Workshop #1: Graphical CDSS authoring tools for increased transparency and efficiency

The workshop was held on 5 December 2023 between 11 am and 1 pm during the Global Digital Health Forum that took place at the Bethesda North Marriot Hotel & Conference Center, Rockville, MD, USA.

We took advantage of the conference in order to gather many relevant participants from clinical and IT backgrounds who are directly involved in Clinical Decision Support Systems (CDSS), especially content generation, adaptation and deployment.

Description

CDSS have demonstrated significant improvement in adherence to guidelines and quality of healthcare. However, development and implementation of CDSS are hindered by the need of advanced programming skills, which in turn make the coded clinical logic difficult to understand, validate, and update to keep up with advances in medical evidence. There is a realization that a graphical CDSS authoring tool would reduce reliance on advanced programming skills, thereby increasing efficiency (and reducing cost) while increasing transparency of the decision logic in knowledge-based deterministic CDSS. Our team has developed two such tools called Medical Algorithm Creator (medAL-creator) and The Rapid Implementation of Clinical Content (TRICC). medAL-creator currently supports diagnostic algorithm design for comprehensive consultations for acute illness. We are planning to further expand its functionalities to meet the majority of algorithm design needs and make it agnostic of the front-end technology in order to increase its usability and integration into the digital health ecosystem. As part of this process, we are reflecting on the broader purpose and requirements of the tool in order to make it as useful to the CDSS implementation community as possible.

Objectives

The purpose of the two-hour workshop was to make sure that all participants understand exactly what is meant by the graphical authoring tool (as compared to other components of CDSS architecture) because these types of authoring tools are still rare in the CDSS implementation community; go through the list of most important and most complex requirements; and get feedback from the participants on the way some of the requirements are currently implemented in medAL-creator (or TRICC) or approaches to implementing the requirements which do not yet exist. A secondary objective of the workshop was to showcase the tools our team has developed and to network with like-minded individuals and find a community for future exchanges.

Facilitators

The workshop was prepared and facilitated by:

- Alexandra Kulinkina – Project Leader, Swiss TPH
- Vincent Faivre – Deputy IT manager, Unisanté
- Fenella Beynon – Head of Digital Health Unit, Swiss TPH
- Rukshan Ranatunge – Health Informatics Specialist, Swiss TPH

Attendees

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Preparation

In preparation for the workshop, we synthesized all of the key requirements for a CDSS authoring tool (Table 1). Subsequently, we selected a subset of requirements across six categories to present and discuss during the workshop as follows:

- Data elements [types and characteristics, clinical ontology, translation]
- Workflow and logic [workflow, conditional and decision logic]
- User interface [diagram editor, data element library, reusable content]
- Validation and testing [bug prevention, content and logic validation]
- Output [interoperability standards, output formats]
- Access and security [public library, version control, regulation]

Table 1: Full table of requirements

Main category	Sub-category	Requirement	Definition
General	General	Auto-conversion L2-L3	Automatic (code-free) conversion of visual diagrams (L2) into machine-readable (L3) format
General	General	Auto-conversion L2-L4	Automatic (code-free) conversion of visual diagrams (L2) into executable (L4) format
Workflow	Basic elements	Questionnaire-related types	Support for the following diagram basic element types: free text, integer, float, single selection box, multiple selection box
Workflow	Basic elements	Calculated field	Support for calculated field as a basic element type
Workflow	Basic elements	Necessity control	Ability to mark diagram basic elements as mandatory or optional. Mandatory ones can't be skipped during execution
Workflow	Basic elements	Clinical ontology	Ability to code variables to a selected clinical ontology concept dictionary (e.g., SNOMED, ICD, LOINC, etc.)
Workflow	Context	User-defined workflow stages	Ability to create/arrange workflow stages per the user's needs and assign variables to each stage
Workflow	Context	Resource availability customization	Customization page to adjust for availability of diagnostic tests, medicines, etc. so that the available drug is recommended by the algorithm by default
Workflow	Context	Epidemiological context customization	Customization page to adjust for local epidemiological context (e.g. high / low malaria burden / HIV prevalence etc.)
Workflow	Logic	Subtrees	Possibility of embedding subtrees within algorithms to simplify visual display and allow for easier reuse of content across algorithms.
Workflow	Logic	Non-linear execution of decision trees	Ability to execute subtrees in a non-linear manner (simultaneously vs. sequentially)
Workflow	Logic	Exclusion rules	Possibility to program exclusion rules for diagnoses, managements and drugs
Workflow	Logic	Substitution rules	Possibility to program substitution rules for drugs and diagnoses
User interface	Diagram editor	Diagrammatic interface	Visual diagrammatic (drag-and-drop) algorithm design interface
User interface	Diagram editor	Rich text input	Ability to input rich text in the authoring tool
User interface	Diagram editor	Freeze functionality	Possibility to "freeze" parts of a diagram to avoid unwanted modifications
User interface	Diagram editor	Content upload	Ability to upload text, image, sound, video as additional explanatory content to be displayed on the 'reader'
User interface	Diagram editor	Error validation programming	Ability to program error and warning messages in the authoring tool for numerical value thresholds displayed in the reader
User interface	Translation	Clinical concept translation	Unambiguous translatation of clinical concepts based on ontologies
User interface	Translation	Facilitated translation mode	User interface mode allowing to freeze all logical elements and present only text fields to the user for editing
User interface	Translation	Automated API translation	Ability to automatically translate text fields on user request via calls to a translation service API.

User interface	Translation	Translation via dictionary	Translation of text elements via dictionary (any format) upload
Output	Main output	Interoperability standards	Support for data health data exchange standards that allow interoperability across a wide range of particular L4 systems (FHIR)
Output	Optional output	Diagram PDF export	Ability to export diagrams in a PDF format
Output	Optional output	Data dictionary	Ability to export a full data dictionary
Storage	Version control	Algorithm versioning	Ability to manage multiple versions of an algorithm, deploy them in different contexts and to revert to previous versions
Storage	Private library	Diagram elements saving	Possibility for the user to save diagram basic elements for own use
Storage	Private library	Diagram saving	Possibility for the user to save diagram for own use
Storage	Private library	Multi-diagram saving	Possibility for the user to save multi-diagram algorithms for own use
Storage	Public library	Workflow sharing	Possibility for the user to share diagram basic elements, diagram and multi-diagram algorithms with other in a public library
Storage	Public library	Selective access rights	Possibility for the user to selectively share saved components with certain users or groups
Validation & Testing	Bug prevention	Authoring action validation	Validation mechanism to avoid authoring actions leading to bugs (e.g. shapes that are not properly linked in draw.io for TRICC)
Validation & Testing	Content validation	Numerical validation	Ability to program set of possible values for entry and create error messages from the authoring tool
Validation & Testing	Content validation	Spell check	Interactive English spell check for text entered in the authoring tool
Validation & Testing	Logic validation	Dead-end validation	Automated validation tests to ensure diagnostic algorithms have no dead-ends (this can be extended to any necessary diagram entity, e.g. treatment)
Validation & Testing	Logic validation	In-built emulator	In-built emulator to enable the user to visually validate the algorithm/workflow as it would be executed in a 'reader'
Security & Privacy	Privacy	User role restricted access	User roles and restrictions (e.g. view only user role), ability to see only pertinent algorithms.
Security & Privacy	Security	2FA	Two-factors authentication using auth-app (more secure) or SMS (easier to access)

High level highlights

- There is a clear need for a visual CDSS authoring tool to speed up digitalization of clinical guidelines, including by the WHO SMART guidelines community.
- These types of authoring tools are still relatively new and uncommon, further outreach is needed to the CDSS community to get them to realize their importance and value.
- There was generally great enthusiasm among the participants for such a tool; everyone was willing to engage in further workshops and feedback sessions.
- The workshop gave visibility to the work of Swiss TPH and Unisanté in this area, and further networking opportunities in other sessions led to the development of a working

group on this topic led by Rubayat Khan from the Endless Network, a foundation that supports digitalization, including that of the health sector.

Logistical issues

- Due to the high level of enthusiasm and lively discussion during the presentation of requirements, the two-hour time slot was only sufficient to go through them and discuss one by one, but not to synthesize that discussion and validate the requirements. This is planned in subsequent workshop and a final online meeting where a Delphi process will be used.
- Conducting the workshop during this popular and well-attended conference had pros and cons. On the one hand, we were able to get a lot of diverse participants that we wouldn't have had if the workshop took place in Switzerland. Thus, we were able to be more inclusive. On the other hand, the conference schedule was rather busy, with lots of parallel sessions, which precluded some of the attendees from being able to participate.
- In subsequent engagements, active moderation is needed to make sure that all objectives are achieved.

Detailed discussion

Table 2: Summary of technical requirement discussion

Topic	Discussion
Data element types and characteristics	We presented how data element types and characteristics are defined in medAL-creator. This fairly straight forward requirement did not spark any discussion. Reuse of variables was discussed (e.g., pregnancy status, DOB, etc.). For some of such variables, it would be necessary to define expiration criteria after which they are no longer valid. Should this be defined in the authoring tool or rather the reader?
Clinical ontology	Currently, medAL-creator does not use any standard clinical ontology; the idea is to connect to the OCL library via an API. Participants agreed that connecting to an existing mapping source makes sense, rather than each implementation maintaining its own.
Translation	Translation is a mandatory requirement, there was no discussion
Approaches to programming content	Two approaches of programming decision support content were presented – a decision logic driven approach (medAL-creator) and a workflow/stage based approach (TRICC). The decision logic driven approach was discussed extensively, the attendees discussed on how multiple diagnoses are represented within a single workflow diagram. The participants commented that clinical decision support diagrams are not pure flowchart like diagrams with one question with one answer, but complex diagrams with one question leading to many different paths along the workflow downstream and to different diagnoses. One participant mentioned that diagrams should be able to be arranged in the same way in order to compare if two diagrams are the same or

	different, otherwise, visual differences can be interpreted as content differences, where in reality they are the same.
Workflow	In medAL-creator, there are set stages of the consultation to which questions can be assigned, rather than following the diagram logic sequence. We proposed the idea of manually creating these stages in a fully flexible approach, but participants suggested that making it fully flexible is not necessary. For algorithms implemented in a clinical setting, there is a fixed number of stages. Thinking through all the different implementation contexts (e.g., inpatient, outpatient, chronic care, community) and developing a list of stages that can work with all those contexts for the user to select from would be sufficient. Some tools that were mentioned that should be considered for diagrammatic standards: BPMN+ (insufficient for non-prescriptive diagrams), CMMN (semantically meaningful), DMN (origin of DMN is how do we break down complex diagrams into something manageable?)
Bug prevention	Features of medAL-creator were demonstrated to prevent very basic bugs such as arrows not connecting, looping, or dead-ends.
Content and logic validation	More advanced validation mechanisms are desired and are currently missing. A lot of conceptualization is needed on how to come up with a validation method that is thorough but manageable. Should it be possible to generate an exhaustive list of all combinations of test scenarios? An emulator was discussed – is it mandatory to have an emulator inside a tool like medAL-creator so the user can see how it will be deployed without actually deploying it in a 'reader'.
Interoperability standards	Currently, no interoperability standards are implemented in medAL-creator. The idea is to adapt the output to create multiple formats, and to adopt interoperability standards such as HL7 FHIR/CQL. That allows support for medAL-creator to support WHO SMART guidelines.
Output formats	We did not discuss what output formats (apart from the default json) would be most desirable for the CDSS implementation community. The TRICC tool works with xls forms which are consumed by ODK, CommCare, Community Health Toolkit. At least this additional format might be beneficial.
Public library	The concept of a public / private library to store content for re-usability was positively received, however concerns of safety and security of the reusable components was raised during the discussion, with potential future work needed to accommodate this requirement with public library and safety of the reusable components.
Version control	Version control is innately part of medAL-creator which is a very desirable feature.
Regulation	Regulation was not discussed.

Future directions

- Refining of the requirements list given the feedback received during this workshop.
- Inception of a diagrammatic standard for visual authoring algorithms with the CDSS community and WHO.
- Formal validation of the requirements collected via a Delphi process.
- Further collaboration with the CDSS community to co-develop a visual authoring tool that meets the needs of various use cases rather than each stakeholder potentially developing their own.
- Developing a sustainability model for a CDSS authoring tool.

Workshop #2: Towards a universal CDSS authoring tool

The workshop was held on 30 May 2024 between 5:30 and 6:30 PM during the Geneva Digital Health Day (as part of the Geneva Health Forum and the World Health Assembly) at Campus Biotech in Geneva, Switzerland. We took the opportunity of this event to reach out to a variety of stakeholders involved in digital health in general and Clinical Decision Support Systems (CDSS) in particular. This workshop was a breakout session of a more general workshop we organized jointly with the WHO: Achieving local authoring, production and sustainability of person-centred digital health solutions at the point of service. During the breakout session, we first presented the current difficulties involved in transforming clinical guidelines into CDSS applications usable in the field by healthcare workers, and then introduced the graphical authoring tool we envisage as a solution. We then discussed and collected participants' opinions on a set of user stories submitted by the organizations in the consortium with which we are re-designing this tool.

Background

At the Swiss TPH Digital Health Unit, we specialize in the implementation of Clinical Decision Support Systems (CDSS) in resource-constrained contexts. At a high level, the process of implementing knowledge-based CDSS involves transforming clinical guidelines validated for a certain context into a software application that can be used by clinicians during consultations. This process is complex and requires numerous iterations between clinicians and health informatics specialists; WHO SMART guidelines provide a conceptual framework for its realization. Within the framework of our mandates, we have developed a series of tools to facilitate this process, enabling clinical decision trees to be built using a graphical interface, and automating certain stages of transformation into an Android application.

Until now, these tools have been used either internally to increase productivity, or within the framework of a specific project. In the latter case, the implementation context is fixed (e.g. pediatric outpatient consultations in rural health centers in Rwanda) and the graphical tool for creating clinical algorithms is part of a software suite developed specifically for this context. However, several stakeholders have expressed an interest in a universal graphical tool for creating clinical decision trees and transforming them into CDSS applications, regardless of context. Clinical program managers around the world would then be able to design clinical algorithms adapted to their context and transform them into field-usable applications more quickly and easily.

However, the challenges involved in creating such a universal tool are far more complex than those associated with context-specific tools. We have launched a project to prepare for the design of such a tool, starting with the definition of its scope and requirements. To this end, we held an initial workshop at the Global Digital Health Forum in December 2023. This initial two-hour workshop enabled us to collect requirements and discuss various technical options with a diverse audience of stakeholders. Following this, we also mobilized around the Endless

Network, a consortium of organizations involved in the field to coordinate our efforts towards the realization of a universal tool. Within this consortium, each of the organizations submitted user stories (descriptions of use cases at an informal level) relating to the future tool. It was these user stories that we intended to discuss and prioritize with a wider audience of stakeholders at the Geneva Digital Health Day workshop. We were also counting on the event to raise awareness of the problem and our proposed solution.

Objectives

1. Increase awareness of the problem and our high-level solution

2. Benefit from experience of stakeholders to prioritize already identified important requirements and choose most valued options

3. Bonus: Benefit from experience of stakeholders to identify new requirements

Facilitators

Four members of the Digital Health Unit served as facilitators during the breakout session. We ensured that their technical or clinical background enabled them to understand the perspectives of the various stakeholders and to answer their questions clearly and comprehensively.

- Paul Spicher – Health Informatics Specialist, Swiss TPH (Technical)
- Fenella Beynon – Head of Digital Health Unit, Swiss TPH (Clinical)
- Patrick Delcroix – Health Informatics Specialist, Swiss TPH (Clinical)
- Gillian Levine – Senior Scientific Collaborator – Epidemiologist, Swiss TPH (Technical)

Workshop design

General workshop with WHO

Initially conceived as an event in its own right, this workshop was adapted to become a breakout session of a larger workshop conducted jointly with the WHO and entitled *"Achieving local authoring, production and sustainability of person-centred digital health solutions at the point of service".* At the request of WHO's Digital Health Technology Unit, we agreed to combine our two workshops in order to benefit from synergies linked to the interconnection of our fields of activity. The total duration of the workshop was 1h45. After a 30-minute joint session, the audience split into two breakout sessions for 50 minutes, before returning to the plenary for a 25-minute summary and discussion (see table).

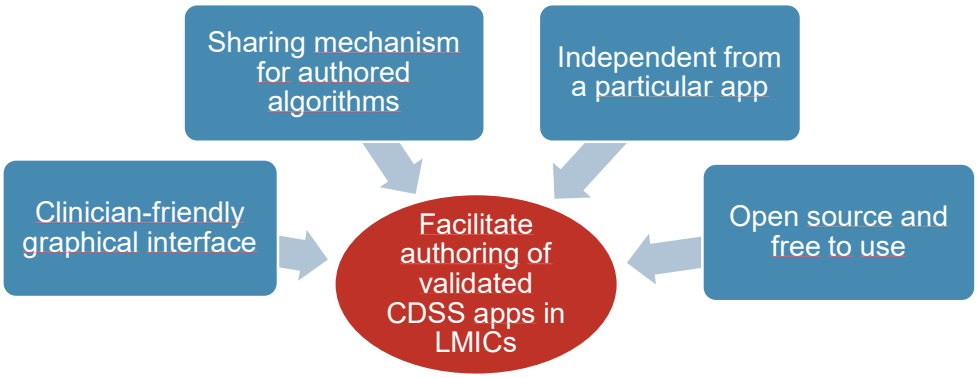
Duration	WHO	Swiss TPH
30 min	Short presentations by various speakers on the issues addressed by their institution	
50 min	**Ecosystem breakout session** - Funding of digital heath interventions - Entrepreneurship promotion - Other ecosystem facilitators for sustainable digital health solutions	**Authoring tool breakout session** - Current difficulties with knowledge-based CDSS implementation - Our vision of a universal CDSS authoring tool - Discussion and evaluation of user stories
25 min	Summary of breakout session results and joint discussion	

CDSS authoring breakout session

Our breakout session was designed in three parts, as described in table below. After a presentation of the problem and our proposed solution to get everyone up to speed, we focused on an exchange with participants to gather as many points of view as possible on the user stories presented. The participants' responses were collected automatically via Slido surveys and accompanied by preliminary explanations and in-depth verbal feedback.

Duration	Content	Modality
10 min	**Problem presentation** Description and explanation of the main difficulties currently encountered in the process of transforming clinical guidelines into field-usable CDSS applications.	Frontal presentation with questions from the audience
10 min	**Solution presentation** High-level description of the envisioned universal CDSS authoring tools and definition of its key properties.	Frontal presentation with questions from the audience
30 min	**User stories evaluation** Presentation of the user stories collected through the Endless Networks, discussion and evaluation of their importance and the challenges they present for the participants.	Interactive presentation with Slido polls to collect participants' inputs – facilitated by the team

The figure below describes the key properties of the proposed tool on which the requirements will be based. The table below presents the user stories discussed and evaluated during the breakout session.



User story	Q number	Evaluation by participants	Digital data
I want to share and access clinical algorithms that can be modified to fit my needs.	1	Importance rating (1-5)	Yes
	2	Challenges foreseen	Yes
	3	Preference: platform vs repository model	Yes
I want to link clinical concepts to medical ontologies to ensure universal understanding without ambiguity.	4	Importance rating (1-5)	No
I want to export in different machine readable formats to ensure compatibility with largest set of L4 applications.	5	Set of apps for interoperable export	Yes
	6	Challenges foreseen	No
	7	Importance rating: export to most popular apps	No
	8	Importance rating: export to virtually any app	No
I want to display the differences between algorithms to understand changes from the reference versions.	9	Importance rating (1-5)	No
I want to constrain the way other authors can modify my algorithm template to ensure compliance with guidelines.	10	Importance rating (1-5)	No
	11	Challenges foreseen	No
I want to constrain the way other authors can modify my algorithm template to ensure compliance with guidelines.	12	Importance rating (1-5)	No
	13	Challenges foreseen	No
Entire tool	14	Overall importance rating (1-5)	No
	15	Preference: platform vs local software	No
	16	Other remarks on the tool	No

Participants

As the capacity of the plenary room is 64 people, it was decided with the organizers that our team and the WHO team would each invite 20 people with guaranteed access to the workshop. The remaining 24 places would be open for registration to all Geneva Digital Health Day participants, on a first-come, first-served basis. In the event, a large number of guests were unable to attend the workshop, and only the 11 stakeholders took part in the CDSS authoring breakout session (see table 4). The reasons for this are analyzed in the discussion.

Name	Organization	Role	Email
Daniel Messer	PSI	Chief Information Officer	dmesser@psi.org
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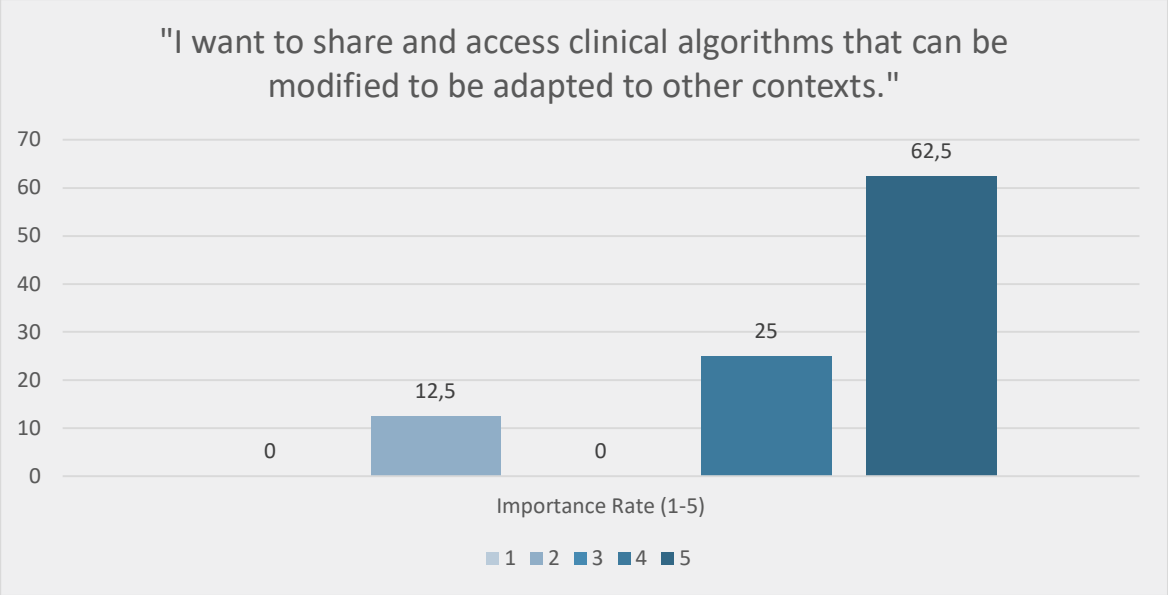
Esther Thea Inau	University Greifswald	PhD student Medical Informatics	
Rukshan Ranatunge	SwissTPH	Health Informatics Specialist	
Camille Renner	-	Health Informatics Specialist	

Workshop results

The workshop was designed to gather participants' opinions quickly and simply, without burdening the exchanges but guaranteeing the possibility of discussing the issues in some depth. Unfortunately, the course of the workshop deviated from the plan, and data could only be collected incompletely, mainly due to lack of time. Out of 15 planned questions, we were only able to collect digital data for the 4 most important ones.

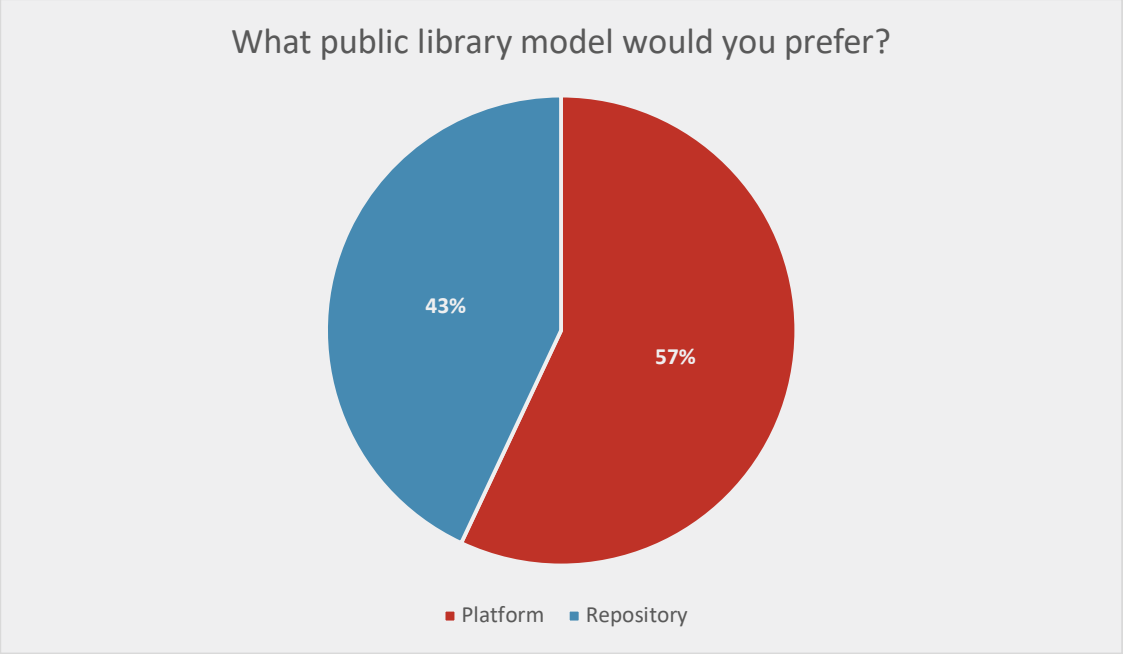
Q1: Importance rating for public library



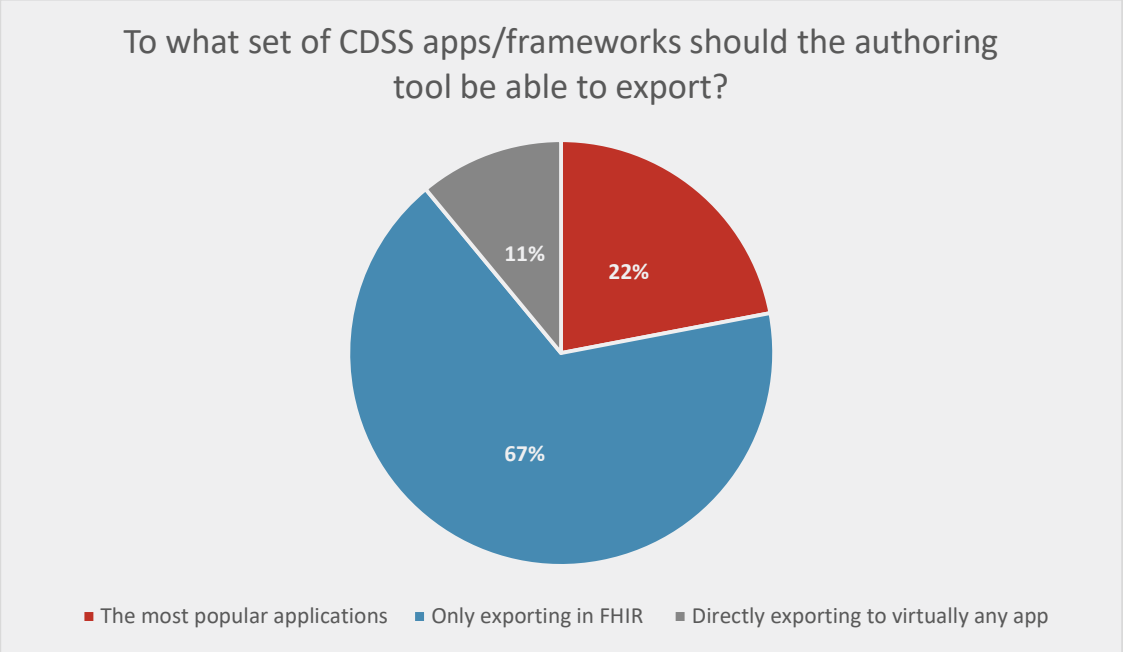
Q2: Foreseen challenges for public library

Creating an organisation and "approver " - community and governance setup to have an oversight and evaluate which changes to accept	Algorithm not updated	Algorithm not adapted for my context/infrastructure	Ensuring authenticity of data	Technical capabilities
Semantics of language interpretation	Error creation in modification	Monitoring changes and governing the adaptation process	Version control and dependencies	Settings may adopt algorithms that aren't aligned with their context, because the template was available
Adding new data elements in a modification	In complex CDSS it may be difficult to track what has been reviewed and adapted	Different interpretation of algorithm	Capacity for this changes	Agreeing on such a sub standard can take a long time

Q3: Preference for public library model



Q4: preferred sets of interoperable CDSS applications/frameworks



Discussion

The first main objective of the workshop was to increase awareness of the problem and our high-level solution. This objective was satisfactorily met, as we reached new stakeholders active in the field. However, we could have achieved more, as the number of participants fell short of expectations. We'll analyse the potential reasons for this below, but it's worth mentioning that our workshop was one of the best attended of Geneva Digital Health Day 2024.

The second main objective was to benefit from experience of stakeholders to prioritize already identified important requirements and choose most valued options. This objective was only partially met. Indeed, while we were able to discuss and obtain participants' opinions on the points we considered most important, there wasn't enough time to tackle all the topics we had planned. We were only able to obtain digital data for a quarter of the prepared questionnaire. This may be mitigated by the fact that participants who wished to do so gave us their e-mail address so that we could complete the questionnaire remotely. However, some participants stressed the need for in-depth discussion in order to be able to answer the questions in an informed manner. One possible solution would be to bring together those interested for a remote workshop.

In general, it is worthwhile analyzing the potential causes of these unexpected events in order to better organize future Digital Health Unit workshops. The figure below attempts to represent them.