EBMEDS®
CLINICAL DECISION SUPPORT

EBMEDS White Paper

DUODECIM
Medical Publications Ltd.

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Duodecim Medical Publications Ltd

Duodecim Medical Publications Ltd is the leading medical publishing company in the Nordic countries. It is owned by the Finnish Medical Society Duodecim, which is the scientific society for Finnish doctors. One of the key activities of Duodecim Medical Publications Ltd is to collect, evaluate and grade international medical evidence into concise evidence summaries. The most important evidence source is the Cochrane Collaboration, which produces high-quality systematic reviews about various medical topics. Duodecim also has a long-standing collaborative relationship with the GRADE Working Group, the Guidelines International Network (G-I-N) and the publishing company Wiley-Blackwell. The evidence is used for maintaining the Evidence-Based Medicine Guidelines (EBMG) collection, which for the moment consists of over 950 point-of-care guidelines, over 4 300 evidence summaries, over 1450 high-quality images and about 80 videos. The EBMG clinical practice guidelines have been translated into 9 languages.

Clinical Decision Support

Clinical decision support (CDS) integrated into Electronic Health Records (EHRs) provides tools for ensuring that accurate information is available at the right time, in the right context and in the right format in order to assist clinicians to follow the proper clinical processes. This enables user organizations to target higher care quality, better patient safety, higher care efficiency and lower health care costs.

Current CDS systems are generally integrated parts of one single EHR. Although many health care organizations base their practice on the same international guidelines and evidence, local clinical experts and IT staff spend a lot of time deriving and maintaining similar local decision support rules. Sharing and centralizing this work decreases the need for reinventing the wheel and promotes the standardization of care on a local, national and international level. A centralized and collaborative model allows organizations to concentrate more of their energy on localizing and fine-tuning the rules for local use.

EBMEDS – Overview

The decision support system created by Duodecim (Evidence-Based Medicine electronic Decision Support, EBMEDS) is developed and maintained using a collaborative model. The EBMEDS rules are developed and maintained using a web-based collaboration tool, the EBMEDS Rule Editor, which is open for use for trained end-users of the system. Plain text descriptions of published EBMEDS rules are available on the public EBMEDS website. The system also contains an application for testing and demonstrating the function of EBMEDS rules.

Duodecim Medical Publications Ltd acts as the coordinator of the system, and provides a set of decision support rules based on the guideline and evidence summary work that has been done in Duodecim since 1987. The EBMEDS Editorial Team consists of an Editor-In-Chief, a Development Manager, a System Specialist and several physicians (Editors). The editorial team works continuously on preparing new decision support rules and maintaining and updating existing rules. The editorial team of EBMEDS works in close collaboration with the editorial teams of EBM Guidelines in Finland, Austria, Germany and Belgium, and with international partners. The Duodecim team is also responsible for maintaining and developing the technical framework of the system.

In the EBMEDS context clinical decision support is defined as providing health care professionals (physicians, nurses, pharmacists) and citizens with patient-specific guidance based on data stored in patient data repositories, such as EHRs. EBMEDS provides

- links to guidelines based on the diagnoses of the patient
- clinical reminders, prompts and alerts based on an analysis of patient data
- quality measures describing evidence and guideline compliance
- "smart links" opening electronic forms and populating them with clinical patient data from the patient data repository
- reports and statistics based on the log files into which all the request and response messages of the system are stored.

Architecture and Integration

EBMEDS follows the concept of service-oriented architecture (SOA) (figure 1). The application is written in JavaScript, and is deployed using Docker containers, making it available on a variety of platforms. EBMEDS has been successfully installed on Windows, Linux/Unix and Macintosh servers, but Linux is recommended for maximum performance.

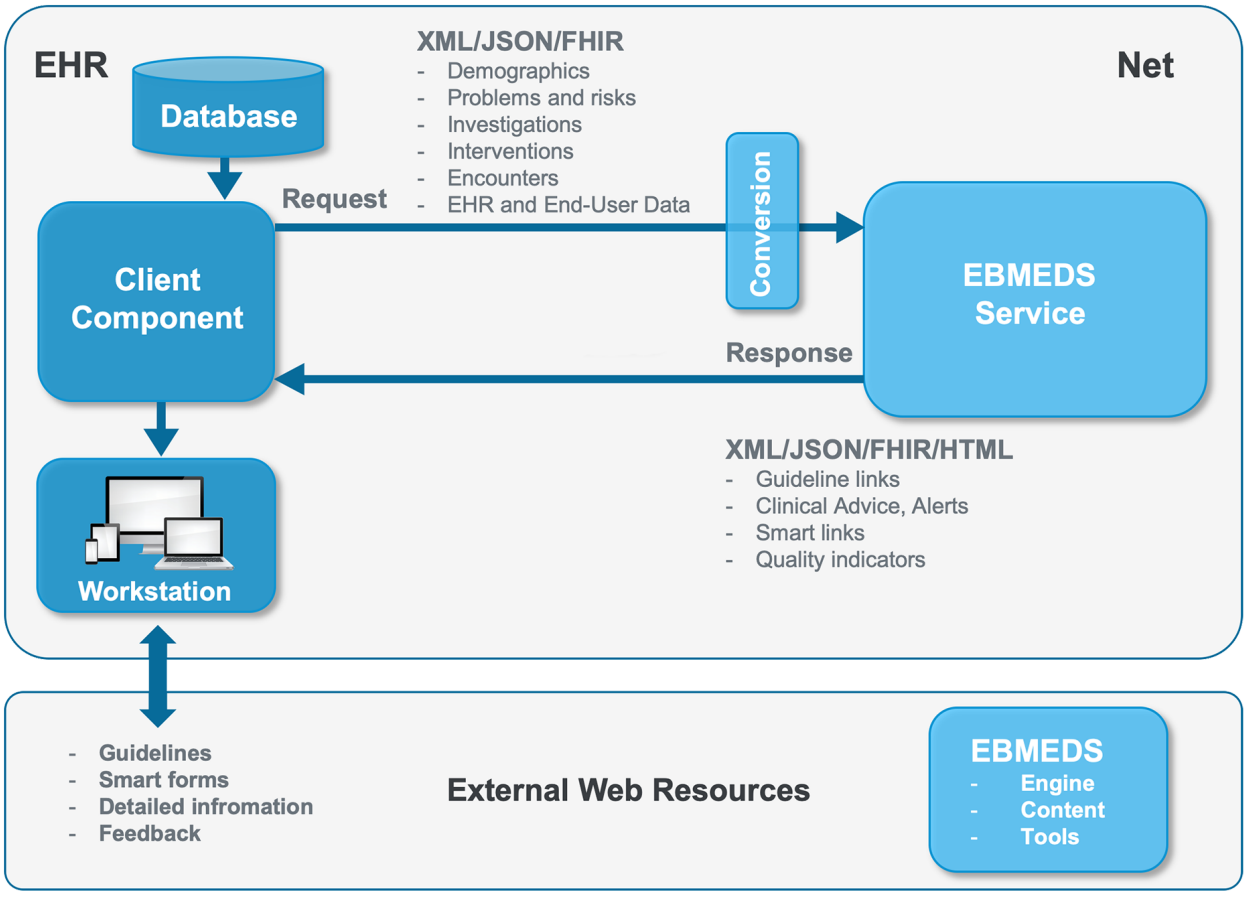

Figure 1. EBMEDS Architecture

EBMEDS provides an API that can be consumed by any patient data repository that has access to structured patient data. The data repository is usually part of an EHR system, but it may also be an independent

repository. The patient data needs to be converted into one of the formats EBMEDS understands before analysis, so a simple adapter layer and client component must be developed by local IT developers familiar with the content and structure of the data repository. The client component also receives the response message from EBMEDS, parses it and displays the feedback in the EHR or data repository user interface. EBMEDS does not have a user interface of its own - it only returns structured feedback.

The supported data formats for the request message are a native XML schema, a native JSON schema, and initial support for FHIR STU3 (with more FHIR support available as the standard develops). The response format can be any of these, with the added option of a simplified, embeddable HTML response.

The performance requirements for a minimal deployment of the service are modest. However, EBMEDS is fully horizontally scalable and can therefore theoretically handle any server load. Typical patient datasets are analysed in under a second, although more complex cases require more processing time.

EBMEDS can be installed as a local service or as a centralized solution serving many organizations at the same time.

Patient Data

EBMEDS requires input of basic and clinically relevant patient data to work. EBMEDS is not able to analyse free narrative text - only structured data can be used in the analysis. Structured data basically means that data must be recorded in slots that have been designated for precisely that kind of data, often conforming to a standardized way of representing the data. This ensures that the data can be interpreted correctly by the CDS. The main data groups EBMEDS is capable of analysing are:

- *Demographic data*. The age, gender and ethnicity of the patient.
- *The diagnosis list*. This list should contain structured data about the permanent diagnoses of the patient and the acute diagnoses or problems from the last four years.
- *The risk list*. Information about risk factors of the patient, such as the smoking status, pregnancy status and information about drugs that have caused adverse effects earlier.
- *The medication list*. This list should contain data about the permanent medication of the patient and the temporary and on-demand medication from the last four years.
- *The vaccination list.* All available data about past vaccinations.
- *The laboratory result list*. For laboratory results, only a short series of the freshest results used in the decision support are needed. Results older than 5 years can usually be omitted from the request – with the exception of e.g. gene test results. Only laboratory results used by the EBMEDS system need to be included in the request message, and these laboratory investigations are listed in a separate XML file. It is important to restrict the number of laboratory results in the request, since large amounts of data may impair the performance of the decision support service.
- *The clinical measurement list.* Results such as height, weight and blood pressure.
- *The procedure list.* Data about all past procedures.

As mentioned above the patient data must be coded. However, EBMEDS supports the use of multiple coding systems, which are mapped to the internal alias system of EBMEDS. EBMEDS also supports the use of multiple measurement units. All measurement units are converted to the internal units of the system during the analysis, but the reminders always use the same units as those used in the request message.

The client component generates and sends the request messages following certain events or triggers in the EHR. The request messages always have the same structure and content, but the triggering event may affect the contents of the response. The most common triggers are opening of a patient's record, prescribing a new drug and setting a new diagnosis.

The structure and content of the request message is defined in an XML Schema (the EBMEDS Basic Interface).

Decision Support Rules

The patient data is analysed using decision support rules written in JavaScript. The rules are designed using the web-based EBMEDS rule editor application. The rule editor is the interface to the central EBMEDS database, from which the entire EBMEDS dataset is generated for each release. Trained end-users are allowed to use the rule editor to localize existing rules and prepare new local rules.

The rules are organized into several independent modules (figure 2), and every module may be used or left unused depending on e.g. data availability in the data repository and already existing functionality in the EHR. The modules are based on Duodecim or third-party data sources. Additional data sources can be introduced in collaboration with Duodecim.

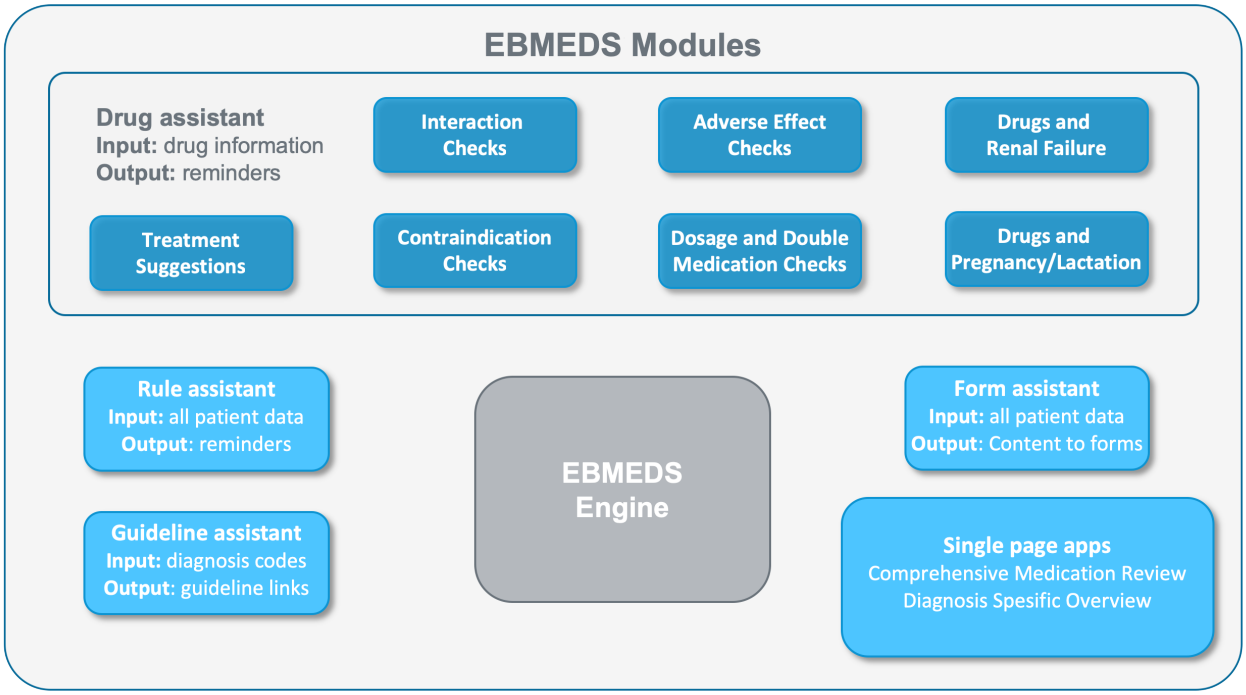

Figure 2. EBMEDS Modules

Descriptions of published decision support rules are available in the "Scripts" section of the EBMEDS web site (https://www.EBMEDS.org). The documents contain a plain language summary describing the functionality in a few words, links to the evidence (Cochrane reviews, Evidence Summaries from the EBM Guidelines and references) and the script messages.

1.1 Links to Guidelines (Guideline Assistant)

The simplest form of CDS is automatic linking to guidelines and other suitable information sources. EBMEDS generates a patient-specific link list according to the diagnoses of the patient. The default guideline collection is EBMG, but other collections may be added after indexing them with diagnosis codes.

1.2 Clinical Reminders (Rule Assistant and Drug Assistant)

Most EBMEDS rules return clinical reminders. Some rules compare patient data to the EBMEDS Datasets, and each datasets can return thousands of reminders. The rules based on data sets generate

- drug interaction reminders
- drug contraindication reminders
- drug choice suggestions (indications)
- reminders of drug restrictions and dosing in renal malfunction
- reminders of drug restrictions during pregnancy and lactation

Other rules are designed for unique clinical situations and return only one or a few reminders. Almost all rules are linked to descriptions of the rules including the reminder texts and evidence data. Most rules also contain quality indicators for showing guideline and evidence compliance.

The primary language of the EBMEDS system is English. However, as the reminders are short they are easy to translate into other languages. Usually the translation is performed by a physician. At the moment, reminders are provided in several languages.

1.3 Redistribution of Patient Data (Form Assistant)

Some reminders contain links to external web resources, and these links may also transfer patient data to different kinds of electronic forms. In this way, EBMEDS can redistribute patient data stored in the patient database into new environments. This saves time for the health care professionals, who have to enter the data only once (into the EHR). Some targets for this kind of data redistribution are

- the Comprehensive Medication Review (CMR), which displays 1) the current medication and the probable indications, 2) relevant laboratory results and 3) decision support reminders relevant for the medication including interaction, contraindication, drug dosing, pregnancy and lactation checks and dosing in kidney/liver failure, 4) a table of the total adverse effect load caused by the patient's drugs (includes suggestions of alternative drugs which may decrease the total adverse effect load)
- the dynamic diagnosis-specific overview, which displays clinically relevant patient data, decision support reminders, links to relevant risk calculators and guideline links according to the selected diagnosis
- clinical calculators, which can be pre-populated with patient data
- interactive algorithms showing the location of the current patient in the pathway
- interactive referrals and certificates, pre-populated with relevant patient data.

Population analysis

As for a single patient, analysis can also be performed on an entire population. Instead of displaying the analysis results for a patient immediately to a medical professional, the results are saved and aggregated in a database. Many EHRs provide statistics on the data they contain, but on top of that EBMEDS provides unique insights on the data that is "missing" in EHRs; unrealized care, conflicting medication, care quality etc.

Quality Process

The quality process of EBMEDS is described in detail in the document "EBMEDS Quality Plan", which is available on the EBMEDS website. The *development of decision support rules* is divided into four stages: 1) the description stage, 2) the programming stage, 3) the testing stage and 4) the maintenance stage (figure 3). Quality requirements have been defined for each stage, and quality problems may require stepping back to an earlier stage.

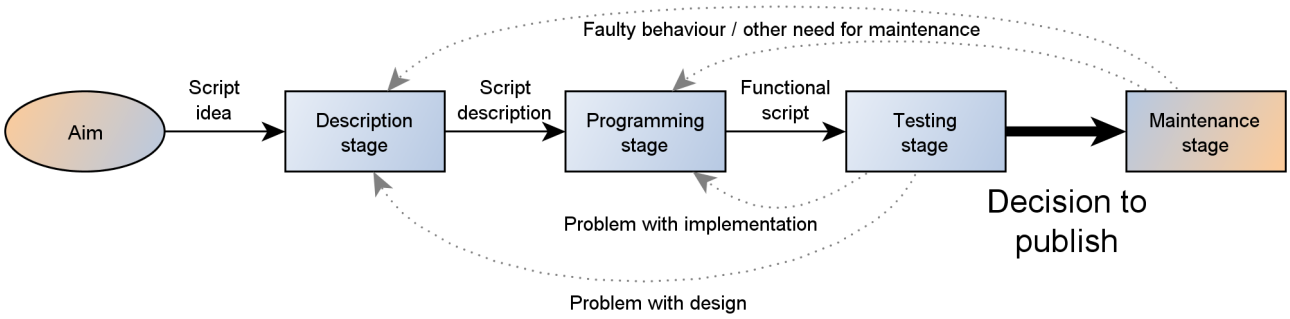

Figure 3. EBMEDS Rule Stages

Development and maintenance of the EBMEDS system also involves quality affecting *parts that are not directly related to the production processes of individual scripts*. Examples include collecting information on user experiences, development of the EBMEDS framework and function libraries, and proactively monitoring quality affecting development in the environment that EBMEDS operates in.

Summary of Intended Use

Within the European Union medical software applications are classified as medical devices according to the Medical Device Directive (MDD). EBMEDS is to be classified as a MDD class I device carrying CE marking. The intended use for EBMEDS as a medical device is defined as follows:

"EBMEDS is intended for use together with health information systems such as electronic health records and other similar software that are able to provide EBMEDS with high quality structured data. EBMEDS provides clinical decision support based on patient data for healthcare professionals and – where appropriate – patients. EBMEDS intends to provide clinical knowledge and patient-related information, intelligently filtered or presented at appropriate times to guide and improve the diagnosis and treatment of diseases and similar conditions, warn about potential mistakes, and aid in the execution of healthcare related processes. It is also possible to use EBMEDS for analytical and research purposes, such as data mining from populations."

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