Issues in Accommodating National Changes and Local Variation in a Computer-Based Guideline for Childhood Immunization and in Related Knowledge Maintenance Tools

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As clinical practice guidelines are increasingly implemented in computer-based form, a major challenge will be to maintain their domain knowledge as new national recommendations are developed and as local customization is required. This maintenance may also need to be performed for any computer-based tools developed to help in the guideline knowledge maintenance process itself. This paper uses the domain of childhood immunization to explore certain issues involved. It describes 1) two recent changes to the national recommendations dealing with the DTP and Polio vaccine series, and 2) several customizations requested by the immunization registries of the State of Oregon and the US Indian Health Service. It then describes how these guideline practice variations are currently handled in three computer-based tools, IMM/Serve, IMM/Def, and IMM/Test. Finally, it discusses how the use of these tools can provide one approach to characterizing the complexity of guideline variations.

INTRODUCTION

As computer-based clinical guidelines are introduced into the clinical environment, it will be a major challenge to maintain their knowledge base (KB) as the clinical field evolves and as local customization of the knowledge is performed [1-3]. It will be most important to test and validate each new version of the guideline in an efficient and thorough fashion. It may often prove useful to develop computer-based tools to assist in this knowledge maintenance process. If so, any domain knowledge contained within these tools will also need to be kept up-to-date.

We have built three computer-based tools to assist in the management of childhood immunization.

1. IMM/Serve [4] is an immunization forecasting program which takes a child's immunization history (e.g., from an immunization registry database) and produces recommendations as to which vaccinations are due and which should be scheduled in the future. IMM/Serve is linked on a test basis to the immunization registry of the State of Oregon, and in pilot operational mode to the immunization registry of the US Indian Health Service (IHS).
2. IMM/Def [5] is a prototype tool which assists in the process of immunization knowledge maintenance (IKM). It is designed to help validate IMM/Serve's rules by automatically generating a central "kernel" of those rules from "definition logic," a simplified expression of the core logic involved
3. IMM/Test [6] is a prototype IKM tool which processes the definition logic and automatically generates a set of test cases to help test IMM/Serve's rule kernel.

All three tools are domain-specific in the sense that they contain knowledge of the immunization domain. As a result, when a new version of the immunization knowledge needs to be placed into computer-based form and tested (e.g., reflecting new national recommendations or local practices), all three of these tools may need to be modified.

Two interesting questions that arise are:

1. How are the guideline variations best represented in each of the tools to facilitate the process of IKM?
2. How might one characterize the complexity of the changes required to the knowledge base?

This paper explores these questions in the context of 1) two recent national modifications in the guidelines dealing with the DTP and Polio vaccine series, and 2) customizations requested by the Oregon and IHS immunization registries.

REPRESENTATION OF GUIDELINE VARIATION IN IMM/SERVE

In the IMM/Serve immunization forecasting program, domain knowledge is stored in two forms: 1) in tabular form and 2) as if-then rules.

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Tabular Knowledge

Tables are used to represent most of the underlying temporal parameters.

1. One table contains immunization forecasting parameters which indicate, for each dose of each vaccine series, information such as minimum acceptable age, minimum recommended age, and minimum wait-interval from the previous dose. For a given vaccine dose, there may be several sets of such parameters corresponding to different clinical conditions.
2. Another table contains dose screening parameters which indicate, for each dose of each vaccine series, absolute minimum ages and wait-intervals which, if violated, render the dose invalid.
3. A third table contains live vaccine interaction parameters, indicating any minimum wait-intervals that should be enforced between doses of different live vaccines (Varicella, Mumps-Measles-Rubella, and Oral Polio).
4. A final table contains several dates used in the underlying logic, which might be modified by different registries.

As described below, several versions of each table can be stored simultaneously in a single version of IMM/Serve.

Rule-Based Knowledge

If-then rules are used to encode the immunization forecasting logic that determines which set of tabular forecasting parameters should be used in a particular case. For example, depending on whether the first Hib vaccination is given before 7 months of age, between 7 and 12 months, or after 12 months, the minimum age and wait-interval for dose 2 are different.

Multiple variations in the rule-based logic can be incorporated into a single integrated set of rules. When the rules are executed, flags (control variables) are set to indicate which variations of the logic should be used for a particular case.

Accommodating Guideline Variation

Certain guideline variations require only modifying the tabular parameters. Other variations require that the if-then rules be changed. To be successfully used in multiple clinics, IMM/Serve needs to accommodate multiple variations in both forms of its knowledge.

To allow IMM/Serve to incorporate simultaneously different versions of this knowledge, an overall "guideline version table" allows different versions of the knowledge base to be defined. Each version of the guideline as a whole specifies a particular version of each table, and a particular set of variations in the rule-based knowledge. Each guideline version is given its own "version name."

When IMM/Serve is run, the immunization registry program passes in the guideline version name, along with the patient history, to indicate which overall version of IMM/Serve's knowledge (which version of each table and which variations in the rule-based logic) should be used for that case.

ACCOMMODATING TWO NATIONAL GUIDELINE MODIFICATIONS IN IMM/SERVE

During the past year, the CDC's Advisory Committee on Immunization Practices (ACIP) has modified its recommendations for both the DTP and Polio vaccine series. In this section we describe these modifications and how they are accommodated in IMM/Serve.

New Recommendations for DTP

In the previous DTP recommendations, DTaP was recommended only for doses 4 and 5, and only for children 15 months of age or older. In the new recommendations, DTaP is recommended for all doses and all ages. (These recommendations assume that no contraindications exist.)

Implementing this change in IMM/Serve required no change to the parameter tables, since the minimum ages and wait-intervals for each dose did not change. This change did require modifications in the portion of IMM/Serve's rule-based logic that determined which vaccine preparation (e.g., DTP vs. DTaP) should be recommended.

When switching from an old set of recommendations to a new set, both versions are maintained in IMM/Serve for a period of time, since different clinics may chose to make the switch at different times, particularly if they are in different States or subject to different regulatory environments.

As a result, two alternative variations of the DTP series rules were incorporated into IMM/Serve. As described previously [7], this was accomplished by

incorporating "control variables" which control the execution of a set of "generic" (variation independent) rules that determine which vaccine preparation to use.

New Recommendations for Polio

The new recommendations for Polio included several changes.

1. In the previous Polio recommendations, OPV was preferred to IPV for all four doses. Although this approach is still acceptable, the new recommendations prefer a "sequential schedule" which uses IPV for doses 1 and 2, and OPV for doses 3 and 4. (These recommendations assume that no contraindications exist.)
2. There is now also an "accelerated" Polio schedule if dose 1 is given after 7 months of age. In this circumstance, OPV is preferred and the wait-intervals between doses are shorter than otherwise.

To accommodate these new recommendations, significant changes were needed in IMM/Serve.

1. Adding the new sequential schedule was handled by creating a set of "generic" rules for polio and using control variables to determine whether the "all OPV" or the "sequential" schedules were to be used.
2. Adding the accelerated schedule required the addition of an entire new set of polio rules. In addition, a new group of tabular parameter sets were added to accommodate the accelerated wait-intervals.

ACCOMMODATING LOCAL GUIDELINE CUSTOMIZATION IN IMM/SERVE

In preparing to use IMM/Serve in different clinical settings, Oregon and the IHS have requested several customizations to the national guidelines.

Customizing the Tabular Parameters

Many of the customizations require changes only to the tabular parameters. For example, the IHS currently estimates that to serve its 100+ clinics nationwide, it will require several different variations in IMM/Serve's tabular forecasting knowledge: DTP (2 variations), Hepatitis A (2 variations), Hepatitis B (2 variations), MMR (2 variations), and Polio (2 variations). Accommodating these changes can be performed simply by changing values in the immunization forecasting table.

Customizing the Rules

Both Oregon and the IHS wanted one major customization to the polio recommendations, the creation of a "generic" polio schedule which recommends that "Polio" vaccine be given without specifying which kind. The user is then free to give either IPV or OPV. In addition, for this generic polio schedule, the minimum ages and wait-intervals for certain doses differ from the national recommendations. Implementing this customization required that a new set of kernel rules be added to IMM/Serve, together with new tabular parameter sets.

In addition, the IHS wanted to include an additional customization to the Hib rules and to the DTP rules. These changes required relatively modest localized modifications to the rules.

ACCOMMODATING THESE GUIDELINE VARIATIONS IN THE TWO IKM TOOLS

The two prototype IKM tools, IMM/Def and IMM/Test, currently focus on the rule "kernel," the central set of rules which respond to all combinations of input conditions. This is the most complex portion of the rules and the most difficult to maintain. IMM/Test also uses the forecasting parameter table. This section describes how the national modifications and local customizations described above were handled in both of these tools.

1. The three new variations of the polio rule-based logic (dealing with the sequential schedule, the accelerated schedule, and the "generic" schedule) were handled by creating new, separate sets of the domain knowledge for the Polio vaccine series within both of the tools. (The program logic of the tools themselves did not need to change.)
2. The more localized changes to the rules did not directly involve the rule kernel. As a result, no changes needed to be made in the two tools. If IMM/Test is extended (as is planned in the future) to generate test cases for additional components of the guideline logic, portions of this expanded domain knowledge would need to be modified.
3. The changes to the tabular forecasting parameters needed to be made in IMM/Test's knowledge. IMM/Def focuses only on the rules, not the tabular parameters and was not affected by these changes.

CHARACTERIZING THE COMPLEXITY OF THE GUIDELINE VARIATIONS

One interesting issue in maintaining a computer-based guideline over time will be the question of how best to characterize the complexity of guideline variations. The use of the three tools described above provides one approach. Guideline variations can be characterized by describing the changes required to the different components of the knowledge in these tools.

For example, for IMM/Serve's knowledge base, one can characterize the complexity of a guideline variation as follows.

1. Forecasting parameter sets
   - # of parameter sets changed, added, deleted.

2. Rules
   - a change not involving the rule kernel (# of rules changed, added, deleted), and/or
   - a change modifying the rule kernel (# of rules changed, added, deleted), and/or
   - a change requiring a new version of the rule kernel (# of rules changed, added, deleted).

From the standpoint of complexity:

1. The three different types of changes to the rules are listed above in order of increasing complexity.
2. Variations that involve changes to the rules involve much more complexity than changes made only to tabular parameters.
3. Merely changing parameter values is much simpler than adding or deleting parameter sets.

Using this approach, the guideline variations described previously can be characterized in terms of the changes required to IMM/Serve's knowledge, as follows:

New Sequential Polio Variation
Forecasting parameter sets: no change.
Rules: a change modifying the rule kernel (2 rules changed, 4 rules added, 34 kernel rules changed to make them "generic").

New Accelerated Polio Variation
Forecasting parameter sets: 10 added.
Rules: a change requiring a new version of the rule kernel (7 rules changed, 21 added).

"Generic" Polio Customization (Oregon & IHS)
Forecasting parameter sets: 4 added.
Rules: a change requiring a new version of the rule kernel (4 rules changed, 10 rules added).

New DTP Series Variation
Forecasting parameter sets: no change.
Rules: a change not involving the rule kernel (5 rules added, 23 rules changed to make them "generic").

Hib Rule Customization (IHS)
Forecasting parameter sets: no change.
Rules: a change not involving the rule kernel (1 rule added, 5 rules changed to make them "generic").

DTP Rule Customization (IHS)
Forecasting parameter sets: no change.
Rules: a change not involving the rule kernel (1 rule added, 1 rule changed).

Tabular Customizations (IHS)
Forecasting parameter sets: 9 changed.

These guideline variations are listed in rough order of decreasing complexity. Once a knowledge engineer has gone through the process of revising the knowledge base once, this information affords a good appreciation of the magnitude of work required to accommodate each of the variations described.

The use of complexity metrics to understand and control software maintenance has been studied in the field of Computer Science over the past several decades [8]. In characterizing the complexity of guideline variations, we have described an approach based on changes to parameter tables and rules. The use of parameter table changes as a measure of complexity has a direct analogy in measuring a program's data structure complexity [9]. Similarly, the use of changes to a hierarchy of if-then rules has a software counterpart in the nesting of conditionals [10].

DISCUSSION

Approaches to Accommodating Variation

There are a number of different approaches that might be taken to accommodate practice variation in a computer-based clinical guideline. The most straightforward approach is to build a completely separate version of the knowledge for each

combination of variations. If there are many different individual variations which can be combined in many ways, however, this approach is unwieldy. As a result, IMM/Serve includes all variations within a single program, and allows a registry to specify on a case-by-case basis which version of the guideline should be used.

We currently take the simpler approach, however, with the two IKM tools, building separate versions of the knowledge for each variation of a vaccine series. (This task is simplified by the fact that the knowledge for each vaccine series is stored separately.) As we refine these tools, we may find strategies to combine several variations in the logic for a vaccine series into a single integrated version of that knowledge.

KB Changes as a Metric of Complexity

This paper has described certain variations in the guidelines for childhood immunization (based either on new national recommendations or local customization), and how those variations are handled in three computer-based tools. The required modifications to these tools in turn provide a basis for characterizing the complexity of a guideline variation.

This approach clearly does not provide an absolute measure of the complexity of a guideline variation. If a more readily maintainable computer-based representation for all, or part, of the guideline is developed, the implied complexity of a given variation (defined in terms of this new representation) may well be less than that implied by the current representation.

Extending the Measures of Complexity

The approach to assessing the complexity of a guideline variation described above is clearly only one approach that might be taken. Other measures might include: 1) how much knowledge engineering time is required to accommodate the variation, 2) how much testing of the system is required using test cases, and/or 3) how many errors are introduced that need to be corrected.

In future work, we plan to explore what further measures of complexity might be developed, and how they might be related to the measures outlined in this paper.

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