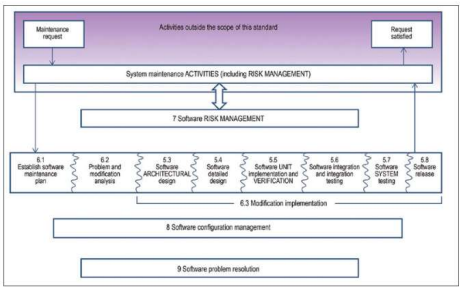

Figure 3: Development process of a software according to IEC 62304

Usability tests

The software must pass usability tests before release. For PEDeDose this meant that these usability tests were performed on the website as well as on the web service and in data management.

Risk Analysis

The Risk Analysis includes 107 risks with more than 350 measures taken. (see Figure 4)

Figure 4:
Risk Analysis of PEDeDose
Legend
white: low risk, red: high risk
Severity:
A: negligible
B: moderate
C: serious
D: critical
E: catastrophic
Occurrence:
1: improbable
2: remote
3: occasional
4: probable
5: frequent

Design risks before mitigation

Occurrence \ Severity	A	B	C	D	E
5		21			14
4				3	42
3				1	4
2					5
1					17

Design risks after mitigation

Occurrence \ Severity	A	B	C	D	E
5					
4		7			
3		8			8
2		4		3	14
1		2		1	60

Market launch, maintenance and outlook

Before the market launch in April 2019, further technical questions about IT security, hosting, availability as well as questions about law, finance (pricing), communication and marketing needed to be answered. The update of the dosing data, the post-market surveillance and the implementation of the quality management system according to ISO 13485:2016 as well as further technical developments have since become challenges for PEDeus. Finally, PEDeDose has to be re-classified by May 2020 as a Medical Device class IIa/b or III.

References

1. Alghamdi AA et al. Drug safety 2019, EPub (PMID: 31410745)
2. Kadmon G et al. Pediatrics 2009; 124(3): 935-9. (PMID: 19706588)
3. Longhurst CA et al. Pediatrics 2010; 126(1): 14-21 (PMID: 20439590)
4. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.
5. MDCG, Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745, October 2019.