Evolution of the HELEN Representation for Managing Clinical Practice Guidelines

Haschler I*, Skonetzki S*, Gausepohl HJ† Linderkamp O†, Wetter T*

November 2, 2004

Correspondence address:

Dipl.-Inform. Med. Ingo Haschler
University of Heidelberg
Institute for Medical Biometry and Informatics
Department of Medical Informatics
Im Neuenheimer Feld 400
D-69120 Heidelberg
ingo.haschler@med.uni-heidelberg.de

1 Summary

Introduction:

In order to implement clinical practice guidelines for the Department of Neonatology of the Heidelberg University Medical Center a modular framework was developed consisting of tools for authoring, browsing and executing encoded clinical practice guidelines. Currently we are focusing on the integration of the adaptation process in our framework.

Methods:

After formulating the requirements we extended the existing HELEN framework in order to implement an adaptation pathway and a control mechanism for the authors of the clinical practice guideline. Like the initial framework the additional functions where also developed using the Model-based Incremental Knowledge Engineering Process (MIKE).

Results:

We have extended the HELEN system by functions to support a structured process of adaptation. Currently we are planning an evaluation project in the Department of Neonatology of the Heidelberg University Medical Center. A guideline for calculating total parenteral nutrition of newborns has been used as an example to demonstrate the flexibility of the HELEN framework as a whole and the usability of the new adaptation pathway. A weekly nutrition reminder system could be generated smoothly by applying the adaptation pathway to a master CPG.

Discussion:

*Dept. of Medical Informatics, University of Heidelberg, Germany
†Dept. of Neonatology, University of Heidelberg Medical Center, Germany

With our extension to the HELEN system we have reached the aim of controlling changes of clinical practice guidelines which have been provided on a national or international level. A pathway for the adaptation process is provided within the authoring environment. Future work shall focus on evidence representation and management. We plan optimized support for entering evidence in the authoring environment and are currently investigating the necessary changes to the ontology.
Keywords: Clinical practice guidelines, implementation, local adaptation, execution

2 Introduction

In order to implement clinical practice guidelines, a modular framework was developed consisting of tools for authoring, browsing and executing encoded clinical practice guidelines (CPGs) [1]. It was implemented and tested in the Department of Neonatology of the Heidelberg University Medical Center.

As the extensive body of scientific research in this field indicates, there already exists a profound knowledge about implementing Clinical Practice Guidelines (CPGs). Furthermore, there are even several suitable technical solutions available to support this process. But as stated even in recently published reviews on guideline representation systems, there still is a need for more research on how to adjust and standardize the support for everyday practice (e.g. [2] and [3]).

Therefore the HELEN system tries to achieve the following additional goals:

- Standardized handling of guidelines from different origins
- Explicit support for the process of adaptation as an integral part of the lifecycle
- Support for implementation and usage in the everyday clinical routine.

To reach these goals we try to enhance the support for the whole lifecycle of CPGs. Within our project we assume that this lifecycle should at least include:

- Estimation of value or usefulness for clinical practice
- Authoring on a national or international level
- Critical appraisal of the quality by an independent organization
- Dissemination over standardized networks
- Guided adaptation to local needs
- Implementation within local institutional system or environment
- Evaluation of successful transfer

Currently we are focusing on the adaptation process, but another goal of our research is the integration of standardized evidence links. We aim at a central repository (on a national or international level) where literature references are stored once they have been rated by experts.

3 Methods

Adaptation is a central process in a CPGs lifecycle if a broad acceptance shall be achieved [4][5][6]. The settings in which guideline usage may be beneficial for quality of care differ in various aspects; therefore the adaptation process has to tailor the guideline recommendations to take into account:

- Lack or availability of resources
- Mode of CPG delivery (e.g. paper-based, on a desktop PC or handheld)

- Local policies for treatment options or drug doses
- Different patient population

In any case, all future users of the guideline have to be included into the structured process of local adaptation.

At the national or international level, where the CPG is initially created, the authors must be able to enforce, permit or inhibit changes on particular parts of a CPG. Additionally, institutions adapting guidelines shall be provided with hints for the adaptation by the original authors.

It can also be helpful for the authors to get a feedback by the adapters to incorporate frequent changes in further versions of the CPG. Also a feedback of the users to the adaptation teams is considered.

Although the process of adaptation means an increased amount of work compared to implementing CPGs directly and omitting this step, it has several benefits which should be considered carefully:

- The amount of work is still less than developing a CPG from scratch
- Processes, responsibilities and resource usage are defined
- All adaptations of a generic CPG use the same evidence base.

A serious disadvantage is the danger of compromising this common evidence base by changing essential parts of the CPG. This problem is addressed later in this paper. Another argument against adaptation is the resulting overhead in case that the original CPG is updated. By providing the adapters with a helpful tool for the adaptation process, this work can considerably be minimized.

Therefore we extended the existing HELEN framework in order to implement an adaptation pathway and a control mechanism for the authors of the CPG.

Like the initial framework the additional functions where also developed using the Model-based Incremental Knowledge Engineering Process (MIKE) [7]. This is a method for developing knowledge based systems based on the Spiral Model of Software Development [8]. Therefore the development consisted of four tasks:

- Analysis of requirements
- Design or refinement of the ontology
- Implementation of an initial knowledge acquisition tool and its extensions
- Evaluation by entering examples and test usage of the encoded information.

In our case the second task focused mainly on the extension of the existing ontology to meet the new requirements. To be able to test the encoded information, we only had to adapt the authoring environment because the processing of adapted CPGs was already implemented sufficiently in the other tools (viewer and execution environment) to meet the new requirements [1].

3.1 Requirements

For implementing different privileges and guidance, the authoring environment shall be split into two modes; one for authors, one for adaptation teams.

Authors of national or international CPGs must be able to establish rules and constraints for the adaptation process on an appropriate level of detail. Therefore a specialized attribute for certain objects[1] is necessary to specify whether the object:

Must_be_adapted The object must be adapted in the local CPG

Can_be_adapted The adaptation team can choose whether to adapt the object

Must_not_be_adapted The adaptation team is not allowed to change the object.

Adaptation teams shall be provided with a pathway in form of a synoptic view of the original and the local version for their work of tailoring the CPG to local needs. With this feature they can see at one glance what to do with each of the objects. All three possible actions in the adaptation process shall be supported by the software by using one of the following three buttons:

Adapt The object is copied to the local CPG and displayed for the adaptation along with the hints defined

Remove The object is removed from the local CPG[2]

Create A new object is created within the local CPG.

In order to meet the mentioned requirements minor changes within the underlying ontology as well as several additional widgets for the authoring adaptation environment are necessary.

3.2 Changes to the ontology

As one can see in figure 1, each of the objects mentioned above was supplied with one field containing the adaptation constraint and another containing a hint for adaptation (printed in bold face). The hint field contains free text, while the constraint field contains one of the three symbols described in the requirements. These two fields enable the authors to control the adaptation process and the adaptation teams to structure their work.

3.3 Knowledge acquisition tool

As the Protégé-2000 user interface adapts changes in the ontology automatically we only had to implement the two modes of the authoring environment. Therefore plug–ins were developed which

- protect adaptation constraint and hint fields by a password

[1] An object can be a knowledge module, a variable or a constant within the HELEN ontology.

[2] It is not deleted but only hidden.

- visualize the pathway to the adaptation teams.

In figure 2 the interface for the authors is shown; the fields will not be editable for the adapters.

Figure 3 illustrates the adaptation view: the three lists on the left side contain all elements of the original guideline, whereas lists with the elements of the local guideline are presented on the right side.

The constraint defined by the authors of the CPG is represented by the color of the icon, so the adapters can see at one glance what to do with each of the elements. If the constraint is Must_be_adapted or Can_be_adapted, one of the three actions defined in the requirements is possible by pressing the corresponding button.

3.4 Other tools and infrastructure

Besides these planned additional functions and changes for the adaptation process, usage of the existing framework in clinical settings revealed the need for further extensions to the user interaction which evolved from implementing the CPG used during tests of the adaptation feature and from our ongoing research. So we needed facilities to let the user review many variables at once and to fill paper forms with values calculated by the execution engine. They were developed using the same method as used for the development of the extensions for the adaptation.

For each requirement we added separate objects within the algorithm section of the ontology: *Review_Variables* and *HELEN_Invoke_Viewer*, as shown in figure 4; the two new classes are printed in bold face.

With the *Review_Variables* module it is possible to present multiple variable values to the user and ask him/her to review them; the interface is shown in figure 5.

The *HELEN_Invoke_Viewer* module is a call from the user's client to the *Guideline Viewer* which fills special HTML documents with values for a specific patient. For access control, the execution engine generates a random number (a so-called ticket) which is included in the call to the viewer and authorizes it to retrieve patient data from the execution engine.

A new flow of patient data is necessary, namely from the execution engine (where the patient data is stored) to the viewer (which did not handle patient data until now) for filling in the HTML forms. To secure this flow, every interaction between the three modules *Guideline Execution Engine*, *Guideline Viewer* and *PDAClient* is encrypted using an IPSec virtual private network (VPN). Figure 6 illustrates the communication for the execution of a *HELEN_Invoke_Viewer* module in an algorithm. Using the intermediate ticket mechanism, storage of patient data on the mobile device can be omitted, thus minimizing the risk of exposure of patient data.

3.5 Evaluation

Since it is hard to find CPGs which are explicitly prepared for adaptation, we used other sources to create, together with medical specialists[3], a generic guide-

[3]The senior medical co-author of this paper has repeatedly published in leading journals on parenteral nutrition of newborns, cf [9]

line for total parental nutrition (TPN) of newborns as a master document. In this CPG we defined several aspects for adaptation: the used nutrition mixtures and their ingredients, the target protein level, and the time which lies between two reviews.

We subsequently used this guideline as a starting point for the adaptation and implementation at the Department of Neonatology. The central function of the guideline is a weekly reminder for the physician to review the nutrition plan of each patient by means of a message on a portable device (PDA). Values used the week before are presented to the physician, who can change or accept each of them (see also figure 5). After the physician has committed the values, a predefined form is filled with the nutrition plan calculated and presented to the physician. The plan is validated and can be printed out for the patient record.

At the moment, it is not easy to evaluate if the evidence base can be protected in general by our adaptation process because there are currently no CPGs which contain the necessary metadata (i.e. adaptation constraints). But after having defined such metadata for the specifically developed master guideline, the process of taking them into account while adapting the guideline proved straightforward and well structured.

4 Results

With this work the following goals were reached:

- We managed to standardize the handling of CPGs of different origin;
- By extending the ontology and the authoring tool we could integrate and support the adaptation process within the guideline's lifecycle. In the used examples the evidence base could be kept stable and valid during the adaptation process only because constraints and hints were added manually to the original CPG;
- We successfully offered support for implementation in everyday clinical routine. We found out that the implementation framework becomes more flexible with every new field of appliance, but also more complex. We aim at a stable state in the near future.

We have extended the HELEN system by functions to support a structured process of adaptation. Currently we are planning a more detailed evaluation project in the Department of Neonatology of the Heidelberg University Medical Center. A guideline for calculating total parenteral nutrition (TPN) of newborns is successfully adapted and implemented mainly as a weekly reminder system.

5 Discussion

With our extension to the HELEN system we have achieved the aim of controlling changes of CPGs which are provided on a national or international level. A pathway for the adaptation process is provided in the authoring environment.

The usability of the HELEN framework is substantiated through the fact that the new functions described in this article could be integrated smoothly through developers not involved in the primary design of the HELEN ontology.

We will now focus on evaluation of the system by observing the effect of guideline usage in the TPN of newborns.

As our concept of adaptation relies for the most part on the quality of existing CPGs published on national or international level, work has to be done to support the authors by creating adaptable guidelines. This means that the constraints have to be defined carefully to minimize the danger of compromising the evidence base during the adaptation process. At the moment[4], in Germany there are only 50 guidelines available of the development level "S3"[5] which could be considered as input for the adaptation process. There is a need for a standard format for CPGs which incorporates evidence references and adaptation meta data.

Future work shall focus on evidence representation and management. An essential advantage of adapted CPGs is that they can rely on the evidence the original guideline is based on. We plan optimized support for entering evidence in the authoring environment and are currently investigating the necessary extensions to the ontology. To reduce the work for guideline authors and adapters/ implementers, we try to achieve a central repository for consistently graded literature references. The GRADE working group [10] [11] is currently developing a standard for grading of evidence which we want to integrate into our framework.

References

[1] Skonetzki S, Gausepohl HJ, van der Haak M, Knaebel S, Linderkamp O, Wetter T. HELEN, a Modular Framework for Representing and Implementing Clinical Practice Guidelines. Methods Inf Med 2004;43(4):413–26.

[2] de Clercq PA, Blom JA, Korsten HHM, Hasman A. Approaches for creating computer-interpretable guidelines that facilitate decision support. Artif Intell Med 2004;31(1):1–27.

[3] Peleg M, Tu S, Bury J, Ciccarese P, Fox J, Greenes RA, et al. Comparing computer-interpretable guideline models: a case-study approach. J Am Med Inform Assoc 2003;10(1):52–68.

[4] Davis DA, Taylor-Vaisey A. Translating guidelines into practice. A systematic review of theoretic concepts, practical experience and research evidence in the adoption of clinical practice guidelines. CMAJ 1997;157(4):408–16.

[5] Silagy CA, Weller DP, Lapsley H, Middleton P, Shelby-James T, Fazekas B. The effectiveness of local adaptation of nationally produced clinical practice guidelines. Fam Pract 2002;19(3):223–230.

[6] Greco PJ, Eisenberg JM. Changing physicians' practices. N Engl J Med 1993;329(17):1271–3.

[7] Angele J, Decker S, Studer R. Domain and Task Modeling in MIKE. In: Domain Knowledge for Interactive Systems Design, Proceedings of IFIP

[4] as of 25/10/2004

[5] S3 means methods obtained from consensus and evidence based medicine are used during the development process. Results are stated in formal logic and decision and outcome analysis are included.

WG 8.1/13.2 Joint Working Conference. Genevam Nay: Chapman & Hall; 1996. .

[8] Boehm BW. A Spiral Model of Software Development and Enhancement. ACM SIGSOFT 1988;4(11):21–42.

[9] Hellstern G, Kaempf-Rotzoll D, Linderkamp O, Langhans KD, Rating D. Parenteral amino acids increase albumin and skeletal muscle protein fractional synthetic rates in premature newborn minipigs. J Pediatr Gastroenterol Nutr 2002;35(3):240–7.

[10] Atkins D, Best D, Briss PA, Eccles M, Falck-Ytter Y, Flottorp S, et al. Grading quality of evidence and strength of recommendations. BMJ 2004;328(7454):1490.

[11] Schuenemann HJ, Best D, Vist G, AD Oxman. Letters, Numbers, symbols and words: how to communicate grades of evidence and recommendations. Can Med Assoc J 2003;169(7):677–80.

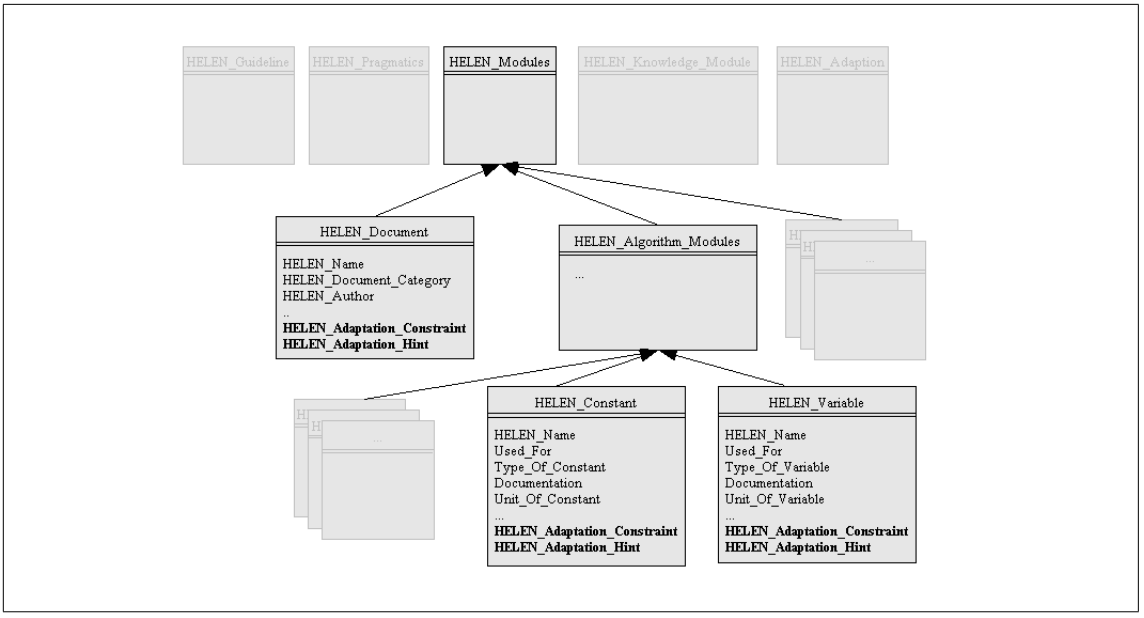

Figure 1: Adaptation constraint und hint in the ontology

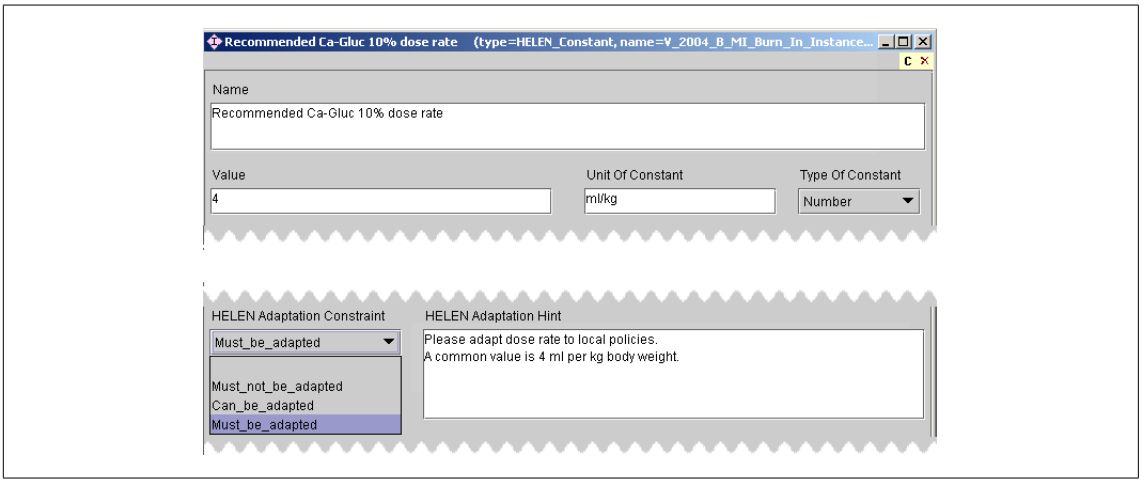

Figure 2: Adaptation constraint und hint in the authoring environment

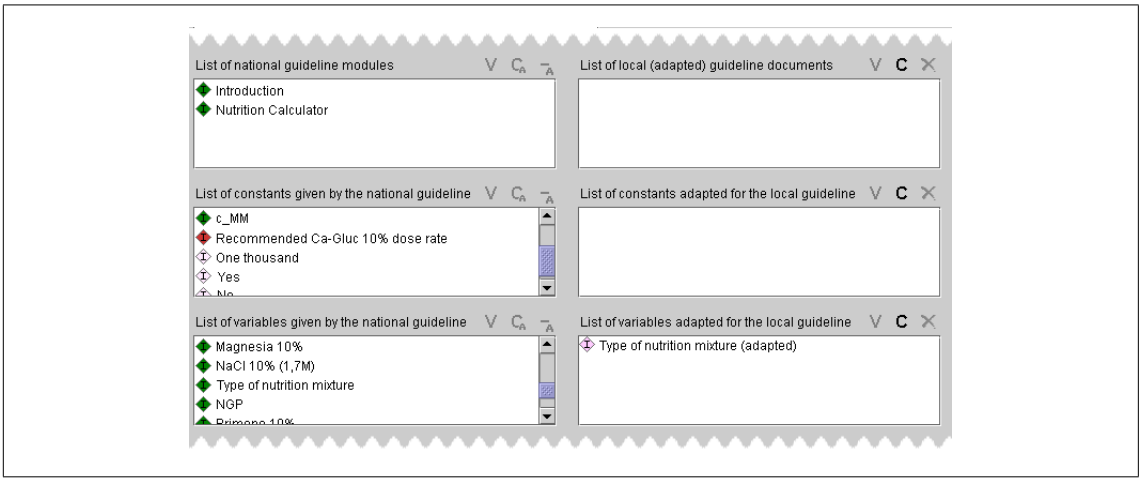

Figure 3: Adaptation pathway overview

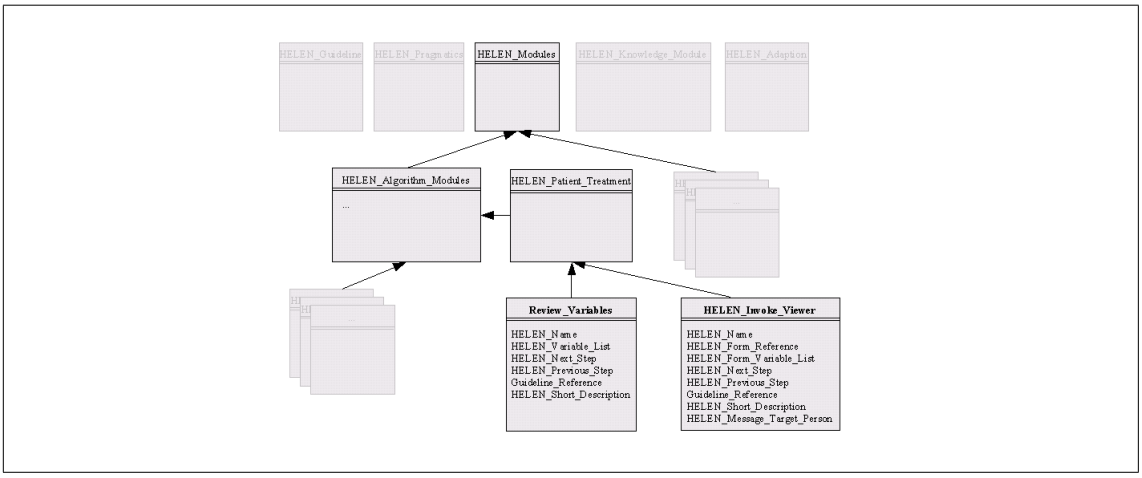

Figure 4: New classes for user interaction in the ontology

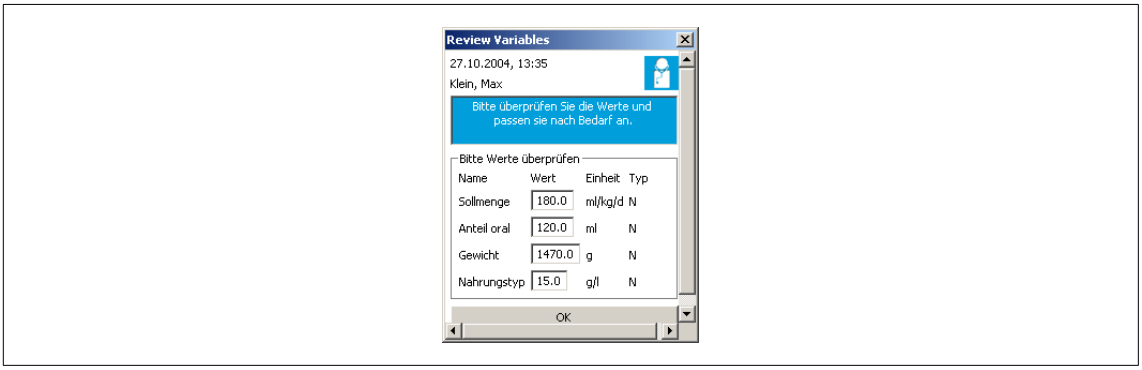

Figure 5: The user interface for *Review_ Variables* on the PDAClient (German version)

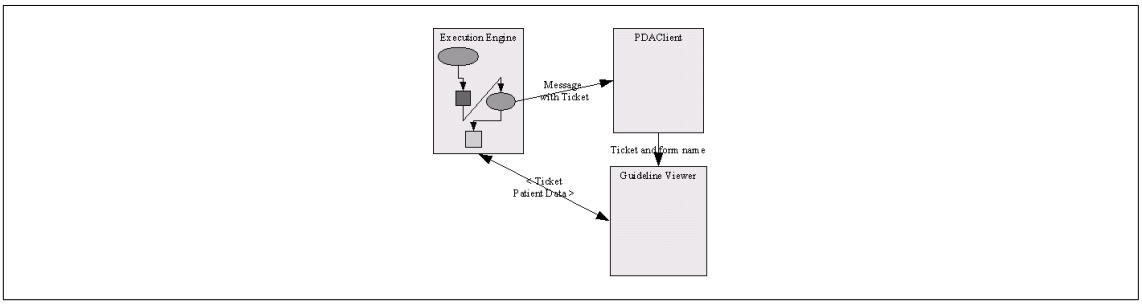

Figure 6: Infrastructure example