A Guideline-Oriented Ontological Decision Support System for Diagnosis and Treatment of Urinary Incontinence (UrInO-DSS): A System Framework

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What’s known on the subject? and What does the study add?

This study is a foreground to design a guideline-oriented ontological clinical decision support system for urinary incontinence, called UrInO-DSS. An ontology for urinary incontinence management will be designed on the basis of a clinical practice guideline. The system will offer a tool to help clinicians manage patients who suffer from urinary incontinence.

Abstract

Objective: To design an ontology-based clinical decision support system based on a clinical guideline for urinary incontinence.

Materials and Methods: The study will be conducted in four phases: Updating the adapted clinical guideline for urinary incontinence for Iranian clinicians; Developing an ontology based on the adapted guideline; Developing a guideline-oriented ontological decision support system for urinary incontinence; and evaluating both the ontology and the decision support system. The GRADE-Adolopment methodology will be used for updating the adapted guideline. The researcher will deploy Protégé 5.5.0 ontology editor for developing the ontology. The rules will be extracted from the adapted guideline for urinary incontinence, and the rule language will be Semantic Web Rule Language. Ontology consistency will be evaluated with Pellet reasoner. The system will be evaluated and analyzed by the GUIDES checklist.

Results: The results of the study will be published and disseminated in peer-reviewed journals.

Conclusion: UrInO-DSS will offer a tool to support clinicians in providing personalized treatment for patients who suffer from urinary incontinence. It can also help the residents and medical students to learn how to diagnose and manage urinary incontinence in the best way. The system can be implemented as an international decision support system for the diagnosis and management of urinary incontinence.

Keywords: Biological ontologies, decision support systems, clinical, practice guidelines as topic, urinary incontinence
Introduction

Urinary incontinence (UI) is one of the most prevalent urologic disorders, particularly among female patients (1). A cohort study predicted 8.5 percent global prevalence of incontinence in 2018 (2). The total prevalence of UI in developing countries was 27.5%, according to a recent meta-analysis study in 2020 (3).

UI is a multifactorial condition. Some of the most common risk factors for UI are obesity, parity, age, urinary tract infection (UTI), a history of hysterectomy, menopause, and type of delivery (1,4,5). Diagnosis of UI and its type is one of the most complex and controversial issues in managing urological diseases (6,7). Background risk factors like bladder dysfunction or neurological conditions can complicate the diagnosis. However, many concomitant disorders, such as functional bowel disorder, affect the diagnosis and management of incontinence.

Recognition and usage of accurate, reliable, and up-to-date information in practice is another challenge for physicians where reducing medical errors is a priority. The lack of time should also be added to these concerns. Clinical Practice Guidelines (CPGs) are one of the evidence-based resources for managing diseases and assist physicians in reliable and appropriate decision-making and improve patient care. However, remembering all the recommendations of guidelines, accommodating them with patient history and physical examination and tests while considering complications and risk factors, and finally making the best decision can be burdensome for physicians and, in some cases, may lead them to bias in decision-making.

Nowadays, developing high-quality and ease-to-use computer-interpretable clinical guidelines are necessary for patient care (8). Clinical Decision Support System (CDSS), as the best evidence-based source, according to Alper and Haynes (9), are valuable tools for this purpose. A CDSSSES can include clinical guidelines, summaries of evidence, and syntheses while integrating with patient information and ultimately becoming the most credible and best support in clinical decision making. This approach fulfills the requirements for complementarity of Evidence-Based Medicine (EBM) and personalized care (10). To this end, it is necessary to improve the interoperability and knowledge sharing among systems, and ontology can play a crucial role. In healthcare, an ontology, by creating semantic relationships between disease/disorders, symptoms, medications, and other related concepts, allows the CDSS to imitate the physician’s reasoning and offer the appropriate recommendations based on patient information (11). Ontologies can be built according to the information available in clinical guidelines and domain knowledge and applied in a knowledge-based system to manage diseases. Simultaneously, when developing a CDSS, structural and content differences in the management of diseases/disorders should be considered.

Ontology-based CDSSs are widely designed and used in medical sciences (12-15). In urology, most ontology-related studies are in the field of prostate cancer (16,17). But as our best knowledge, no ontology-based decision support system has been developed for UI. Many decision support systems are designed for the diagnosis and management of UI, but neither is ontology-based (18,19). In the absence, we design a guideline-oriented ontological CDSS for the UI, called UrInO-DSS.

Materials and Methods

This study aims to design, develop and evaluate a guideline-oriented ontological clinical decision support system for UI. This system will support clinicians in the diagnosis and management of UI according to guideline recommendations. The goal of the system is to use it in the primary and secondary care setting. Ethical approval was obtained from the Ethics Committee of the Tabriz University of Medical Sciences under Grant (TBZMED. REC.1398.132).

Study Design

This study involves four phases: 1) updating the adapted UI clinical practice guideline for Iranian clinicians; 2) developing an ontology based on adapted CPG; 3) designing and developing a clinical decision support system for UI based on developed ontology and 4) evaluating the system.

Phase 1: Updating the Adapted Clinical Practice Guideline for UI

We used the GRADE-Adolopment methodology for updating the adapted guideline for UI (20). An adapted clinical practice guideline for managing UI entitled “Clinical practice guideline: Female Urinary Incontinence” has been used since 2013 (21). Updating this guideline is under development in collaboration with the Urogynecology Knowledge Management Unit of the Research Center for Evidence-Based Medicine (RCEBM) and Urology Department. The guideline updating team included female urologists, urogynecologists, clinical librarians, and guideline methodologists. The expert panel assessed and confirmed clinical questions (PICOs) of the adapted clinical guideline and other related PICos for updating the guideline. According to the PICOs, we searched and screened the most updated and recent relevant guidelines for all new and updated recommendations. Tables 1-3 presents the PICOs. New, updated, and consistent recommendations were selected from the guidelines. If the answers to some outcomes of PICOs were not available in the recommendations of the guidelines, de novo systematic reviews were conducted to get the answers.

A draft of the updated guidelines was translated to Persian. Guideline developers and experts assessed the translated draft, and necessary modifications and edits were made. If any specific recommendation needed to be adapted, further research was
conducted to find evidence-based relevant studies. Then based on the results of the studies and considering the cultural and organizational setting, the necessary modifications were made. The expert panel was assembled consisted of urologists, female urologists, urogynecologists, neuro-urologists, gynecologists, midwives, physiotherapists, nurses, health economists, epidemiologists, pharmacists, representatives of the patients, and other We are currently creating GRADE evidence tables and Evidence to Decision (EtD) frameworks and grading the strength of the recommendations. The grading strength of recommendations will be done electronically by guideline developers and the panelists through GRADEpro (http://gradepro.org). The strength of recommendation will be rated according to the GRADE system to "Strong" and "Weak" (22). The panel will approve the final draft of the adapted CPG for implementation in the setting.

**Phase 2: Ontology Development Based on the Adapted Clinical Practice Guidelines for UI**

Reusability, interoperability, easy sharing, and formality of knowledge are known as the features and benefits of ontology. These benefits make ontologies a suitable approach for knowledge representation and management in CDSSs. Due to the critical role of guidelines and pathways in practice, a significant number of systems have focused on developing ontologies based on guidelines and pathways and applying them to the system.

Ontologies can represent both conceptual knowledge and procedural knowledge. Conceptual knowledge represents the specific domain concepts and their relationship, whereas procedural knowledge represents the procedures and measures needed to be taken (23). Conceptual knowledge will be extracted from adapted clinical guidelines, articles, the website of reputable and well-known universities and scientific associations. The ontology will be developed according to the Kuziemsky and Lau (24) approach. The accuracy of the concept will be confirmed by experts (25). The information extracted from adapted clinical practice guidelines for UI diagnosis and management will be used for ontology development of procedural knowledge.

In the process of ontology development, we searched and reviewed the available related ontologies. To the best of our knowledge, there was no ontology for UI. However, we will use standard ontologies such as Symptom Ontology, Human Disease Ontology (DOID), Clinical Signs and Symptoms Ontology (CSSO) and Unified Medical Language System (UMLS) for selecting and using standard concepts in the development of our ontology. The ontology will be developed on the basis of UI diagnosis and management process, and it will represent concepts for the UI and related examinations, tests and procedures. A bilingual ontology will be developed.

For the process of UI diagnosis and management, the ontology consists of the domain ontology and patient ontology. Overall, the ontology includes five main classes: Demographic Information, Clinical Assessment, Diagnosis, Treatment and Patient (Figure 1).

Note that the Patient class represents patients’ personal information collected and updated in the form of ontology concepts. Patient information will be gathered through CDSS (Phase 3) and will be updated based on the system recommendations and physician’s final decisions. These updates will be applied in the form of a system input to the ontology. Additional sub-classes, individuals, and properties will be defined and created during ontology development. The Delphi method will be used for eliciting and collecting experts’ opinions. Protégé 5.5.0 ontology editor (https://protege.stanford.edu) and Web Ontology Language (OWL) are used for ontology development. The rules will be modeled using SWRL. The rules will follow adapted CPG for UI. The rules will fall into two categories: the rules for UI diagnosis, and UI treatment.

**Phase 3: Designing and Developing a CDSS for the Diagnosis and Management of UI Based on the Developed Ontology**

To design an efficient system, it is necessary to assess the system and end-users requirements (26). Users’ characterizations, requirements, and the workflow for diagnosis and treatment of UI should be identified and analyzed. There are valuable and standard tools for requirement acquisition, such as interviews, observation techniques, focus group discussions and others (27). In this study, interviews with stakeholders, observation, and prototyping will be used for gathering requirements. Part of the requirements that can be implemented through the ontology will be met with the developed ontology. The remaining requirements will be implemented in the system.
design. Considering the process of UI management is shown in Figure 2, a knowledge-based decision support system will be designed using the ontology developed in phase 2. The system will operate according to the latest adapted CPG in UI for Iranian clinicians. The system recommendations and decisions will be based on clinical practice guideline rules (CPG rules). The ontology will be updated with the latest updates and changes as needed and, consequently, will be applied to the system. A significant portion of these changes will be patient information and their personalized diagnosis and treatment that will automatically be added to the ontology through the system. Patient medical information, such as their symptoms and signs, laboratory tests, urodynamic tests, and vital signs, will be added to the patient ontology.

Patient information is collected through the user interface in a database. The latest data from the repository database will then be synchronized automatically to the ontology. In the following steps, electronic health record (EHR), laboratory test ordering system, and urodynamic test system will be connected to this system and the required information from these systems, such as personal patient information, patient history, results of the patient’s tests, and examinations, will be semantically integrated into the ontology. Patients and their guardians will receive oral information about the system operation, and a written informed consent form was obtained from the patient upon admission. Diagnosis and treatment of the individual patient will be based on their mapped information in the ontology and enable personalized patient care. Based on the patient ontology and rules, the systems recommended management options are offered to the physician. Considering the patient’s condition, the physician offers the patient the appropriate management options, discusses each option’s benefits and risks according to Number Needed to Treat (NNT) and Number Needed to Harm (NNH). The final decision will be made by the physician based on a shared-decision making. Ultimately, personalized diagnosis and management of the patient will be added to the ontology.

Three security dimensions, including confidentiality, availability and integrity, will be considered in the system design. Users’ access level to authorized information will be possibly based on permission management. The data access permission will be based on the data protection regulations of the Ministry of Health of Iran. The architecture of the prototype system is shown in Figure 3.

**Phase 4: System Evaluation**

Evaluation of UrInO-DSS will be carried out in two steps: 1) evaluation of the developed ontology and content validation and 2) evaluation of the designed system.

The developed ontology will be evaluated for correctness based on three metrics: Accuracy, completeness, and consistency (25).
Pellet reasoner will be used to determine the ontology consistency. The accuracy and the clinical content of the developed ontology will be validated by domain experts independently and based on adapted CPG and International Continence Society (ICS) terminologies. The completeness evaluation will be performed in collaboration with experts and ontology developers. Experts will include a urologist, a female urologist, a urogynecologist, and a physiotherapist.

### Statistical Analysis

The system will be evaluated and analyzed using the GUIDES checklist during the development (28). The GUIDES checklist is a tool to help system developers for a successful guideline-based CDSS implementation. The GUIDES checklist is a valuable tool that provides a detailed understanding of the elements contributing to an effective guideline-oriented decision support system. The checklist includes 16 factors that affect the success of CDSS in the four domains (Table 4). The technical evaluation will be performed by system developers, a member of the guideline developers, a urologist, a female urologist, and a urogynecologist during development. The electronic version of the checklist will be used to collect data (www.guidesproject.org). In an iterative process, checklist results will be used to upgrade the system to achieve a successful and well-structured system.

In the first phase of testing the system, the system will be used as a standalone system in the urology department of a referral teaching hospital for urological disorders. Patient information will be mapped between the local database and the UrInODSS. The system will be tested and evaluated by eight clinicians (29) including three urologists, two female urologists, a urogynecologist, a physiotherapist and a family physician. They will first be trained on how to use the system. We will define a set of test scenarios for diagnosing and managing various types of UI. The clinicians will use the system to get recommendations.

| Table 1. Clinical questions (PICOs): Diagnostic assessments of UI |
|-----------------|-------------------|-----------------|-------------------|-------------------|
| **PICO-1: Physical examinations** | **P (Population)** | Adult women with suspected urinary incontinence | **E (Exposure)** | Physical examinations | **C (Comparison)** | Other exposures; None | **O (Outcomes)** | More accurate diagnosis of urinary incontinence |
| **PICO-2: Valid questionnaires & Bladder diaries** | **P (Population)** | Adult women with suspected urinary incontinence | **E (Exposure)** | Patient questionnaires | **C (Comparison)** | Other exposures; None | **O (Outcomes)** | More accurate diagnosis of urinary incontinence |
| **PICO-3: Diagnostic tests** | **P (Population)** | Adult women with suspected urinary incontinence | **E (Exposure)** | Diagnostic tests | **C (Comparison)** | Other exposures; None | **O (Outcomes)** | More accurate diagnosis of urinary incontinence |
| **PICO-4: Urodynamics** | **P (Population)** | Adult women with suspected urinary incontinence | **E (Exposure)** | Urodynamics | **C (Comparison)** | Other exposures; None | **O (Outcomes)** | More accurate diagnosis of urinary incontinence |
| **PICO-5: Imaging** | **P (Population)** | Adult women with suspected urinary incontinence | **E (Exposure)** | Imaging | **C (Comparison)** | Other exposures; None | **O (Outcomes)** | More accurate diagnosis of urinary incontinence |

| Table 2. Clinical questions (PICOs): Non-surgical interventions for UI |
|-----------------|-------------------|-----------------|-------------------|-------------------|
| **PICO-1: Lifestyle interventions** | **P (Population)** | Adult women with female urinary incontinence | **I (Intervention)** | Lifestyle modifications | **C (Comparison)** | Any other interventions; Sham interventions; None | **O (Outcomes)** | Cure, improving quality of life, reducing adverse effects |
| **PICO-2: Behavioural and Physical therapies** | **P (Population)** | Adult women with female urinary incontinence | **I (Intervention)** | Pelvic floor muscle training, bladder training, ... | **C (Comparison)** | Any other interventions; Sham interventions; None | **O (Outcomes)** | Cure, improving quality of life, reducing adverse effects |
| **PICO-3: Pharmacological management** | **P (Population)** | Adult women with female urinary incontinence | **I (Intervention)** | Pharmacological interventions | **C (Comparison)** | Placebo; None | **O (Outcomes)** | Cure, improving quality of life, reducing adverse effects |

UI: Urinary incontinence
make a decision and manage the disorder. Our system, called UrInO-DSS, offers a tool to support clinicians in providing personalized treatment for patients suffering from UI. The system will cover all stages of the UI diagnosis and the management process. Because of the complexities of diagnosing and treating UI, UrInO-DSS can help residents and medical students learn how to manage UI in the best way.

The Standardization Steering Committee (SSC), a committee of the ICS, seeks to promote the standard of the terms related to incontinence and Lower Urinary Tract Dysfunction (LUTD). The results of these standardization of terminologies are presented in numerous articles (30). The terminologies are updated periodically on the ICS official website and in published articles. The developed ontology for UI can be a valuable tool in achieving this goal. In collaboration with the ICS, the standard terms of incontinence and LUTD could be used in the ontology building. Simultaneously, this ontology can gather and integrate vocabularies related to UI and LUTD from various sources and it can be a reference for standardization and updates of UI terminologies for better management.

Because ontologies organize domain knowledge into concepts and the relationships between them, they standardize concepts and integrate data extracted from different sources and create a common knowledge structure that can be shared between specialists and other individuals. It is possible to reuse and share the ontology, and to enrich the concepts of ontology over time. Based on the above, ontologies can play a crucial role in “knowledge management, data integration and decision support” (31). The use of CPGs in the construction of ontologies has been increasingly used in CDSSs recently. The evaluation of these systems indicates the initial useability and performance of these systems (32,33).

As far as we know, this is the first ontology developed for UI. The ontology could provide the basis for developing more effective and reliable knowledge-based systems in the field of incontinence and LUTD in the future. A strength of this study is applying bilingual ontology in the system. The ontology could be modified for any country with a different language.

**Study Limitations**

The limitation of the study may be that in the first phase, the system does not support full interoperability with the EHR, laboratory test ordering system, and urodynamic test system.

**Conclusion**

Although UrInO-DSS is being developed on the basis of an adapted CPG, with modifications to the knowledge base, the system can be implemented in any healthcare setting. Using ontology in the system and storing personalized care information
could pave the way for establishing an international CDSS for diagnosis and management of UI and exchanging information among experts. In future work, we plan to evaluate the effectiveness of UrInO-DSS in the diagnosis and management of UI in a trial study.

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Ethics

Ethics Committee Approval: Ethical approval was obtained from the Ethics Committee of the Tabriz University of Medical Sciences under Grant [TBZMED.REC.1398.132].

Informed Consent: A written informed consent form was obtained from the patient upon admission.

Peer-review: Externally peer-reviewed.

Authorship Contributions


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