MEDINFO 2004
M. Fieschi et al. (Eds)
Amsterdam: IOS Press

Evaluating Provider Adherence in a Trial of a Guideline-Based Decision Support System for Hypertension

A.S.Chan [a,b,f], R.W. Coleman [f], S.B. Martins [f], A. Advani [a,f], M.A. Musen [a], H.B. Bosworth [c], E.Z. Oddone [c], M.G. Shlipak [d], B.B. Hoffman [e], M.K. Goldstein [af]

[a]Stanford Medical Informatics, Stanford University School of Medicine, Stanford, CA
[b] Department of Family and Community Medicine, Univ. of California, San Francisco School of Medicine, ,San Francisco, CA
[c]Durham VA Medical Center and Duke University School of Medicine, Durham, NC
[d]San Francisco VA Medical Center and Univ. of California, San Francisco School of Medicine, San Francisco, CA
[e]Boston VA Medical Center and Harvard Medical School, Boston, MA
[f]VA Palo Alto Health Care System and Stanford University School of Medicine, Palo Alto, CA

Abstract

Measurement of provider adherence to a guideline-based decision support system (DSS) presents a number of important challenges. Establishing a causal relationship between the DSS and change in concordance requires consideration of both the primary intention of the guideline and different ways providers attempt to satisfy the guideline. During our work with a guideline-based decision support system for hypertension, ATHENA DSS, we document a number of subtle deviations from the strict hypertension guideline recommendations that ultimately demonstrate provider adherence. We believe that understanding these complexities is crucial to any valid evaluation of provider adherence. We also describe the development of an advisory evaluation engine that automates the interpretation of clinician adherence with the DSS on multiple levels, facilitating the high volume of complex data analysis that is created in a clinical trial of a guideline-based DSS.

Keywords:

Clinical decision support, Guidelines, Hypertension

Introduction

Measuring adherence to guideline-based decision support systems (DSS) at first glance appears to be a straightforward task. Guidelines by definition are designed to document what are considered best practices and thus may be used as benchmarks for comparison of providers against an accepted standard of care. The overall aim of implementing decision support is to improve patient outcomes. Evaluation of a DSS on patient outcomes involves a continuum of measures. At the top level, the most stringent and ultimately most important test of a DSS would be its impact on patient outcomes- that is morbidity and mortality. However, decision support is one small factor among many in determining overall patient morbidity and mortality; it would be quite difficult to measure with accuracy the effect of a DSS on such distant outcomes. Intermediate outcome measures, such as the impact of the DSS on blood pressure control, are more proximate measures of efficacy. Finally, evaluation of provider adherence to a particular recommendation made by the DSS is the most direct indicator of the ability of a DSS to affect clinical decision-making.

Considering adherence at a primary message level

Most clinical guidelines have at their core a primary message about the overall management of a disease or clinical syndrome. The primary message of hypertension guidelines is to achieve improved blood measure control, thus reducing associated morbidity and mortality. One measure of the guideline-based DSS is to examine the effect of the intervention with regard to the primary message. Consider for example, an intervention for hypertension. Using this approach, one would simply measure blood pressure control during the study period as an indicator of provider adherence to the guideline. This is problematic, however, when one realizes there may be several possible influences on hypertension control external to the effects of the DSS.

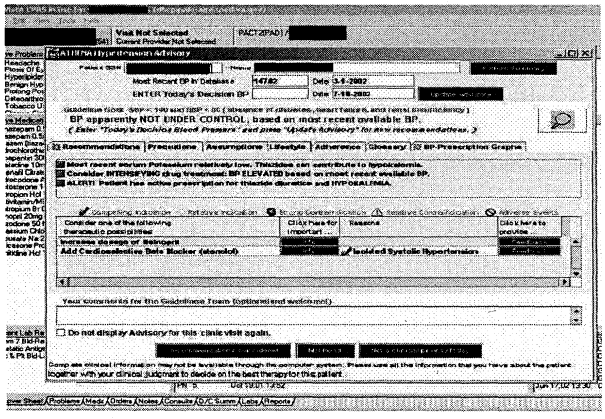

Figure 1 - An example of the ATHENA advisory, which is displayed when a study patient's medical record is accessed in the CPRS

Considering adherence at the recommendation level

Perhaps the most direct measure of adherence is an evaluation of the provider adherence to particular recommendations made by the DSS. This method also presents some interesting challenges. Several studies indicate that information from the electronic medical record (EMR), which is used by the DSS to generate recommendations, may be flawed or incomplete [1, 2]. Our own lab studies indicate that in the case of the VA Computerized Patient Record System (CPRS), certain blood pressure readings such as home readings stated by the patient are not included in the EMR. Thus, a partial or full deviation from the guideline may be legitimate if the provider has access to additional information not available to the DSS.

Thus, it is extremely important to consider the intentions of the provider when assessing their choices for treatment. Shahar [3] makes the distinction between an outcome intention- the patient state that the guideline attempts to achieve, and a process intention – the care-provider's actions that will be used to achieve this outcome. Critiques of adherence require a better understanding of how deviations from the guideline may still represent an intention to meet the guideline's primary message[4]. Truly intelligent quality assessment of guideline adherence considers both the guideline author's primary intention and the different ways providers adhere to the guideline [4, 5]

Considering adherence at the visit level

One method of assessing the relationship between guideline adherence and recommendations made by a DSS is to focus on the delivery of care on a visit-by-visit level. This provides for a temporal relationship between the recommendations made by the DSS and the provider's actions in the clinical context in which the DSS advisory was displayed. By subsequently tracking what changes occurred in the patient's care plan, one can infer the effect the DSS had on the provider.

Considering the Impact of Multi-step Guideline DSS on Evaluation

Many trials involving clinical decision support to date have involved single step reminder or alert systems. There are few examples of evaluation of large-scale implementations of complex guideline-based decision support. Maviglia et al discuss the implementation of complex, multi-step guideline-based decision support for therapy of hyperlipidemia at Brigham and Women's Hospital (BWH). In their initial studies, they documented that 69% of patients with atherosclerotic vascular disease failed to meet one or more of the National Cholesterol Education Program goals. 2,258 reminders for 690 patients were delivered in the first year of their evaluation [6]. The final evaluation of the ability of their DSS to influence guideline adherence has yet to be described. Micieli et al described one of the few multi-center trials of a guideline-based DSS. Implemented at four Italian centers, Micieli demonstrated compliance with a clinical guideline for acute ischemic stroke from the American Heart Association decreased mortality by 15% at six months [7]. The sheer volume of data and varied outcomes in multi-step guideline-based DSS add yet additional complexity to the evaluation process.

Introduction to ATHENA DSS

ATHENA DSS (Assessment and Treatment of Hypertension: Evidence-Based Automation Decision Support System) is a guideline-based decision support system for the treatment of hypertension. Based on widely accepted national guidelines for hypertension (JNC 6 and the Veterans Administration (VA)), ATHENA DSS delivers treatment advisories to clinicians at the point of care. ATHENA DSS acts this via an interface to the VA CPRS system, a uniform EMR in patient care delivery settings nationwide.

The ATHENA DSS consists of two main components: a hypertension knowledge base modeled in Protégé [8] and a guideline interpreter that applies the information in the knowledge base to the clinical information retrieved from the CPRS to create patient-specific recommendations for a patient encounter, on a visit-by-visit basis [9, 10, 11].

In the ATHENA DSS, we use the concept of a primary recommendation to describe the aim of the DSS to deliver a recommendation based on the overall intention of the guideline. If there is a relevant recommendation, ATHENA DSS delivers to the provider a specific list of drug recommendations (the DSS' process intentions) that describes how to achieve the outcome intention of the guideline. No recommendations are made if the patient's care is in complete concordance with the guideline.

ATHENA DSS recommends adding, substituting, or changing the dose of medications in three distinct scenarios: inadequate blood pressure control, choice of therapy that is not concordant with the guideline, and the presence of compelling comorbid conditions that would benefit from the addition of a specific antihypertensive medication without regard to blood pressure control. In situations when blood pressure is well controlled or compelling indications in therapy are not present, the DSS recommends no change in management. These recommendations are presented to the clinicians in the form of a "pop-up" advisory window superimposed on the EMR that is available for viewing in preparation of a visit or during the patient visit. Both the recommendations of ATHENA DSS and the medication management of the patient after the visit are recorded in a database for subsequent analysis.

Considering Provider Adherence to ATHENA DSS

The analysis of adherence to ATHENA DSS' three main advisories – add, substitute or increase dosage – requires further discussion. With single step guidelines, the evaluation of adherence is a binary state. The provider is strictly evaluated on the presence or absence of appropriate response to the guideline.

Table 1: Specific advisories provided by ATHENA DSS

1. Addition of a recommended medication
2. Substitution of a recommended medication This includes discontinuation of one drug and replacement with another drug
3. Increase in the dose of the recommended medication

Individual assessments of clinician adherence to add, substitute, or increase dosage messages provide only one level of positive

adherence to the guideline. What if, for example, ATHENA DSS gave a primary recommendation to intensify therapy and recommended medication X, but the clinician chose to start the patient on a different medication Y? Did the clinician simply ignore the recommendation? Or did the clinician recognize that ATHENA DSS recommended intensifying therapy and added a different medication based on patient-specific information not available in the electronic medical record?

Additionally, we know that blood pressure data in CPRS may not be fully updated at the time of advisory generation. Thus, the provider may correctly decide not to alter therapy based on an updated controlled blood pressure value not seen by the ATHENA DSS.

In addition to the three specific messages issued by ATHENA DSS, we have identified a number of scenarios that represent an intention of the clinician to intensify therapy. Table 1 describes the primary advisories that are explicitly recommended by the ATHENA DSS. Table 2 lists other actions by the provider that suggests that the intent was to adhere to the primary message of the DSS to intensify treatment of hypertension.

Table 2: Additional actions by the provider that indicate a process intention to intensify therapy

1. Addition of a hypertensive medication other than as explicitly recommended by ATHENA DSS
2. Increased dosage of any of hypertensive medications in the patient's current list of medications
3. Partial adherence to the substitution recommendation of a medication, either:
a. Discontinuation of the recommended medication
b. Addition of a medication recommended as a substitute

Evaluation of the criteria presented in Tables 1 and 2 will allow us to calculate both strict adherence to the guideline recommendations and adherence to the primary goal of any hypertension guideline: to intensify hypertensive treatment so as to improve blood pressure control. Failure to consider these other treatment outcomes would underestimate the ability of the DSS to encourage improved clinical treatment.

Materials and Methods

As part of a randomized trial to assess the overall effect of ATHENA DSS on blood pressure control, recommendations were generated on a daily basis for 15 months at nine dispersed clinical sites within the VA Durham, Palo Alto, and San Francisco Health Care Systems. These recommendations were presented to primary care physicians in the intervention arm of the study during clinic visits with hypertensive patients. Patients with secondary hypertension or hypertension requiring management in a hypertension specialty clinic were excluded from the study.

Since each individual patient visit generated a pop-up advisory, the required number of evaluations of provider adherence multiplied rapidly. The complexity of outcomes and sheer volume of data necessitated a solution for an automated approach to guideline adherence evaluation.

We developed the Advisory Adherence Evaluator (AAE) to facilitate a more comprehensive analysis of provider adherence to the ATHENA DSS recommendations. The evaluation engine, written in the Java programming language, interprets data generated by the interaction of the hypertension knowledge base, the guideline interpreter, and the VA electronic medical record. The AAE is maintained externally both to the clinical data and the hypertension knowledge base, creating a separated, yet automated approach to the data analysis.

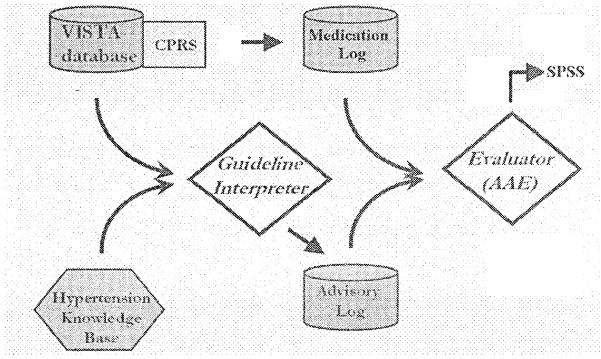

Figure 2 - An illustration of the processing of data in the ATHENA DSS. Patient data from the CPRS is considered along with information from the hypertension knowledge base by the Guideline Interpreter, generating one or more advisories. These advisories are stored in a SQL database and then compared to the medication log by the Adherence Advisory Evaluator (AAE).

ATHENA DSS advisories are initially recorded into a log on a Microsoft Structured Query Language (SQL) Server. This log records patient and visit identifying information, the provider, and the advisories generated by ATHENA DSS. A separate extraction is performed to record the active medication list of the patient before and after the visit at which the ATHENA DSS advisory window is displayed in the SQL databases.

The AAE performs multiple levels of analysis to determine adherence to the ATHENA DSS recommendations. First, the AAE assesses if the provider strictly adhered to the recommendations of either add, substitute, or increase dosage messages by noting changes in patient's active medication lists as compared to the recommendations offered by the ATHENA DSS. The AAE also assesses if there were any changes in the medication list after the advisory that indicate a provider's intention to meet the recommendations. This includes adding or increasing an antihypertensive medication not specifically recommended by ATHENA or partial adhering to the substitution recommendation. The AAE creates output files that include text descriptions of the evaluation and ordinal representations that are easily exported to statistical analysis software such as SPSS.

To test the accuracy and functionality of the AAE, we included data from all clinicians at one of the three study sites. The composite analysis of all three study sites, including information about experimental and control group providers, will remain blinded until the final analysis of the study data.

Results

Preliminary results demonstrate that the AAE can accurately and efficiently evaluate the multiple potential outcomes from a large volume of ATHENA DSS recommendations. We have tested the AAE on a total of 67,452 recommendations involving 29,960 patient encounters by 59 clinicians.

Table 3: A demonstration of the importance of considering multiple definitions of adherence to a substitution advisory

Substitution Recommendation Adherence	Number of Advisories
Adherence to strict definition	72 (1.2%)
Adherence to medication discontinuation only	2,093 (33.5%)
Adherence to medication addition only	250 (4.0%)
Total of partial adherence to substitution rec.	2,343 (37.5%)
Total # of Substitution Advisories	6,242

To illustrate the discovery of additional definitions of guideline adherence, we discovered via the AAE that strict evaluation of a "substitution" advisory from ATHENA DSS (i.e. the discontinuation of a recommended medication and addition of a recommended medication) would have failed to fully describe the number of providers who complied with at least one arm of the DSS recommendation (37.5% vs. 1.2%) (Table 3).

Table 4: Considering both strict adherence to the DSS recommendations and the provider's process intention to meet the guideline's primary message yields potentially additional information about how providers respond to guideline recommendations.

Types of concordance	Number of concordant encounters
Strict interpretation of ATHENA DSS Recommendations	9,629 (32.1%)
Antihypertensive medication not specified by ATHENA DSS was increased in dose or added	3793 (12.7%)
Total Number of Encounters	29,960

Additional insight is gained from assessing how well provider's attempted to satisfy the primary message of the guideline – intensification of therapy or addition of a drug for secondary prevention, despite not strictly following the recommendations of ATHENA DSS. Considering these actions would account for an additional 12.7% of encounters that are concordant with the primary message (Table 4).

Discussion

Perhaps the most direct method of assessing the effect of interactions with ATHENA DSS would be to observe provider behavior and care delivery after the display of recommendations and subsequently interview the provider about his or her decisions. While potentially revealing rich data about physician interaction, we determined that this type of analysis would require a significant technical and financial commitment, given a trial of a DSS that delivers thousands of recommendations to multiple geographically dispersed care sites over a significant period of time.

Instead, we developed an automated approach to assess provider adherence to our guideline-based decision support that will be used in the final study outcomes analysis. During this development, we discovered that to fully appreciate the extent of the provider's adherence to complex clinical guidelines such as the JNC 6 / VA hypertension guidelines, one must account for the multiple subtleties in treatment selection that a provider considers when selecting appropriate therapy. Strict interpretation of adherence to JNC 6 and ATHENA DSS may not adequately account for the provider's intention to follow the guideline's primary message – in this case, the control of hypertension. Any valid measure of adherence must consider the extent to which the provider strictly follows the guideline and the provider's more clinically relevant higher-level intention to follow the primary message of the guideline[4].

We hope to add to our investigation two additional modes of analysis - feedback comments provided by clinicians at the time of display of the advisory and surveys of study clinicians – to further understand clinicians' intentions. Ultimately, we plan to link these data with the results of provider concordance discussed in this work to gain a deeper understanding of clinician interaction with guideline-based decision support systems such as ATHENA DSS.

We have described a method for evaluating provider adherence in a large, multi-center randomized clinical trial of a guideline-based decision support system for hypertension, ATHENA DSS. The modularity of the evaluator allows for easy modification of the rules that define adherence to the guideline recommendations without disturbing the underlying structure of the knowledge base and log of patient encounter events. Additionally, an external analysis process such as the one described here can also facilitate rapid interpretation of study data, even as the study is in progress. Inclusion of such a process in the design of trials of guideline-based decision support will become increasingly valuable as complex clinical guideline DSS that generate large volumes of clinical decision data , such as ATHENA DSS and BWH decision support for NCEP cholesterol guidelines, are implemented.

Acknowledgements

This work was supported by grants from the National Library of Medicine LM 07033, VA HSR&D CPI 99275 and NIH 5 R01 LM06806. Thanks to Ms. Hoi Yan Yiu and Ms. Grace Xiao for their assistance in the initial phase of the method implementation. Views expressed are those of the authors and not necessarily of the Department of Veterans Affairs or other affiliated institutions.

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Address for correspondence

Albert S. Chan, MD
Stanford Medical Informatics
MSOB X-215
Stanford, CA 94305-5479