

Standardised Electronic Clinical Decision-Support Algorithms: Linking Diagnostics and Appropriate Treatment to Improve Patient Outcome in the Context of Universal Healthcare

Workshop Report and Target Product Profile

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Glossary of Terms

API	Application Programming Interface
APP	Application
CRP	C-Reactive Protein
DHIS2	District Health Information System 2
eCDA	Electronic Clinical Decision-Support Algorithm
EDL	WHO's Model List of Essential In Vitro Diagnostics
EHR	Electronic Health Records
EML	WHO's Model List of Essential Medicines
EMR	Electronic Medical Record
FDA	US Food and Drug Administration
FIND	Foundation for Innovative New Diagnostics
GDPR	General Data Privacy Regulation
GPS	Global Positioning System
HIE	Health Information Exchange
HIS	Health Information System
HIV	Human Immunodeficiency Virus
HL7	Health Level Seven International
iCCM	Integrated Community Case Management
ICD	International Classification of Diseases
IMAI	Integrated Management for Adolescent and Adult Illness
IMCI	Integrated Management for Childhood Illness
IMDRF	International Medical Device Regulators Forum
IMNCI	Integrated Management for Neonatal and Childhood Illness
IVD	In Vitro Diagnostic
LMIC	Low- and Middle-Income Country
ML	Machine Learning
MoH	Ministry of Health
NPV	Negative Predictive Value
OS	Operating System
POC	Point of Care diagnostic
PPV	Positive Predictive Value
RCT	Randomised Controlled Trial
RDT	Rapid Diagnostic Test
SaMD	Software as a Medical Device
SMS	Short Message Service
SNOMED	Systematized Nomenclature of Medicine
TPP	Target Product Profile
UNICEF	United Nations International Children's Emergency Fund
WHO	World Health Organization

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Executive Summary

Healthcare workers in low resource settings often lack the tools, including diagnostics, to diagnose, treat and manage patient illness at point of care following clinical recommendations that are based on evidence. Mobile digital technologies that guide diagnosis that includes the use of diagnostic tools and treatment decisions at point of care have the proven potential to transform healthcare and save lives. The development of a target product profile (TPP) for electronic clinical decision support algorithms (eCDAs) that integrate diagnostic tools will help align the needs of end-users with the targets and specifications that developers, and implementers alike, should meet to ensure appropriate performance and operational functionality to impact patient health.

To discuss this issue, a workshop on eCDAs to link diagnostics to treatment decisions took place November 27th, 2018 in Geneva, Switzerland. The workshop was organised by the Foundation for Innovative New Diagnostics (FIND) with the World Health Organization's (WHO) Essential Medicines and Health Products group and the WHO Digital Health Innovations and Reproductive Health and Research department. This was the first meeting convened by FIND and WHO on this subject and involved 39 experts from academic institutions, industry, private and public sectors from 11 countries. Experts were researchers, software developers, implementers and representatives from ministries of health, international organizations and funding agencies.

The objectives of the workshop were to:

1. Understand the current landscape and use of eCDAs in low- and middle-income countries (LMICs), linkage to diagnostics and impact on healthcare
2. Discuss requirements for standardized eCDAs that integrate point of care tests as part of a draft TPP
3. Identify required implementation guidance (studies/data/compliance) to support linkage of algorithms to diagnostics

The workshop reviewed the evidence for improving health outcomes with digitised clinical decision-support algorithms and the need to integrate point of care diagnostics and other essential health products. The workshop also reviewed the landscape of different eCDAs implemented at point of care, their impact and the challenges with development and implementation in resource- and connectivity-challenged settings. Participants discussed the critical elements of a draft TPP for an eCDA and point of care diagnostics toolkit, to which changes to the document were proposed along with requests for further discussions. Participants indicated that eCDAs should be contextualised and built on established or new evidence, and implemented on top of existing local infrastructure with local buy-in. There was agreement that eCDAs should be based on evidence but that validation of eCDAs is equally crucial. Participants noted that validation should include both clinical validation studies and validation based on user experience *in situ* as the most evidence-robust toolkit can fail in the targeted “uncontrolled” setting. Furthermore, the workshop discussed that the system should support clinical workflows appropriate to the user and the setting, inclusive of workflow adapted to include diagnostics.

The workshop group recommended another convening be organised to discuss validation methods specifically. The group also requested a separate meeting to discuss data standards as they apply to eCDAs. In terms of access, some participants showed concern in the market readiness for eCDAs alone and recognised that market shaping and potential donor backing will be needed to increase access and support country adoption of these tools individually or as toolkits with diagnostics.

Following the workshop, the TPP draft was revised to include feedback and comments provided during workshop discussions. To facilitate consensus over TPP characteristics, a Delphi-like process was set up to collect stakeholder input. After two rounds of review, consensus agreement was reached for all characteristics and the TPP was finalised. The final TPP was included in a manuscript available on the FIND website.

A. Workshop Report

Standardised electronic clinical decision-support algorithms: linking diagnostics and appropriate treatment to improve patient outcome in the context of universal healthcare

Workshop organised by FIND and WHO

November 27th, 2018 | Hotel Royal, Geneva, Switzerland

1. Introduction

The meeting was opened by the meeting Chair, Garrett Mehl (WHO), Francis Moussy (WHO) and Sabine Dittrich (FIND). There has been significant interest in the use of IVDs to improve healthcare delivery at WHO in recent years, leading to the publication of the EDL in May 2018. Digital diagnostics is the next step, and can ensure that the right treatment is provided using the right protocols and that patients receive the best possible quality services. In line with this objective, FIND's mission as a product development and delivery partnership is to support access to high quality diagnostic for resource-poor settings. Part of this mission is to enable that diagnostic tests are appropriately used to guide treatment decisions at point of care and hence the use of digital diagnostic and electronic clinical decision-support algorithms (eCDAs) are critical tools to improve patient management and care.

The objective of this meeting was to define the role of eCDAs as tools that translate diagnostic results into therapeutic decisions, with the aim to contribute to the development of a draft TPP for a toolkit composed of eCDA and point of care diagnostics to guide different stakeholders (e.g. ministry of health, health programme implementers, software developers) in the development and selection of appropriate eCDAs. The meeting agenda can be found in **Annex 1**.

Workshop participants included relevant stakeholders who have developed and implemented electronic clinical algorithms for childhood illness in LMICs and work in the eHealth area, as well as representatives from FIND and WHO (see **Annex 2** for participant list).

2. Session 1. Existing evidence and needs for implementation

2.1 Impact of digitalising clinical algorithms

Presented by Mark Mitchell (University of California, Berkeley)

The IMCI is a typical protocol, or series of protocols, that takes clinicians through a step-by-step assessment of children with particular symptoms to a treatment based on evidence. The WHO has performed a large multi-country study demonstrating that the IMCI protocols work when followed. However, the standards are often not used correctly, and one of the key reasons for this is that physicians are often embarrassed to use the paper version of the IMCI in front of patients. Instead they prefer to memorise the protocols, which can lead to errors and misdiagnoses. Digitalising the IMCI has been shown to significantly improve adherence to the protocols, partially due to physicians' perceiving use of a digital application as less embarrassing to use compared with paper algorithms.

Due to the need for inclusion of subtle differences in symptoms to ensure accuracy of diagnoses, algorithms like the IMCI appear highly complex when presented on paper. It is difficult to produce protocols that are easy to follow but that give consistent results across users. Digitalisation allows improvements in layout that can reduce the appearance of complexity and make the experience more user-friendly, but the underlying algorithm must be well-designed in order to ensure that consistent results across users are generated.

In summary, getting the perfect algorithm is the first step in a long journey. Ensuring that it is used correctly is at least as important. Therefore, there is a balance to be achieved between the complexity of the algorithm and the simplicity of use.

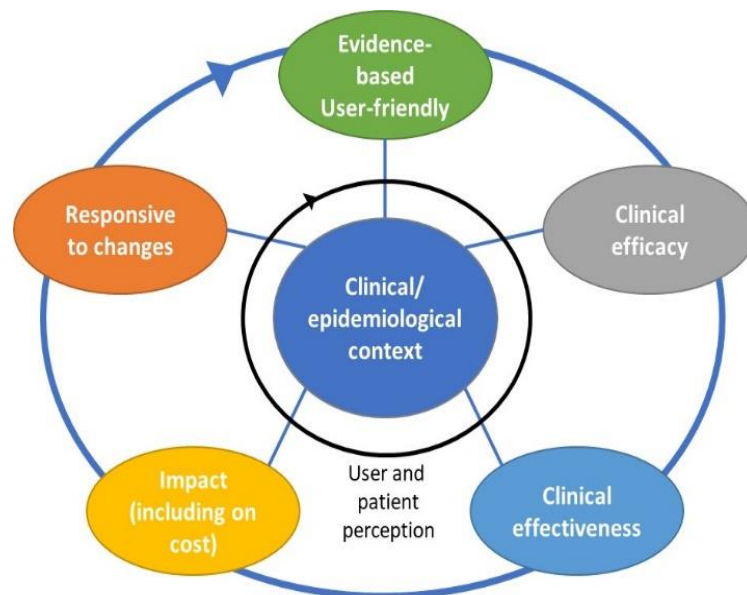
2.2 Clinical evidence for improving assessment of childhood illness with eCDAs

Presented by Kristina Keitel (Swiss Tropical and Public Health Institute)

This presentation discussed the evidence required to develop and validate an eCDA. Algorithms are a set of rules that precisely define a sequence of operations. They differ from guidelines in that they are more precise and do not allow for user interpretation. The IMCI is a guideline as it defines a set of routine practices but can be ambiguous in that there is no fixed pathway. Transformation of the IMCI into digital therefore required decisions to be made regarding the medical content in order to create a decision tree.

A validation step is always required when a guideline has been transformed into an algorithm, but there is no standard validation pathway for eCDA. Typically, validation requires a variety of study types, including epidemiological studies, analytical studies (assessing performance across diseases or in comparison with other diagnostic methods), and clinical and outcome based studies (**Figure 1**).

Figure 1. Validation approach for electronic clinical decision algorithms.



Adapted from Keitel K. and D'Acromont V., 2018¹

¹Keitel, Kristina and D'acromont V. (2018). Electronic clinical decision algorithms for the integrated primary care management of febrile children in low-resource settings: review of existing tools *Clinical Microbiology and Infection*;24:845-55.

To date, very few clinical outcome study data are available for decision tools in the field of common childhood infections, and so there is a lack of evidence on how well these tools align with clinical guidelines. This may partially be due to challenges in publication resulting from the 'classic RCT mindset' of publishers, as eCDA outcome data often come from subgroup or secondary analyses of larger studies. In any case, a clinical trial environment can limit recruitment due to stringent inclusion criteria, and effectiveness studies in real-world settings are still required. There is a need for new innovative validation approaches but these must be methodologically sound.

An added benefit of electronic diagnostic tools is that they can contribute to a global evidence base. There is great potential for integration into health systems to assist with disease surveillance and epidemic detection, representing opportunities beyond clinical trials. However, robust outcomes to measure and evaluate these aspects need to be developed.

The group agreed that the lack of gold-standard evidence was disappointing, particularly given that country implementers will make decisions based upon evidence levels. The question of how an eCDA can be valued in terms of cost-effectiveness was discussed. The consensus was that cost-effectiveness is difficult to measure; trial methodology must be pragmatic and adaptive (e.g. Bayesian) but should also be designed to provide information useful to country implementers.

2.3 Integrating diagnostic tests into eCDAs

Presented by Karell Pellé (FIND)

The importance of diagnostics in healthcare delivery is well-recognised. However, physicians often rely upon clinical guidelines to translate diagnostic results into treatment actions, thus it is important that POC results are integrated into diagnostic algorithms in accordance with guidelines.

The IMCI fever panel was the first algorithm to incorporate diagnostic tests, with the inclusion of the malaria RDT (in endemic areas only). There is significant potential for addition of other diagnostic tests to further improve accuracy. Recently, Egypt's IMCI has been further adapted to include a new branch for sore throat, using predictive signs, that can increase the pre-test probability of streptococcus A sore throat. A potential next step could be to incorporate an RDT to confirm this bacterial infection and more precisely target care. Other available IVDs that could be incorporated into this or other branches of the IMCI include host biomarker based tests such as CRP or urine dipstick and pathogen-specific RDTs for typhoid, leptospirosis, and scrub typhus if the cause of infection is bacterial, RDTs for dengue, influenza if the cause of fever is viral, as well as severity markers such as respiratory rate and oximetry.

ePOCT is a novel eCDA developed by the Swiss Tropical and Public Health Institute, which includes use of available POC tests in addition to clinical signs and symptoms to improve accuracy². ePOCT was developed based on a literature review of evidence on disease prevalence and accuracy of clinical predictors, and data from studies designed to identify

² Keitel K, Kagoro F, Samaka J, Masimba J, Said Z, Temba H, Mlaganile T, Sangu W, Rambaud-Althaus C, Gervais A, Genton B & D'Acremont V. (2017). A novel electronic algorithm using host biomarker point-of-care tests for the management of febrile illnesses in Tanzanian children (e-POCT): A randomized, controlled non-inferiority trial. *PLoS Med.* 2017 Oct 23;14(10):e1002411. doi: 10.1371/journal.pmed.1002411. eCollection 2017 Oct.

biomarkers, necessary tools and assess performance. In an efficacy study performed at 9 outpatient clinics in Dar es Salaam, Tanzania, the ePOCT was compared with the validated IMCI-derived algorithm ALMANACH. A significant reduction was observed in the number of prescriptions for antibiotics and in the risk of clinical failure with ePOCT versus ALMANACH, demonstrating the value of including diagnostic tests in eCDAs.

Integration of POCs into eCDAs must be evidence based. There are a number of factors to consider, including test performance, appropriateness for the setting, pre-test probability and suitability of data thresholds. Additionally, the algorithm must be able to correctly interpret the diagnostic results and adhere to relevant guidelines, and provide treatment outputs consistent with country recommendations.

2.4 Enhancing the impact of WHO's model list of essential in vitro diagnostics through eCDAs

Presented by Francis Moussy (WHO)

It is hoped that the recently published EDL³ will have a similar impact to the EML, which was first developed 40 years ago and is one of the most valued WHO tools. The EDL presents a group of IVD tests that are recommended by WHO for use at various healthcare levels of a tiered laboratory system, and aims to provide guidance for member states who are developing or updating national lists for universal health coverage interventions as well as for selecting and implementing IVDs. Adaptation at the country level is encouraged, taking into account factors such as local demographics and pattern of disease, availability of treatment facilities, training requirements for healthcare workers, robustness of supply chains and quality assurance needs. However, it is not possible to estimate the cost burden for adaptation and adoption of the list, as this will be specific to each country.

The EDL is intended to be relevant to public health, evidence based, and free of conflicts of interest (no brand names or specific products are included). The first edition of the EDL includes tests for high priority diseases such as HIV, syphilis, tuberculosis, hepatitis and human papillomavirus, as well as general laboratory tests. In total, 62 categories of tests are listed. The list indicates which tests can be used in primary care, and which require laboratory support; assay format and specimen type are also specified. For each test, a link is provided to WHO-prequalified products if available, and to any WHO supporting documents. There will be a dedicated page on the WHO website to centralise all information supporting implementation of the EDL. The EDL will be frequently updated, with an annual review to assess applications for new IVDs, similar to the process used for the EML. Applications for the first revision are already being reviewed, will be available on the WHO website in February for pre-consideration, and will be reviewed by the EDL committee in March.

Electronic algorithms are not currently part of the EDL, but have the potential to increase its impact, by increasing the number of decisions made on quality assured diagnostic data. It is possible that diagnostic tools in more general terms, including decision tools, may be included in the EDL at a later stage. Meanwhile, there are numerous other activities ongoing at WHO with regards to digital tools, including the release of the Classification of Digital Health

³ WHO (2018). Model List of Essential In Vitro Diagnostics, First Edition.
http://www.who.int/medical_devices/diagnostics/WHO_EDL_2018.pdf. May 16 2018.

Interventions⁴, a shared language to describe the uses of digital technology for health, earlier this year.

The group noted that the domain of the regulator is important, particularly as the US Food and Drug Administration (FDA) have already designated certain types of electronic tools as medical devices. At the moment the WHO has no plans to look at electronic tools in a regulatory capacity, although this may be considered in future.

2.5 General Q&A

The points were raised during the general discussion session that followed the presentations described above are summarised in **Table 1**.

Table 1. Comments from general discussion session.

Topic	Comment
General comments	<p>“There is currently a disconnect between the different processes that make up a tool kit (i.e. diagnostics, algorithms and biosensors), and it is important that going forwards, each element continues to move at the same pace. There is a balance to be achieved between gaining as much information as possible and obtaining the minimum amount needed to effectively and efficiently treat a patient.”</p>
	<p>“There are two different elements to consider – the ‘magic diagnostic bullets’, and development of better ways to capture basic data. For example, respiratory rate is badly recorded and yet many protocols are based on it. As well as identifying key diagnostic targets, it is important to consider which simple data points that we need for our diagnoses are currently being captured poorly.”</p>
Specific diagnostic measures	<p>“Respiratory rate can vary with other measures such as temperature, so it should be looked at more broadly in combination with other biomarkers such as wheezing, in order to improve pneumonia diagnosis. Improving classifications of pneumonia can lead to reduced antibiotic use, as has already been shown.”</p>
	<p>“Pulse oximetry can be used to accurately read a number of measures including tachycardia, pulmonary refill time, and changes in core temperature. It is a low-cost technology with good long-term clinical studies, so should be discussed more broadly than just in terms of low oxygen levels.”</p>

⁴ Classification of digital health interventions. Geneva: World Health Organization; 2018(WHO/RHR/18.06). Licence: CC BY-NC-SA 3.0 IGO.

**Regulatory
issues**

“In terms of introducing laboratory tests into the clinical guidelines, it will be important to determine whether health authorities should be involved, or if a syndromic approach is sufficient.”

Connectivity

“In areas where connectivity is poor or expensive, it may be worthwhile considering use of free whitespace (i.e. below cellular band connectivity). For example, radio transmission can be used to packet data in an offline manner. For this the Ministry of Communications would need to be involved as well as the Ministry of Health.”

3. Session 2. Introduction to existing eCDAs

3.1 MSFeCARE-Ped

Presented by Clotilde Rambaud-Althaus (Médecins Sans Frontières)

The MSFeCARE-Ped (MSF electronic Clinical Algorithms and REcommendations for Pediatric primary care) is the Médecins Sans Frontières version of the IMCI, designed as a tablet application for remote dispensaries. It is not intended to replace consultants, but aims to help apply best practices. So far, it has been applied in 5 different countries, and 135 workers have been trained. Although it was initially challenging to convince healthcare workers to move away from the more complex guidance that they were using, which was intended for hospitals rather than primary care, feedback from users suggests that healthcare workers find the systematic nature of the tool to be valuable and to improve diagnoses.

The MSFeCARE-Ped uses a simple syndromic approach with no ambiguity. The scope of the IMCI has been extended for MSFeCARE-Ped to meet Médecins Sans Frontières standards of care, and new structure with stepwise approach has been added to support rational prescription of antibiotics. Due to time constraints the MSFeCARE-Ped will not be adapted to every country, therefore it includes unambiguous graphic representation designed to efficiently display the proposed pathway for healthcare authority review.

Lessons learned during the development of MSFeCARE-Ped included the importance of involving clinicians in the design, and of ensuring a high level of control for the logic backbone, to prevent errors and to allow evolution of the algorithm. Converting from a linear to a non-linear pathway was particularly challenging, as it was important that this should not disrupt consultation, and should be able to inform the clinician regarding the rationale of the process throughout the consultations. Incorporating the flexibility to adapt content to available resources and local epidemiology, by allowing context parameters such as the optional introduction of diagnostic tests to be programmed, was also important. Challenges in implementation of the application included the need to ensure that health workers did not become dependent on the tool.

FDA draft guidance for clinical decision support software states that tools are not considered to be medical devices if they enable healthcare workers to independently review the basis for recommendations, i.e. they rely on clinical judgement rather than the software. As MSFeCARE-Ped displays current consensus, helps healthcare workers navigate expert recommendations, and gives access to underlying content and evidence, with the impact on clinical outcome highly dependent on training and supervision, it is not considered to be a medical device.

While MSFeCARE-Ped is intended to allow agile iterative improvement, it will not include new diagnostic methods until these have been validated at a high level, as it is important to have sufficient evidence for all aspects of the algorithm in order to convince ministries of health of the value of the tool. At the moment the tool is used as a 'one-shot' consultation without follow up, although there may be potential in the future to include follow-up information and to link with electronic medical records.

3.2 leDA

Presented by Riccardo Lampariello (Terre des hommes)

leDA (Integrated eDiagnostic Approach) is a battery of tools developed by Terre des hommes, a leading Swiss child relief organization. It is a digitalised version of the IMCI designed to improve diagnosis and treatment of children in Burkina Faso, where the IMCI is poorly implemented. While previously only one in three children had consultations with the IMCI, leDA now reaches more than 90% of children in Burkina Faso.

Healthcare workers are equipped with a tablet on which the application is installed. Signs and symptoms of disease are entered by healthcare workers, and the diagnosis and prescription are returned by the application. Healthcare workers can access individual records and aggregated data reports from national and district-level dashboards; these dashboards are also accessible by district, regional and central level healthcare managers. leDA improves healthcare management through several methods, including digital job aid (reducing paper work, and improving accuracy), enabling e-learning (reducing training costs, and allowing individualised training), and improving data management and quality control.

The implementation of leDA in Burkina Faso was the result of a cross-sectional partnership including the Ministry of Health, WHO, and private and public sector investors, as well as universities and research institutes involved in validation of the tool. Now there are over 4000 active users of leDA, performing approximately 200,000 consultations per year, and with more than 1.7 million patients registered overall. Community support has been important in uptake of the tool, with many people requesting that their child be diagnosed with leDA. Terre des hommes will fully transfer leDA into the hands of the Burkina Faso Ministry of Health in 2019–2020.

A 5-year study on the impact of leDA has been performed by the London School of Hygiene and Tropical and Medicine; data will be released in December 2018. The study compares leDA with an ideal scenario in which the IMCI paper version is widely and correctly used. Results showed that antibiotic over-prescription was significantly reduced with leDA, which also scored better on achieving a correct diagnosis and identification of danger signs compared with the IMCI. A cost-effectiveness analysis is ongoing. In addition, multiple other projects designed to enrich leDA are ongoing, including addition of POC testing, civil registry support, and improvements in diagnosis and treatment of malnutrition.

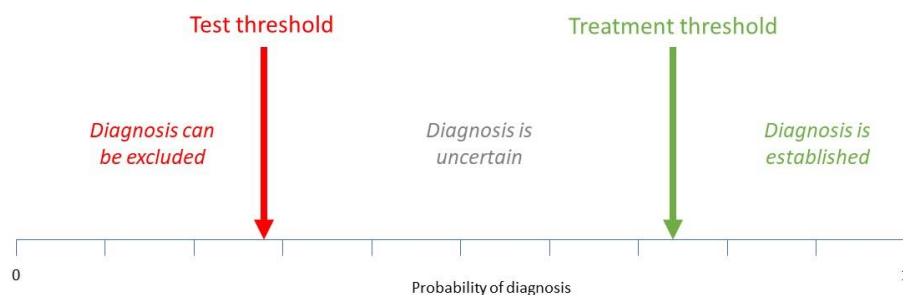
3.3 Medal-C

Presented by Valérie D'acremont (Swiss Tropical and Public Health Institute)

Medal-C, a platform to create evidence-based eCDAs for clinicians and health authorities, is currently being developed by the Swiss Tropical and Public Health Institute for different use cases, based on their experience with ALMANACH and ePOCT. Medal-C can be designed for front-line community healthcare workers whose main concerns are whether to refer or admit a patient, which diagnostic tests to choose, and interpretation of diagnostic results in a clinical context. Medal-C provides diagnoses for children aged <5 years presenting with fever.

Development of Medal-C was performed in a stepwise manner. Firstly, the relevant literature was reviewed (including over >12,000 articles), and evidence gaps were identified. Studies were then performed to fill these data gaps. Next, combinations of clinical and laboratory predictors were tested to attempt to obtain the desired pre-test probabilities for inclusion and exclusion of the diagnosis (**Figure 2**). The test and treatment thresholds differ by country and by disease (for example, malaria can only be excluded if the test threshold is <0.1%).

Figure 2. Targeting test and treatment thresholds of disease probability.



As the probabilities initially targeted for Medal-C could not be reached with existing diagnostic tests, a study was performed to look for alternative host biomarkers to predict end-point radiological pneumonia. However, no biomarker with improved detection over CRP was detected, so the target probabilities had to be adjusted.

Following establishment of the thresholds, the algorithm was created and is being passed through a validation cycle. In addition to clinical efficacy and effectiveness, outcomes will include a safety component and a measurement of rational use of resources. The next step will be to move from a static to a dynamic algorithm to allow adaptation to local trends. The DYNAMIC project, being performed in collaboration with FIND, aims to extend the medical content, create new user-friendly software and incorporate biosensors and RDTs into the algorithm.

3.4 MEDSINC

Presented by Barry Finette (University of Vermont and THINKMD)

MEDSINC is an eCDA that aims to replicate a physician's approach to diagnosis through complex network analysis and machine learning. It has an interface that is designed to be able to be used by anyone, anywhere, and is aimed at community level healthcare workers. It is geographically configurable, acquires key clinical and user data points, is operation-system and device agnostic and fully functional without internet connectivity, and since a recent collaboration with FIND, can incorporate malaria RDT testing.

MEDSINC has been tested by physicians in five countries, and was compared with local routine clinical practice. Results showed a 2-fold increase in the number of consultations, a 2–8 fold increase in counselling visits, a 40–60% increase in compliance, and a decrease in training costs of over 70%. However, it was noted that there are some limitations to using physicians as a gold standard, given that they do not always reach the correct diagnosis.

The MEDSINC tool is capable of machine learning, via a random forest decision tree approach, reproduced with >95% correlation. A number of challenges were encountered

during implementation of machine learning into the tool, including the need for accurate data sets and server-independent algorithms, and limited availability of confirmatory diagnostic testing, outcomes and geospatial epidemiological data.

While the underlying rationale behind the clinical decisions made by MEDSINC are not open to the user, the machine learning method is supervised in that it is possible for the application owner to view and dissect the process. It was noted that there have been some recent concerns in the media regarding validation of eCDAs following the controversy surrounding the Babylon Health GP at Hand tool in the UK. MEDSINC is much more complex than these controversial applications, although it was acknowledged that it may be challenging to explain the differences to non-experts.

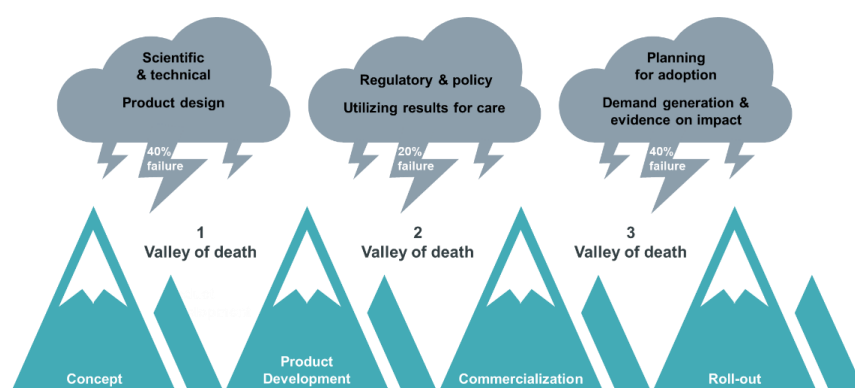
4. Session 3. Target product profiles for eCDAs

4.1 Introduction to Target Product Profiles

Presented by Sabine Dittrich (FIND)

There are three areas in which a diagnostic test can fail on the pathway from development to market (**Figure 3**). The first is science and technology, as if the product design does not meet the required criteria, the test will not reach market. Secondly, following initial development, the test must fulfil regulatory and policy requirements. Finally, in order for the test to be adopted there must be sufficient demand and robust evidence for the positive impact of the test. TPPs aim to define the key characteristics that are necessary to build a test that will have the desired impact in all three areas. They are made transparent to developers and include information on target users, settings and populations, performance and operational characteristics, and price. As well as including minimum required features, they also state features that would provide a competitive advantage.

Figure 3. Three ‘valleys of death’ confront (diagnostics) innovators.



Draft TPPs are generally developed and shared with stakeholders via a Delphi refinement process to ensure alignment between users, clinicians, and technological experts. They are used to benchmark existing diagnostics, to call for the initiation of clinical trials and to increase recognition of development of particular diagnostics as a high priority for funding. In an eHealth context, TPPs must take into account the individual components of a toolkit, including the

diagnostic tests and biosensor readings as well as the eCDA, and must consider how these individual elements should be adapted to allow them to work together effectively.

The attendees were split into three focus groups to discuss potential TPP characteristics for an eCDA toolkit. Each group was provided with a draft TPP document covering the following topics, to aid discussion:

- Focus group 1: Algorithm validation, performance and machine learning
- Focus group 2: Diagnostic data and disease prediction
- Focus group 3: Clinical workflow and application functionality

Feedback from each group is summarised below and in **Table 2**.

Table 2. Summary of focus group feedback on selected criteria of the draft TPP.

TPP Characteristic	Draft minimal requirement	Draft optimal requirement	Focus group recommendations
Focus group 1			
Algorithm/ Decision Logic	Based on a WHO guideline decision tree (i.e. IMNCI, IMAI) adaptable to country context and use cases	New decision logic (such as probabilistic algorithms) adaptable to different country context and use cases, and approved by the local government	<ul style="list-style-type: none"> • Restrict TPP to certain user type/healthcare level; target user should be clearly defined • TPP should state that the tool should include definition of target population (e.g. age group, inclusion criteria and relevant restrictions) • Not appropriate to say that one decision logic process is preferable to others
Therapeutic Guidelines	Therapeutic recommendations shall be compliant with national treatment guidelines and national EML	Same and the application shall provide recommendations that support antimicrobial stewardship	<ul style="list-style-type: none"> • TPP should state that medical content of the algorithm must be evidence-based • TPP should state that a literature review should be performed and expert advice on evidence gaps sought • Algorithms should not be forced to comply with out-of-date or non-evidence based guidelines
Machine Learning	None. The algorithm is static	Predictive model on cloud running in the back-end and not changing the decision logic. Gating mechanisms are in place to trigger decisions for a change in the algorithm to go live	<ul style="list-style-type: none"> • Agree with minimum requirement of 'no machine learning' • The optimal should be to include machine learning • Topic requires further in-depth discussion

Evidence of Impact	Equivalent clinical outcome compared to existing guidelines, if changes are made to previously validated clinical algorithms, and/or Equivalent adherence to clinical guidelines compared to existing guidelines, if previously validated algorithms are digitised	Improved clinical outcome compared to existing guidelines, if changes are made to previously validated clinical algorithms and/or Improved adherence to clinical guidelines compared to existing guidelines if previously validated algorithms are digitised	<ul style="list-style-type: none"> • Validation requirements in terms of safety, efficacy and user-friendliness should be included • Performance should be assessed according to both clinical outcomes and rational use of resources • Comparator should be routine care; tool should be shown to provide equivalent or improved outcomes
Focus group 2			
Diagnostic Tests and Other Relevant Medical Devices	POCs or other relevant medical devices prompted for use by the application shall be locally relevant, i.e. recommended by EDL or relevant national equivalent, or country program	Same and newly emerging diagnostic tools and medical devices relevant for the targeted settings	<ul style="list-style-type: none"> • Agree with 'locally relevant' for minimal requirement • Rather than 'relevant for target settings', optimal requirement should be 'widely available in the local setting'
POC Data Inputs	Qualitative data such as positive/negative/invalid lateral flow test results	Same and quantitative data such as white blood cell count	<ul style="list-style-type: none"> • Minimum requirement should be binary 'yes/no' result • Optimal requirement should be quantitative data • Optimal requirements should include ease of use, time to result and connectivity • A section for POC data output should be included
Regulatory	POC diagnostic tests are regulatory approved and implemented in compliance with local regulations	All toolkit components are regulatory approved	Regulatory requirements for diagnostic tests and medical devices are different; this should be taken into account
Disease Risk Likelihood	Based on pre-test probability	Based on a pre-test probability and POC positive/negative predictive values	<ul style="list-style-type: none"> • Rename category 'Disease likelihood' • Minimal requirement should be POC outcomes • Optimal requirement should be POC outcomes plus pre-test probability

Focus group 3			
Data Access and Transparency	All data collected via the Application is visible to the Application owner (i.e. the healthcare programme or research establishment) and available for transmission. The owner has control over the destination and content of all transmissions (no hidden data feeds to other opaque destinations).		<ul style="list-style-type: none"> • Rename category 'Data ownership'; data access should be incorporated into separate privacy and security section • Transmission is an ambiguous term and should be avoided • Agree that the application owner should have visibility of all data
Access	The Application should have publicly available standards based interface to allow transmission of data to user configured destinations (such as in-country lab information management systems)	Open source	<ul style="list-style-type: none"> • Rename 'system access' to distinguish from data access • Divide into 2 sections for API and transparency • Application should have publicly available API protected by authentication and authorisation • Technical standards should be adhered to as a minimum • Adherence to HIE/HL7 should be an optimal requirement • Transparency of algorithm/architecture for purpose of validation and trust should be a minimal requirement, with open source as optimal
Interoperability	Data is structured, and uses commonly used, machine readable formats		Now covered by the system access section above
Workflow	Sequential: begin and end one consultation before starting a new one	Simultaneous: start a new consultation while one is ongoing	Tool should support multiple, simultaneous consultations with capability to stop and resume as minimum
Navigation	Sequential: the user follows a strict sequence of data input to reach a final recommendation	Non-sequential: the user can move in any direction through an assessment and change input data to reach a final recommendation	Agree with sequential as minimum and non-sequential as optimal

Task Management	No multitasking	Multiple patient windows can be opened at a time by one user; Patient profile can be recovered based on user access rights; Task shifting capability (i.e. move from one age-specific algorithm to another)	<ul style="list-style-type: none"> • Divide into sections for initial encounter, task management and follow-up • Tool should allow multiple patient windows to be opened at a time by one user as optimal requirement • Tool should allow multiple algorithms supported simultaneously against a common dataset as optimal requirement • For follow-up, tool should have ability to retrieve patient information using anonymised patient registration information as minimum and additional built-in function to send reminders via SMS/phone as optimal requirement
Data Storage	Data is stored in a server/cloud accessible to high-level country authority on a web interface	Data is stored in a server within the country	Reword optimal requirement to 'Data can be stored in a server within the country'

4.2 Focus group 1: Algorithm validation, performance and machine learning

The group agreed that the TPP should allow for different populations and settings, but acknowledged that a single TPP cannot cover all clinical decisions. It was decided that the TPP should be restricted to a certain user type/healthcare level. Rather than defining the target population in the TPP, it should simply state that any algorithm must include a definition of its target population, including age, inclusion criteria and restrictions (i.e. groups to which the TPP does not apply, for example immunosuppressed patients). Similarly the target user must be clearly defined. It was noted that using IMCI and IMAI would leave out children aged 5–13 years; efforts should be made to ensure that this age group is included.

Regarding decision logic, the group did not feel that it was appropriate to say that one process was preferable, although it was noted that some may be more appropriate than others for certain healthcare levels.

The TPP should state that the medical content of the algorithm must be evidence-based, but should not restrict to an IMCI-based format or to existing guidelines. Guidelines may be out of date or may not be evidence-based; in this case, it is important that the algorithm does not align. The TPP should also state that a review of the literature to define the level of existing evidence should be performed, and that an expert group should be convened to provide advice on any gaps.

The TPP should define validation requirements up to a certain point in the validation cycle; safety and efficacy requirements should be included, as well as some measure of user-friendliness, but other aspects such as adherence will come from post-marketing data and therefore are difficult to include in a TPP. Internal validation is essential, in terms of ensuring that the content is understandable and that the output is as intended.

Performance should be assessed according to both clinical outcomes and rational use of resources. The comparator should be routine care, and the tool should be shown to provide equivalent or improved outcomes. It was noted that if the responsibility of the TPP is limited to efficacy, then it cannot include comparisons to the effectiveness of the IMCI. User friendliness requirements include an ability for the software to stop at certain point of a consultation. The group did not reach a conclusion on whether adherence to IMCI guidelines as a validation measure should be included in the TPP.

The place of machine learning in the TPP was difficult to define. It was agreed that the minimum requirement should be 'no machine learning', and the optimal should be to include machine learning, but the group felt that this requires further in-depth discussion to define exactly how machine learning should be applied.

4.3 Focus group 2: Diagnostic data and disease prediction

It was agreed that the minimal requirement for diagnostic tests and devices should be that they are locally relevant, but for the optimal requirement, rather than including newly emerging devices targeted to the local setting, the TPP should state that these should be widely available in the local setting.

The TPP should include sections for POC data output as well as POC data input. For data input, the minimum requirement should be a simple binary 'yes/no' result, and the optimal requirement should be quantitative data, and should also take into account ease of use, time to result, and connectivity considerations. It was noted that regulatory requirements for diagnostic tests and medical devices differ considerably; this should be taken into account in the TPP.

'Disease likelihood' was preferred over the terminology 'Disease risk likelihood' to describe the probability element of the performance section of the TPP. For this characteristic, the group proposed for the minimal requirement POC data, and for the optimal requirement POC data and pre-test probability.

4.4 Focus group 3: Clinical workflow and application functionality

It was felt that 'data ownership' was a more appropriate terminology than 'data access and transparency' to describe the visibility of data, as data access usually refers to privacy. It was agreed that data access, privacy and security should be included in the TPP, but that this would require a separate workshop as it is such a complex and topical issue. 'Transmission' was also thought to be an ambiguous word as this usually refers to push technology in software terms. For data ownership, it was agreed that the application owner, which in this case refers to the client rather than the software developer, should have visibility of all data.

It was recommended to name the access component 'System access' to distinguish between the availability of the algorithm and availability of the source code. The tool should have a publicly available API, to allow other systems to 'talk to' the tool through commonly known programming languages. This should be protected by authorisation and authentication that as a minimum requirement adhere to usual technical standards, and optimally would adhere to HIE and/or HL7 medical standards. It was noted that adherence to HL7 can be expensive, hence this was proposed as an optimal rather than a minimal requirement. It was also noted that interoperability is covered by this section and therefore a separate line in the TPP is not required.

The group noted that it is important to build in an element of validation and trust into the TPP. The tool should be sufficiently transparent that it can be validated by other parties and can be trusted by users. Open source could be an optimal requirement but it was not felt that this was necessary to achieve sufficient transparency.

The tool should allow multiple consultations and patients as a minimum requirement; sequential workflow was not considered to be useful. In terms of navigation, the group agreed that sequential movement through the assessment should be a minimum and non-sequential an optimal requirement (including the ability to go backwards and forwards).

The group broke the existing 'task management' section into three parts: encounter, task management and follow-up. Ability to support multiple encounters on a single device and multiple algorithms active in a single application should be optimal requirements; no minimal requirements were proposed for these categories. The ability to retrieve patient information for follow up should be included, as a minimum through anonymised patient identification, and optimally with the ability to send reminders to patients via telephone or SMS.

For data storage, the group recommended a slight amendment to the terminology to indicate that the capability for server storage should be available as an optimal requirement.

5. Session 4. Implementing electronic clinical decision support algorithms

5.1 Digital health implementation in Tanzania

Presented by Elias Mturi (University of Dar es Salaam)

The initial focus of healthcare digitisation in Tanzania was to capture and provide essential core data for planning and monitoring the performance of the health system, to better control resources, and to improve efficiency by implementing hospital management and nationwide logistics systems. The focus has since changed to improving quality of care and patient safety through implementation of electronic medical record systems, including Bahmni and OpenSRP. However, much of the workflow and medical records are still paper based. As such, efforts to implement eCDAs are still limited. Challenges to implementation and potential solutions are shown in **Table 3**.

Table 3. Challenges of eCDA implementation in Tanzania and proposed solutions

Challenges	Proposed solutions
Governance	
<ul style="list-style-type: none"> • Lack of funding • Inadequate eHealth leadership skills among clinicians • Misalignment between health plans and digital health plans 	<ul style="list-style-type: none"> • Obtain buy in from national health and eHealth leadership • Build strong eHealth leadership skills in clinicians not only IT group • Integrate eCDA need into national eHealth strategy
Infrastructure	
<ul style="list-style-type: none"> • Lack of power and connectivity in remote regions • Poor interoperability standards (development of terminology and data exchange formats is slow) • Legal and regulatory issues • Inadequate skills to adopt universal guidelines into national level standards 	<ul style="list-style-type: none"> • Build solutions for the African setting, i.e. limited resources and infrastructure • Support standard development • Support development of legal and regulatory standards
eHealth	
<ul style="list-style-type: none"> • Slow uptake of electronic medical record systems • Inadequate technical skills for translation of medical guidelines and protocols into code • Issues implementing health information exchange solutions 	<ul style="list-style-type: none"> • Build capacity of local eHealth developers in medical information • Integrate eCDA requirements into current electronic medical record implementation initiatives

Adoption by healthcare workers

- Low literacy and lack of training for healthcare workers on use of computerised information systems
- Establish and implement effective change management strategies

It was noted that any tool should be built on top of existing infrastructure. Additionally, the government will restrict to a single solution, so it is important to ensure that tools do not overlap in terms of output.

The Tanzanian experience resonated with other members of the group who have been involved in the implementation of eHealth tools in LMICs, particularly with regards to the fact that for eCDAs, one size does not fit all; a tool developed in one setting may not necessarily be appropriate for another. Implementing an eCDA without taking this into consideration can cause more problems than solutions. It was proposed that a compilation of all the challenges experienced in implementation of eCDAs could be included as an addendum to the TPP.

5.2 Introduction of an eCDA in Kano State, Nigeria

Presented by Nasir Mahmoud (Kano State Primary Healthcare Management Board)

Currently, health indices in Kano are poor compared with other Nigerian states. Some measures have been recently taken to improve healthcare provision, including task shifting and task sharing, implementation of a health insurance scheme, and development of a policy on medical service plans. However, there is still work to be done, and the use of eCDA could provide substantial improvements in outcomes.

A 6-week pilot study of the MEDSINC tool was performed at five implementation sites to examine the effect on outcomes in children aged 2 months to 5 years, including measures of usability, accessibility and adherence. A 40% increase in IMCI compliance was observed (from 30.6% to 71.4%). Community health workers found the tool to be valuable, and 100% stated that they would be likely/extremely likely to recommend the tool to colleagues. Overall, 93% agreed that it was easy to learn and to use.

The pilot study demonstrated that MEDSINC was effective for supervising and monitoring of healthcare workers, useful for monitoring the pattern of diseases and for indicating outbreaks, and reduced training costs through a distance-learning approach. Challenges encountered during the study included network issues, connectivity and syncing to the platform. Scaling up will require more human resources and funding, and a highly reliable internet connection will be critical to increasing adoption. In particular, the training of community healthcare workers was internet-based, so this could be challenging to expand to rural areas with poor connectivity.

It was noted that as the tool is targeted at the community healthcare level, training focusses on how to use the platform; it is assumed that medical knowledge is limited so there is no need for the users to view the medical content of the algorithm. Exposing users to electronic tools during preservice training is recommended based on the experiences of users in the pilot study.

5.3 Ongoing digital health efforts at WHO

Presented by Garrett Mehl (WHO)

Following an official request in 2016 from member states for guidance on selection and prioritisation of eHealth and mobile health tools, WHO initiated the development of guidelines on the use of digital health interventions for health systems strengthening; the first edition has been approved and will be released imminently. This is timely given the recent World Health Assembly resolution for the advancement of global digital health that aims to assist governments with the acceleration of digitalisation of health systems. The WHO guidelines approach digital health as something to be used to improve quality or coverage of existing interventions of known efficacy, and include eight recommendations for achieving universal health coverage with digital tools, one of which relates to digital decision support.

It was noted that the guidelines will demonstrate that WHO supports the use of electronic clinical decision support tools in routine care and will give countries confidence in their investments. However, there is a lack of high-quality evidence to show that digital decision tools improve outcomes, which will need addressing in order to achieve global acceptance in the same way that ICMI has been widely accepted. It was also noted that while many countries are enthusiastic about digital systems, scaling to a national level is challenging even with evidence of effect. The amount of support and training and cultural change required is significant, and this is reflected in the guidelines.

In addition to the guidelines, WHO is also working on the development of 'computable guidelines' to facilitate adoption of specific WHO clinical and public health recommendations. WHO clinical guidelines generally include implied decision trees, but these are difficult to interpret for non-physicians (for example, they may or may not include performance metrics of interest, and ICD codes are released separately), thus they are not designed to be digitalised. The computable guidelines will be derivative products to accompany the main guidelines, and will be appropriate for incorporation into a software system.

The format of these computable guidelines is still under development, but could include a concept dictionary, standards for data exchange (e.g. HL7), business process descriptions, and computable functions as a service. They are intended to act as a starting point for the development of guideline-aligned eCDAs, and aim to dissuade constant reinvention. The initiative will start with a few health domain areas that have recently released or updated clinical and public health guidelines.

5.4 Marketplace preparation

Group discussion led by Zach Katz (FIND)

The group discussed what the marketplace for eCDA should look like and whether any shaping of that market may be required. It was clear that there was no consensus on a marketplace and the topic should be re-raised in future meetings. What was clear, is that a mechanism for understanding what products are out there and how they are offered and priced would be helpful for product selection.

Various pricing models are currently offered within the eHealth space and there are lessons to be learned (including from Dimagi, who prices equally across countries, as mentioned in the meeting), especially across open source, open access and proprietary systems.

The comments from the experts are shown in **Table 4**.

Table 4. Feedback on eCDA marketplace shaping.

Topic	Comment
Development needs	“It could be helpful to develop a tool kit to facilitate thinking around how developers can analyse market features, similar to the method used by telephone providers. This would benefit organizations such as FIND and WHO as well as acting as a resource for developers”
Pricing and responsibility	“It is important to consider what the product is – it’s not a phone or tablet, it’s health. It is difficult to determine who will pay for this as healthcare can be funded by individuals, government, or donors. Also, 10 years from now all health is going to be digital, so digital health is not a market in its own right.”
	“In terms of what the product is, you are trying to purchase a health outcome that is favourable – this can be priced.”
	“If we believe that we are going to save lives with eCDAs, then the primary responsibility for implementation lies with the government. Plus most healthcare facilities are government owned. Technology leadership in the government is a good starting point. Also, we need to avoid problems resulting from having multiple different tools.”
	“The drive to open source solutions has created a market failure. A pricing model needs to be identified that accommodates the needs of countries, the donor community and investors as well as developers. It isn’t easy to standardise pricing, and organizations such as GAVI, and the World Bank need to discuss this with ministries to provide more transparency.”
Potential challenges	“The challenges experienced when implementing HIE in countries such as Nigeria and Tanzania tell us that market shaping will be really difficult. Also, unless the market is shaped in the correct way, we won’t necessarily derive any benefit from it.”

	“The hard part will be building a baseline of infrastructure that can cope with eCDAs, including training needs, connectivity issues, and so on. This should be recognised and made part of the conversation.”
Involvement of other organizations	“It may be important to get UNICEF on board, as many countries will procure their digital systems from them, and they have very specific inclusion criteria for their catalogue.”
	“Other international financial organizations that advise governments on procurement could also be brought in. It is important to understand the supply chain and the potential impact of external forces upon it.”
	“Complementary to market shaping, it is also important to create astute consumers and encourage governments to ask the right questions.”

6. Workshop deliverables and next steps

Workshop deliverables include refinement of the TPP that will include feedback received from the workshop. The TPP will then be reviewed and finalised by consensus using a Delphi-like process. The next steps are to inform stakeholders of the availability of the TPP and to disseminate and advocate its use for development of new eCDA toolkits and to guide the selection of toolkits for implementation. We will also continue engaging with the group in the form of joint publications, follow-up working groups and meetings to discuss topics identified during the workshop which include eCDA validation methods, data standards and implementation, as well as market readiness for these tools (i.e. how do we make eCDAs more available to country programmes? how can developers plan for market readiness, under what model?).

B. Annexes

Annex 1. Workshop Agenda

Time	Agenda	Speaker
Session Theme: Outline the evidence and identify needs for implementation		
Meeting Chair: Garrett Mehl, Lead Digital Innovations Research, WHO/RHR		
08:30 – 09:00	Coffee	
09:00 – 09:10	Welcome and Introduction: workshop goal, objectives and agenda _	Sabine Dittrich, Head of Programme Malaria and Fever, FIND Francis Moussy, Lead AMR Diagnostics, Department of Essential Medicines and Health Products, WHO Garrett Mehl, Lead Digital Innovations Research, WHO/RHR
09:10 – 09:25	The role of Target Product Profiles	Sabine Dittrich, Head of Programme Malaria and Fever, FIND
09:25 – 09:40	Clinical algorithms: impact on child health, health systems strengthening, family and community practices, and challenges	Marc Mitchell, Professor, University of California, Berkeley
09:40 – 09:55	Update on the disease landscape and clinical evidence to improve assessment of childhood illnesses	Kristina Keitel, Scientist, Swiss Tropical and Public Health Institute
09:55 – 10:10	Prioritising point of care tests to integrate in electronic clinical algorithms	Karell Pellé, eHealth Scientific Officer, FIND
10:10 – 10:25	WHO Essential Lists to advance universal healthcare coverage: how to link them and enhance their impact through electronic clinical algorithms	Francis Moussy, Lead AMR Diagnostics, Department of Essential Medicines and Health Products, WHO
10:25 – 10:35	Q&A	All
10:35 – 10:50	Coffee break	
10:50 – 11:30	Landscape of electronic clinical algorithms and challenges with development, integration of diagnostics and implementation	Clotilde Rambaud-Althaus, Digital Health Advisor, Médecins Sans Frontières (MSF) Riccardo Lampariello, Head of Health Programme, Terre des hommes Valérie D'acremont, Group leader, Polyclinique Médicale Universitaire & Swiss Tropical and Public Health Institute

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		Barry Finette, Professor of Paediatric University of Vermont and founder of THINKMD
11:30 – 11:45	Q&A	All
11:45 – 13:00	Lunch (on site)	
Session Theme: Identify critical criteria for a Target Product Profile and guidelines to support implementation		
Meeting Chair: Garrett Mehl, Lead Digital Innovations Research, WHO/RHR & Karell Pellé, eHealth Scientific Office, FIND		
13:00 – 13:10	TPP to guide the selection and effective implementation of electronic clinical algorithms in combination with diagnostic tests to improve treatment decisions.	Karell Pellé, eHealth Scientific Officer, FIND
13:10 – 14:30	Breakout Focus Groups: discussion and proposals for critical TPP characteristics Focus Group 1: Algorithm Validation, Performance, Machine Learning Focus Group 2: Diagnostic Data, Disease Prediction Focus Group 3: Clinical Workflow and App Functionality	ALL
14:30 – 15:15	Report from Focus Groups and open discussions	Group Rapporteurs
15:15 – 15:30	Coffee break	
15:30 – 16:00	Challenges, lessons learned and country proposals to support implementation	Elias Mturi, Deputy Managing Director, Computing Center, University of Dar es Salaam Nasir Mahmoud, Executive Secretary, Kano State Primary Healthcare Management Board
16:00 – 16:40	Sustainable implementation: what policies and documentation are needed/required to supplement a TPP? 1. Update on WHO's digital health initiatives and upcoming digital health recommendations	Garrett Mehl, Lead, Digital Innovations Research, WHO/RHR ALL

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	2. Discussion on documentation and policies needed for implementation	
16:40 – 16:50	Summary of TPP characteristics, guidance needs and next steps	Sabine Dittrich, Head of Programme Malaria and Fever, FIND Karell Pellé, eHealth Scientific Officer, FIND
16:50 – 17:00	Towards an access model for electronic clinical algorithms and diagnostic bundles	Zach Katz, Chief Access Officer, FIND
17:00 – 17:10	Concluding remarks	WHO & Meeting Chair
17:10 – onwards	Reception and Networking (on site)	

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