Towards a National Clinical Decision Support Framework for Norway: Expert Assessment and Proposed Architecture

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Abstract— **Computerized Clinical Decision Support (CCDS) is an important component for making available latest medical evidence at the point of care. With the aim to gain knowledge on the best approaches for implementing a nation-wide CCDS, we performed a survey by sending an extensive questionnaire about CCDS architectures, use of standards, and use of terminologies to international experts and CCDS vendors. The responses to the questionnaire were analyzed and mapped to the requirements of the Norwegian health IT context. With this correspondence between responses and requirements, we designed a national architecture with the components needed for providing CCDS at a national scale in Norway. The architecture leverages different components aiming to allow supporting several standards and terminologies, performing both national and local governance, reusing CCDS functionality, and adapting CCDS modules to local contexts.**

Keywords- E-health Services; Clinical Decision Support; Clinical Guidelines; Computerized Clinical Decision Support; Interoperability; Software Architecture; Electronic Health Records.

I. INTRODUCTION

The Learning Healthcare System concept has motivated efforts in different areas of the health Information Technology (IT) realm worldwide [1]–[3]. Examples are the general adoption of Electronic Health Records (EHRs), the development of health data analytics platforms, the development of data reuse networks, and the definition of large-scale clinical decision support frameworks [3]–[5]. In this context, Norway has allocated significant funds to build momentum for advancing medical informatics [6]–[9]. EHRs have been adopted to enable data reuse including highly structured formats, such as openEHR [10]; projects for data reuse have been funded setting the basis for what later has become a national primary care research network [7]; and several initiatives have provided knowledge on best approaches for Computerized Clinical Decision Support (CCDS) interventions [11]–[14]. CCDS systems are software systems designed to provide useful information at the point of the clinical workflow when it is needed. Previous projects about CCDS have provided very valuable knowledge specifying requirements and success factors during EHR adoption. However, when it comes to building a large-scale national infrastructure to govern and manage CCDS systems, knowledge about their architecture and organization is still needed. On the one hand, it is needed to better understand how to optimally leverage the plethora of technologies, clinical information standards, and biomedical terminologies; and, on the other hand, it is needed to determine how to organize the development and management of CCDS algorithms. The Norwegian context, is complex as a result of a mixture of legacy and recently introduced Health Information Systems (HIS) that operate using different clinical information standards and terminologies. For example, the main vendor of hospital information systems relies on a free text EHR, and has been evolving it into an openEHR-based EHR [10]. The Central Norway Regional Health Authority, recently procured Epic for its introduction in the incoming years. Regarding terminologies, Norway uses the International Classification of Diseases (ICD-10), the International Classification of Primary Care (ICPC-2), and other well established terminologies [15]. In addition, Norway has recently become a member of SNOMED International [16]. Currently, the aim is to pilot parts of SNOMED-CT for clinical use in the Central Norway Health Region. This scenario poses requirements for CCDS systems that need to be able to work in a multi-standard environment with various Clinical Information Models (CIMs) and terminologies.

In order to design strategies for this scenario, the Norwegian Directorate of E-health (NDE) requested a survey from the Norwegian Centre for E-health Research in order to get information about CCDS, clinical information standards, and biomedical ontologies. Thus, in 2017, we performed a study enquiring CCDS experts and vendors about different topics that directly affect CCDS infrastructures. A summary of the results was published in two reports [17] [18]. In this paper, we provide a more detailed and deep analysis of the responses, and we map them to the Norwegian scenario drawing an architecture that leverages, on the one hand, the advise from experts and, on the other hand, the requirements of the Norwegian scenario. The remaining of the paper is organized as follows. Section 2 presents the methods for performing the survey and analyzing the results. Section 3 presents the results of the analysis of the questionnaires by inductively analyzing them and collating the information to form main categories of recommendations, observations, and future perspectives. It also provides the architecture

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designed using the information gathered for covering the Norwegian requirements regarding the CCDS domain. Finally, Section 4 discusses the architecture proposed and relates it to previous studies.

II. METHODS

We performed a survey as part of two studies performed for the Norwegian Directorate of E-health during 2017 [17] [18]. The survey was sent to 25 experts and vendors on CCDS. Among the representatives invited to participate, there were researchers, consultants, and vendors. Thirteen respondents were vendors and 12 were experts in CCDS or biomedical ontologies. The invited participants were known companies, researchers, and consultants of the CCDS arena. It was a requirement for the invited participants to be involved in CCDS projects that had been deployed in an operational environment, and not only in research academic projects.

Of the 25 invited participants, 11 responded agreeing to participate. Of these, finally 9 provided the completed questionnaire requested. We sent a word document with all the questions to be answered that the respondents could edit freely without a word limit. The complete questionnaires are available at the previously published reports [17] [18].

Eight participants provided extensive information about the topics and the architecture of their CCDS interventions. Respondents provided schemas and detailed descriptions in their CCDS interventions. In addition, all participants shared impressions and their future vision regarding the CCDS arena. Among the participants that agreed to participate, we received 8 completed questionnaires. Four questionnaires corresponded to researchers involved in small CDS companies and research, and 4 corresponded to major vendors. One of the respondents was an expert on biomedical ontologies who participated as an active developer of them, but that did not have experience with CCDS. This respondent completed only the part of the questionnaire associated with ontologies and not CCDS. We collated the results by marking the topics that appeared in each of the responses. We proceeded inductively grouping the topics identified in main categories and subcategories. This categorization was used to report the results that follow.

III. RESULTS

A. Overview

We identified the following main categories and subcategories: a) *software architecture and information standards*, with the subcategories architecture, and *clinical information standards*; b) *biomedical terminologies*, with subcategories *role of terminologies in CCDS* and *ontology-based terminologies*; c) *Organization, governance, and shared development*, with subcategories *authoring*, *governance frameworks*, and *local adaption/customization*; and, d) *Knowledge base (KB)*. The best design factors identified in the survey were used to develop the proposed architecture. The following describes, first, each of the categories identified in the survey and, second, the architecture developed from the survey results and adapted to the Norwegian context.

B. Software Architecture and Information Standards

1) Architecture

Respondents considered the following aspects if the architecture as critical: speed, concurrent support for many clients, high availability and error tolerance, support for interoperability standards, and support for both EHR and population queries. With this regards, all the respondents agreed that, in general, Service Oriented Architectures (SOAs) were the optimal choice for fulfilling the mentioned requirements in large and distributed CCDS environments. That is because SOAs encapsulate CCDS functionality making it available to various clients through a Web service, thus enabling concurrent support, easier fault tolerance, interoperability, and support for queries over disparate systems.

More specifically, the use of RESTful stateless Web service architectures is also seen as beneficial for simplifying the architecture. Both synchronous and asynchronous ways of operating are needed. One respondent wrote that, in general, SOA is better but it is important to understand the requirements because the optimal architecture may be a mixture of some approaches (SOA, stand-alone, process oriented, etc.).

Another advantage of the encapsulation provided by SOAs concerns the inference engine and logic specification mechanisms. When it comes to the decision algorithm, respondents considered that SOA allows encapsulating any algorithm implemented in any technology inside the Web service. This algorithm is then exposed through a standard API based on information standards. This way, SOA alleviates the need of a separate formalism (e.g., Arden syntax) that is later translated into the language used by the inference engine. For example, openCDS operates directly with JBoss Drools instead of using another specification formalism for abstracting the logic representation [19].

One respondent considered that, although for reusing CCDS functionality SOA was the optimal solution, embedding the CCDS functionality within the EHR had advantages too. The reason is that embedded CCDS provides better performance due to the possibility of performing pre-processing of data structures that makes significant data are rapidly available when a CCDS triggers.

2) Clinical Information Standards

Standardization of CCDS was considered essential by all respondents but with subtle differences. Most respondents considered standardization of the CCDS data schema, a.k.a. Virtual Medical Record (VMR), and the SOA payload as paramount for all CCDS systems. Standardization was seen as a way to communicate the payload of Web service

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messages in and out of the CCDS Web service in a normalized way that all clients can understand. This approach makes the CCDS client (often an EHR) responsible for committing to that standard data format.

Recalling the previous section, one of the respondents indicated the advantage for embedding CCDS into the EHR, but acknowledged the need for standardization in a national-level CCDS. Another respondent leveraged both views by relying on openEHR for both the VMR and the EHR. This approach can directly reference the same standard information schema that the EHR relies on. In order to implement such design, both the EHR and the CCDS system need to work on the same set of openEHR archetypes or rely on effective abstraction mechanisms. However, this is not always easy to achieve having CCDS and EHR operating at different levels of granularity. It is likely that several standards will coexist and that transformation mechanisms will need to be provided as discussed below.

The role of HL7 Fast Healthcare Interoperability Resources (FHIR) is considered very relevant as a standard for sharing patient data extracts with CCDS Web services. For CCDS interoperability, FHIR is the preferred standard by respondents since they claimed it to be the one with the highest acceptance rate across vendors. In addition to the FHIR standard, there is the library for authentication and integration, SMART [20]. SMART on FHIR was seen as a positive but not critical addition on top of FHIR. One of the respondents considered it to be particularly useful for authentication; while other pointed out the value regarding its applications deployment framework. For example, one respondent remarked the possibility of using SMART for showing context-specific data with graphical user interfaces (with relevant data, literature, etc.). Regarding the implementation of the VMR, one respondent mentioned HL7 vMR as a very comprehensible standard; however, the same respondent also pointed out that it had a low adoption rate. Noteworthy, the open source initiative openCDS has developed conversion mechanisms from HL7 vMR to FHIR [19]. Two respondents used proprietary formats, and one used openEHR archetypes.

A standard mentioned for embedding CCDS functionality in the EHR was CDS Hooks [21]. Respondents considered CDS Hooks a useful and disruptive standard for embedding CCDS requests in the appropriate part of the clinical workflow. Thus, it may allow some context awareness if it is used in the appropriate way. One respondent pointed out that CDS Hooks still needed to be extended and constrained. Actually, while writing, it is a Standard for Trial Use (STU) release in its version 1.0 [21]. Several respondents pointed out that for new CCDS developments CDS Hooks should be seriously considered since it allowed to perform workflow aware CDS actions (triggering at a precise point of the clinical workflow) and accelerate CCDS implementations.

Another relevant topic is the management of CCDS systems in environments where several information standards coexist. This is the Norwegian case where openEHR is used for structuring EHRs in secondary healthcare and FHIR is recommended for EHR extracts exchange [22]. In this case, the respondents pointed out the complexity of the scenario and the need for implementing transformation methods among different standards. To that end, several solutions were proposed. One respondent mentioned that, for this kind of complex scenarios where iso-semantic models were present, a common agnostic representation would be needed. Another respondent indicated that when several information models are present, the messages will need to be written using a normalized model of choice, which is preferred by the national centralized system. Client systems not supporting such a model natively will need to transform to and from that model in order to consume the national CCDS.

C. Biomedical Terminologies and Ontologies

1)Role of terminologies in CCDS

Respondents considered that terminologies play a critical role. Respondents agreed that the CCDS main function is to avoid ambiguity and allow identifying the same concept in multiple ways, thus providing a standardized way to define CDSS criteria at the points of care, population management queries, and predictive analytics. For coherence, the management of terminologies should be centralized if possible. Terminologies are essential for expressing the semantics of patient data and the recommendations captured within terminology concepts, therefore the inferences over terminology concepts are needed within any CCDS. Terminology concepts have been used for content binding providing the subset of possible values to fill a specific slot in a CIM, but also as a semantic binding for specifying the meaning of a specific element of the CIM. The use of CIMs in combination with terminologies is not a clear issue and, as we pointed out in previous studies, it is still dependent on the needs for automatic interpretation of clinical data [23] [24].

With regards to terminologies, the situation is similar to the one of CIMs. Proprietary terminologies will need to be mapped to the reference value sets used by the national CCDS. The value sets used by guidelines need to be governed and maintained.

2) Ontology-based terminologies

We asked our respondents about the use of ontology-based terminologies. We use the word ontology in the computer science sense, i.e., classifications with some description logics or model-theoretic semantics underpinning. The only ontology used by the respondents was SNOMED-CT.

Most respondents considered that ontology-based terminologies such as SNOMED-CT could be useful for the maintenance of complex terminologies, the maintenance of CCDS rules, and the definition of mappings across terms from different terminologies. Regarding mappings among terminologies, respondents also pointed out that mappings and transformations should be made with caution. One respondent warned that, for example, “topical steroids and

systemic steroids have different contradictions"; thus, "mapping all drugs that contain steroids may lead to inappropriate recommendations from CCDS systems". The same respondent made two observations about the definitions of value sets using SNOMED-CT. The respondent pointed out that SNOMED-CT has many inconsistencies in its logical structure; and, for this reason, a better way to proceed is to manually curate the concepts into explicit value sets than using logic definitions over SNOMED-CT for defining subsets.

We asked our respondents about the use of other ontology-based terminologies, e.g., for allowing EHRs to support genomic medicine, but all of them agreed on the fact that this aspect is considered as not crucial at the moment. SNOMED-CT has sparse support for molecular biology and more specific ontologies would be needed for that. One respondent actually said that simpler CCDS functionality that does not require complex semantic analysis should be first implemented.

Curating and pre-processing of ontologies into the internal CCDS format is common. Also, implementing support for third party terminologies is needed due to the amount of proprietary code systems. Other vendor considered a better solution to be in an inside-system embedded for performance without a specific Terminology Server (TS).

The use of the logic underpinning of SNOMED-CT was rather sparse. As the expert in ontologies indicated, currently the formal semantics of SNOMED-CT are used for the maintenance of the terminology itself, e.g., when defining new concepts. The only use from its underlying logic model was subsumption. Subsumption ("is-a" relationships) reasoning is considered useful for facilitating the setup and maintenance of rules in CCDS, but respondents observed that in order to truly use this capability, a supportive infrastructure is needed. SNOMED queries would require the SNOMED OWL representation and a classifier.

D. Organization, Governance, and Shared Development

1)Authoring

For implementing a national CCDS infrastructure respondents indicated that there should be a sufficient collaboration among clinical centers. Those centers should discuss about the national clinical practice guidelines to base the computerized CCDS on. According to them, authoring tools are needed so that different stakeholders can collaborate in a distributed manner having discussions and defining clinical decision algorithms. Respondents considered that a national portal with narrative and semi-structured guidelines can be helpful in the CCDS development. In addition, two respondents indicated that measuring and monitoring the impact of CCDS interventions would be needed to clarify their effect and decide on their long-term maintainability. Another respondent recommended the locally deployed CCDS environment for performance.

For Computer Interpretable Guidelines (CIGs) one respondent recommended to start by defining the goals that the CCDS intervention pursues and then, once the goal is clear, to identify the steps towards improving that goal. Other vendor with CIGs implementation experience pointed out that for each clinical guideline, a medical specialist is appointed. That specialist is often a national or regional leading figure that already has active participation in guidelines development. That specialist is the one responsible for the acceptance and follow-up of the deployment.

2) Governance frameworks

Respondents agreed that the architecture for the governance framework should enable access to terminology services, access to evidence-based guidance, and access to editorial tools for the development and maintenance of CCDS content. Respondents pointed out that CCDSs need to be shared and contrasted among organizations. To that end, organizations should gradually incorporate more CCDS modules performing pilot interventions and running studies to evaluate them. Thus, gradual adoption of CCDS was considered as an important factor.

A mixed model for governance was recommended. On the one hand, a centralized governance body for guidelines development and governance should be settled. On the other hand, smaller local governance bodies should exist in the institutions that could actually make use of the CCDS services. The editorial teams should have cross-membership between the central and local governance bodies. The centralized workgroup would coordinate subgroups and delegate work to the other CDS editorial groups.

3) Local adaption/customization

One respondent recommended for a maximum standardization without too much localization to work defining guidelines incrementally from narrative to structured format. The same respondent proposed a layered organization of rules. In such organization, the most internal levels of the CDSS represent goals, while more external levels represent recommendations. The latter are adapted as local workflows (indicating when and who to show recommendations to).

Respondents also agreed on clinical guidelines to be built via consensus, and once their content is agreed, they should be pushed to the EHR with the consent from clinical users. Consequently, respondents recommended to start with non-controversial content and develop reusable CCDS modules from parts that are not dependent on the local context. These modules will become the building blocks of more complex CCDS to be adapted in the local context.

E. Knowledge Base and Inference Engine

In this section, we summarize the responses with regards to the KB and the inference engine. By KB we mean the set of rules that conform a CCDS algorithm to provide a recommendation (in the case of rule-based systems); or the

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statistical model that performs an estimation/prediction (in the case of statistical or machine learning models).

Regarding the specification of medical decision algorithms, rule-based and logic-based methods (i.e., rules-based and ontology-based ones) are seen as the most intuitive and efficient ones. Respondents considered logic-based methods as intuitive and simpler for knowledge management. Graph structure formalisms such as GLIF were considered difficult to implement and integrate. In addition, latest approaches such as FHIR Plan Definition are considered more flexible and easier to translate to different inference engines. Several respondents considered that the formalism of specification could be the one provided by the technology to perform the inferences (e.g., JBoss Drools). To that end, it should be hosted in a Web service, and it should be made accessible through a standard API.

Respondents considered statistical methods to be important but more effort intensive for certain scenarios. Some systems report to use rules but trigger the invocation of a statistical model when necessary. Nevertheless, all respondent pointed out that the use of machine learning and statistical models are becoming increasingly relevant and those should be considered when appropriate.

F. Proposed National Architecture for Norway

Following the opinions and comments from the respondents, we draw a general architecture covering the requirements to be fulfilled in the Norwegian scenario for building a nation-scale CCDS framework. The schema in Figure 1 depicts the architecture proposed for a national centralized CCDS service.

At the top of the figure, it is shown a national governance committee that uses a common online authoring tool for designing CCDS modules based on best practices. CCDS modules are minimal stand-alone algorithms that serve a CCDS purpose in a context and that may be combined forming more complex CCDS flows. The national governance and editorial committee depicted use semantic interoperability resources provided by external repositories. These resources are of two main types: a) externally curated and approved terminology value sets; and, b) CIMs that may be FHIR profiles approved for national use, or openEHR archetypes published by the Norwegian Clinical Knowledge Manager. The governance and editorial committee use these artifacts imported through the authoring tool as the data schemas referenced by the decision logic that they define. This coupling of algorithms, CIMs, and terminologies, should be done through a proper graphical user interface that shows only the relevant information. Fine-grained technical details should be managed by the backend automatically.

The Norwegian context currently has organizations that base their developments on openEHR , FHIR, or both. The authoring tool allows for building CCDS algorithms that reference one standard or the other, thus creating a CCDS library where some algorithms use openEHR as a VMR and the others use FHIR as a VMR. For example, algorithms aiming for performing CDS in hospitals that belong to the regions working with an openEHR-based EHR should be written taking nationally published archetypes as a basis. Conversely, regions or services using FHIR may ask the editorial committee to prioritize the design of the algorithm using FHIR as an information schema for the VMR. Since CCDS modules require lots of professionals to be developed, their cost is very high. This poses a need for performing transformations among openEHR and FHIR in order to allow clients to use algorithms regardless of the standard they are based on. In Figure 1, the cloud between the FHIR and openEHR boxes represents transformation software. This way, a system operating in FHIR should be able to invoke a CCDS algorithm that was designed using an openEHR VMR. The client will invoke the FHIR endpoint (interaction n) and, internally, the received FHIR payload will be transformed into openEHR compliant extracts (interaction i) to execute the algorithm. Once a response is provided, data will be transformed back into FHIR compliant data (interaction i) and returned in the SOA payload to the client (interaction n). For openEHR clients with the need to invoke a FHIR-based CCDS algorithm the situation is the inverse.

When an algorithm is not logic- or rule- based, the statistical models component is invoked in a similar way to the described above (see interaction lines j and k). Statistical models should be imported in Predictive Model Markup Language and approved by the governance and editorial board. In some cases, as described by one respondent, rule or logic-based algorithms delegate some part of the computation to a statistical model. In this case, the presented architecture allows the models that contain logic-based models to do so (see interaction lines *i* and *m*).

The Web service layer represents the interface offered online to the clients of the CCDS framework. Two main endpoints should be offered, one based on FHIR compliant payload, and the other based on openEHR-compliant payload. This way, different iso-semantic models used by clients can be utilized. For example, Hospital C represents a hospital in Central Norway health region where openEHR is not adopted, thus interoperation is based on FHIR. The national framework should allow such hospital to consume a CCDS module developed by other regions that rely on openEHR. This is possible by using the transformation mechanisms previously described.

Finally, the human-like figures at the extremes of the bottom of the figure represent local governance and editorial committees that are responsible for approving and, if needed, adapting certain CCDS module to their organization local context. As recommended by the respondents, these committees should coordinate their actions with the national governance and editorial committee in order to properly escalate the CCDS interventions and developments (see interaction lines *a* and *b*). When adaption to the local context has been performed, the new modified modules should be made available for contrasting them with other deployments. This is shown in the layered architecture represented in the two logic CCDS modules. In that approach, CCDS modules

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are layered, containing on the top layer a "core" set of the main goals to fulfill. Secondly, there is an implementation of the parts of the CCDS actions that are common to all contexts and that are uncontroversial. Finally, these logic components are specialized each into a more superficial layer that is exposed to the clients. These superficial layers are the ones adapted to the local context of each organization when needed. This adaption is performed with exhaustive control from the committees in order to minimize deviations from the original algorithm and guarantee future scalability and governance. It is important to understand that, although the figure shows only one Web service, there may be several instances of the CCDS Web service with different collections of the CCDS modules available. Currently, this is achievable by using containers technologies such as Docker and Kubernetes.

IV. CONCLUSION

The proposed architecture attempts to agree with many of the principles for already published best practices. For example, Kawamoto et al. [25] recommended the SOA architecture for large-scale CCDS. We believe that the recent developments in openCDS will help in setting a reference for that [25]. Actually, many of the components required to build a national CCDS infrastructure could be borrowed from openCDS and openEHR GDL [26]. Since both are open-source projects, many of their components could be merged to build the multi-standard framework presented.

Regarding the internal structure of CCDS modules, the layered architecture of CCDS modules is based on the concepts proposed by Boxwala et al. [27], but in the most internal layer, instead of narratives, we prioritize the inclusion of the main goals to achieve in the clinical setting as recommended by one respondent and proposed elsewhere [28]. The transformation mechanisms between FHIR and openEHR can be based on previous research [29].

Despite machine-learning has recently received lots of attention, our respondents considered that for CCDS there are some "low hanging fruits" to be focused on before building complex artificial intelligence frameworks at national scale. In addition, as pointed by Fox [28], logic formalisms have demonstrated to be as good as Bayesian methods for specifying medical knowledge. This does not imply that we should not perform research in machine learning. But it means that we still need to be able to deploy large-scale CCDS frameworks where the most pressing challenges are related to governance, adaption to local contexts, and different information and knowledge representation formats. We believe that once these requirements are clear and a proper edition and governance framework is in place, most machine-learning algorithms will fit in the framework. These algorithms will complement logic-based CCDS modules when required, thus leveraging the best from both logic and statistical methods.

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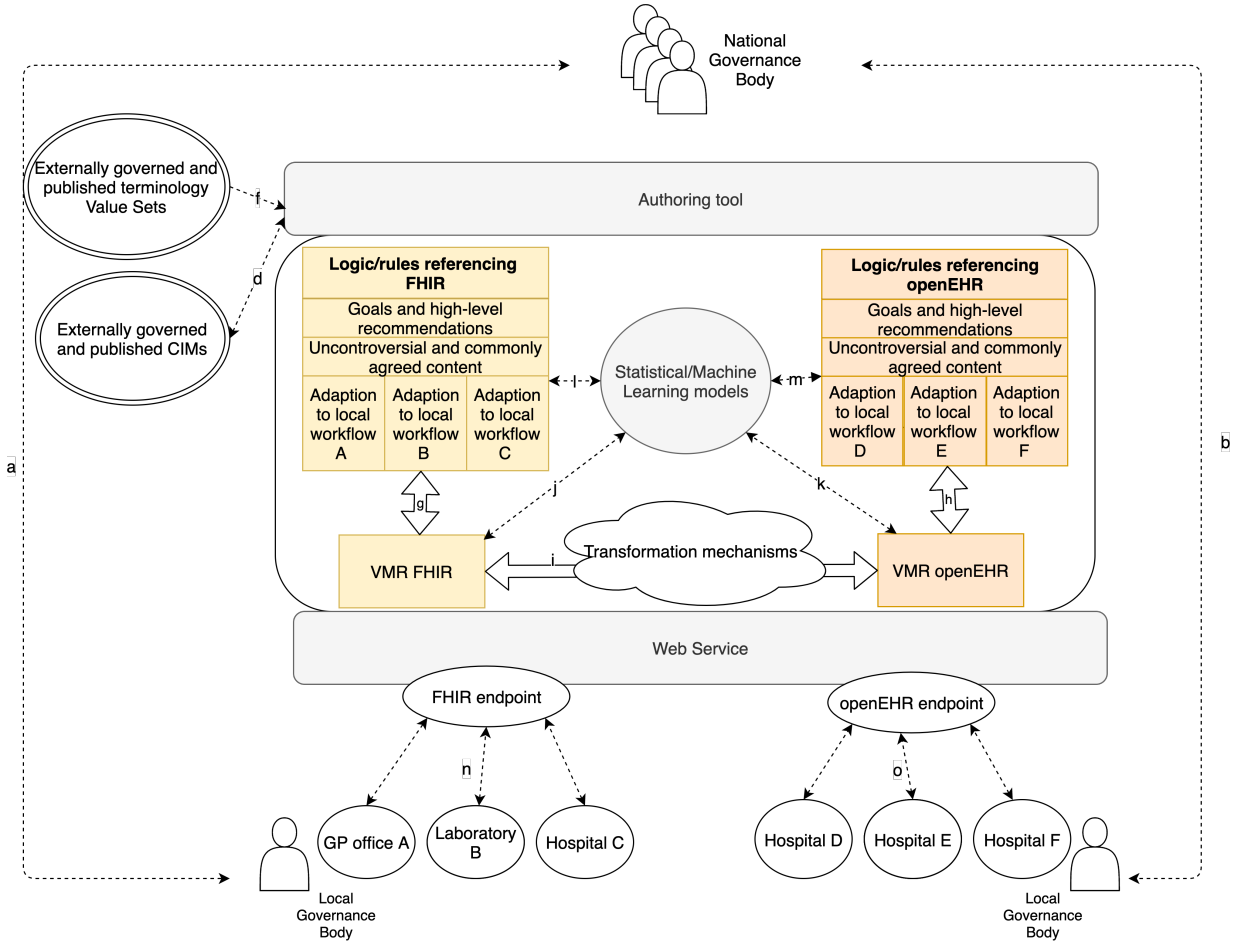

Figure 1. Architecture for the edition, governance, and deployment of CCDS in the Norwegian context.