electronic Journal of Health Informatics
www.eJHI.net
2015; Vol 9(1):e6

Fundamental Elements Identified for Success of Disease State Management Clinical Decision Support Systems

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Abstract
Traditional forms of communicating best practice disease state management do not adequately support appropriate prescribing in patients with complex needs, such as those with multi-morbidities or aged patients. An effective solution is the use of clinical decision support systems; however, currently available systems do not meet the needs of health professionals (HPs). We wished to evaluate whether HPs find the way in which an early-stage prototype delivers information is useful; however, during prototype development, articles defining fundamental elements of clinical decision support systems (CDSS) success, process model and data requirements were found to be widely dispersed and lacking. We describe a new CDSS prototype for healthcare information delivery tailored for health professional using the identified fundamental elements for success. Concepts described in this article could be used to as the foundation for other CDSS and to inform electronic medical record design.

Keywords: clinical decision support system; decision support system; requirements; database architecture; usability

1 Introduction

Clinical practice guidelines have been used to improve and standardise clinical practice. Despite potential benefits, clinical guidelines have been criticised for failing to take into account patients with multi-morbidity, drug therapy individualisation and end of life care, and because they can be time consuming to use.[1-4] Other barriers to clinical guideline use include health professionals (HP) feeling that their clinical autonomy is under threat, a lack of awareness of or time to search for guidelines and difficulties in individualisation of recommendations.[5-7] Multi-morbidity is the norm rather than the exception in ageing people[8-11] and as the average age of the population increases[12, 13] there is an increasing need for effective delivery of evidence based information to assist in management of complex patients. Decision support systems (DSS) also known as expert systems, can help overcome barriers with clinical practice guidelines. DSS intend to mimic human experts[14] and aim to assist users through alerts and messages, providing definite answers where available or by displaying other information that may influence the user's decisions.

The primary purpose of DSS in medicine, or clinical decision support system (CDSS), is to improve the quality of patient-care. CDSS are able to improve practitioner performance[15], adherence to evidence-based practice,[16, 17] decrease medication errors and reduce adverse drug reactions[18] and potentially decrease costs.[19] There is also some evidence that CDSS can improve medication dosing and frequency choice, compliance with local guidelines, decrease pharmacist intervention due to inappropriate medication choice, and

improve patient satisfaction and outcomes.[16, 20-23]

CDSS can have varying degrees of sophistication, can operate independently or be integrated into computer physician order entry (CPOE) systems, dispensing or other patient information documentation systems to provide automatic alerts, reminders, and recommendations. Despite the potential benefits of CDSS, there have been numerous barriers to their use in practice, including type of information displayed and its quality, as well as non-adherence to basic rules of system development, and lack of overall data structure and terminology standardisation within the e-Health industry.[24-27] Unlike other information-driven fields, such as accounting and business, medicine lacks effective and usable solutions.[28]

Previous work revealed that a new information resource is required that assists in the disease state management of complex patients by display of patient relevant information when HPs would otherwise conduct a literature search to answer their questions on appropriate patient management.[6] Based on these results, a prototype system was designed, developed and evaluated to determine whether HPs find the way in which the early-stage prototype delivers information is useful; however, during prototype design and development, articles defining fundamental elements of CDSS success, process model and data requirements were found to be widely dispersed and lacking. Therefore, this paper aims to describe these fundamental elements applicable to any CDSS by:

Exploring past CDSS successes and failures; Examining the clinical decision making process; Describing the development and initial usability testing of an early-stage prototype system (MedManAGE).

2 Part 1: Past Successes and Failures

2.1 Aims

This section aims to explore reasons for past failures of CDSS and determine what features are significant in improving CDSS usability and success.

2.2 Method:

MedLine (1966-2013) was searched for relevant studies by using the search terms: [“Computer Physician Order Entry” OR “Clinical Decision Support”] AND [“usability” OR “implementation” OR “lessons” OR “testing”]. The searches were restricted to English language. The reference lists were reviewed to identify additional articles.

Articles that described the design, development, or evaluation of disease state management CDSS, where a CDSS was defined as a system designed specifically to assist HPs during the clinical decision-making process regarding treatment of disease states were included. Articles that described CDSS that were administrative in nature, for example that dealt with appointments, diagnostic test results, and laboratory result alerts, were excluded from the review. Focus was kept on “clinical” rather than “administrative” CDSS as features that make one type of CDSS successful or unsuccessful may not be applicable to other types.[29] Articles were included if information pertaining to reasons for success or failure of CDSS or discussion of CDSS data requirements was provided.

2.3 Results

The search of MedLine yielded 105 results. Sixty-one articles met the inclusion criteria.

2.4 Lessons from the past – Contributors to technology induced errors

The majority of technology-induced errors stem from inappropriate integration of the CDSS into usual workflow and unusable system interfaces.

A mixed method study, conducted in 2005, in major urban tertiary care teaching hospitals in the USA involved interviews, focus groups, observations and surveys that aimed to “identify and quantify the role of CPOE in facilitating prescription error risks” highlighted that medication errors predominately stemmed from information errors as well as workflow and interface issues.[30] Information errors arose from auto-filling drug doses using drug strengths available in the pharmacy rather than doses recommended by clinical guideline.[30] Interface sources of error relevant to decision support included legibility issues related to the font size and colour, lack of easy “one screen fit” for patient information and an inflexible system regarding medication order entry (including non-formulary and modified formulation items).[30] Many of the sources of error came from what seems to be an incomplete understanding of usual workflow, for example, failure to provide medications after surgery, antibiotic renewal failure, and charting difficulties.[30]

The Children’s Hospital of Pittsburgh conducted a retrospective study examining the mortality rates of admitted children before and after CPOE implementation.[31] The study period, October 2001 to March 2003, encompassed 13 months without, and 5 months with, a CPOE system. Analysis revealed an unexpected

increase in mortality rates after the introduction of the CPOE system. The primary reason was that the CPOE interfered with usual workflow resulting in delayed vital medication ordering, decreased patient-practitioner face-to-face interaction, unwanted duplication of tasks and inefficient use of HPs. Although some of the issues that arose may have been due to inexperience with the CPOE, most would not have been rectified with experience.[31] This study inspired a commentary describing eight lessons learnt from this experience, from the number of clicks required when using the system to the overall CPOE implementation strategy.[32]

A study that investigated the number of medication errors and pharmacist interventions during two four-week periods, before and after the implementation of CPOE in a UK hospital, found that there was a lower rate of medication errors (absolute reduction of 1.8% CI 0.9-2.7%) and a decreased number of pharmacist interventions (absolute reductions of 1.1% CI 0.2-2%) after implementation.[20] This decrease was not due to decision support however, as the only decision support provided was default dosing. Unexpected errors due to selection of inappropriate medication, omission of drugs, excessively frequent dosing of "PRN" drugs, selection of incorrect dosing frequency, selection of inappropriate formulation were errors deemed to be due to the system itself. [20] Errors such as these can potentially be minimised with interface solutions such the use of appropriate font size and colours and autocomplete boxes rather than selecting items from lists;[33] these lessons can be seen as relevant to all health information technology (HIT).

A Canadian study specifically examined what features of interface designs contribute to adverse events.[34] Seven emergency department physicians were observed using four different CDSS.[34] The number and types of events were recorded.[34] Errors that could potentially contribute to patient harm included inability to record patient data accurately because terms were not predefined, inappropriate screen layout, lack of prompts to indicate patient data or order entry fields were left blank unintentionally and automatic screen population of data fields (e.g. providing a standard dose rather than requiring manual dose entry).[34]

2.5 Previous successes

Many of the components that make CPOE successful are relevant to CDSS; key features are summarised in Table 1 and discussed below.

Gadd et al. in 1998 identified properties that improve usability and acceptance of internet-based DSS. These include clear viewing screen set out, flagging of potential problems and easy identification of problem importance, and the provision of the rationale for DSS recommendations with ready access to more information if desired by users (Table 1).[35] Numerous studies since then have identified the desired features have not changed.[6, 36-50] A multi-method observational study involving developers, users and managers of the systems in US hospitals and medical clinics that used CPOE and CDSS identified some additional desired features. [36] These concerned workflow integration and separate CDSS components, up-to-date high quality knowledge base, work flow integration, feedback mechanisms after implementation and involvement of HPs during development of the systems (Table 1).[36] Sweidan et al. determined what features of electronic prescribing systems support high quality and safe use of medications in primary care (Table 1).[37] The features were initially identified using an extensive literature review, key informant interviews and expert panel member recommendations resulting in 114 features, ten of which were considered "aspirational". Only one aspirational feature was considered relevant to DSS: recommendation of best practice therapy.[37] Twelve experts with backgrounds in general practice, public health, quality and safety, health informatics, pharmacy and consumer health issues, then rated the features according to impact across four domains (patient safety, quality of care, useful to clinician, useful to patient) using a three round modified Delphi technique. Although these features were developed with electronic prescribing system in mind, many are relevant to CDSS. Similar themes were identified by an exploratory study that used three general practitioner (GP) focus groups (Sydney, Melbourne and rural NSW) to explore the strengths and weaknesses of prescribing software (Table 1).[38] Kawamoto et al conducted a systematic review of the literature and identified CDSS features that were considered crucial for improving clinical practice.[51] Of the 71 reviewed CDSSs, 48 significantly improved clinical practice (Table 1).[51] Other studies exploring user satisfaction, preferences, expectations, or lessons learnt from HIT implementation have mirrored these findings (Table 1).[6, 39-50]

A follow up study to Sweidan et al.[37] evaluated the presence of the features that were thought to have a high impact of safety or quality of care, excluding "aspirational" features, in seven general practice electronic prescribing software packages commonly used in Australia, some of which are available overseas.[52] Results illustrate the shortfalls of currently available systems. Only 34-62% of the 50 evaluated features were fully implemented across the seven evaluated electronic prescribing software packages. Although most had im-

General Features
Use of a computer to generate decision support.[6, 51]
Fast system.[51]
Clinician-system interaction features
Saves clinician time or requires minimal time to use.[51]
Clear and intuitive user interface adhering to usability guidelines and developed using human factor engineering methods.[6, 35, 40, 41, 43, 46, 49, 51]
Key information can be seen all on the one screen.[41, 43, 49]
Keyword based search rather than menu-based search.[20]
Any CPOE and CDSS must fit into the usual workflow of the organisation.[36, 49]
• Integration with charting and order entry system.[51]
• Provision of decision support at time and place of decision making.[51]
• No need for additional or duplicate patient data entry.[44, 46, 51]
Documentation of actions: [6, 35, 45, 51]
• Request documentation of rationale for not following CDSS recommendations.[6, 35, 51]
• Recommendations executed result in automatic documentation of agreement.[35, 51]
Have methods to stop "easily overriding" important alerts.[38]

Table 1: Summary of Features Associated with CDSS Success: Desired Features. Continued on next page.

portant safety features such as drug-drug interactions, allergy alerts, and pathology reminders, the following CDSS-specific shortfalls were identified:

1. There was little or no decision support for harmful dosage regimens, and safety warning issued by Australia's Therapeutic Goods Administration;
2. None had information from the key Australian drug and clinical information sources: the Australian Medicines Handbook[53] and Therapeutic Guidelines[54];
3. Systems provided limited drug information and used only approved product information;
4. Linking indications to prescribed medications was optional providing incomplete information given to other health care professionals;
5. Drug selection was made difficult by the use of small and cramped lists with similar named products placed in close proximity;
6. The patients' current and past medications were poorly defined;
7. Medication lists produced for patients were inappropriate – many included abbreviations, Latin terms, and omitted crucial information such as indication;
8. Some systems did not have allergy warnings for potential cross-sensitivities;
9. There was no standard way of recording non-pharmacological treatment initiated; in some cases they were not recorded at all; and
10. Many had minimal patient resources.

2.6 Conclusion: Part 1

Features that contribute to CDSS failure or, conversely, contribute to improved usability and success have been identified. These features should form the basis of overall system design and are vital for success, including:

Clear definition of CDSS purpose; Appropriate design and development; Thorough testing before, and periodic testing after, implementation; Continual improvement; and Appropriate implementation.

Use of human factor methods, adherence to usability standards and end-user involvement throughout design and development contribute to the development of a usable and effective system. End-user involvement not only gives insight into usability issues, but also helps developers ensure that HIT integrates well with workflow. To avoid repeated patient data entry CDSS should integrate with locally used CPOE or EHR systems. Clinical recommendations need to be based on high-quality, up-to-date information and verified for accuracy by an appropriate disciplinary expert panel. Summarised recommendations should be accompanied by rationale and access to supporting evidence.

CDSS Capabilities

Provides patient individualised recommendations.[6, 37, 46]
Flag all important interactions (Figure 4) [35, 37, 38, 50] while avoiding "alert fatigue".[43, 44, 50]
Alerts are prioritised and distinguishable by importance/severity, potentially with the use of colours and positioning.[6, 35, 37, 38, 40, 45, 46, 50]
Allergies need to be highlighted; it should be extremely difficult to prescribe a medication if the patient is potentially allergic.[37, 38, 44]
Monitoring of laboratory results and alerts where indicated.[37]
A medications list should be producible from the stored patient information that lists current medication by diagnosis/condition and current/past medication.[6, 37, 38, 41, 44]
Inclusion of dosage, renal function, etc... calculators.[37, 38]
Easy sending of information to the local body in charge of collecting information on adverse drug reactions; for example in Australia this would be the Advisory Committee on the Safety of Medicines (ACSOM).[37, 38]

Communication of content features

Knowledge base should include the following:

- Contain high quality local data.[6, 36, 37]
- Appropriate procedures need to be in place to ensure the knowledge base is kept up to date.[36, 37, 44]

Use standard vocabulary and database architecture to allow for easy understanding and information exchange with other systems.[36, 37, 40, 41, 43]
Assessments and recommendations are accurate.[51]
Provision of key information, with access to further information if required.[6, 40, 42, 45, 50]
Provision of a recommendation, not just assessment.[6, 39, 51]

- Justification of decision support via provision of reasoning.[6, 35, 51]
- Justification of decision support via provision of research evidence.[6, 35, 51]
- Users should be able to access the resource used to give a recommendation; at the very least, the recommendation should be referenced.[6, 35, 38]
- Decision support needs to be based on clinical guidelines and independent drug information other than approved drug monograph.[35, 37, 38, 46]
- Avoid default dose for DSS within CPOE systems .[34, 43]

Provision of key counselling points.[37]
Promotion of action rather than inaction.[51]

Other Features

Active involvement of local opinion leaders.[51]
Alignment of decision support objective with organisational proprieties and with the beliefs and financial interests of individual clinicians.[44, 51]
System developed through iterative refinement process.[51]

- Local or end user involvement in development and evaluation process.[36, 43, 49, 51]
- After implementation, avenues for receiving and acting upon user feedback should be established.[36, 43, 49, 51]

CDSS accompanied by conventional face-to-face education such as grand rounds.[51]
Ability to personalise system.[41]
Provision of decision support results to patients as well as providers.[51]

Table 1: Summary of Features Associated with CDSS Success: Desired Features

3 Part 2: Examining the Clinical Decision Making Process

3.1 Aims

To examine the clinical decision making process in order to describe a universally applicable decision making model and associated data requirements.

3.2 Method

In order to identify the clinical decision-making process, Australian and international online publications regarding the medication review and quality prescribing process, including World Health Organization (WHO) and National Prescribing Service (NPS) were reviewed.

Australian approved drug monographs were examined to identify drug characteristics that influence therapy choice. In addition, disease state management literature and guidelines for four disease states, five associated symptoms and numerous population types and subtypes were reviewed. Guidelines were used to describe the usual clinical decision making process, identify drug factors that affect pharmacological therapy choice, and for database population. Information sources included the National Health and Medical Research Council guidelines (NHMRC) and disease specific bodies such as the National Heart Foundation, Diabetes Australia, Diabetes Educators and Arthritis Australia.

3.3 Results

The World Health Organisation has released the "Guide to Good Prescribing" as an international standard.[55] They describe six core steps to rational prescribing:

1. "Defining the patient's problem."

o The correct diagnosis must be established prior to choosing an appropriate treatment.

2. "Specify the therapeutic objective."

o Objectives may change under different circumstances. This process assists with minimising drug-overprescribing and later evaluation of treatment efficacy.

3. "Verify whether your P-treatment [or available treatment] is suitable for this patient."

o Any treatment, whether pharmacological or non-pharmacological should be safe, effective and cost-effective for the patient. Choosing an appropriate drug requires taking into account patient and drug attributes.

4. "Start the treatment."
5. "Give information, instruction and warnings."
6. "Monitor (stop) the treatment."

o Treatment failure generally results from three basic causes: 1) the treatment was ineffective, 2) the treatment was unsafe (e.g.: side effects), 3) the treatment was inconvenient to administer due to the nature of administration or dosing schedule. When choosing to re-treat with a new therapy, these need to be taken into consideration.

The National Prescribing Service (NPS) of Australia published a document entitled "Competencies Required to Prescribe Medicines: Putting quality use of medicines into practice" that describes five areas of competency required for prescribing irrespective of the HP type that reflect core steps described by the WHO.[56] These overall principles for disease state management are echoed globally indicating that the clinical decision making process is the same irrespective of geographical location.[57-60]

Disease state management guidelines were used to help identify disease specific considerations that may not have been identified otherwise.[53, 61-88] Common factors considered by all the guidelines were used to describe a universal prescribing process model (Figure 1). This information was utilised to develop the process model implemented in our prototype system (Figure 2).

Note: Precipitating drugs are those that may be causing the disease or symptom that the patient is experiencing.

Patient physical and medical factors as well as patient preferences influence medication choice.[55, 56] Patient factors include, but are not limited to, past and present medication and medical history, laboratory results and other observations, adverse drug reactions, allergies, physical or mental impairment that may affect medication taking and social status. In addition to these, pharmacogenomics will have a larger influence on drug choice as the body of information regarding genetic factors impacting pharmacokinetics (PK) and pharmacodynamics (PD) grows; these should be included in CDSS, electronic health record (EHR) and CPOE systems and populated with emerging information.[89, 90] Disease state management factors influencing treatment choice include evidence for effective pharmacological and non-pharmacological treatment and disease state targets such as blood pressure or blood glucose.[53, 61-88] Drug factors revolved around PK and PD properties, as well as local availablity and cost.[53, 61-88] The overall process of choosing pharmacological therapy is summarised in Figure 4.

'IF... THEN' algorithms can be developed based on these influences (Figure 3), as well as algorithms to identify drugs that may be precipitating presenting symptoms.

CDSS should mimic the thought process of a HP, at

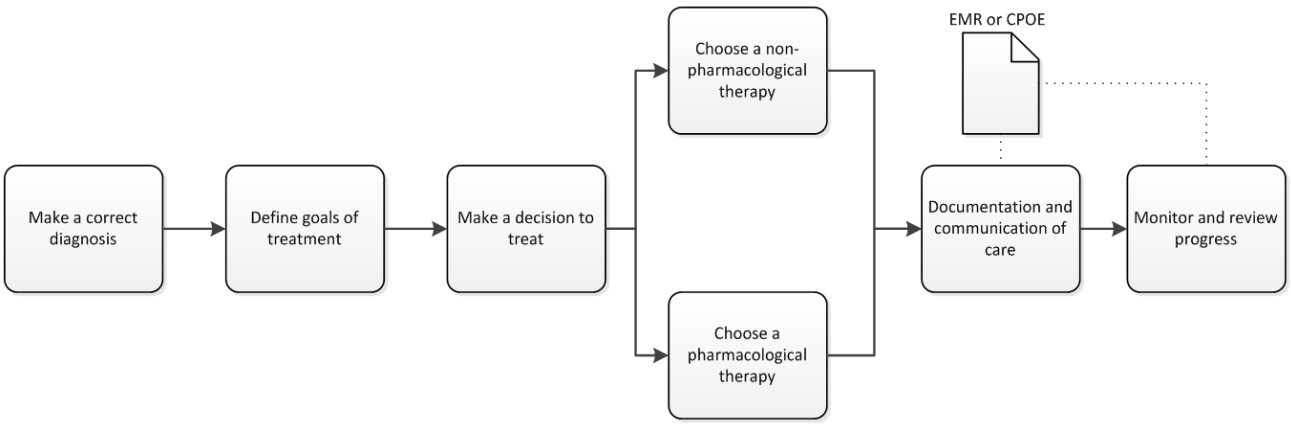

Figure 1: Summary of universal prescribing process model

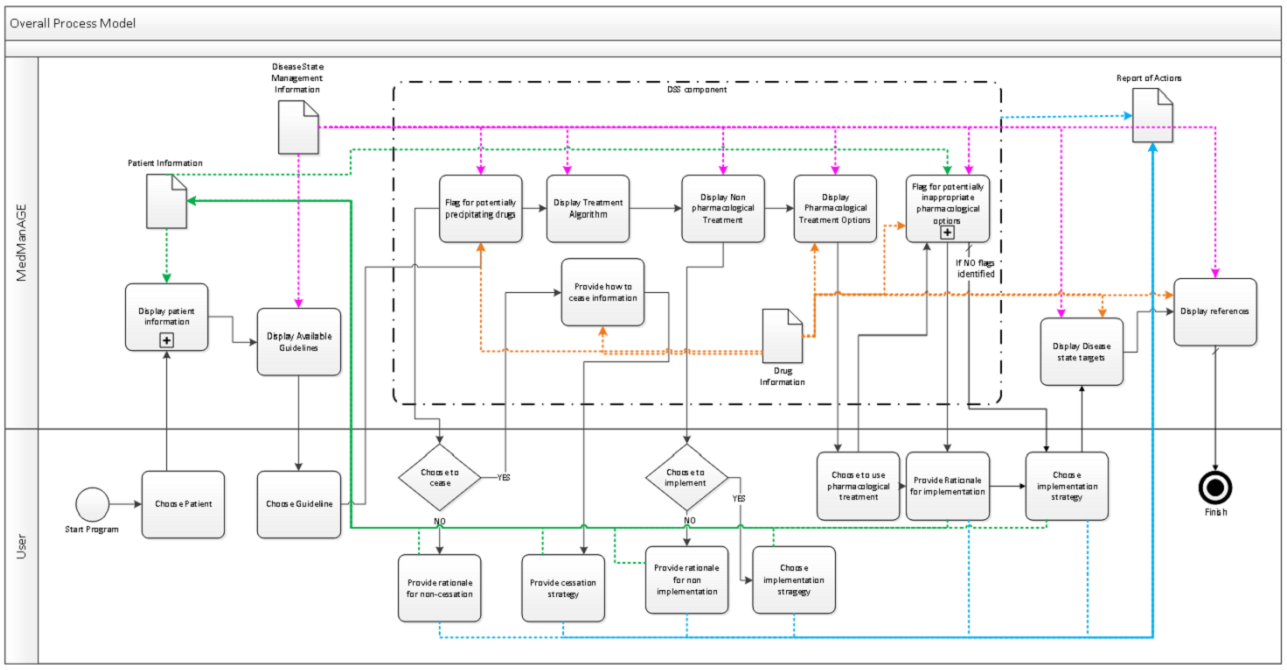

Figure 2: Process model implemented in MedManAGE.

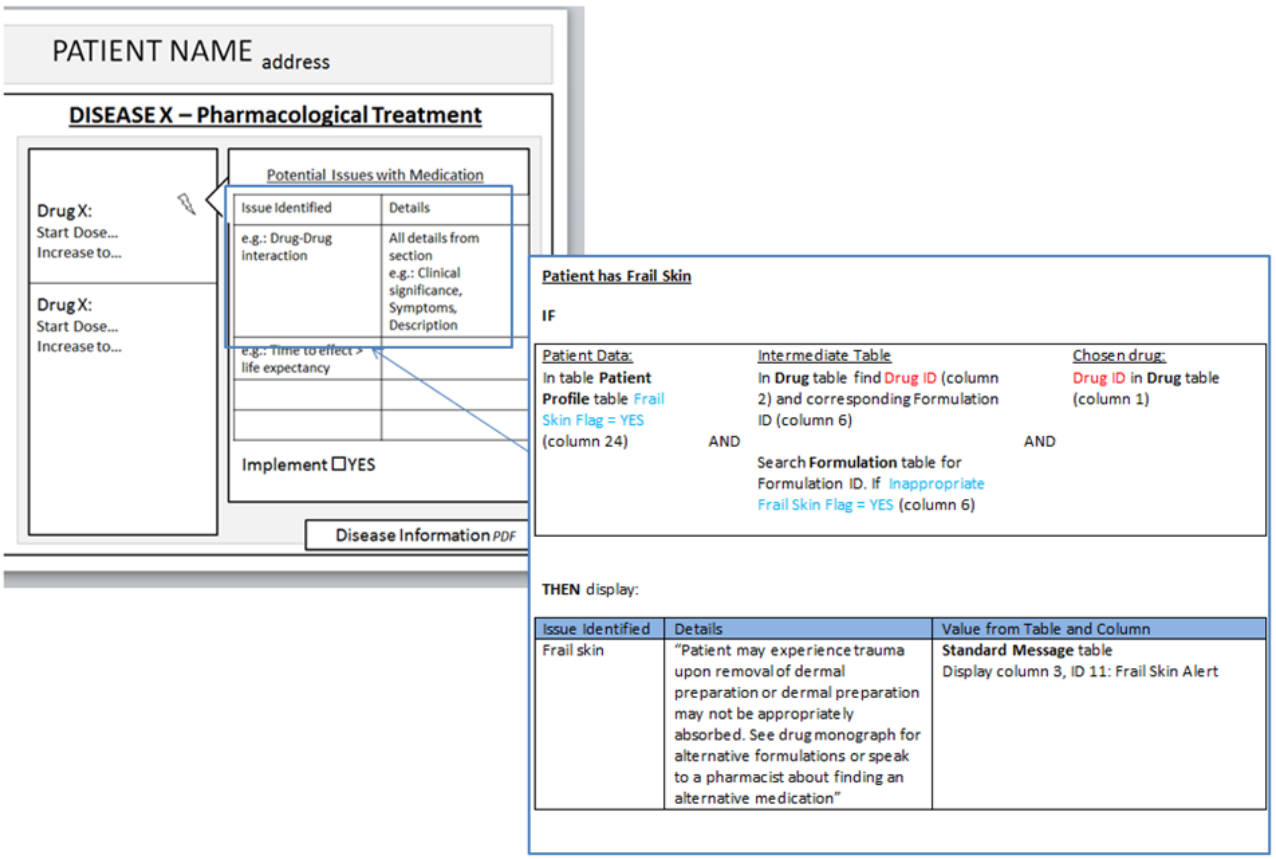

Figure 3: Example of IF-THEN algorithm for identifying potentially inappropriate pharmacological therapy due to patient frail skin used in MedManAGE

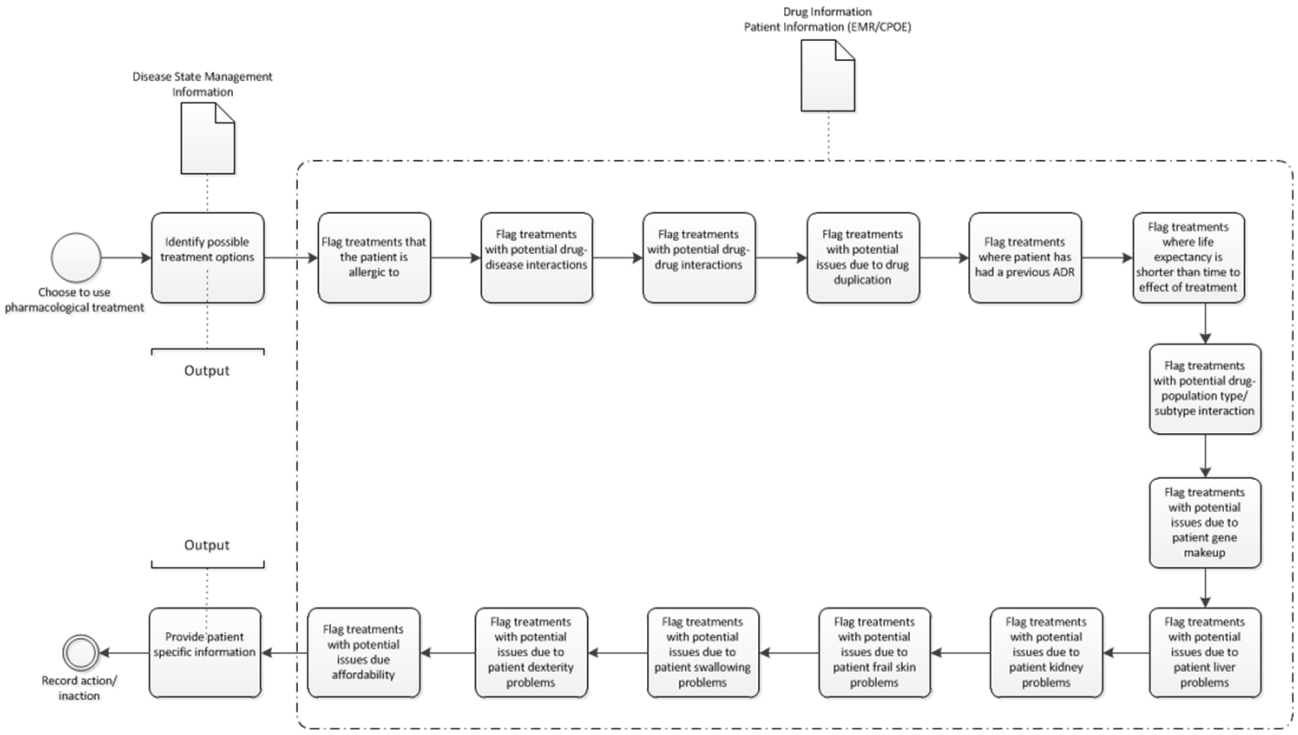

Figure 4: Overall pharmacological therapy choice process.

least partially, in order to come to a similar conclusion regarding best patient care; therefore, factors discussed above that are considered during clinical decision making are the basis for the information CDSS needs to provide meaningful recommendations/alerts to users (Table 2).

3.4 Conclusion: Part 2

When choosing a safe, effective, and affordable medication, there is interplay between effective treatments available for use to manage a disease state in a patient, the patient's current and past medical history, their preferences, and drug PK and PD properties, as well as affordability and availability. All of these need to be considered in order to provide "appropriate" treatment. A foundational clinical decision-making model was developed and corresponding data requirements described that can be utilized as the basis of most CDSS process models, and associated algorithms and database architecture.

4 Part 3: System Development and Usability Testing

4.1 Aims

To develop a system based on identified HP needs and fundamental elements of successful CDSS and perform initial usability testing to evaluate whether HPs find the way in which the system delivers information useful.

4.2 Method

4.2.1 System Development

Agile methodology was used to develop the system. Requirements for this CDSS were based on in Part 1 and 2 of this paper, as well as previously identified HP desires.[6] Visual Studio[91] C# language .4NET[92] was used to develop the system. Programming was undertaken by a final year computer science student (AB), in line with Monash University's collaborative policies. AB was given all system requirements including process model, populated database, basic interface design and business rules, which were modified during development as necessary.

4.2.2 Initial Usability Testing

As the system was an early-stage prototype, a convenience sample of five clinical pharmacy academics were asked to provide initial feedback on the system. Participants were asked to use the system to decide on the management of a patient's newly diagnosed osteoarthritis while pretending to be a user with given attributes, rather than themselves (Table 3). The user's and patient's characteristics were based on real life where the user represented an average medical practitioner and the patient represented an aged and complex patient. The goal of the scenario was to use the system as it would be used in practice; specifically to:

1. Choose an appropriate treatment guideline
2. Implement treatment strategies

a. Make a decision regarding precipitating drugs,

b. Make a decision regarding non-pharmacological treatment,

c. Make a decision regarding pharmacological treatment,

d. View monitoring requirements.

Participants were asked to think aloud during the sessions and provide insight into usability, aesthetics, and overall usefulness in the way information is presented in the system. The sessions were observed by a researcher who took notes regarding usability issues, user likes and dislikes, and overall program issues. In order to establish the usability of each interface screen, the observer attempted to answer the following questions:[93]

1. What effect was the user trying to achieve by selecting this option?
2. How did the user know that this option was available?
3. Did the selected option achieve the desired effect?
4. When the option was selected, could the user determine how things were going?

Sessions took place over two consecutive days. Minor changes were made to the interface based on feedback after day one (3 participants) and the new interface was used for day two testing.

Table 3: User attributes

Education
Is a registered medical practitioner in Australia
Relevant work experience
Completed their medical degree 8 years ago
Has been registered as a GP for 6 months.
Experience with DSS
Uses MIMS drug interaction identifier.
Operating Systems and Software Packages used Frequently (at least once a week)
Microsoft Windows 7
Microsoft Outlook
Apple, iTunes, Microsoft Office (Word, Excel, etc...), Google Chrome, Adobe Reader, Skype, Internet Explorer
Various prescribing software, MIMS, AMH, eTG
Experience with Complex Patients

System Design	Data needed		
	Patient information (EHR component)	Drug information	Disease management information
Documentation of Non-pharmacological therapy	Patient non-pharmacological therapy including what and implementation strategy		Non-drug therapy used for disease/symptom including what and rationale.
Documentation of action	Rationale for use/ comments section for each patient in drug or non-drug treatment history.		"Drug therapy used for disease/symptom
Documentation of inaction	Rationale for non-use/ comments section in patient treatment history. "If a drug is has been ceased, the reason for cessation needs to be stored."		
Warnings and alerts should be colour-coded to their severity.	Any interactions/ alerts should have a "severity code".		
Flag for all important alerts			
Allergy	Patient drug or drug class or allergy class stored.	Drug class and allergy class stored for each drug.	
Drug disease interactions	All diseases/ symptoms stored for each patient. "Whether these are current, intermittent or past conditions."	Drug-disease/symptom interaction and a description of the interaction.	
Drug-drug interactions	"All patient drugs are stored in patient treatment history, including illicit drug use and smoking status." "Whether these are current (chronic or short term), intermittent or past medications is clear."	Drug interactions and a description of the interaction.	For each disease management guideline – what population types and subtypes they are relevant to.
Previous adverse drug reaction (ADR); and easy sending of information to local governing bodies.	All drug-ADR stored in patient history including details of reaction as per local drug-ADR form (in Australia this is the Advisory Committee on the Safety of Medicines (ACSOM) form).	All ADR (disease/symptom a drug can cause) stored for each drug.	
Drug-population type/subtype interaction	Patients can be part of a number of population types/subtypes. These include but are not limited to:	Drug min and max age of use.	
	Age	Drug-gender interaction.	
	Gender (male/female)	Drug-pregnancy status/stage interaction.	
	Pregnancy status and stage (if applicable)	Drug-breastfeeding interaction.	
	Breastfeeding status (if applicable)	Drug-frailty score interaction.	
	Frailty score	Drug-Race interaction.	
	Race	Descriptions of each interaction.	

Table 2: CDSS overall system design and corresponding data needed. Continued on next page.

Drug-liver dysfunction interaction	Patient liver function.	"Drug-liver function interaction severity, description and dose adjustment."	
Drug-renal dysfunction interaction	Patient renal function.	"Drug-renal function interaction severity, description and dose adjustment."	
Drug-frail skin interaction	Patient skin frailty flag.	Drug inappropriate with frail skin flag.	
Drug-swallowing difficulty interaction	Patient swallowing difficulty flag.	"Drug inappropriate with swallowing difficulty flag, whether it is due to the drug itself or the formulation type. "	For each disease management guideline – what population types and subtypes they are relevant to.
Drug-dexterity problems interaction	Patient dexterity problems flag.	"Drug inappropriate with dexterity problems flag, whether it is due to the drug itself or the formulation type."	
Drug-cost issues	"Patient entitlements. For example, relevant to Australia is patient eligibility for:"	"Local cost requirements. For example, relevant to Australia:"	
	Medicare	Whether the drug is subsidised by the Pharmaceutical Benefits Scheme (PBS)	
	Concession	If the drug has any special requirements for subsidisation.	
	Safety net		
	Repat		
Pharmacogenetic factors impacting PK and PD	Patient allele type.	Gene affecting drug PK or PD and description of impact.	
Monitoring of laboratory results and alerts where indicated.	"Patient monitoring results including what type measurement was taken, date and result."	Drug target for each disease/symptom and population type/subtype. Drug-monitoring interaction.	"Disease/symptom targets (e.g.: blood pressure, etc.) for each population type/subtype."
Provision of key counselling points		Drug counselling points stored including ancillary labels.	

Table 2: CDSS overall system design and corresponding data needed

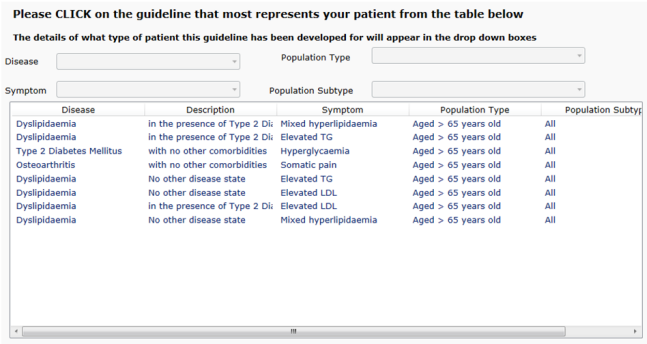

Figure 5: Choose the appropriate treatment guideline screen.

Encounters complex patients as part of their role as a GP; at least 5 times a week for the past 6 months.

4.3 Results

A testable early-stage prototype was successfully built within the allowed time fame.

4.3.1 Initial Usability Testing

Only minor usability issues were identified during initial usability testing, the majority of which were associated with the "EHR" component of the system. This component was developed as part of the early-stage prototype for simplicity as integration with currently available EMR was not considered necessary at this stage of development and evaluation. Although the system's primary purpose was not to act as an EHR, information gained may be useful to developers.

Day one of testing indicated that labels and instructions caused the most confusion; these were changed to be more clear and concise. Comments were made regarding button position (such as save, view more information, etc…); it was agreed that they needed to be in an obvious or intuitive place, although opinions varied as to what was "intuitive". Participants also commented that they preferred drop-down combo boxes for short lists and autocomplete combo boxes for longer lists to assist in searching. Use of colours to separate sections of the screen was considered a useful way to guide users. No new categories of issues were identified on day two, although the same issues were identified in new areas of the interface that others had missed.

Participants had the most difficulty with the "choose the appropriate guideline" screen (Figure 5) and required explanation from the researcher. Once the screen concept was explained, participants were able to successfully select a guideline. Otherwise the way in which information was presented was deemed useful and informative by participants.

Overall, most participants stated that they would find the program easier to use with practice and suggested that an initial demonstration would be helpful for first time users.

4.4 Conclusion: Part 3

A testable prototype CDSS was successfully built although not all requirements were implemented. Initial usability testing suggests that way in which the early-stage prototype system delivers information is useful despite minor interface issues; further more-robust studies are required to confirm these results.

5 Overall Discussion

5.1 Overcoming Past CDSS Problems and Researcher Recommendations

An early-stage prototype CDSS was developed that delivers information to HPs in a way that they deemed useful despite minor issues with the user interface; however, significant efforts to develop the system further and additional testing will be required to confirm these results.

Clinical autonomy is an important to clinicians using decision support, electronic or otherwise.[6, 7] Previous research also has demonstrated that HPs occasionally find guidelines selected by CDSS inappropriate for their patient. [6, 94, 95] Therefore to overcome this and to maintain clinical autonomy, we allowed HPs to view all available guidelines and choose the one they felt most closely represented their patient; however, this was the most problematic screen for participants. Although clinicians choose their own guidelines in practice this is a new concept in CDSS as most automatically choose the guideline for the user, and may explain why participants found this page somewhat difficult to manage. Nevertheless, when the page was explained, participants easily understood the screen concept.

Relational model was used to build the business rule engine. Other CDSS have used XML or non-relational database archetypes due to the hierarchical nature of diseases and symptoms.[96-100] A relational model was chosen as flagging for inappropriate treatment options (e.g.: drug-disease interactions) is relational in nature. Although somewhat hierarchical in nature, disease/symptoms can be stored as relational data; use of hybrid database may be considered in future development of this or similar systems. Non-relational models are also used due to the complex branching of most disease state management guidelines. As algorithms are an effective format for displaying complex guidelines con-

taining decision trees and are preferred by most HPs,[5, 6, 101] the issue of complex branching was overcome with the display an algorithm (picture) rather than coding for treatment guidelines.

While CDSS are able to improve patient outcomes and decrease health cost, currently available CDSS in common use in Australian medical practice do not yet meet the HP needs.[6, 24, 25, 27, 52] In order to improve the usability and increase the chances of CDSS success, the following should be considered:

5.1.1 Integration into Workflow

Any HIT needs to integrate into usual workflow and enhance work efficiency rather than hinder it; [36, 44, 46, 49, 51] therefore, defining the exact purpose of the system before any other design begins is imperative.[25] For instance, if the CDSS is part of a CPOE, then the decision support should allow users to work effectively while only alerting them of high risk issues (e.g.: wrong dose, drug-drug interactions, etc...) to prevent alert fatigue. Conversely, if the CDSS is more comprehensive, in order to answer specific practitioner queries, an opt-in or "plug in" that utilises patient data in the CPOE may be more appropriate. In order to best define the purpose of HIT, and ensure appropriate design and integration into usual workflow, HPs should be involved in all stages of the design and development process.[102-104] Regardless of purpose, CDSS should be able to integrate with locally used CPOE or EHR systems to avoid repeat patient data entry.[44, 46, 51] Involvement in HIT design and development can also positively influence physicians' attitudes regarding HIT and improve perceived usefulness,[21, 43, 102] and is possibly why the most effective systems are developed locally.[16]

In addition to work flow and physician attitude, available human and technological resources need to be taken into consideration when creating HIT.[105] Resource poor developing countries are most likely to benefit from DSS as they may be lacking in appropriately trained physicians, but may also be lacking the infrastructure to support DSS.[103] These barriers must be considered when developing HIT and whether the appropriate hardware is available to support DSS.

5.1.2 Adherence to Usability Standards

Human factor methods such as ergonomics and human-computer interaction (HCI) techniques should be used when designing and evaluating HIT. HCI can improve the usability and efficacy of programs, as well as decrease re-engineering costs.[104] Numerous medical systems have been developed that have low usability, resulting in staff "working around" interface problems, inappropriate use of the system, ultimately putting patients at risk.[28]

Most of the identified usability issues surrounded the EHR component of the system. Although not the primary purpose of the system, the patient data entry section was necessary to allow for patient specific information to be displayed to users. However, usability issues identified echo other research; appropriate use of colours and font has been identified an simple way to guide users, add consistency to the system, and increase overall appeal,[6, 40, 46, 106] although it is suggested that interfaces be developed in black and white initially and tested for usability to account for colour blind users.[106] Use of autocomplete combo boxes or key word search seems is desired by users when a long list of possible responses are available (e.g.: drug name).[20] Finally adherence to usability guidelines, including appropriate labeling and instruction on the interface screen, is imperative to avoid confusion and assist in system use. [6, 35, 40, 41, 43, 46, 49, 51]

5.1.3 Using the "Right" Data

An identified barrier to e-Health success is the lack of standardisation, including the minimal patient data that should be collected and utilised in a meaningful way.[27] Patient information required by CDSS described in this paper can serve as a guide for the minimal patient detail captured by CPOE or EHR. Four disease states were reviewed when defining the clinical decision-making model and data attributes required for CDSS. As a result all disease specific considerations may not have been considered; however, other information sources were utilised during development, including Australian and international standards for quality prescribing and past CDSS success and failures. In addition, three of the researchers are qualified HPs (community pharmacist, hospital pharmacist and geriatrician) and are familiar with the clinical decision making process. As a result, the majority of data attributes used to make clinical decisions have been accounted for and the clinical decision making model developed can be used as the foundation of other CDSS.

Website developers have found that although usability and aesthetics influence first and overall impressions, content has the greatest influence of users' intention to revisit, intention to recommend, and overall impression of a website.[107] The same is most likely true for CDSS content. The information in the knowledge base should come from sources that the HPs themselves would use – i.e.: clinical guidelines and reputable independent drug information sources other than

approved drug information.[21, 30] Knowledge acquisition should be facilitated by experts in the field to ensure that information is of adequate quality.[35, 37, 38, 46] Any HIT needs to be thoroughly tested prior to implementation and periodically thereafter for continual improvement and to insure appropriate information output.[36, 43, 49, 51]

5.2 Limitations of usability testing

HPs were used during usability testing rather than usability experts. However, usability experts are not necessarily required as non-experts are able to provide quality insight into usability issues parallel to experts.[108] We only used five participants to test the usability of the system, all of whom were clinical pharmacy academics. It has been suggested that for most usability studies five participants are sufficient to identify most major usability errors.[109, 110] Indeed, Nielsen argues that "discounted" usability testing such as this one are valid, and at the very least, better than no testing.[111] Further system testing with different HPs using a larger sample size to provide more robust usability results have already begun.

6 Conclusion

This paper describes the fundamental elements for successful disease state management CDSS identified during the design, development and initial testing of an early-stage prototype that provides patient relevant information to HPs. These elements include use of usability standards during design and development, appropriate data usage, and good workflow integration. In addition, a universally applicable clinical decision-making model and associated database attributes have been defined using Australian and international principles for quality prescribing. These could be used as a starting point for other CDSS design.

Initial evaluation results suggests that, despite minor user interface issues, the prototype developed using identified fundamental elements provides information in an informative and useful manner to users. Further system development and more robust usability evaluation will provide additional insight into the effectiveness of this information delivery system.

Acknowledgements

We thank the Editorial Board for the assistance in establishing the journal. We are also very grateful to Marina Malenovic for her technical support and guidance during database development.

Conflicts of Interest

None of the authors has any conflict of interest in the manuscript. There were not any financial or other relations with relevant parties that could have affected the results and conclusions of the study.

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