Data interchange standards in healthcare: semantic interoperability in preoperative assessment

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Chapter 5

The Role of standardized data and terminological systems in computerized clinical decision support systems

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Abstract

Introduction: Clinical decision support systems (CDSSs) should be seamlessly integrated with existing clinical information systems to enable automatic provision of advice at the time and place where decisions are made. It has been suggested that a lack of agreed data standards frequently hampers this integration. We performed a literature review to investigate whether CDSSs used standardized data and which terminological systems have been used to code data. We also investigated whether a lack of standardized data was considered an impediment for CDSS implementation.

Methods: The relevant articles were identified based on a former literature review on CDSS and on CDSS studies identified in AMIA's 'Year in Review'. Authors of these articles were contacted to check and complete the extracted data. A questionnaire among the authors of included studies was used to determine the obstacles in CDSS implementation.

Results: We identified 77 articles published between 1995 and 2008. Twenty-two percent of the included articles used only numerical data in CDSS. Fifty one percent of the studies that used coded data applied an international terminology where ICD (International Classification of Diseases) (68%) and LOINC (Logical Observation Identifiers Names and Codes) (12) were the most frequently used ones. More than half of the authors experienced barriers in CDSS implementation. In most cases these barriers were related to the lack of electronically available standardized data required to invoke or activate the CDSS.

Conclusion: Many CDSSs applied different terminological systems to code data. This diversity hampers the possibility of sharing and reasoning with data within different systems. The results of the survey confirm the hypothesis that data standardization is a critical success factor for CDSS development.

5.1. Introduction

It has been demonstrated that clinical guidelines provided by real-time clinical decision support systems (CDSSs) significantly improve patient care [1] and reduce practice variability [2, 3]. The success of CDSSs requires that they are seamlessly integrated with clinical workflow and with existing patient information systems [4, 5] to enable the automatic provision of advice at the time and place where decisions are made. However, integrating CDSSs with other information systems has been shown difficult [6]. It has been suggested that this is due to lack of agreed standards for semantic interoperability [7-11].

Semantic interoperability is the ability of computer systems to exchange information and have that information properly interpreted by the receiving system in the way as intended by the transmitting system [12, 13]. Achieving semantic interoperability requires not only the use of communication standards such as HL7 with its underlying models and specifications, but also needs common concepts and their interpretation, including concept grammar and terminological systems [14]. A terminological system relates concepts of a particular domain among themselves and provides their terms and possibly their definitions and codes [15]. Terminological systems facilitate the integration of CDSSs with the patient information system by binding the patient data in the patient information system with the concepts in the decision rules of a CDSS. They smooth the progress of CDSS development by enabling terminological reasoning. For example, without a terminological system the CDSS rule "If a patient already suffered from a renal disease, then a urine analysis test should be done before surgery" would have to be repeated for each type of renal disease i.e. polycystic kidney disease, pyelonephritis, renal acidosis, etc. When a terminological system is used all these subtypes would be recognized as types of renal disease and only one rule will be sufficient to represent this preoperative assessment recommendation. In this way the readability of the knowledge base and its maintenance are simplified [16]. Although in theory the benefits of terminological systems for facilitating CDSS implementation are clear, there is a lack of knowledge on the actual role of terminological systems in CDSSs in clinical practice.

In this study we analyzed the literature regarding CDSSs and performed a survey to answer the following questions: 1) Do CDSSs use standardized (numerical and/or coded) data? 2) Do authors of CDSS studies consider a lack of standardized data an impediment in CDSSs implementation? and 3) If coded data were used, e.g. for diagnoses or procedures, which terminological systems have been used to represent this data type?

5.2. Methods

5.2.1. Materials

Our starting point was the set of included articles from the systematic review of Garg et al. on effects of computerized clinical decision support systems on practitioner performance and patient outcomes. This systematic review was based on literature retrieved from MEDLINE, EMBASE, Evidence-Based Reviews databases (Cochrane Database of

Systematic Reviews, ACP Journal Club, Database of Abstracts of Reviews of Effects, and Cochrane Central Register of Controlled Trials), and INSPEC bibliographic databases [17]. It covers 88 randomized controlled trials (RCTs) and 12 non-randomized trials from 1974 till September 2004. In our study, we included all RCTs from 1995 referenced by Garg et al. One option to extend this set of articles with articles published after 2004 was to use Garg's search strategy for the more recent time period. Due to time and resource limitations we decided to use CDSS studies identified by the American Medical Informatics Association (AMIA)'s "Year in Review" from October 2004 till October 2008. During each "Year in Review" session of the Annual AMIA Fall Symposium the previous year's publications of RCTs in the medical informatics field are discussed. They identify RCTs examining more than 100 patients or providers by extensive literature review and a poll of American College of Medical Informatics (ACMI) fellows. The strategy used can be found on [18]. As AMIA's 'Year in Review' was restricted to RCTs we decided to also restrict ourselves to RCTs from Garg's review. Based on full-text review, only studies evaluating a CDSS that provided a computerized advice based on patient-specific data items were included.

5.2.2. Data extraction

To systematically capture the information that was relevant for answering the research questions, an extraction form based on reviews of the literature [1, 9, 17] and expert consensus was designed. The form has 3 parts: General information about the study, CDSS characteristics, and knowledge representation. The first part includes data items regarding publication year; study design; clinical setting, and arena; and findings on the effect of the CDSS on patient or practitioner performance outcomes. For each study we collected up to three primary outcomes mentioned in the article. The second part consists of data items regarding activation of the CDSS, the systems integration within its surrounding information infrastructure and the system's style of communication. The last part consists of items such as the data types used in decision rules i.e. numerical data, coded data or free text that invoked the system or generated the advice, and the use of terminological systems for coding the data (see appendix A for data extraction form).

The extraction form was examined for coverage, clarity, and content validity in several consensus meetings. Four randomly selected articles were reviewed by all six authors of this study, and extracted data were discussed to refine the extraction form and solve ambiguities in the form. To have the same interpretation of the identified data items during the data extraction the definition of each data item was described (see appendix B). In addition, the data extraction form was circulated for external review. Two authors of recently published articles on CDSSs [19, 20] checked whether the data items were sufficiently clear.

For each included study the extraction form was completed by two independent reviewers. Disagreements were resolved through discussion between the two reviewers. If reviewers could not reach an agreement, disagreements were discussed with other authors. The filled-in extraction form was sent to the corresponding author of the included studies to

check the data extracted from their article and to complete any missing data. A document including the definitions of the concepts that we used in our data extraction form was accompanied (see appendix B). In addition we asked the authors five questions: four of these questions were about data types used in the system and the application of terminological systems; the fifth question was whether authors had ever decided not to start or to abandon developing a CDSS because of problems regarding required data or other types (e.g. financial or organizational) of problems (see appendix A, section II).

Authors were sent one email message and, if necessary, up to two reminders. When primary authors did not respond or could not be reached we contacted the second author or the last author.

To test differences between the use of standardized data versus non standardized data regarding features of CDSSs and practitioner performance or patient outcomes we used chi square statistics. We interpreted $P \leq 0.05$ as statistically significant.

5.3. Results

5.3.1. Study selection

Garg's review and AMIA's "Year in review" resulted in 112 potentially relevant articles. Of these, 77 articles [6, 21-96] were included (figure 5.1). Most of the excluded studies (n=31) described a system that did not provide computerized advice based on patient-specific data items. Authors of 48 (62%) studies [6, 21, 22, 24, 25, 29, 32-34, 36-38, 41, 42, 44, 48, 52-54, 57, 60, 61, 63, 64, 66, 67, 69, 72, 75-79, 81-85, 87-96] confirmed the extracted data and provided answers to the additional questions.

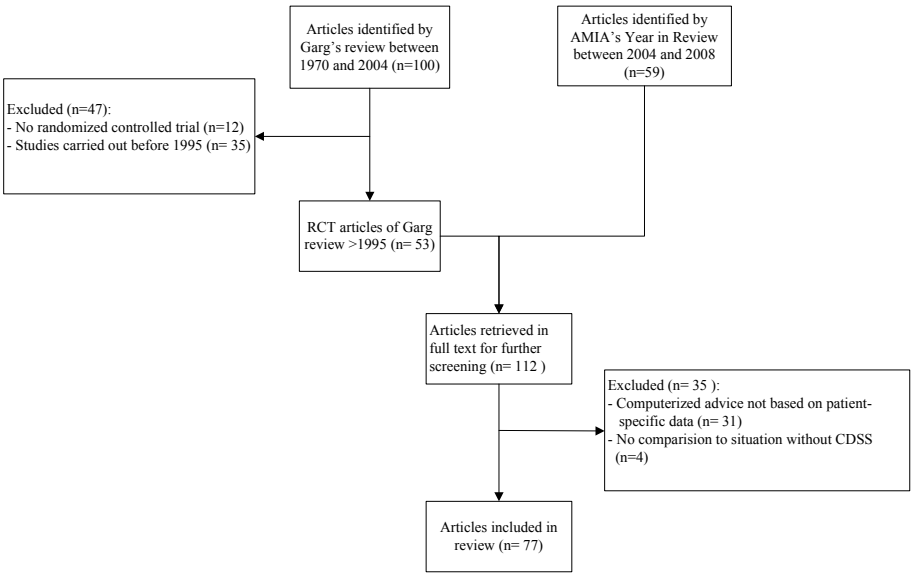

Figure 5.1: Selection process of studies on clinical decision support systems

5.3.2. Description of studies

Part one of Table 5.1 describes the characteristics of the included studies. Fifty one percent of the studies have been performed in a multicenter setting, 33% of them were managed by a single health maintenance organization. Most studies described systems which were developed for Disease management (35%) and Treatment (23%), followed by Drug dosing and prescribing (10%), Prevention (12%), Patient education (5%), Screening (5%), Diagnosis (4%), Risk assessment (4%), and Clinical documentation (1%).

5.3.3. Description of clinical decision support systems and Users

Part 2 of Table 5.1 shows features about the way the CDSSs were implemented and integrated into the workflow. None of the 77 included studies reported a negative effect of CDSS on patient outcome or practitioner outcome. In 82% (n=45) of 55 integrated CDSSs (second row of part 2 in table 5.1), systems prompted the user automatically and did not need to be initiated manually to get advice. In 44% (n=24 out of 55) of the integrated CDSSs additional input from users was required to get the advice. CDSSs which used a consulting style of communication (systems that give users advice about what they should do) required additional data entry in 74% (n=28 out of 38) of the cases; while critiquing systems (systems that provide feedback on the actions that users perform or intend) required additional data entry in 50% (n=6 out of 12) of the cases, and reminder systems (the systems that remind users of something that they have not done) in 32% (n=8 out of 25) of the cases. System developers mostly used the consulting model (49%) as communication style of CDSSs. Systems which needed to be initiated manually to get advice required additional data entry in 81% (n=22 out of 27) of the cases.

Table 5.1: Characteristics of the included studies and features of decision support systems (n=77). See appendix B for the definitions of the characteristics presented in the table

Characteristics of the included studies		**Number of studies (%)**
Publication year	1995-1999	23 (30)
	2000-2004	23 (30)
	2005-2008	31 (40)
Country of study	United states	53 (69)
	United kingdom	9 (11)
	Canada	3 (4)
	Norway	3 (4)
	Italy	2 (3)
	The Netherlands	2 (3)
	France	1 (1)
	Lithuania	1 (1)
	Multiple countries	3 (4)
Study setting [a]	Single center	37 (48)
	Multiple center, single HMO [b]	13 (17)
	Multiple center	26 (34)

Characteristics of the included studies		Number of studies (%)
Clinical setting [a, c]	Primary care	34 (44)
	Secondary or tertiary outpatient care	19 (25)
	Secondary or tertiary inpatient care	22 (29)
Clinical arena addressed by CDSS	Family medicine or general practice	20 (26)
	Internal medicine	18 (23)
	Cardiology	8 (10)
	Supporting specialties	6 (8)
	Hospital wide	6 (8)
	Hematology	3 (4)
	Home Care or Nursing care	3 (4)
	Intensive care medicine	3 (4)
	Psychiatry	2 (3)
	Other specialties	8 (10)
System features		**Number of studies (%)**
System activation [d]	System automatically prompts the user	49 (64)
	System should be initiated manually	27 (35)
System integration	Integrated (linked system)	55 (71)
	Independent (stand-alone system)	22 (29)
Style of communication [d, e]	Consulting model (system gives advice about what user should do)	38 (49)
	Critiquing model (system criticizes user about his/her action)	12 (16)
	Reminder system (system reminds user of something that (s)he has not done)	25 (32)
System requires data entry	System requires user input to give the advice	43 (56)
	System does not require user input to give the advice	34 (44)
Users of the system [f]	Physicians	66 (86)
	Nurses	21 (27)
	Paramedics	4 (5)
	Patients	5 (6)

[a] One study evaluated a web-based clinical decision support systems which was used by patient at home. [b] Health maintenance organization. [c] One study was carried out in both primary care and secondary or tertiary outpatient care. [d] There were one missing data item regarding system activation, and one regarding style of communication. [e] One system applied two modes of communication consulting and reminder. [f] one system could have different users.

Authors of 48 studies who responded to our questionnaire reported the following ways of invocation of their CDSS; the CDSS automatically selected the relevant cases in 44% (n=21), cases were selected automatically by another computer application in 15% (n=7), the system was invoked manually by the end-user in 25% (n=12), and the system was invoked by another person (e.g. a research assistant) in 12% (n=6). In 4% (n=2) of the studies the CDSS invocation was changed during the study from automatic invocation to manual invocation.

5.3.4. Data types used in clinical decision support systems

Table 5.2 indicates different data types that were used in CDSSs. Of the 77 included studies, 17 (22% of the) studies used only numerical data items, 11 (14%) of the studies used only coded data items, 31 (40% of the) studies used combination of numerical and coded data items, and the other 9 (12%) studies used free text with or without numerical and/or coded data items to invoke the CDSS or generate an advice. In 9 studies the used data types were not described and authors of these studies did not provide the required information. Authors who responded to our questionnaire reported that the numerical data items were mostly used for demographic and health data (n=20) (e.g. age, weight and BMI), in which the data item age (n=18) was the most frequent one, followed by laboratory test results (n=16) (e.g. hemoglobin), and physiological parameters (n=10) (e.g. vital signs). Other numerical data items were medication parameters (n=6) (e.g. medication dosage), results of diagnostic tests (n=6) (e.g. ejection fraction), disease risk factors (n=3) (e.g. cardiac risk score) and other numerical data items (n=5) (such as number of visits and days in the hospital).

Studies that used free text (n=9), extracted patient diagnosis, medications or other clinical data from the free text records. Extraction of the data from free text was done, for example, by using a natural language processing method or by personal reviewing of the patient records. For instance, a pharmacist reviewed the patient prescriptions and determined if a prescription should be discontinued based on existing guidelines. More information about coded data can be found in the section 5.3.6. .

The percentage of positive practitioner performance outcomes was higher among the systems that did not use free text (79% versus 50%, p-value= 0.038). The percentage of patient outcome seems to be higher among the systems that used standardized data but the difference was not statistically significant (45% versus 33%, p-value=0.51)

Table 5.3 presents the frequency of using standardized data (numerical and/or coded) and free text data based on different system features. Standardized data were used more often in systems that automatically prompted the user (p-value=0.038).

Table 5.2: Outcome of clinical decision support systems based on data types used into the system

Data type	**Number of studies (%)**	**Number of positive outcomes/ total number of outcomes (%)**			
		Practitioner performance outcome		**Patient outcome**	
Numerical data	57 (74)	44/57 (77)	45/57 (79)	27/60 (45)	27/60 (45)
Coded data	49 (63)	40/56 (71)		17/41 (41)	
Free text	9 (12)	5/10 (50)		3/9 (33)	

The categories in this table are non-exclusive as one study could use different data types. The presented result is based on all 77 included studies. In 9 studies the used data types were not described. For each study up to three outcomes were considered.

Table 5.3: Frequency of using standardized data and free text based on system features. See appendix B for the definition of the concepts presented in the table

System features		Data type [a]		P-value
		Standardized data (numerical and/or coded)	Free text	
System activation [a]	System automatically prompts the user	40	3	0.038
	System should be initiated manually	18	6	
System integration	Integrated (linked system)	42	7	0.681
	Independent (stand-alone system)	17	2	
System requires data entry	System requires user input to give the advice	31	5	0.866
	System does not require user input to give the advice	28	4	

[a] Data was missing regarding data types (n=9), and system activation (n=1)

5.3.5. Obstacles in clinical decision support systems implementation

We asked authors whether they have ever decided not to start or to discontinue developing a CDSS. In 58% of cases, the authors had experienced problems with developing a CDSS (Figure 5.2). Ninety-two percent of these problems were related to data (standardization) required to develop the CDSS. Eight percent of the experienced problems were non-data related problems including financial or organizational problems.

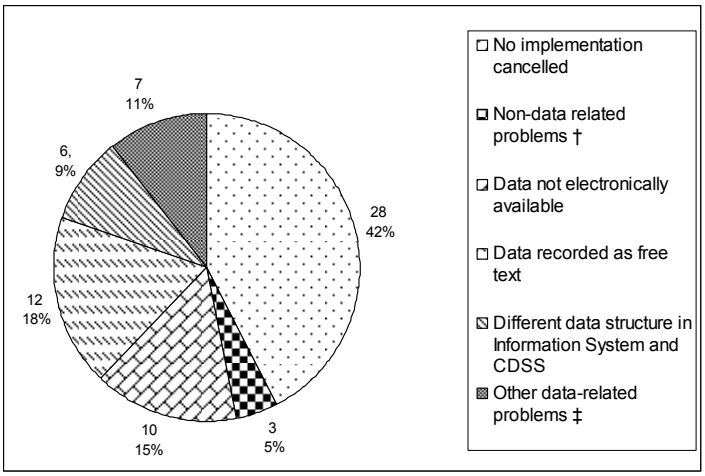

Figure 5.2: Authors' responses regarding obstacles in clinical decision support systems implementation *

* Authors could choose more than one answer.
† Non data related problems including financial or organizational problems
‡ Authors mentioned low data quality and incomplete data as other data related problems.

5.3.6. Terminological systems used in clinical decision support systems

Studies most frequently used an international terminological system (n=25) compared to national (n=15) or local terminological systems (n=23), where a terminological system is considered international when it is in wide use in multiple countries. Authors who responded to our questionnaire used terminological systems for representing 93 coded data items. Figure 5.3 presents the terminological systems that were used to code these data items. One study could involve several coded data items. International terminological systems were used mostly for representing diagnoses (68%), whereas national terminological systems for representing medications (50%). The international terminological systems that were used were ICD (International Classification of Diseases) n=23 (68%), LOINC (Logical Observation Identifiers Names and Codes) n=4 (12%), and other terminological systems n=7 (20%). Nearly all studies that used international terminological systems were carried out in the USA (n=24), except one study that was performed in The Netherlands. National terminological systems were applied in the USA (n=12), United Kingdom (n=2) and in The Netherlands (n=1). The national terminological systems included NDC (National Drug Code), CPT (Current Procedural Terminology), Read codes, FDA drug list (Food and Drug Administration), and NDF (National Drug File). Other countries used local terminological systems to represent the coded data (e.g. a predefined list of medications). Recent studies used international terminological systems more frequently: 72% (n=18 out of 25) of the studies that utilized international terminological systems were carried out after 2003.

In general, terminological systems were more frequently utilized in integrated CDSSs. Eighty eight percent (n=22 out of 25) of the studies that used international terminological systems applied these in integrated systems. Moreover, 93% (n=14 out of 15) of the studies that used national terminological systems and 70% (n=16 out of 23) of studies that used local terminological systems applied these in integrated systems. While studies that used local terminologies required additional input from user in 57% (n=13 out of 23) of the cases, those studies that applied international terminological systems and national terminological systems required additional input in only 32% (n=8 out of 25) and 40% (n=6 out of 15) of the cases respectively.

5.4. Discussion

This literature review showed that 22 percent of the studies used only numerical data items in a CDSS, 14% of the studies used only coded data, and 40% of the studies combined numerical data with coded data to invoke the CDSS or generate an advice. The lack of standardized data is mentioned by a majority of responders of our questionnaire as a major obstacle in CDSS development and implementation. The most frequently used terminological system was one of the ICD family, but still 42% of the studies used a local terminological system to standardize data.

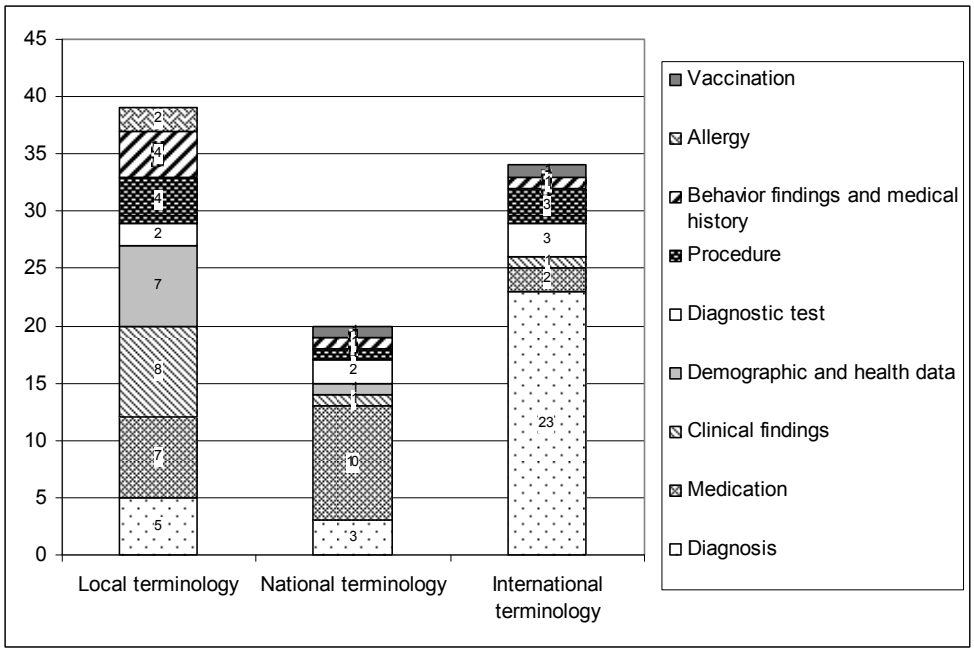

Figure 5.3: Terminological systems used in clinical decision support systems *

* The presented results in this figure are based on the studies that used coded data and their authors responded to our questionnaire.
The international terminological systems were ICD: The International Classification of Diseases (n=23), LOINC: Logical Observation Identifiers Names and Codes (n=4) , DRG: Diagnosis-Related Group (n=3), ATC codes: Anatomical Therapeutic Chemical Classification System (n=1), GPI: Generic Product Identifier (n=1), ICPC: International Classification of Primary Care (1), and DSM IV Diagnostic and Statistical Manual of Mental Disorders (n=1).

The specificity of the CDSS advice varied considerably, which can be explained by the number of data items that were used by the CDSS to trigger relevant recommendations. Some systems simply checked a numerical data item, e.g. patient's age, to discern appropriate interventions, whereas others used multiple factors (e.g., diagnoses, laboratory results, and medications) in generating recommendations. Numerical data are an easy way of standardization as numerical values are unambiguous, and interpretable by both human and computer. Consequently, such values are easy to use for reasoning in CDSSs. They require a standardized measurement method and unit to be exchanged in a standardized format among different systems.

The CDSSs studied in this review used different terminological systems to present coded data to be used for decision making. The diversity of these terminological systems is an obstacle for the CDSS shareability. This diversity even existed within country borders. The most frequently used terminological system, ICD, groups together similar diseases and procedures and organizes related entities for easy retrieval [97].

Currently there is widespread enthusiasm for introducing CDSSs in healthcare. However, uptake has been slow, and multiple challenges have arisen at every phase of

development and implementation. The majority of these challenges, as indicated by the authors of the included studies in this review, were related to semantic interoperability. If developers of CDSSs could pass the first challenge "availability of required data", they may face other data related challenges such as different style of data documentation (free text) or different information models, which are used for presentation of data in existing patient information systems.

To our knowledge this study is the first literature review focusing on the role of data standardization and terminological systems in CDSS implementation. Other literature reviews [1, 4, 9, 11] on CDSS features did not investigate these features of the CDSS as a factor affecting the system performance. Real improvement in the success of CDSSs will not come with only solving technical issues, but also with the more accurate capture of data items required for decision support, obtained through the maintenance of large standardized medical databases [98-101].

Wright and Sittig [102] developed a four-phased framework for evaluating architectures for CDSS that consist of: Feature determination, Existence and use, Utility, and Coverage. They pointed among other features of CDSS the following success features: "Avoids vocabulary issues", "Shareability", and "content integrated into workflows". An important step in creating interoperable CDSSs is the binding of terminology used in patient information system to terminology used in the decision rules. In some knowledge representation languages like the older version of the Arden syntax a term used in a patient information system had to be mapped to the specific terms used in the decision rules to activate a logical statement [103]. As this kind of language can not support using different but synonymous terms, any encoding of clinical knowledge in the decision rules must be adapted to the local institution in order to use the local vocabulary. In the Arden syntax this problem has become known as the "curly braces problem", because Arden syntax contains non-standardized names and expressions in curly braces. This problem affects the shareability of the defined decision rules. To overcome this problem some knowledge representation languages defined domain ontologies and used them in their decision rules [104, 105]. Recent knowledge representations such as GLIF (Guideline Interchange Format) and SAGE (Standards-Based Active Guideline Environment) deal with vocabulary issues by specifying a clinical information model which includes vocabulary standards. Using standard terminological systems in guideline formalization and in patient information systems will facilitate the interoperability and reusability of the formalized guidelines and thereby ease implementation of the guideline into a CDSS [106, 107].

In the domain of preoperative assessment we developed a core dataset and we intend to create SNOMED CT subsets for items in this dataset for documentation of patient information in anesthesia information management system (AIMS) [108]. We also formalized the preoperative assessment guidelines by using SNOMED CT to create guideline-based DSS in AIMS and to facilitate binding the concepts used in the guidelines with concepts captured in AIMS [109]. This will eliminate the process of context-specific mapping of data between the CDSSs and the patient data in AIMS. Moreover, sharing CDSS rules with other systems using the same terminology will be facilitated.

The results of our study show that international terminological systems were used mostly in integrated systems, providing the possibility of sharing decision support content. It has been described that systems that are provided as an integrated component of health information systems are significantly more likely to succeed than stand-alone systems [1]. Stand-alone systems avoid vocabulary issues entirely since they do not interface with other patient information systems and they can simply be copied from one computer to another. However, this kind of system is not recommended as they request more time and effort from the users as this kind of systems does not have the desirable feature "content integrated into workflows". Integrated systems reduce the need for additional data entry by the healthcare provider, enable the display of the most up-to-date data and patient information, and maximize healthcare provider exposure to the recommendations. However, 44% of the integrated systems that are evaluated in the included studies of this literature review still required additional data entry by the healthcare provider. Arduous data entry was suggested as a reason for poor system acceptance in other studies [110, 111], as physicians are not willing and do not have time to interact with a system that requires them to do more work.

Our study covers the situation of CDSSs over the last 15 years concerning the use of data standardization and terminological systems. It is perceived that some specific features of CDSS improve patient outcome and practitioner performance. In this study we also found that the practitioner performance was significantly improved in studies that did avoid using free text compared to those systems that used free text (Table 5.2). However, due to the limited amount of studies, underreporting of data standardization, and heterogeneity of systems and sites included we are not able to provide strong evidence on this subject. Future reports of CDSS evaluations should provide as much detail as possible when describing the systems including the use of terminological systems and information models in a structural way. The trend towards using international terminological systems may be consolidated with the world-wide uptake of SNOMED CT, a terminological system that provides formal representation which can facilitate defining decision rules. SNOMED CT is considered to be a reference terminological system which is designed to document the information during the course of patient care and due to its formal representation of concepts and their characteristics. As such, it is one of the most promising terminological systems to bind CDSS to electronic patient records [97, 112]. However, no mention was made of the application of this terminological system in CDSSs described by any of the included articles. This result is in line with findings of a literature review on SNOMED CT [113]. As the implementation of SNOMED CT, is expected to increase rapidly in many setting in coming years we recommend specific evaluation studies in these settings.

5.4.1. Limitations

Some limitations of this study need to be mentioned. First, we did not run a new search strategy as we relied on articles identified by Garg's search strategy [17] and updated it by studies identified by AMIA's "Year in Review". Garg's search strategy was a comprehensive search that was run in several databases and Masys et al applied a broad search string and a poll of experts in the field to indentify the relevant studies for the "Year

in Review". Second, as we restricted our inclusion to RCTs, some relevant studies might be missed. Moreover, some CDSSs may not be evaluated or their evaluation results were not reported as a scientific study. For instance, we know that Kaiser Permanente Health Connect is an information management system including CDSS which uses SNOMED CT [114] but we did not find any RCT on CDSS using SNOMED CT. Nevertheless, we believe that our results are not influenced by these choices, as one can not say the included systems were developed in a fundamentally different manner than those that were not included. This is very unlikely given the diversity of systems and settings (academic versus non-academic, commercial versus non-commercial) that were included in our review. On the other hand, in the RCTs investigators generally evaluate systems that have the potential of being used in practice and applied at a larger scale. A third limitation is that many studies did not clearly report on data items that are used for CDSS invocation or advice generation, and on any terminological systems used for presenting coded data. To overcome this limitation, we contacted the authors of the included studies. Our response rate was 62% which is comparable to Garg's study [17]. Some bias might be introduced in the question regarding abandoning the development of a CDSS, because of the suggestive formulation of this question and its answer categories. However, we started the answer categories with two answers describing the absence of any problem and any non-data related problem. Therefore, we expect that the overall conclusion that a majority of authors observed some obstacles in CDSS implementation due to a lack of data standardization is still valid.

5. 5. Conclusion

Still a lot of work needs to be done to come to fully integrated and interoperable CDSSs. This can be explained by the fact that CDSSs applied different terminological systems to code data items. This diversity hampers the possibility of sharing and reasoning with data within different systems. Using local terminological systems, which were the case in presentation of about half of the coded data, will negatively affect the shareability of the data and decision rules. A survey among authors of articles included in this study revealed that the lack of standardized data is a major obstacle for CDSS implementation. To adequately use a CDSS, quality, availability and standardization of data are essential.

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Appendix A: Data extraction form and questions

Section I: Data extraction form

Name reviewer:		Study number:	First author:
Inclusion		☐ Yes ☐ No, Reason: ☐No DSS ☐ Other:	
General information about study			
Country:		Year of publication:	
Study Setting		☐ Single center ☐ Multicenter, single HMO ☐ Multicenter	
Primary Outcome Measures and findings	Outcome measure 1: …….. ……..……...	☐ Practitioner performance ☐ Patient outcomes	☐ + effect ☐ 0 effect
	Outcome measure 2: …….. ……..……..	☐ Practitioner performance ☐ Patient outcomes	☐ + effect ☐ 0 effect
	Outcome measure 3: …….. ……..	☐ Practitioner performance ☐ Patient outcomes	☐ + effect ☐ 0 effect
Clinical task (Single answer)		☐ Counseling (psychotherapy) ☐ Diagnosis ☐ Patient education ☐ Evaluation ☐ Disease management ☐ Prevention ☐ Rehabilitation ☐ Risk assessment ☐ Screening ☐ Treatment ☐ Drug dosing and prescribing (CPOE only) ☐ Clinical documentation	
Clinical domain:			
Clinical setting		☐ Primary care ☐ Secondary/tertiary out patient care ☐ Secondary/tertiary inpatient care	
System characteristics			
Users of the system		☐ Physicians ☐ Nurses ☐ Paramedic ☐ Patients	
System activation		☐ System automatically prompts the user ☐ System should be initiated manually	
Requires data entry		☐ Yes ☐ No	
System integration		☐ Independent (Stand-alone system) ☐ Integrated or linked system	
Style of communication		☐ Consulting model ☐ Critiquing model ☐ Reminder systems	

Knowledge representation

Data type (Multiple answers possible)	Numeric	☐ Yes ☐ No ☐ Unknown
	Free text	☐ Yes ☐ No ☐ Unknown
	Coded items	☐ Yes ☐ No ☐ Unknown
Terminological system that is used for representing coded data	☐ Local terminological system, Name: ☐ National terminological system, Name: ☐ International terminological system, Name: ☐ Not applicable	

Comments regarding extracted data:

Section II: Questions

Below, we distinguish the procedure to invoke the Decision Support System (DSS) from the algorithm to generate the actual advice. Please answer the following questions:

1- How was your DSS invoked during the study? [Please pick one answer]

- ○ The DSS automatically selected the relevant cases.
- ○ Cases were selected automatically but by a separate computer application, after which the DSS was started.
- ○ The system was invoked manually by the end-user.
- ○ The system was invoked manually by another person (e.g. a research assistant).
- ○ In another way [please explain]:

2- What kind of data was used in the procedure to invoke the DSS? [Multiple answers possible]

- ○ Numerical data (e.g., patient age, INR, cholesterol, blood pressure).
  Please specify which data items:
- ○ Coded data (e.g. patient with diagnosis='C21234'), either based on (inter)national coding systems or a local pre-defined list of items (it refers also to a simple list e.g. defined for "gender" including male, female, …).
- ○ Non-coded free text data. Please specify which data items:

3- What kind of data was used by your DSS to generate the advice, once it had been invoked? [Multiple answers possible]

- ○ No other than those mentioned in Question 2.
- ○ Numerical data (e.g. age, INR, cholesterol, blood pressure).
  Please specify which data items:
- ○ Coded data (e.g. patient with diagnosis='C21234') either based on (inter)national coding systems or local, pre-defined list of coded (it refers also to a simple list e.g. defined for "gender" including male, female, …).
- ○ Non-coded, free text data. Please specify which data items:

Questions 4 only has to be answered if your DSS used coded data.
4- Which types of clinical data were used to invoke the system and to generate the advice? Please provide for each used data type whether any coding system or terminological system is used to standardize the data (and which ones).

Data item (E.g., gender, diagnosis, anti-coagulation medication, procedure, ..)	Please indicate whether this data type was used to invoke the system or to generate the advice	Coding system or terminological system		
		Local coding list, or pre-defined list of data	National terminological system (Provide name)	International terminological system E.g. ICD9CM, UMLS SNOMED CT, RxNorm, DSM IV (Provide name)
E.g. anticoagulation medications	Invoke system	List of anti-coagulants was defined		

5- Have you ever decided not to start, or to abandon, developing a decision support system because of problems with data needed to invoke the system or data needed to generate advice by the system? [Multiple answers possible]

- ○ No, this never happened
- ○ No, but it did happen because of non-data-related problems e.g. financial problems, personnel related problems etc.
- ○ Yes, because the required data was not (electronically) available.
- ○ Yes, because the required data was electronically only recorded as free text.
- ○ Yes, because the required data had a different structure than what was needed in the decision algorithm.
- ○ Yes, because of other data-related reasons, namely:

Comments regarding defined data in DSS:

Appendix B: Definitions of concepts used in the data extraction form.

Study setting

Single centre: Study was performed in a single centre.

Multicentre, single HMO: Study was performed in multiple centers, belonging to one Health Maintenance Organization (HMO).

Multicenter: Study was performed in multiple centers, not belonging to one HMO.

Clinical task

Counseling (psychotherapy): DSS was used for psychological therapy directed at mental health problems.

Diagnosis: DSS was used for identification of a medical condition or disease.

Patient education: DSS was used for impart information to patients to alter their health behaviors or improve their health status.

Evaluation: DSS was used for assessment of patients' health condition.

Disease management: DSS was used to coordinate health care interventions and communications for populations with conditions in which patient self-care efforts are significant. It is the process of reducing healthcare costs and/or improving quality of life for individuals by preventing or minimizing the effects of a disease, usually a chronic condition, through integrative care.

Prevention: DSS was used for primary prevention of disease such as immunization. Secondary prevention of disease should be classified as 'Disease management', not prevention.

Rehabilitation: DSS was used during the treatment to develop, maintain and restore maximum physical and psychosocial function throughout life after a medical event.

Risk assessment: DSS was used to assess the risk to develop a disease or health outcome.

Screening: DSS was used to detect a disease in individuals without signs or symptoms of that disease. This can be in people who belong to a certain group (for example, all children of a certain age), or in a smaller group of people based on the presence of risk factors (for example, because a family member has been diagnosed with a hereditary disease).

Treatment: DSS was used to give advice regarding a type of therapy (for example medication) used to remedy a health problem.

Drug dosing and prescribing (CPOE only): Determination of the right drug and dose using a CPOE system (Computer Physician Order Entry). Trials concerning drug dosing and prescribing not through CPOE should be classified as 'Treatment'.

Clinical documentation: DSS was designed to notify the users about the completeness of patient information.

Clinical domain

The medical specialty which was involved in the study. When an intervention involved multiple specialties, for example with a preventive intervention, the category 'hospital wide' should be chosen. When no medical specialties were involved but other hospital staff, for example the laboratory, the category 'supporting specialties' should be chosen.

Clinical setting

Primary care: Health services that play a central role in the local community. It refers to the work of health care professionals who act as a first point of consultation for all patients, for example a general practitioner or family doctor.

Secondary/ tertiary outpatient care: Service provided by medical specialists and specialized consultative care for not hospitalized patients.

Secondary/ tertiary inpatient care: Service provided by medical specialists and specialized consultative care for hospitalized patients.

Users of the system

Users of the system are those who receive the system's advice.

DSS activation

System prompted the user automatically: If users of the system do not need to take any action for getting the advice of the system, for example when a reminder automatically shows up.

System should be initiated manually: If it is required to take any action for getting the advice of the system, for example starting up the program and entering data.

Requires data entry to use the DSS

When any data, for example patient characteristics need to be entered into the system by the end users to get the advice this box should be ticked.

DSS integration

Independent (stand alone system): A system that is operational without being linked to other systems.

Integrated or linked system: A system that is operational and linked with other systems, for example with a medication order system or the electronic health record.

Style of communication

Consulting model: The system gives users an advice about what they should do.

Critiquing model: The system criticizes the things that users do, or intend to do.

Reminder system: If the system reminds users of something that they have not done, then this system is a reminder system.

Data type

Type of data required to invoke the DSS, or generate an advice including numerical, coded and free text data.

Terminological system that is used for representing coded data

Local terminological system: terminological system, developed in the institution(s) in which the study is performed.

National terminological system: terminological system, developed and maintained within one country.

International terminological system: terminological system, developed and maintained by an international organization.