

Barriers for Adoption of Analytical CDSS in Healthcare: Insights from Case Stakeholders

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Abstract. Most analytical Clinical Decision Support Systems (CDSS) remain within a research and development (R&D) environment and lack implementations in clinical contexts. This study discusses these implementation challenges as IT adoption barriers and gives possible solutions for these barriers. For this, we have studied the stakeholder perceptions of the case of an analytical CDSS implementation called ‘Big data for small babies’ (BD4SB) which analyzes medical data to predict the probability on sepsis for prematurely born babies and to support the physicians’ decision-making on ministering antibiotics. The stakeholders explain that the system shows promising results; however, the transition from the R&D environment to the clinical environment is complex. From this study, we learn new insights regarding the adoption of analytical DSS systems in the clinical field and we developed a new generalizable method for analytical DSS projects in an organizational context.

Keywords: analytics; clinical decision support system; artificial intelligence adoption

1 Introduction

Compared to other sectors, healthcare has the lowest adoption rate of artificial intelligence and related techniques [20]. This can be explained from the complicated effects on the patients’ health and the influence of numerous stakeholders on the adoption of clinical decision support systems (CDSS) [40, 69].

CDSS are systems for clinical decision making [49]. A CDSS must be a legalized medical device for clinical practice. A medical device is any instrument, apparatus, appliance, software, material or another article, including software to be used specifically for diagnostic and/or therapeutic purposes [22]. Analytical CDSS (aCDSS) collect and analyze knowledge for simulating human reasoning to generate advice. However, sometimes, this is not transparent enough, which is a problem for physicians. They need to trust the recommendations given by such systems [19]. Once the knowledge is acquired and stored from structured and unstructured datasets, computational reasoning provides diagnostic or treatment assessments. Such a system is recently introduced, for example, by IBM with Watson for Oncology (WfO) [70].

WfO was trained with data of 15,000 patients, protocols, patients' cases and expertise from Memorial Sloan Kettering (MSK) Cancer Center. The physician enters specific patient data in WfO and the system compares it with historical patient data, 600 journals, 400k other data sources and statistical evidence from literature. Based on this data, WfO advises the physician on the diagnosis and ranks treatment options. Somashekhar et al. [70] analyzed 638 breast cancer cases in which WfO and the multidisciplinary tumor board reached a concordance for 93% of the cases. This shows that an aCDSS might be helpful for breast cancer treatment. To achieve such specialized knowledge, aCDSS needs experts to train it with labelled information which takes a substantial amount of time [26, 31]. Medical journalists claim that MSK's WfO training resulted in a bias towards MSK's physicians' preferences [57, 62]. Other technology companies such as Google and Microsoft have developed similar aCDSS [55]. These systems remain within the R&D environment and have not been implemented in clinical practice yet [20].

This article explores the analytical CDSS implementation environment by studying the relevant stakeholders' perceptions of barriers and accompanying solutions of the 'Big data for small babies' (BD4SB) project, which aims to implement an analytical CDSS to support physicians' decisions for administering antibiotics for sepsis to prematurely born babies. This research aims to answer the following research questions:

1. What are stakeholders' perceived barriers and possible solutions for an analytical clinical decision support system implementation project?
2. What can be learned from these perceptions regarding the effective realization of aCDSS implementation projects?

These questions are relevant for the sharing of professional experiences and for the generation of insights in effective aCDSS projects and possibly avoidable project risks. To answer these questions, this research applies a laddering technique [12] to extract data and subsequently categorize barriers mentioned by expert stakeholders. Besides of a systematic search for barriers, we also try to identify solutions for them that could be part of an implementation project design. This research is relevant because current literature discusses many barriers (i.e. user resistance, poor quality of technology, organizational inflexibility, and lack of technology and organization fit) for implementing healthcare information systems [69], however, not tailored for understanding analytical CDSS adoption problems.

The next section gives a literature review on analytical CDSS and related adoption challenges. The third section explains the methodology for detecting relevant stakeholders' perceptions, their mentioned barriers and solutions. The fourth section presents and discusses the results. Lastly, the fifth section entails the conclusion and reflects about generalization of our findings to other analytical DSS of implementations.

2 Literature review

A aCDSS can contain multiple techniques to support medical decision making, like visualization of clinical data [74, 79], zooming, sorting, and filtering functions to

deepdive in specific sections of relevant data, image and video recognition applied to CT and MRI scan data or skin pigments [23, 24, 42], and (advanced) analytic evidence-based medicine analysis with data from multiple sources like the EHRs and genomic data for predicting the success, efficiency, and risks of treatment alternatives for a patient [59]. Natural language processing (NLP) can also be used to extract the meaning from natural language text notes in medical records [36, 38, 67]. More complex forms of technology could involve machine learning, i.e. “a set of methods that can automatically detect patterns in data, and then use these patterns to predict future data, or carry out other types of decision making under conditions of uncertainty” ([54], p.223). aCDSS like MSK/IBM’s WfO incorporate a form of prescriptive analytics by ranking treatment alternatives along predicted effectiveness for a given diagnosis. Based on a recent extensive literature review, Mehta and Pandit found the following analytic techniques for aCDSS mentioned, summarized in Table 1 [51].

Table 1. Analytics techniques in clinical DSS [51]

Technique	Healthcare application examples
Cluster analysis	Detecting obesity clusters for high-risk groups; Detecting clusters with specific health determinants in need of treatment
Machine learning	Predicting disease risk; Detecting epidemics
Neural networks	Diagnosing chronic diseases; Prediction patients’ future diseases
Pattern recognition	Improving public health surveillance

Mehta and Pandit [51] state that not one of the mentioned aCDSS techniques of Table 1 is implemented in a clinical context. All these studies describe, develop and test a model or algorithm to show its added value, however, do not mention anything about implementation. Mehta & Pandit [51] suggest that a reason for the lack of these aCDSS implementations is that the current body of literature does not provide adequate quantitative evidence that these techniques can be trusted by medical practitioners in their clinical use. Also other review articles state that different from research contexts, medical clinical contexts have very high levels of ethical, legal and reasoning transparency demands that are difficult to meet in practice [19].

A comparative study on the implementation of Health Information Systems (HIS) determined several inhibiting factors for HIS implementation: user resistance, poor quality technology, organizational inflexibility and/or instability and lack of ‘fit’ between social, technological and organizational domains [69]. These inhibiting factors and the accompanying references are grouped in Table 2 in which we identify analytics workflow related barriers and peripheral business barriers for aCDSS use. The analytical workflow includes data availability, data integration, data preparation, analysis, accuracy and reliability validation, and results utilization attributes as sources of barriers [65]. For all health information systems, the peripheral business attributes are important for effective implementation or a source for barriers. These peripheral business attributes are grouped as legal, ethical, and resource issues. Previous research of health information systems has strongly emphasized the role of organizational and institutional factors on the effective use of systems. Table 2 gives a list of this literature with the barriers mentioned.

Table 2. Barriers for implementation of IT in healthcare

Barriers	References
Data availability	[50, 63]
Data integration	Interoperability [18, 56, 64], integrating (un)structured data [8]
Data preparation	Data structures and standardization [11, 59]
Outcome transparency	[7, 59]
Accuracy & reliability	Inaccuracy & inconsistency [11, 14, 29, 43, 71], limited re-tests [63], reliability of data [64], inability to assess algorithms [47]
Use in decisions	User resistance [25, 32, 57, 69], usefulness & ease of use [33, 66], lack of human decision control [35, 48]
Ethical & legal	Privacy and confidentiality [30, 32, 37, 77]
Resources	Technical & organizational incompatibility [3, 15, 35, 47, 60, 72, 76], scientists & managers skills [8, 79], organizational change needs [9, 21, 33, 41], quality of technology [4, 45, 58], high investments [37, 71], data usage knowledge [71]

McNutt et al. [50] and Rumsfeld et al. [63] claim that analytics has great promises for the fields of oncology and cardiovascular diagnoses and treatments respectively, but that these promises only can become realized when sufficiently large and reliable datasets are available. Unfortunately, this is difficult to achieve. For realizing such large data sets hospitals will have to share their data [18, 56, 64]. Lack of systems interoperability and different data taxonomies prevent such inter-hospital data sharing and thus further structuring and standardization of systems and data is needed [7, 59]. A possibly important new type of data can be added nowadays by natural language processing of informal language that describes patient's status and medical doctor's thoughts. This unstructured data is available via electronic health records (EHR), but accessibility of EHR data for analytics is legally and ethically complicated and classifying natural language in medical terminology is still not very reliable [8]. Besides of all these analytical workflow challenges, aCDSS are also difficult to use from the perspective of the medical practitioner. Medical practitioners are especially concerned regarding the accuracy of classifications and predictions when the data sets are too small [11, 14, 29, 43, 71] and the algorithms used are non-transparent or incomprehensible [47]. Intransparency of algorithms may result in feelings of loss of reasoning control which is unacceptable for medical professionals during their diagnosis and treatment decision making [19, 35, 48]. Experiences with unreliable registrations in patient files also do not contribute much to trust in aCDSS [64]. Consequently, the literature has extensively reported about medical professional resistance against not well proven technology [27, 34, 60, 72] and perceptions of low usefulness of new technologies [35, 69]. Many of the reasons for not trusting and resisting aCDSS are not technical or psychological (i.e. the medical professionals risk perception) but are rooted in ethical, legal, and managerial requirements being insufficiently met. For example [1, 5], report about the very large and complex medical privacy issues in patient data sets. Finally, also the actual realization of a clinical aCDSS requires new knowledge, expertise and training in use and interpretation of results and new IT personnel that can give the proper support and use conditions. Given the increasing costs of healthcare these extra resources are difficult to fund.

3. Methodology

As stated in the research questions, this research wants to register the stakeholders' perceptions of barriers and solutions for a concrete implementation of an aCDSS. To realize this, we have selected a case for which key stakeholders were willing to participate in this study. We first describe this case in the following subsection, after which we go in details about the stakeholders, our interviewing technique, and our analyses.

3.1. The BD4SB case study

The Utrecht University Medical Center (UMCU) initiated the Applied Data Analytics in Medicine (ADAM) project in spring of 2017 to make healthcare more personalized with analytics in collaboration with external partners such as Siemens, Philips, SAS, and Accenture. This is a hospital-wide project with a special team of clinicians and data scientists and is supported by the board of directors. ADAM enables pilots from four departments within the UMCU, among which the BD4SB pilot within the Neonatology department that cares for premature babies. Babies that are born too early are sensitive to infection. Regretfully, treatment with invasive procedures, such as intravenous lines, blood samples and ventilation are all potential entry points for bacteria and add to the risk of illness. The BD4SB project focuses on the treatment of sepsis. The Neonatology department wants to know as early as possible when a patient will become ill and what treatment is most appropriate. The current healthcare process is as follows: (1) the physician suspects an infection (e.g., skin color change, blood pressure or temperature instability), (2) the physician takes a blood culture, (3) this blood culture is examined for bacteria in the laboratory, and (4), when the culture is positive, the blood is examined by gram staining (bacterium are colored to make them visible under the microscope to identify the species). This whole process can take up to 48 hours which can be crucial in the development of the infection and the administration of antibiotics. Not administering antibiotics must be considered carefully since sepsis has negative consequences for the patient, however, administering antibiotics can also have negative consequences such as an increased chance on other diseases as asthma, cancer, intestinal diseases or obesity.

The BD4SB aCDSS aims to support the physicians when they consider administering antibiotics. The aCDSS focuses on predicting with a minimum of false negatives. False negatives are the most dangerous situations because the advice is not to give antibiotics when it is needed.

The BD4SB CDSS uses different data sources from the database of neonatology which consists of 6,000 children born between 24 and 32 weeks. This data originates from several systems whose data must be integrated and prepared within data management before analysis. The model development method applied for analysis is a 'gradient boosting' technique which is a form of predictive machine learning.

3.2 Data collection techniques

We first identify the key expert stakeholders and next ask them about barriers and possible solutions. We fully transcribed the recorded interviews of our informants. Within this study the stakeholders concern the individuals or groups that affect the implementation process of the BD4SB CDSS. The stakeholders are listed and described in Table 3. The respondents were visited or approached at an event.

Table 3: BD4SB stakeholders and respondents description

Nr.	Expert stakeholder respondent description
R1	Ex-chairman of the board of AMC
R2	Director ADAM and ambassador e-health & big data, UMCU
R3	Business development manager EHR data platform, CERNER
R4	Physician and clinical owner BD4SB, UMCU
R5	Professor & education director health informatics hospital, AMC
R6	Physician and clinical director, Vitaalpunt
R7	Healthcare director, SAS
R8	Senior technical consultant, SAS
R9	System engineer healthcare, SAS
R10	Ex-physician and senior sales executive healthcare, SAS
R11	Ex-physician and data scientist, UMCU
R12	Physician and clinical owner BD4SB, UMCU
R13	Program manager ADAM, UMCU
R14	CEO business intelligence organization healthcare, Vektis
R15	Managing partner CDSS developer, Finaps
R16	Ethicist and member medical ethical commission, UMCU
R17	Business engineer CDSS developer, Finaps
R18	Research methodologist, UMCU
R19	Inspector e-health, inspection healthcare
R20	Ex-physician and analytics entrepreneur
R21	IT/ICT manager, UMCU
R22	Clinical CEO notified body, Dekra
R23	Projectmanager data registration national federation of academic hospitals

This research uses semi-structured interviews which provide openings for a narrative to unfold while also applying questions based on the literature review [28]. The unscripted narrative enables the researcher to explore the respondents' expertise. To structure the questions in relation to the BD4SB implementation plan, this study applies the 'laddering technique'. This results in a categorization and content analysis of the connections between attributes, consequences, and values experienced by stakeholders. The laddering technique aims at finding the means-end associations in the mind of the respondent by a focus on attributes, the consequences and values [10]. Skytte and Bove [68] define 'attributes' as "... the product, i.e. its features, and its components parts, process or activities" (p.6). The 'consequence' level entails asking a respondent how an attribute or activity has or will influence him or her. The consequences are "... the outcomes produced by the attributes" ([68], p.5). The last stage of the hierarchy entails 'value', i.e. "... preferred end-states of existence" ([68], p.5). The respondents were asked to describe features, components, processes or activities of the BD4SB CDSS

and describe their consequential barriers, which we next categorize by the list of barriers of Table 2.

3.3 Data analysis

The data from the semi structured interviews is analyzed via coding with ATLAS.ti, a qualitative data analysis and research software. The codes are categorized within the barriers and solutions for implementing BD4SB for each attribute. The full coding scheme is available upon request. Since the respondents are experts on each subject, an attribute/subject will often only be discussed with one respondent (e.g. ethicist, methodologist or e-health inspector) and statements cannot be supported by other respondents. However, some attributes/subjects are discussed with multiple respondents. When two or more experts share an opinion on a certain subject this will be considered as a reliable result. When a result is based on the opinion of a single person, the result will be triangulated by comparing it with data from multiple investigators, research methods and theoretical perspectives [17]. However, triangulation is not always possible and when this is the case, the result will be considered indicative which will be clarified in the text.

The interviews are recorded, transcribed and sent to the specific respondents who are given the opportunity to give feedback and corrections in the transcript which will be incorporated in the definitive results by the researcher.

4. Results: BD4SB barriers and solutions

In this section, we present data for the six analytics workflow attributes of Table 2 (availability, integration, preparation, analysis, accuracy and reliability and use) and the three peripheral business attributes (ethics, legal and resources).

4.1 Data availability

The current data warehouse is not designed to make data available within a short time span since it is designed for research which does not require data availability within a short time span. R11, ex-physician and data scientist UMCU, gives two causes of this phenomenon:

R11: *“Firstly, some data producing machines within the UMCU are validated and CE approved for research and not for healthcare which is needed for BD4SB, a new CE approval of the data warehouse is required to realize this transition. Secondly, data source HIX (EHR) is currently updated once a day, however, only converted to usable input for analytics once a week.”*

A possible solution to execute the BD4SB CDSS analytical process within 24 hours would be a single hospital wide critical data layer according to R12.

R12 (clinical owner BD4SB): *“All the data the CDSS requires can be extracted from the hospital wide critical data layer for analytical proceedings by means of an API call. This data layer collects patient specific data from each individual by means*

of patient ID. We need this step or else we will still be looking at retrospective data. This data layer is currently under construction, technologically feasible, however, realization depends on commitment and budget.”

This layer would automatically collect, integrate and prepare the data from different data sources.

4.2 Data integration

R12 (clinical owner BD4SB CDSS): *“There is no automated process that collects data for analysis and makes it available to other solutions, all the data is still in its original source and has to be extracted and integrated manually by somebody to enable the following analysis.”*

Hence, the BD4SB CDSS functions well in the R&D environment but encounters hurdles for implementation in a clinical context. R12 and R15 (managing partner CDSS developer) are aware of database permission hurdles and see the single hospital wide critical data layer as a solution. Additionally, R8 points at a need for data protocols:

R8 (Senior technical consultant SAS): *“Data protocols describe among other things what data was used, where the algorithm was developed, which version it was and how it should be utilized. This increases the controllability and auditability. They are not used currently. Every system generates its own data in a way that is most easy for this system. Which is not wrong of course. Only when you want to join the data from these systems, you might realize that you should have done it in a different manner.”*

4.3 Data preparation

According to R12, clinical owner of BD4SB, data preparation and interpretation of data input are an ongoing process since the algorithm constantly detects new relationships between different variables.

R12: *“We collected all the data but did not know for sure if all the data was accurate. Let’s take the rhesus factor. In the model this factor seemed to be an important predictive factor. I asked our infections specialist about the variable and they told me it might be possible that a baby has more infections when he/she is rhesus negative. Still struggled by this relation, I asked for the data and found out that it was the rhesus factor of the blood donor instead of the patient that was influential. A baby with the infection will receive more transfusion, this is logical and hence not per definition a consequence of the rhesus factor. This shows that we continuously have to look carefully at the data we use in the CDSS.”*

According to R11 and R12, it is impossible to fix all the data preparation hurdles in advance, it requires constant evaluation by medical experts. It is important to involve clinicians within the data science team to continuously assess the context and relations among variables.

The data quality in healthcare in general suffers from inaccurate registration according to R8, R11, R13 and R15. This problem is solved at the UMCU by means of automated data preparation proceedings constructed by the BD4SB CDSS developers. However, it is likely that this inaccurate registration is still apparent at other hospitals

which negatively influences the external validation proceedings for BD4SB. R5, R6 and R13 state that the inaccurate registration is partially caused by the high registration load within healthcare and users' inability to see the benefits of registration.

R5: *"I believe that a lot of professionals are not satisfied with the registration load whereas it still is not possible to benefit from this registration."*

R23, program manager 'registration at the source', states that there is an increasing need for registration in healthcare for quality measurements, benchmarks, management information, research and epidemiological purposes but,

R1: *"There is a tension between how we can standardize the systems input and how can we keep the input requirements user friendly, this is still not solved accordingly."*

R2, R12, R13 and R18 propose that hospitals join forces to make agreements on registrations, these forces should consist of medical professionals as well as information professionals according to R13. These agreements would focus on only registering clinical valuable information. Aligned with this need, the national federation of academic hospitals (NFU), started the project 'registration at the source' to develop and implement healthcare information building blocks (HIBB). According to R21, IT/ICT manager UMCU, the HIBB should remove hurdles experienced by different registration formats among hospitals. The Dutch government supports HIBB by recognizing it as the healthcare information exchange standards for the Netherlands within the 2018 bill for the 'digitally exchanging healthcare information' legislation. However, according to R23, it is unclear when the legislation will be constructed and vindicated. Still, according to R21 and R23, this legislative support from the government would benefit the implementation of HIBB. Furthermore, the implementation of the HIBB is currently not obligatory and the responsibility fully lies with the hospitals and the EHR suppliers.

4.4. Analysis attribute

The transparency of the data analysis is essential, according to R10.

R10: *"The analytical process often requires transparency. For example: which algorithm was used six months ago, which data was used and who entered or changed the data, were they entitled to do so, does the data sources supply the required quality or how it was analyzed. If a physician stands in front of a judge, he/she must be able to exactly explain how the process was executed."*

The BD4SB project team is aware of these requirements and can meet them according to R8, R11, and R17. However, it is not clear if this meets the standards for CE approval.

R17 (business engineer developer BD4SB CDSS) states that the gradient boosting technique within the BD4SB CDSS can show the decision tree which visualizes the decisions process within the analysis. Additionally, according to R11 and R17, the model can quantify the impact of each variable by a Shaply value for each of the 50 variables within the analysis of BD4SB CDSS by values ranging from -1 to +1.

4.5. Accuracy & reliability attributes

R12 (clinical owner BD4SB): *“The negative predictive value of the algorithm meets an acceptable threshold, we chose a threshold of 75%. However, the system still misclassifies some patients because they had other symptoms or something special, only 6 of the 500 children. This is not much, however, if all 6 babies die, this is hard to explain, of course.”*

Optimizing the accuracy of the CDSS remains an ongoing process. However, R7, R10, R11, R12, R17 and R18 state that this is at an acceptable level and thus does not withhold the BD4SB CDSS from implementation.

Choosing the correct result format still requires a study by means of expert meetings and interviews accompanied by retrospective case studies according to R11 (ex-physician and data scientist UMCU) and R12 (clinical owner BD4SB). These expert meetings or interviews will focus on the influence of the format on the users’ decision making.

4.6. Utilization attribute

Physicians show resistance in using CDSS, because of several reasons: (1) an algorithm intervenes with the physicians’ right to exist which is based upon his/her knowledge, (2) the responsibility of a physician is high, and (3) physicians often distrust algorithms. Consequently, physicians are hesitant in taking advice from an algorithm providing external knowledge.

R20 (ex-physician and analytical entrepreneur): *“Physicians often feel that they add unique value when they do something unique for an individual patient. They want to feel like their intelligence adds something on top of everything else, this seems to be part of their psychological makeup. Many physicians hope to be a sort of Dr. House. However, it is clear that working strictly from guidelines and protocols delivers the best possible care - variation added by physicians reduces the outcome for the patient and thus destroys value most of the time. CDSS technology enforces strict working according to guidelines and thus may deprive physicians from their sense of added value. This perhaps is the single biggest reason why working with CDSS technology is so slowly being adopted - it makes physicians feel less valued.”*

R13 (Program manager ADAM): *“It does not matter if the algorithm says to intervene or not to intervene, the physician is always responsible and therefore hesitant in using these systems.”*

R10 (ex-physician and senior sales executive healthcare SAS): *“Trust is another important aspect. A physician must be able to trust the CDSS when something goes wrong. When a complaint is made, a hospital/clinician has to justify every step within the treatment process.”*

The trust in the CDSS must be from such level that the physician finds it a substantiated source to deviate from his own choice (R10, R11 and R20). According to R20, ex-physician and analytics entrepreneur, physicians used to trust their own emotional certainty for decision making and now must trust a machine. This is something a physician must accept for analytics to succeed in healthcare according to R10 (ex-physician and data scientist UMCU).

R7 (healthcare director SAS): *“Hospitals have another problem. A cultural problem, the physicians are too distant from the IT department. I believe IT gets insufficient priority to realize these analytical projects.”*

According to R7, the physicians are too distant from the IT department which implicates there is insufficient knowledge on utilization of IT by physicians. According to R2, R11, R12, R13 and R14, involving physicians within the development stage of the analytical CDSS will be beneficial for trust and acceptancy of an analytical CDSS.

R11 (ex-physician and data scientist UMCU): *“We create awareness with physicians by expert meetings in which we discuss how we created a model. It is important to bring along a group of physicians within this process or else you will get the 'not invented by me syndrome'.”*

Additionally, R1(ex-chairman board AMC), emphasizes to involve technical and non-technical savvy physicians. Usually, only technical acquainted physicians take part within these kinds of projects, however, it is essential to extract feedback from the less technically acquainted physicians. Furthermore, R1 suggests that it is important to include the patients within the development process and according to R8, R9 and R12, trust is created by means of understanding of the decision process within the BD4SB CDSS.

R8 (senior technical consultant SAS): *“The user adoption process can be strengthened by using patient cases from the past and let a physician decide and the model decide, so they can compare results afterwards. These kinds of tests could benefit the physicians' trust in a CDSS.”*

According to R11, R13 and R20 utilization of analytical CDSS could be kickstarted by incorporating the CDSS within a protocol. This would create a more trusted environment for usage of the analytical CDSS. Protocols require the physician to justify why he/she did not follow them because a protocol describes the standard proceedings that physicians usually apply according to R20, ex-physician and analytics entrepreneur. However, incorporating an analytical CDSS within a protocol is not something that is easily done because it requires a clinical trial according to R13 (program manager ADAM), as is the case in the CE approval process, and is time consuming since it requires publication of a scientific article on the appliance of the CDSS within a peer reviewed journal which can take up to years according to R11, ex-physician and data scientist UMCU.

4.7. Ethical issues

Whereas the full responsibility for medical decisions lies with the physician, R16 states that there is a certain kind of moral responsibility that lies with the developer.

R16: *“If an algorithm makes a mistake or if a device makes a mistake, the developer is partially responsible since they built this into the algorithm, when there is a causal link between the mistake and the algorithm. There is a difference between legal and moral responsibility. I do not know the legal side, but in my view the moral responsibility lies with the developer.”*

Developers are hesitant within this area since society holds higher standards for technology than for humans which is remarkable since humans often make more mistakes which we forgive more easily than technology mistakes (R16). With the

introduction of an CDSS such as BD4FB, the traditional decision process will change since the physician and patient are accompanied by a third party which moves the proportion of decision making. This shift and the exact consequences for decision making are still unknown and should be clear before implementing the BD4SB CDSS according to R16, ethicist UMCU, and R20, ex-physician and analytics entrepreneur. A related study should describe new authority routes within decision making with an analytical CDSS which could take years to implement according to R20, ex-physician and analytics entrepreneur.

4.8. Resources

Every medical device, as BD4SB CDSS will be, must have a business case in which it describes the financial added value and/or improvement in quality of care. BD4SB is not able to directly save costs since the antibiotics are not expensive, the added value is in improving the quality of care by (R17).

R17 (Business engineer CDSS developer): *“It is not clear if the improvement of care is worth the costs of data scientists, medical trial, infrastructure and maintenance of the BD4SB project.”*

R13 (Program manager ADAM): *“The validation process for BD4SB is unclear which makes the budget for implementation unclear.”*

As the BD4SB project approaches the implementation stage it becomes more important to quantify the business case which is complex since it is largely dependent on the validation design which remains unclear.

Allocating budget for implementing the BD4SB CDSS is a large barrier for implementation according to R13 and R17. Without resources it is not possible to implement the BD4SB CDSS, hence it is an important barrier to overcome for which there are no solutions proposed.

4.9. Legal issues

BD4SB CDSS must be CE approved which shows that it meets the European requirements for software as a medical device. This CE approval process requires: (1) describing intended use, (2) medical device classification, (3) quality management system (QMS), (4) technical files, and (5) a clinical evaluation report (CER). The related five documents must be assessed by a notified body to obtain the CE approval and ISO certificates for a medical device (Emergo, 2018).

The Medical Ethical Assessment Committee (METC) assesses medical trial requests for the clinical evaluation report based upon the legal framework within the WMO (law for medical research). However, according to R16, ethicist and member METC, there is no clear legal framework for a predictive algorithm within the WMO. The lack of related legislation within the WMO would require the METC to assess a medical trial requests outside the legal framework which makes it complex according to R16. Furthermore, within this medical trial request, the requester must hand in a risk assessment.

R11 (physician and data scientist UMCU): *“CE approval requires the description of risks when it goes wrong for which you need a test period. To execute this test period, you need to deliver a risk assessment to the METC, this is a vicious circle.”*

This vicious circle implies that there is insufficient historical clinical research on predictive algorithms to construct a risk assessment. The BD4SB team currently aims to construct a risk assessment with retrospective patient data, however, it is not certain if the METC approves this. Also, legislation only states to execute a good risk assessment, there is no specification on requirements for predictive algorithms within such an assessment (R17, business engineer developer CDSS).

According to R19, inspector e-health, the EU is currently developing norms for artificial intelligence which are also applicable to analytical CDSS. These norms could also give more foundation to the METC within the medical trial approval since it provides a greater understanding within a legal framework.

R19, R20 and R22 state that the legislation involved for the CE approval of software as a medical device is a grey area. According to R19, e-health inspector, the new legislation for medical devices in 2020 (MDR) gives more clarity on the requirements for software as a medical device to developers. However, R19 states that the concrete text within the legislation does not limit the incorporation of an algorithm as BD4SB as a medical device, however, the notified bodies interpret the text within the legislation to construct specific requirements and to apply within the CE approval process of these medical devices. These notified bodies generally do not share the specific requirements because they are government recognized organizations and no consultancy organizations.

The specific requirements for the CE approval process of analytical CDSS remain vague to developers:

R22 (global clinical director notified body): *“In general it is very hard for developers to know what is acceptable for Notified Bodies. Notified Bodies work with internal or external clinicians. Together we conclude if there is enough data that provides us the required trust to give the CE approval. The data that a developer supplies should show that the product is safe, effective and has a place on the market (state of the art).”*

The interpretation of the MDR is still under construction:

R22 (global clinical director notified body): *“Dekra (NB) has updated its procedures to the new legislation on European level, the MDR. The inspection healthcare (IGJ) and representatives of other EU member states reviewed and validated the new MDR procedures during so-called joint assessments. Very often during these joint assessments the EU member state representatives had different interpretations of the regulations. Hence, it took 7 years to write the new legislation, then you have a meeting with representatives of a notified body from several countries and the healthcare inspection (IGJ) and they are still discussing what the MDR exactly says. The new legislation leaves some room for interpretation and this was probably done as 100% alignment of all EU member states were difficult to reach.”*

The most optimal design for a clinical evaluation study is a randomized control trial (RCT) as exemplified by R4:

R4 (clinical owner BD4SB): *“The best way would be a randomized experiment where half will be exposed to the algorithm and the other half not. This is seriously hard, randomizing thousands of patients and the algorithm might be only suitable for*

our own population, we have to look at how we can show the clinical relevance without a randomized study.”

RCT is also hard to execute as it is timely, costly, patients might not approve and there is a saying ‘One RCT is no RCT’ according to R18, methodologist UMCU. Furthermore, R22, global clinical director notified body, states that they want to see more description of the long-term effects of a certain medical device in studies. Due to this fact, R18 states that the RCT is not the most suitable because the innovation changes over time.

R22 states that including a regulatory expert in the R&D team might be beneficial to the CE approval process preparation of the BD4SB project team:

R22: *“A regulatory professional within a R&D team involved from step one can think of what Notified Body or food and drug administration (FDA) market approval conditions are. Large companies see this and include a regulatory professional from the concept stage.”*

This implies that including more regulatory knowledge within the BD4SB project team would enable it to meet the notified body requirements based on the MDR easier.

R22 states that next to the MDR in 2020, a database will be made available to developers:

R22: *“Eudamed will be the European database that contains significant information concerning the CE approval process (e.g. study protocols, approvals, side effects). Notified Bodies and developers must upload data to this database. This database will give more transparency which helps the developers by looking at the CE approval process of other developers. The Eudamed will officially become available to developers alongside the MDR in 2020.”*

4.4. Case summary and discussion

We summarize the found barriers, solutions and peripheral business issues below.

4.1 Data availability barrier: data warehouse is unable to produce data timely. Solutions: hospital wide data layer and EHR update.
4.2 Data integration barrier: no complete automatic data integration. Solution: single hospital wide critical data layer and data protocols.
4.3 Data preparation barrier: constant need for new relations, inaccurate registrations, dissimilar registrations among hospitals Solution: involve medical experts in the data science team, standardize registrations.
4.4 Analysis barrier: lacking transparency in analytics. Solution: clear explanations according to CE quality standards.
4.5 Accuracy & reliability barrier: Inconclusive results because of small samples, Solution: increase data sets also by collaborations and data sharing among hospitals.
4.6 Use barrier: user resistance because of autonomy loss, IT department is too foreign from physicians, insufficient positive experience with aCDSS, and predictions have to be based on a too small dataset. Solution: involve physicians and also patients, explain and build trust.
4.7 Ethical barrier: responsibility of IT for the decisions is unclear. Solution: new authority routes needed in medical decision making with some responsibility for the developer.
4.8 Legal barrier: no clear yardstick for assessing algorithms and medical devices approval. Solution: development requirements, evaluation procedures and involve regulatory expert in implementation processes.
4.9 Resources barrier: unable to quantify business case and thus difficult to allocate a budget. Solution: business case development method.

Obviously, many solutions are possible, but they all have a different time frame and sequence of development needed to be realized, and thus planning the implementation in a project is hard. The major peripheral business items need the involvement of complex lawmaking and governmental agencies for solving legal and ethical issues, business case development in collaboration with health insurance firms, and the development of new roles for IT experts in the health value chain, which all may take at least one year. However, these peripheral business issues are difficult to settle without a clearly developed concept of an aCDSS in which medical professionals can be convinced about its usefulness and the aCDSS can be developed free from errors and risks. For not getting stuck in a chicken and egg dilemma, an aCDSS needs development as a proof of concept for the peripheral business actors. After this concept is well developed by incentive (research) funds, the legal and ethical issues may become clearer and can be solved (if it cannot, the project will stop). When the legal and ethical issues are solved a business model can be created with insurance firms and the aCDSS can be rolled out to other hospitals. Figure 1 shows the BD4SB barriers and solutions as boxes and ovals respectively within the analytical CDSS development project.

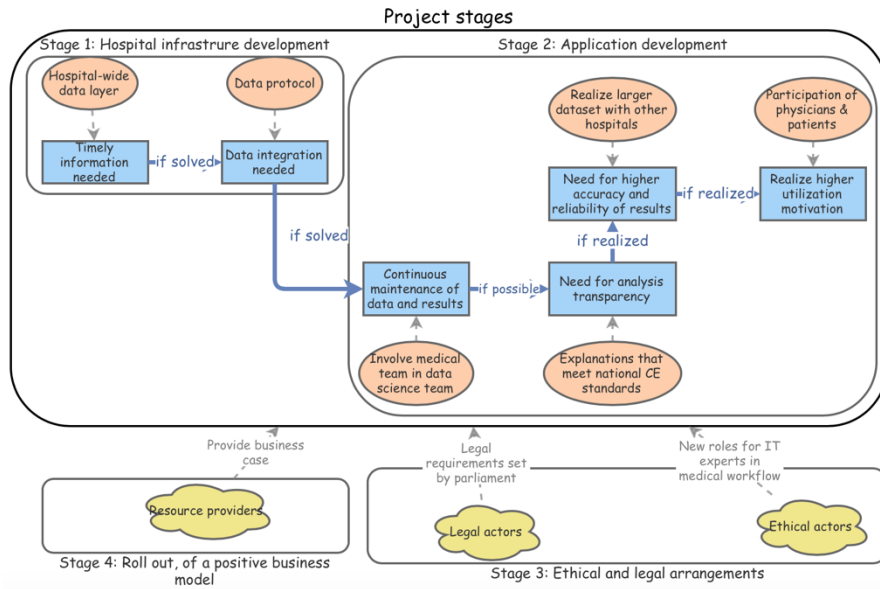


Figure 1: The aCDSS development project in its current state for the BD4SB case

5. Conclusions and Contribution to the literature

This study posed the following research questions:

1. What are stakeholders' perceived barriers and possible solutions for an analytical clinical decision support system implementation project?
2. What can be learned from these perceptions regarding the effective realization of aCDSS implementation projects?

Via interviews with stakeholders of an aCDSS implementation project, we found evidence for previously mentioned analytics workflow and peripheral business barriers for aCDSS implementations in the clinical context. The collection, availability, quality and integration of data are often insufficient for clinical analytics use. Because of a lack of data quality and data integration between institutes, the required external validation of medical analytics models cannot be performed well and the models therefore cannot be trusted in clinical settings. A new emphasis on correct, standardized, and complete registrations is essential for analytics to pass a trust threshold. Given the high responsibility of physicians in medical decision making a high level of resistance in the use of aCDSS is not just a defensive action but based on lacking evidence of trust in aCDSS and possibly a wise abstention [2].

Regarding the law, many new rules and regulations are being produced by the EU and the national government that can improve the quality of data and settle the legal user requirements for aCDSS systems. The new rules also enable system developers to know the requirements and development their systems accordingly. The law in this sense is not so much a showstopper, although it can act as showstopper for some privacy

issues, but the law is especially an enabler of new systems and processes [66]. From an ethical perspective, a new kind of decision-making process is in development with new roles for physician, patients and CDSS.

The technology acceptance is not only a personal socio-psychological characteristics, like perceived usefulness, norms and values as is common on most TAM studies [76], but it is especially an institutional development process given the need for new laws, business case methods and ethical rules. This is highly in line with previous insights about the health industry which indicate that major IT innovations are not anymore in control of a medical professional, but much more the outcome of political and, more recently, market factors [16].

For the research field of analytics adoption in general, the more powerful and relevant it becomes, the more use-context dependent research is needed. Despite the popularity of analytics, statistics and machine learning for finding new insights, the major challenge becomes to detect how these techniques can change organizations and decision making. In the medical field, this implies a need for research in required changes of organizational structures and decision processes, new challenges for health institutions' information management, and new insights in the legal, ethical and resource aspects of aCDSS. For understanding the challenges an aCDSS implementation, we gained a four-stages development model on basis of stakeholder perceptions presented in Figure 1 that can analyze and visualize these processes. We think that further modeling of these aCDSS processes as system dynamic processes, as has been done before in the project management literature [46][44], might be both practically and theoretically resulting in more predictive insights on the effectiveness of aCDSS efforts.

Because this study is based on an extensive case study, many questions may be raised about the indexicality of the gained insights for UMCU only or The Netherlands. One could ask if non-academic hospitals would have similar problems. We think that non-academic hospitals often lack resources for advanced data management and probably have a larger distance between developers and physicians that could result in more adoption problems, and thus aCDSS have to be mature before being distributed over to non-academic institutions. One could also ask if similar problems will appear in other countries. We think that countries with a stronger nationally centralized health system could be in an advantage because they probably have a stronger developed set of ethical and legal arrangements and a more coherent infrastructure for reusing larger data sets for predictive modeling and validation [75]. We also could ask the question if the implementation of aCDSS would be easier in a more government or more market led health system. Our initial thought about this is that if developments get out the hands of medical professionals, they are more complex to realize because of complex peripheral business, but not putting it in the hands of national and international government, professionals and market platforms will give it a too small ecosystems to become successful. Regarding business cases, they will probably follow these developments, because the resulting eco-systems will give the roles and tasks of different institutions in this context, after which it is known who will have to do the negotiations for the business case.

Regarding the generalizability of findings for non-health sector purposes, we think that most industries have less ethical and legal constraints or rules that should be set, but privacy and data ownership of customers is as much an issue in current debates

[39]. We also believe that the actual involvement of users is a critical dimension in effective data science projects. Medical professionals are highly trained persons with rather high skills in statistics and strong abilities of understanding machine learning. This is not the case in most other professions, like lawyers, architects or marketeers, who could theoretically profit much from data analytics but could underestimate or misunderstand (and maybe overestimate) its value [2]. This means that especially stage 2 developments may be difficult in many cases and receiving the resources for roll out may be even more difficult than in the medical field. The current data analytics knowledge thus has to be complimented with sufficient insights on adoption possibilities and challenges by users.

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