Publets: Clinical Judgement On The Web?

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Abstract

The Internet is now a major channel for publishing medical research data and documents, including clinical practice guidelines. It is now possible to capture guidelines in a computer interpretable form opening up the capability of using the internet to deliver patient-specific management advice. A technology based on extensions to the PROforma guideline technology and a development lifecycle for publishing and delivering such services at the point of care are described. As with all new technologies, however, the new methods entail risks as well as opportunities. The paper closes with a discussion of quality and safety requirements for the new technologies and some possible techniques.

Introduction

The internet is now a major channel for publishing documents and data in many fields. In medicine it is used for dissemination of research results (e.g. the Cochrane Library of systematic reviews1, research trials (e.g. the PDQ cancer trials database2). More recently it has become a means of disseminating practice guidelines by many organisations, including the Scottish Intercollegiate Guidelines Network3, the UK’s National Institute for Clinical Excellence 4 and the US’ National Guideline Clearinghouse5. This trend is also reflected in initiatives by established medical publishers, such as BMJ publishing’s Clinical Evidence6.

The creation of national and other large repositories of guidelines has many benefits, including the provision of an accepted authoritative source of information for practitioners, the opportunity to set quality standards for content and presentation etc. Despite these benefits however the limitations of a purely document-based approach to disseminating knowledge of best clinical practice are increasingly recognised, viz:

- Busy clinicians have little time to read guidelines and converting them from paper to electronic pages may not substantially change this reality.
- Even if a clinician has time to read the content of a guideline it may not be reliably memorised and correctly applied in practice.
- Conventional guideline documents do not provide recommendations that are tailored to the needs of individual patients.

There is therefore growing interest in distributing guidelines in an “enactable” form based on standard formats that are machine interpretable. (e.g. the Arden Syntax and more recently ASBRU, EON, GLIF, Prestige, Prodigy and PROforma7). Technologies based on such formats can provide many services that have been proposed by medical informaticians, including patient-specific prompts and reminders, decision support, monitoring of risks and adverse events, scheduling of clinical tasks and so on.

Publets

A further refinement of enactable guidelines would be to publish them as web-accessible services. A “publet” is an encapsulated chunk of knowledge that has been specifically prepared for network access. It is like a conventional publication in that the preparation may involve familiar disciplines like peer review but it is distinctive in that the knowledge content is wholly or partially formalised for use by a computer, not just to be read by people. This will permit the computer to actively apply that knowledge to support clinical practice at the point of need, via the internet or a secure intranet or extranet.

1 http://hiru.mcmaster.ca/cochrane/cochrane/cdsr.htm
2 http://cancernet.nci.nih.gov/trialsrch.shtml
3 http://www.sigm.ac.uk/
4 http://www.nice.org.uk/nice-web/Cat.asp?c=29
5 http://wwwguideline.gov
6 http://www.evidence.org/
7 See www.openclinical.org for summaries.
8 Publet is a contraction of publication and applet.
ERA (Early Referrals Application) is a set of simple publets which have been designed to help primary care physicians comply with practice guidelines published by the British National Health Service. The guidelines set out criteria for deciding whether to refer suspected cancer patients for urgent specialist services. ERA includes textual material from the paper guideline (translated into web pages) augmented with an enactable procedure written in PROforma. This procedure captures the patient history, interprets it, and advises whether or not referral is appropriate under NHS policy. A typical ERA output screen is shown in figure 1.

Figure 1: ERA referral recommendations

Publet development cycle

Now that it is possible to enact decision support and execute guidelines and care pathways etc. we can expect medical service providers, publishers and other organisations to increasingly adopt such methods. If this is to become routine, however, we shall require appropriate tools and processes for authoring, submitting and disseminating publets.

The National Guideline Clearinghouse invites organizations, societies, and other developers of clinical practice guidelines to submit completed guidelines and related background information [with] two paper copies of each guideline …together with electronic copies on disk (if available) for each guideline submitted”. While the NGC publishes on the web its submission and quality review processes are conventional.

BioMed Central publishes peer reviewed research across all areas of biology and medicine with immediate, barrier-free access for all”. While the peer review process is open and on the web the content is otherwise standard.

Recognising the greater opportunities and needs for future web based publishing, Ida Sim has pointed out that the natural next step in clinical-trials reporting will be to describe trials not just in text but also using knowledge engineering and database technologies to facilitate reporting and retrieval of trial data [1]. For trial banks to be truly integrated, they must share a common conceptual model of clinical trials supported by an appropriately adapted publishing and review process.

An extended publishing cycle for publets is shown in figure 2. The cycle is a simple development from a conventional authoring and editorial process.

Figure 2: A possible publet life-cycle

1. The author prepares the knowledge content that is to be embedded in the publet (guideline, protocol, care pathway, clinical algorithm or other knowledge) using appropriate tools. These may be downloaded from publisher’s sites or used directly over the web; the latter would be preferable where publet development is a group project.
2. As part of the preparation process, the knowledge content of the publet is checked for syntactic correctness and for

9 http://www.doh.gov.uk/pub/docs/doh/guidelines.pdf
10 www.acl.cam.ac.uk/lab/era
11 www.biomedcentral.com
logical adequacy by running the application against patient data.

3. Authors submit the publet to publisher’s web site (e.g. by email) with key words reflecting the content. Authors include the patient data against which the application has been validated.

4. A software agent receives the publet and screens it according to technical and quality standards (e.g. syntactic rules, use of standard clinical terms and, if a standardised conceptual model is available, semantic checking).

5. Submissions that fail screening are returned to the author with an automatically generated report. Acceptable submissions are posted on the publisher’s site, and an acknowledgement, URL and password are returned to the author.

6. The next phase of publication is an adapted form of peer review. The publishing agent maintains a database of reviewers and their areas of clinical expertise and interest. It creates a short-list of reviewers by matching to the keywords provided by the authors. The responsible (human) editor makes a selection and sends the publet’s URL to the preferred reviewers.

7. Reviewers critically evaluate the submission, running the application (over the web) against the authors’ cases and additional test data as needed. An anonymous report is prepared and sent to the editor and authors (along with any additional test data that have been used).

8. If the publisher follows the standard peer review process for conventional publications, a decision to accept, reject or request revisions may be made at that point. However the web also offers further possibilities, e.g. a further “open commentary” step, in which publets are made available for a limited period, together with the anonymous reports, permitting open discussion between authors, referees and community.

9. Accepted publets appear with appropriate ancillary documentation (see discussion below) on the publisher’s web site.

Tools for creating publets

We have created a set of software tools to support a basic version of this lifecycle. The core tool is shown in figure 3. It provides a range of facilities for authoring publets in the PROforma language, checking syntax, testing their correct enactment and submitting the publet to a selected website.

A software agent has been designed which automatically receives PROforma submissions. This provides basic services for installing publets and acknowledging submissions, with the URL of the installed publet. Our agent currently expects the submission to be a PROforma application but we hope to develop a version that can accept submissions in other formats, such as Arden, Asbru and GLIF.

Finally, an enactment engine, Solo, permits users to access any PROforma application and run it in a standard web browser. Following installation, the publet is immediately available for use and Solo automatically creates generic HTML pages for the application [2]. These generic pages can be tailored to provide a “look and feel” for the specific application and/or the imprimatur of the publisher.

![Figure 3: PROforma authoring system](image)

Publet quality management

In order to maintain quality standards for this new kind of publishing, we must develop an appropriate methodology. Some of the quality issues for guideline systems generally are reviewed elsewhere [3] but publets raise additional issues. Since they bring together conventional documents and executable knowledge systems, we can expect that requirements will need to be met by techniques from publishing and software quality traditions.

Drawing on techniques used in conventional publishing, we expect to see the routine use of peer review, as outlined above. As we have observed, however, new forms of
review are likely to be developed, ranging from open commentary to automated semantic analysis and validation against formal models.

Publets must obviously be documented to a high standard. The designers of the Arden Syntax [4] set out a comprehensive documentation scheme for decision support modules. Fourteen general requirements are identified including documentation of \textit{applicability} (e.g. when was the module produced? Which version is this? To what extent has it been validated?) and \textit{library} information, including citations that may support or question the assumptions of the application and its clinical role (e.g. what is its purpose? In what context is it appropriate?!). Publets should include at least this level of documentation, and all of it should be accessible at the point of use.

The enactment of codified medical knowledge to give patient-specific advice is a type of clinical intervention and so is subject to the same \textit{provenance} requirements as any other clinical procedure. Ideally, publets are based on reliable and reproducible evidence of their efficacy and safety. If the content cannot be evidence-based, it should be consensus based.

As a web-based publishing method, publets offer the obvious possibility of including links to research and other relevant background documents (such as the evidence base published in the Cochrane Library and TrialBank). In addition, however, as with “expert” and other kinds of decision support software, the \textit{patient-specific} justification for all recommendations should also be accessible in an appropriate form. Peer review and screening processes should reflect these requirements.

Since a publet is a piece of software as well as a medical publication, the authoring process should support good engineering practice as well as good science and good scholarship.

As the range of available publets develops, there will be an increasing need for a \textit{component-based} approach to design and documentation, both to support reusability and reduce development costs. A publet that offers advice on the management of heart failure, for example, may include a component publet dealing with the use of ACE inhibitors published by an independent source. Quality requirements will therefore include making provision for reuse in the component as well as ensuring access to the component’s own documentation from within the main application. This was one of the original objectives of the Arden Syntax though success has been somewhat limited by procedural and other features of the model [5]. More recent proposals like Asbru, EON, GLIF and PROforma try to avoid such features, though more experience is needed to determine how much reusability is possible in practice.

More critically, as with many drugs and medical procedures, publets may have safety implications if they are used improperly or in settings that are not anticipated by the designers. We therefore follow Wyatt and Spiegelhalter [6] and others in emphasizing the importance of \textit{clinical validation} of publets. Again, this should be routinely supported as part of a systematic publishing lifecycle [3].

Although some version of conventional peer review may be sufficient for assessing the broad efficacy and usability of a publet we doubt that any form of peer review will be sufficient to ensure technical reliability and safety. For this we believe that it will be necessary to adopt the concept of a “safety case” (from the software safety community) for applications where there may be significant morbidity or mortality issues. A safety case documents the safety issues associated with the application together with a description of the design and testing methods used to address them. Techniques for developing software safety cases, including HAZOP (Hazard and Operability Analysis) [7] and safety lifecycles [8] are well established and need to be brought into this field. These techniques are reviewed in detail with reference to medical decision support and guideline systems by Fox and Das [9].

Finally, since publets are designed for use in practical clinical settings we need to consider \textit{usability criteria}. Much is known about good design of screen layouts, command languages, menu design and other interface functions (e.g. [10]). A valuable collection of resources can also be found at \url{http://world.std.com/~ueweb/biblio.htm}. This body of knowledge is as relevant for web browsers and other user interfaces for publets as for any other class of software (e.g. [11]). The body of human factors research aimed specifically at medicine is more scanty, though the demands and constraints of clinical environments seem
particularly challenging (see [12] for a discussion of some general principles).

Conclusions

The internet and also hospital and corporate intranets are becoming an important channel for publishing medical knowledge. We have demonstrated the feasibility of integrating decision support systems and enactable guidelines into such publications, and it seems likely that this will be an increasing feature of medical publishing in the future.

We have argued that the combination of conventional electronic publishing and knowledge engineering will require new methods for ensuring quality and safety. A major component of this will be the development of an explicit publishing lifecycle and associated tools to support the creation of medical content and peer review of the evidence base and usability of the application. The publet should also provide on-line access to comprehensive documentation of the medical content, technical design and safety case.

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REFERENCES