# A Design Theory for Intelligent Clinical Decision Support

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## Abstract

Poor or inadequate design of intelligent clinical decision support systems (ICDSS) can result in low adoption and use of these systems. These are some of the prevalent factors stimulating physician resistance. This resistance facilitates low physician involvement and creates a lack of trust in these systems. This is addressed through the development of a design theory for ICDSS. This is demonstrated through mapping and identifying extant literature in the context of the socio-technical model (STM). The gaps were identified through the relationships of the STM and developed into characteristics that are translated into meta-requirements informing design principles. The primary result of this research includes a design theory for ICDSS development. The developed design theory motivates and enables efficient ICDSS development, physician adoption, and more effective patient care. The design theory will also provide managers and researchers deeper insight into designing ICDSS to further improve physician adoption and use of ICDSS.

### *Keywords*

Design theory, intelligent clinical decision support, socio-technical model, system design, meta-requirements, design principles

## Introduction

The development of technology is one of the most strategic elements in organizations (Garavand et al., 2016). In healthcare, intelligent systems that support clinical decision-making are rapidly evolving (Petitgand et al. 2020). However, physicians are getting left behind as the intelligent systems get more complex, and the poor design facilitates low physician involvement, inexperience and inherently creates a lack of trust in the systems (Coiera 2015; Khairat et al. 2018; Klarenbeek et al. 2020; Trinkley et al. 2019; Van de Velde et al. 2018). The holy grail of the IS field is effective support for people's most demanding intellectual tasks, such as decision-making (Markus et al. 2002). Consequently, the increase in healthcare data enables the development of these intelligent systems to improve the efficiency and effectiveness of the patient care process (Ahuja 2019). They also assist physicians in improving patient care by enhancing their decision-making (Agyemang-Gyau 2021; Ahuja 2019). Due to the increase in data and the complexity of systems, a design theory is necessary to strengthen the development of intelligent systems.

This paper focuses on intelligent clinical decision support systems (ICDSS). ICDSS has been met with enthusiasm because it enables a predictive, preventative, personalized, and participatory model of medicine (Briganti and Le Moine 2020). Physicians use these systems to make fast and accurate diagnostic decisions (Cai et al. 2019; Wang et al. 2021) by acting on meaningful insights produced with the application of artificial intelligence (AI). Yeasmin (2019) has defined AI as the theory and development of intelligent systems that perform visual perception and decision-making tasks that require human intelligence.

The current literature on ICDSS focuses on developing and evaluating these systems without addressing effective design and socio-technical concerns. For example, a recent article has investigated the challenges and evaluation techniques for the use of intelligent mechanisms in clinical decision support (Magrabi et al. 2019). The primary challenges are related to evaluating the intelligent models, whether the findings are actionable, dealing with the black-box challenge, and the availability of data. Additionally, Casal-Guisande et al., (2022) developed an ICDSS aimed at preventive diagnosis of breast cancer. This study focused on developing a system to improve accuracy in evaluation and reduce uncertainty. It also provided a prototype and logical design for the system. The key issue is that these papers focused on evaluating and developing an ICDSS but did not offer a prescriptive generalizable solution to other systems. Developing and assessing ICDSS are crucial to advancing the technology. Therefore, it is necessary to develop a design theory for IDCSS to address development reliability and the plausibility of success during implementation (Haj-Bolouri et al. 2016). Walls, Widmeyer, and Sawy (1992) define a prescriptive information system (IS) design theory and integrates normative and descriptive theories into a design path to produce a more effective IS. An example of a design theory was implemented in Walls et al. (1992), which included a unique solution and design strategy to address system requirements (Markus et al. 2002). Consequently, this creates an opportunity to investigate the design of ICDSS.

To our knowledge, these systems are being developed and evaluated without consideration for socio-technical characteristics or adoption by physicians. The incorporation and development of a design theory can assist with addressing the socio-technical and systems design implications that are "fuzzy, difficult, and not amenable to technical support" (Markus et al. 2002; Todd and Benbasat 2000).

Therefore, we present a design theory for ICDSS design to aid in developing these systems for adoption and use by physicians. The main contribution is developing a design theory for ICDSS design to further support the development and implementation of these systems. This is accomplished by using the socio-technical model as a kernel theory to evolve characteristics into meta-requirements that inform the design principles.

## Development of the Design Theory

Walls et al., (1992) noted two aspects of a design theory (Spagnoletti and Resca 2012). Notably, design product and design process. This study focuses on the design product composed of characteristics, meta-requirements, and testable design principles (Spagnoletti and Resca 2012). An ICDSS design theory is proposed to address the interrelated components as follows: 1.) a set of characteristics for a family of design problems derived from the literature, 2.) a set of meta-requirements that meet the requirements addressing the design characteristics, and 3.) a set of design principles deemed effective for guiding the design process so that a set of system features is selected and implemented that meets a given set of meta-requirements (Hanseth and Lyytinen 2004). The design theory development process is shown in Figure 1.

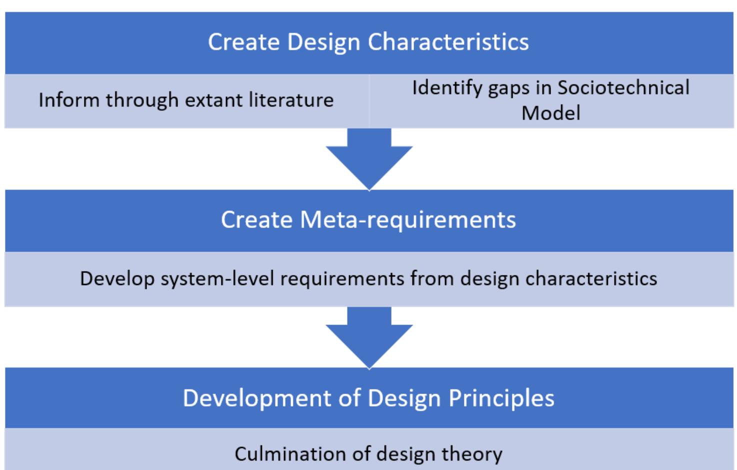


**Figure 1. Design theory development process**

## *Socio-technical Model as a Kernel Theory*

The socio-technical model (STM) is used as the kernel theory to derive the characteristics and meta-requirements for the design principles. The STM is a systems design method that considers the technological, actor, task, and structural factors in the design of systems (Baxter and Sommerville 2011; Sarnikar et al. 2014). The first step to beginning the creation of the design theory was to identify the factors of the STM in the appropriate context. Technology refers to the ICDSS that will be used to perform the work activity. Actor refers to the physicians utilizing the systems. The task is focused on addressing patient care. The structure component refers to workflow as a seamless flow of processes that end at the completion of a task. This model ties the four factors together and is denoted as relationships in Figure 2. The gaps are identified below between actor-tasks, technology-actor, tasks-structure, structure-technology, technology-task, and structure-actor.

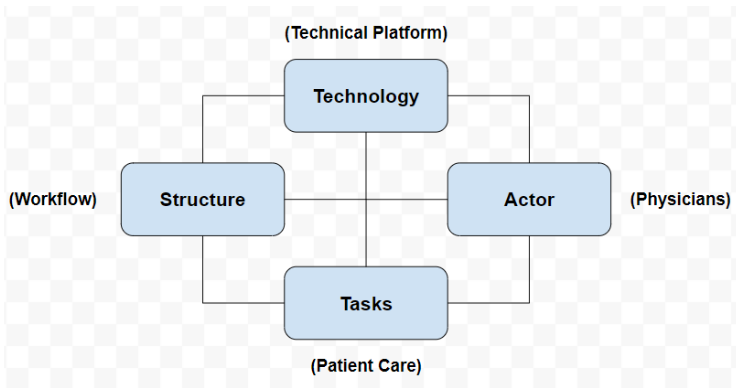


**Figure 2. The proposed STM**

### Actor-Tasks

Physicians are concerned that ICDSS will hinder their patient care process. However, embracing these systems will allow physicians to increase time spent on human skills such as building relationships, exercising empathy, and using human judgment to improve patient care (Fogel and Kvedar 2018). The focus is on integrating clinical practice with the ICDSS, which requires a mutually beneficial relationship between the physician and the ICDSS (Buch et al. 2018).

### Technology-Actor

Physicians are a primary component of the adoption and acceptance of ICDSS (Romero-Brufau et al. 2020). Their attitudes and perceptions around these systems are important due to potential resistance from the idea that the ICDSS will replace their jobs (Collado-Mesa et al. 2018; Gong et al. 2019; Khairat et al. 2018; Romero-Brufau et al. 2020). The current design of ICDSS has caused significant concerns with physicians using the systems. Physicians are concerned explicitly with how recommendations provided are explained and appropriately assessed for the patient (Antoniadi et al. 2021; Knop et al. 2021; Magrabi et al. 2019; Reddy et al. 2019; Silcox et al. 2020; Strachna and Asan 2020; Xie et al. 2020). Another significant concern is about the black box phenomena surrounding ICDSS and the transparency of results from using intelligent algorithms such as machine learning and neural networks (Antoniadi et al. 2021; Magrabi et al. 2019; Mehta et al. 2021). The role of intelligent systems is not about replacing physicians but about optimizing their workflow and improving upon what they already do (Ahuja 2019; Norman 2018).

### Tasks-Structure

Past literature has noted significant challenges in integration into the business process (Mehta et al. 2021; Romero-Brufau et al. 2020). For example, a recommendation was given at an inappropriate time and incorrectly integrated into the workflow (Mehta et al. 2021). A key component of this is understanding the workflow and effectively defining it as a "specific ordering of work activities across time and place, with a beginning, an end, and identified inputs and outputs: a structure for action (Davenport et al. 1996; Markus et al. 2002). The explicit definition of the workflow can assist with the appropriate collection of data and the opportunity to adopt a data-driven workflow.

**Structure-Technology**

Markus et al., (2002) define process management as a way to map the process, streamline it, and implement those changes to improve the systems performance as a whole as opposed to the specific activities within it. One of the most common process pitfalls is that the current ICDSS is not designed as a Drs. Assistant (Wang et al. 2021). Another primary concern by system users is that it often disrupts the workflow as developed and does not display task-relevant information (Kubben et al. 2019; Mehta et al. 2021; Reddy et al. 2019; Strachna and Asan 2020). Incorporating a streamlined and intelligent data-driven workflow into the ICDSS design is a way to enhance the current process. This denotes a key gap between the workflow implemented and the ICDSS.

**Technology-Task**

The ICDSS plays a key role in addressing patient care. Providing intelligent clinical decision support requires more than just the retrieval, communication, and recommendation of relevant contextual information (Musen et al. 2014) that traditional clinical decision support offers. Musen (2014) states that the ICDSS must provide the right information in the right format, through the right channel to improve health care decisions for patients. It is also important to address patient care concerns through new and improved technologies to support patient care. ICDSS must include data cleaning mechanisms due to the low-quality data used by previous systems (Mehta et al. 2021; Silcox et al. 2020). High-quality data can enable an ICDSS to offer more timely predictions and deeper insight into the patient's condition and improve patient care.

**Structure-Actor**

Providing insights and irrelevant features in the workflow creates resistance from the physician. Physicians have reported that the intelligent mechanisms should ensure the appropriate recommendations are given in the right context (Magrabi et al. 2019). Each class of physicians has a different role or context in which they are caring for the patient. The significance of these six relationships is important in developing a design theory for ICDSS.

The literature reviewed draws focus on physician "acceptance" (Khairat et al. 2018), "clinical decision support" (Montani and Striani 2019), "workflow integration" (Middleton et al. 2016) and "patient safety". These four categories tie in with the STM and are included in the development of the design theory. Researchers and professionals have long recognized the importance of informing the design characteristics with the STM (Kwan et al. 2020).

## *Design Characteristics*

The design characteristics are created to address the gaps as identified in the STM. These characteristics were developed as follows: 1.) Design the system to empower the physician during the patient care process; 2.) Design to provide prescriptive recommendations for the patients treatment; 3.) Integrate intelligence into the patient-care workflow; 4.) Incorporate the intelligent workflow into the decision support artifact; 5.) Design appropriate data mechanisms for the ingested data; and 6.) Use data algorithms that are minimized from bias and incorporated in the proper context.

## *Meta-requirements*

The next step is to discuss the system-level meta-requirements that support a successful, intelligent CDSS (Markus et al. 2002). The meta-requirements were developed from the abstracted design characteristics developed and discussed in the previous step. The six meta-requirements are as follows: 1.) Provide optimal care from physicians to patients with the assistance of intelligent mechanisms; 2.) Recommendations provided must be transparently explained and appropriately assessed by the physician; 3.) Intelligence integrated into the workflow must assist with the appropriate data collection; 4.) The intelligent system must incorporate a data-driven approach to support decision-making; 5.) The system design must incorporate new technology that enables data cleaning and storage mechanisms to store and use high-quality data; and 6.) The data-driven architecture must enable high performance, data storage, and system integration. These are system-level requirements that are developed to be incorporated at the ICDSS level. Using the system level meta-requirements, six generalizable design principles were developed.

## *Design Principles*

This final step develops the design principles by addressing the meta-requirements and synthesizing them with design constructs identified from the extant literature. The synthesis process is described in Table 1 below. The constructs were identified under each category from the extant literature. By abstracting and synthesizing the literature, six design principles were identified and mapped to relevant design constructs, namely, *functionality, explainability, information quality, effort expectancy, performance expectancy, and system quality* in the context of ICDSS (Markus et al. 2002) design. Each category is expected to capture the full essence of the design principles proposed below.

*Design Principle 1:* Design the system to provide optimal evidence-based conclusions to treat the patient effectively. The intelligent mechanism must address the appropriate *functionality*. The ICDSS must have meaningful, evidence-based functionality such as medical information searches (Wang et al. 2021), useful visualizations (Antoniadi et al. 2021), and information filters (Xie et al. 2020) to assist the physician.

*Design Principle 2:* Provide readily available recommendation explanations for the physician. The intelligent mechanism must provide *explainability*. The presented information to the physician should be clear and include explanation and reasoning in reference to how the intelligent mechanism derived the recommendation. The recommendations must be explainable and transparent to the physician (Antoniadi et al. 2021; Knop et al. 2021; Magrabi et al. 2019; Mehta et al. 2021; Reddy et al. 2019; Silcox et al. 2020; Strachna and Asan 2020; Xie et al. 2020)

*Design Principle 3:* Integrate a data-driven approach into the workflow for enhanced patient care. The intelligent mechanism must provide high *information quality*. The data-driven approach should enable the storage and access of high-quality data and the integration of cleaning mechanisms (Mehta et al. 2021; Silcox et al. 2020). The integration of those mechanisms will minimize bias toward populations (Mehta et al. 2021; Reddy et al. 2019) and assist with finding an appropriate algorithm for the task (Magrabi et al. 2019).

*Design Principle 4:* Implement a data-driven workflow into the design of the intelligent system. The design must display minimal *effort expectancy*. The physician should interact with a low-effort system through a well-designed user interface with an appropriate alert design (Mehta et al. 2021). Intelligent systems should allow for fields to automatically fill with relevant data (Bizzo et al. 2019; Wang et al. 2021) and be appropriately and accurately labeled for physician data entry (Silcox et al. 2020; Wang et al. 2021).

*Design Principle 5:* Provide data cleaning and storage mechanisms to enable more effective and accurate data for the intelligent mechanisms. Provide readily available recommendation explanations for the physician. The intelligent mechanism must *perform as expected*. The technology must appropriately address the task. The intelligent mechanism should recommend an initial diagnosis (Bizzo et al. 2019), present recommendations of next steps of the care process (Antoniadi et al. 2021; Bizzo et al. 2019; Magrabi et al. 2019; Wang et al. 2021), allow for recommendation customization (Xie et al. 2020), and only show relevant information for the task at hand (Mehta et al. 2021; Reddy et al. 2019; Strachna and Asan 2020).

*Design Principle 6:* Provide the appropriate data-driven infrastructure required for effective physician use and fast response times. The intelligent architecture must provide a data-driven *system quality*. The data-driven qualities encapsulate the storage of high volumes of data (Silcox et al. 2020), interoperability (Mehta et al. 2021; Wang et al. 2021; Xie et al. 2020), and high performance (Antoniadi et al. 2021).

| Characteristic | Meta-requirement | Design Principle |
|---|---|---|
| | ***Actor-tasks*** | |
| 1. Design the system to empower the physician during the patient care process | Provide optimal care from physicians to patients with the assistance of intelligent mechanisms | Design the system to provide optimal evidence-based conclusions to treat the patient effectively |
| | ***Technology-actor*** | |
| 2. Design to provide prescriptive recommendations for the physicians treatment | Recommendations provided must be transparently explained and appropriately assessed by the physician | Provide readily available recommendation explanations for the physician |
| | ***Task-structure*** | |
| 3. Integrate intelligence into the patient-care workflow | Intelligence integrated into the workflow must assist with the appropriate collection and cleaning of data | Integrate a data-driven approach into the workflow for enhanced patient care |
| | ***Structure-technology*** | |
| 4. Incorporate the intelligent workflow into the decision support artifact | The intelligent system must incorporate a data-driven approach to support the decision-making process | Implement a data-driven workflow into the design of the intelligent system |
| | ***Technology-task*** | |
| 5. Design appropriate data mechanisms for the ingested data | The design of the system must incorporate new technology that enables data cleaning and storage mechanisms to store and use high-quality data | Provide data cleaning and storage mechanisms to enable more effective and accurate data for the intelligent mechanisms |
| | ***Structure-actor*** | |
| 6. Use a modern data-driven architecture for data collection and analysis | The data-driven architecture must enable high performance, data storage, and system integration | Provide the appropriate data-driven infrastructure required for effective physician use and fast response times |

**Table 1. Design theory**

## Conclusion

This study specifically investigated ICDSS design and development through the development of a design theory. Understanding and incorporating design principles into ICDSS development is crucial to enhancing the adoption and use of intelligent systems. In turn, managers and researchers can more deeply understand physicians' adoption and use of the systems. Physicians will benefit through increased usability and higher adoption rates. Researchers will be able to use this design theory as a foundation for further development and design of ICDSS. The primary contribution of this study is a design theory for ICDSS to address development reliability and the plausibility of success during implementation. Future research includes investigating the efficacy of the design principles using survey research. An additional case study could be performed to interview physicians to understand their perspectives of the ICDSS at a deeper, more contextual level.

A limitation of this study is that during the coding process of the literature, bias may have been introduced due to only one researcher coding and categorizing the data. The inclusion process of the articles was limited to 2016-2021 and English language. Another limitation is regarding the databases used for the literature search. We cannot claim this was an exhaustive search due to limited academic database access.

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