



Trillium II- MOCHA Stakeholder Consultation Meeting

Digital Health Policies for Children's Health: Focus on Immunisation

21st & 22nd November 2018

**Strengthening child immunisation in Europe through
health data standards: Connecting holistic health
records, patient summaries, EU vaccination cards, and
immunisation registries.**

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Convenors: Dr. Catherine Chronaki – Trillium II / HL7 Foundation
Prof. Michael Rigby – MOCHA / Imperial College London

Rapporteur: Shalmali Deshpande – MOCHA / Imperial College London

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1 Background

Vaccination is key for primary prevention of disease and has proven to be one of the most cost-effective public health measures. Currently, it is the best defence against a number of serious, preventable diseases. Widespread immunisation rates have led to eradication of diseases such as smallpox, and virtual elimination of many others. Despite this success, Europe faces unprecedented outbreaks of vaccine preventable diseases, such as measles, suggesting sub-optimal levels of immunisation. Contributing factors vary from vaccine hesitancy to vaccine shortage to lack of updated, accessible immunisation records for people.

The previous Trillium II-MOCHA workshop concluded that there were many health and other European agencies concerned about immunisation, specifically concerning children, with many recommending initiatives. However, there is a lack of co-ordination mechanisms across all issues within the EU and EEA and children, and parents and civil society seem not to be involved in discussions. There is a need for clarity and policy harmonisation for child immunisation data linkage. This stakeholder meeting was agreed after the first Trillium II-MOCHA workshop hosted in CEN-CENELEC by CEN TC/251 on September 18-19, 2018, in order to give significant opportunity to progress the discussed issues in the context of informed mutual sharing. A variety of stakeholders presented their positions on improving immunisation and strengthening child immunisation in Europe.

1.1 European Centre for Disease Prevention and Control (ECDC)

ECDC (ecdc.europa.eu) is a public health agency of the European Union aimed at providing evidence for decision-making, strengthening public health systems, and supporting response to public health threats. Within this remit, vaccine-preventable diseases are included, though the focus remains on managing vaccination coverage rather than on standards or policymaking. One specific aim of the ECDC is Immunisation Information Systems (IIS), which focuses on sharing experiences, addressing variation in immunisation amongst and within countries, and bettering support for immunisation services in Europe.

The focus of their presentation in this workshop included the need to offer technical standards and solutions to develop standardised immunisation data to allow linkage to other countries or sectors outside of healthcare by supporting the creation or update of national IIS. Briefly mentioned was the creation of a 'network of expertise', which includes IIS managers and collaborations with other organisations. This role is highlighted by the engagement of ECDC in the implementation of key council recommendations on vaccination.¹ ECDC is asked to establish a European Vaccination Information System (EVIS) supporting guidelines for a core vaccination schedule, contributing to National Immunisation Technical Advisory Groups (NITAGs) with scientific evidence, and improving vaccination coverage monitoring systems. ECDC will also support a European vaccination portal which will provide authoritative, scientific, evidence-based and transparent up to date information on immunisation as well as tools to support Member States in fighting vaccine hesitancy.

1.2 The European Joint Action on Vaccination (EU-JAV)

EU-JAV (<https://eu-jav.com>) is a new project that is co-funded by the Health Programme of the European Commission. The project aims to reinforce vaccination efforts in order to increase immunisation rates by addressing vaccine hesitancy and strengthening cooperation between national immunisation advisory groups. The project covers 20 countries, of which 17 are EU

¹ <https://ecdc.europa.eu/en/news-events/ecdc-implement-key-council-recommendations-vaccination>

Member States and 3 associated countries. Within this project, workpackage WP5 – Immunization Information Systems to strengthen surveillance of vaccine coverage² is solely focused on strengthening IIS in Europe to increase vaccine surveillance capabilities and to increase vaccination coverage using MMR as example.

The specific objectives of the overall project include monitor more accurately vaccination coverage, ensure that everybody in the European Union has access to vaccination, improve forecasting of vaccine stocks and systems for the prevention of shortages, set priorities for research and development on vaccination, enhance the public confidence in vaccination. These imply assessing interoperability, testing feasibility of vaccination coverage estimations, and evaluating vaccine recall and reminder systems within and across the IIS systems. The importance and challenges of these objectives were described, with the end goal being achieving a sustainable European platform for strengthened cooperation on vaccination.

1.3 Trillium Bridge II - Reinforcing the Bridges and Scaling up EU/US Cooperation on Patient Summary (Trillium II)

Trillium II (www.trillium2.eu) is a Horizon 2020 project that starting with broad adoption of patient summary standards aims to: (a) Improve international interoperability of eHealth Systems in US, in Europe and globally; (b) Accelerate establishment of interoperability standards in eHealth with validated open source interoperability assets and sharing lessons learned with standards developing organizations; (c) Facilitate secure, seamless patient summary sharing offering clarity and oversight.

Originally the primary point of care considered for use of these summaries was Hospital Emergency Departments in situations of emergency or unplanned care. It should be noted that a patient summary is considered as a snapshot of care and thus differs from a patient history. A patient summary is described as a window to a patient's health information or 'dashboard' to explore key data about a person's health. Thus, it is a much briefer and quicker way to obtain essential patient information, compared to a patient history.

In establishing this patient summary, the aim is to establish a global community of practice for digital health innovation for patient summaries. This global community would help change the attitude around standards and facilitate bridging patient summary initiatives (alignment) across countries, purposes, and regions. Highlighting the social value of patient summaries and associated standards, would help promote the collaborative use of data in health and care. A patient summary includes information such as health problems, medications being taken, allergies, and vaccinations. In order to achieve the full potential of patient summary standards, it is important to identify the required clinical data and establish standardised vocabulary and value sets. The decision of IHTSDO to offer a free core data set for use in the HL7 IPS is recognised as step in the right direction.

The brief introduction from Trillium-II in this workshop addressed patient summaries for child health focusing on child immunisation, and particularly how the patient summary will attest the child's immunisation status, effectively serving as an immunization card. Further focus was on

² <https://eu-jav.com/the-project/wp5/>

how to ensure the presence of updated child patient summaries within and outside the health system, so that patient summaries could serve as home records.

1.4 The Models of Child Health Appraised (MOCHA)

The MOCHA Project (<http://www.childhealthservicemodels.eu/>) has been funded by DG Research to examine primary care systems for children in 30 countries. The MOCHA project collected data on Electronic Health Records (EHRs) and IIS use, including data on consent for HPV vaccination, and on how countries handle differences between the young persons and their parents over immunisation and access to their records. Identified gaps and differences signal the need for aligned health data standards in immunisation records, an observation also confirmed by an ECDC study and Technical Briefing.

1.5 Vaccines Europe (VE)

VE (<https://www.vaccineseurope.eu/>) is a trade association for vaccine manufacturers in Europe, focusing on developing new vaccines and therapies for the European population. It is a specialised vaccines group within the European Federation of Pharmaceuticals Industries and Associations (EFPIA), representing twelve companies. These represented companies are research based, operate in Europe, and are dedicated to improving public health through immunisation. The mission of VE is to support improved access to immunisation, enabling better protection of the health of individuals and the wider community throughout life, with both existing vaccines and those in development.

1.6 WHO European Regional Office- Child and Adolescent Health

The World Health Organisation (WHO) is the responsible authority for public health within the United Nations system. The WHO Regional Office for Europe serves 53 countries, which differ vastly in terms of size, geography, culture, and politics. A recent recurrence of measles, a vaccine-preventable disease, has resulted in an urgent need to improve the recording and sharing of immunisation data, in order to help increase the prevalence of immunisations. The launch of recommendations from WHO on home-based records also demonstrates the level of emphasis required on tools for recording immunisations. An active collaboration with MOCHA on this topic presents the current situation within the European region reflecting heterogeneity among home records and surrounding policies in the countries of the WHO Europe region.

An introduction from WHO in this workshop focused on ‘vaccination synchronising’ and sharing of information both between countries and within countries (i.e. between school health services and primary care services). Briefly mentioned were the technologies that could be used to address sharing of information (e.g. electronic health records) and the associated problems, particularly within the context of children and adolescents (e.g. competency for self-advocacy and privacy from parents).

It is apparent that many valuable initiatives are currently being researched and in place. However, common policy, standards, and implementation actions are largely overdue and require attention. The WHO European Regional Office hosted this consultation meeting with the aim to connect stakeholders from immunisation programs, home-based records, patient summaries, and EU vaccination cards. This meeting aims to identify actors, resources and projects to carry child immunisation forward.

2 Objectives

In the previous Trillium II-MOCHA workshop, it was agreed that a cohesive body of work was required to enable data handling, record keeping, and eHealth to be more effective as a key means of improving immunisation coverage, and the recording of this.

The joint Trillium-II MOCHA work suggests that health data standards for immunisation and related health data, could be a valuable way of aligning not just immunisation records, but also of improving immunisation uptake and ultimately other aspects of preventive health by addressing the needs of individuals informedly in their local context. Thus, the two projects have a commonality of interest in health data standards for children, and have committed to working together to advance understanding, implementation, and policy alignment.

The **eStandards Roadmap methodology** is employed to advance interoperability in digital health services for children. First, **trust and flow** of health data is seen as the basis of well-functioning health systems. Consistent child immunization information across holistic home-based records, vaccination cards, and the child's patient (health) summary is critical to building trust and securing dynamic flow of health data across settings to ensure safe informed care.

Second, the **eStandards Compass** balances and respects the perspectives of health systems, workforce, citizen, and the market when educating about health data standards and incentives in collecting, understanding, and aligning needs around programming, delivery, and reporting of immunization information. Third, the **eStandards Roadmap Component Inventory** supports reuse of effective policies and components that help assess the extent to which child health scenarios drive uptake of child immunization along with trust and flow of high quality health data and indicators. Interlinked **Co-Creation, Governance, Alignment** circles bring data, actors, processes, methods together: **Co-creation** to make digital health real using standards, **Governance** to drive digital health adoption in large-scale, and **Alignment** to make digital health flourish in a measurable sustainable way through concrete actions.

The following topics were suggested for discussion for the WHO Europe hosted stakeholder meeting in the report of the earlier meeting in CEN/CENELEC, September 2018:

- Sharing to the wider stakeholder audience of the situation briefing.
- Analysis of the use cases to highlight key data, process, and information features.
- Scenario data requirements – e.g. parent at home, primary healthcare professional, emergency room, school.
- Immunisation and holistic home-based record content and processes.
- The role, contents, and processes of the proposed European Immunisation Card.
- Opportunities for use of eHealth technology, including portals and electronic home-based records and similar mobile health apps.
- Autonomy and self-management or co-production of health interventions of older children; does a mirror of Assisted Decision-Making principles give opportunity, and how would it work?
- The harmonisation of these initiatives to achieve common goals, and contributory common solutions such as agreed data definitions, data sets, and data exchange.
- What work strands or projects are needed?
- Who would lead these, and who contribute?
- What funding or resourcing is available?
- What coordinating mechanism?

3 Discussions

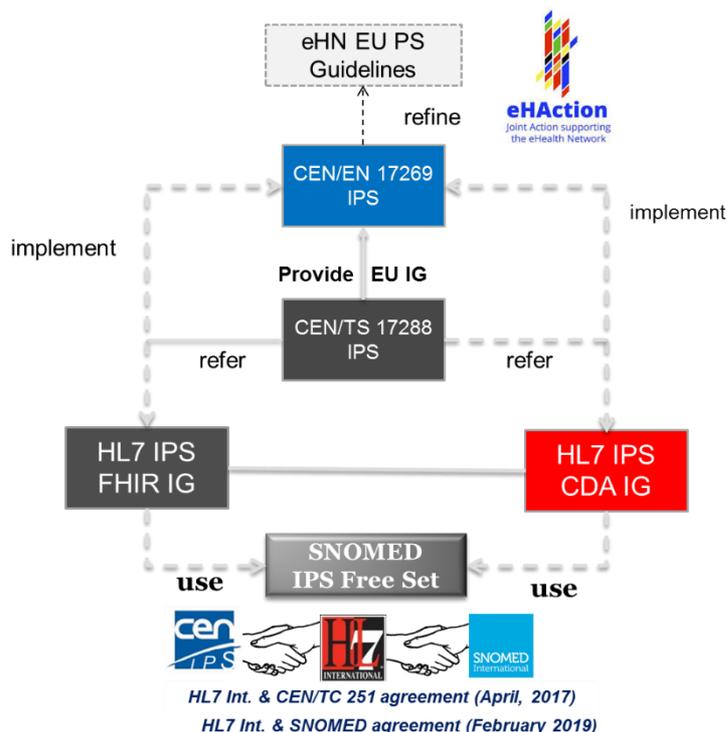
Plenary discussions during the meeting focused on overviewing child immunisation initiatives and considering different country perspectives, to ascertain the degree of common ground, and the areas and issues needing most attention.

3.1 Overview of Child Immunisation Initiatives

3.1.1 HL7/CEN cooperation, HL7 FHIR International Patient Summary (IPS)

HL7 International is a not-for-profit, standards developing organisation. Its mission is to provide standards that empower global health data interoperability. Its aim is to make electronic health information more accessible to support clinical practice and health services. To improve interoperability and access to healthcare, the use of application programming interfaces (APIs) is at the core of HL7 Fast Healthcare Interoperability Resources (FHIR), the newest family of HL7 standards. APIs in healthcare could manage the flow of information between different systems and better serve end-user needs. Further to this, the HL7 FHIR) standard is an HL7 development that responds to the need for agile standards development.

HL7 and CEN/TC251 cooperate on the International Patient Summary Specification to create a standard that meets the needs of the EU guidelines for cross border care and is consistent with implementation that have global scope. The connection among different data standards appear in the picture below.



The International Patient Summary (IPS) is an extract of a patient’s electronic health record information. It is not a full electronic health record (EHR), but represents a snapshot of a core set of information. The FHIR IPS implementation guide aims to provide a high quality, safe, and standardised approach to aggregate and merge patient health data from separate EHR sources. This type of patient summary, including information on when the vaccine was given and when/if a booster is required, could be extremely useful for migrants or unaccompanied minors. In this

meeting, there was discussion on the feasibility of collecting patient health data from different sources and combining it on to one patient summary that can serve the needs of the European Vaccination Card and the home record.

3.1.2 GS1

GS1 is a global, independent, not-for-profit organisation, that develop global supply chain standards, used in sectors such as retail, foodservice, healthcare and more. The aim is to aid and automate the movement of goods and standardise the supply chain processes using a standardised global language of business. One of the important tools are standardised barcodes on products, containing the Global Trade Item Number (GTIN®) and other relevant information. The use of these standards in healthcare allows increased patient safety, improved traceability of medicines, and enhanced clinical effectiveness. Through the GS1 standards the aim is to achieve global unique identification, incorporating vaccine standards.

The 'Falsified Medicines Directive' is to be fully implemented by February 2019. This directive will ensure medicines are verified and authenticated through a unique identifier and an anti-tampering device, which will stop falsified medicines being mixed into circulation with authentic, regulated medicines. In the context of vaccinations, this means that every vaccine will have its own unique identifier, which will include information such as: the product code, serial number, batch number and expiry date of the vaccine. This process endeavours to support vaccine production, batch traceability, and pharmacovigilance. In this stakeholder meeting, discussions focused on how GS1 processes could be used to promote a cohesive and standardised system for delivery of vaccinations, with the aim to improve European vaccination coverage.

3.1.3 SNOMED

SNOMED International is a global, not-for-profit organisation that has 35-member countries with other affiliates (organizations in non-member countries which use SNOMED). Membership to the organisation is dependent on healthcare strategies within countries and the ability to support the use of SNOMED with a terminology release center.

Their aim is to enable international exchange of healthcare information by determining standards for a codified language, representing groups of clinical terms. These terms have been developed collaboratively, ensuring that the terminology is in clinical terms rather than specific codes, so clinicians can relate to this initiative globally. Much of the work by SNOMED currently is based on the requirements of the users, with the new approach being 'what is required by the users?'

Information in the United Kingdom has been coded through SNOMED for some time and this is now mandated in all GP surgeries within the country. The main issue discussed during this stakeholder meeting focused on the interoperability between other coding standards (ICD10) and between global drug dictionaries (IDMP). With their own strengths and merits, multiple platforms can lead to inefficiencies, such as duplication and coding errors. Within the context of vaccination, the introduction of a vaccine product model was discussed, with the driver being the Canadian Vaccine Catalogue (CVC). Briefly, the CVC is a comprehensive, standards-based resource for vaccine terminology and vaccine product information.

It is evident that patients and healthcare professionals benefit from higher quality, consistent and safe health records, within a healthcare service. Emphasis on safe, accurate and effective exchange of health information to improve global healthcare is an important objective for both SNOMED and this stakeholder meeting.

3.1.4 Youth Health Program Netherlands

Immunisation of children (from 0 -18 years old) is seen as a public health task in the Netherlands. The vaccination program is the responsibility of the RIVM (National Public Health Institution) and performed by municipal health institutions.

NICTIZ is a not-for-profit organisation funded by the government in the Netherlands, focusing on developing and refining national standards for electronic communications in healthcare. As such, NICTIZ provides immunisation standards and certifies the IT systems on interoperability of immunisation transactions in the Netherlands.

In the Netherlands, all medical records are digitalised, making it easier for a patient's healthcare data to move with them, as they move around the country. All immunization data is collected into one system, supported by the RIVM (National Public Health Institution), called Praeventis. This system allows the recording and tracking of vaccinations, allowing healthcare professionals to determine the volume of vaccinations given throughout time. For example, a decline in vaccination is seen during winter, whilst a spike is seen when there are mass vaccinations at schools.

During this meeting, discussions focused on issues surrounding this electronic system and GDPR, issues around parent/child confidentiality and autonomy, and incorporation of standards to allow data to be shared internationally. These issues were not specific to the Netherlands and were apparent in all countries that were represented in the meeting.

3.1.5 The European Academy of Paediatrics (EAP)

The European Academy of Paediatrics (EAP) is a non-technical organisation consisting of 40 countries as members. As a section within the European Union of Medical Specialists (UEMS), the aim is to promote child health in Europe with influence in a political arena. EAP improves standards in training, service, and research to also represent paediatricians in the EU. Within this organisation, there is a Vaccination Working Group (VWG) that comprises representatives from all European regions, who are involved in their national immunisation programmes. The aim is to build effective and interactive networks in order to improve harmonisation of national immunisation programmes, with the ultimate goal of achieving optimal vaccination coverage.

VWG meets biannually to discuss the current situation of immunisation in Europe using data that is collected through surveys. Key topics include: implementation of recommended vaccines; national monitoring of vaccination coverage; measures to increase vaccination coverage; ensuring equitable access (including migrant population); approaches to deal with vaccine refusal; shortages in vaccine supply; and others.

Collaborations with European organisations are in place in order to optimise efforts in achieving these goals, all the while advocating vaccination for children and young people, as well as for professionals. The shared vision amongst all these organisations being, "a European Region free of vaccine-preventable diseases, with equitable access to high-quality, safe, affordable vaccines and immunisation services throughout the life course"³.

³ EAP Vaccine Working Group. Accessible on: <https://eapaediatrics.eu/working-group/vaccination/>. Date of access 12/01/19.

3.2 Examples of Country Positions and Policies

3.2.1 Denmark

In Denmark, vaccinations are delivered by GPs through primary care, since it is well-established at the heart of the healthcare system. Danish citizens with their unique identifier, known as the CPR, are entered in the Danish Vaccination Register. There are no registered vaccines delivered unless an individual has a CPR. Although this allows high quality assurance, this leads to problems with asylum seekers since they do not have a national ID and therefore, their data cannot be recorded until they are granted asylum status by the Red Cross.

For Danish citizens, access to their vaccination record is obtainable through a website allowing both patients and healthcare professionals to input data. In fact, GPs are required by law to input vaccination data in order to ensure that health records are integrated. Within this system, patient reminders are a vital component and as a result of reminders, vaccination coverage has improved by 5% in Denmark. Since the recording of personal data is bound by privacy regulations and laws, public health data is non-identifiable. This means that statistics are not as robust as other European countries, the quality of data is lower, and data is less generalisable since they cannot go back to the individual.

3.2.2 Greece

In recent years, Greece has been actively trying to reform its healthcare services to reduce healthcare spending and to increase positive health outcomes. This is a result of the 2007/2008 financial crisis, which had a significant impact on access to healthcare services in Greece. Consequently, there has been a strong focus on improving primary health care services by integrating care and maintaining good vaccine coverage. In Greece, primary healthcare services are provided through a mixture of publicly funded health services and private general practitioners (GPs).

In Greece, the National Immunisation Program (NIP) is set by the Ministry of Public Health and Social Solidarity, Greek Center for Disease Control (KELPNO) and is provided free of charge to all residents, including immigrants. The NIP is comprised of a vaccination schedule typically provided by paediatricians for children, and GPs for adult health needs. Public health nurses have an important role in immunisation delivery in both the hospital and in primary care. Since there is no tender for a single service to provide vaccinations, there are a lot of choices available and therefore a great deal of variability even within cities. There is currently no national IIS and thus no system in place to send reminders to parents for vaccinating their children.

Therefore, for paediatricians, the Greek home-based record (the child health book) is an important record of the child's immunisation history. This is because, although there is an electronic patient records system in the public sector, there is no immunisation registry in place and therefore no robust data. Further, there is no connection between an individual's social security number and denominator data in municipalities making it even harder to generate reliable data. It is also important to note that there are still areas within Greece where there are still no digital health records at all. In the context of children, although vaccination records are kept in schools, there is uncertainty surrounding whether it is digitised. Further, there are no policies in place that exempt children from school if they have not been vaccinated. An effort to evaluate vaccination coverage for MMR using ePrescription data did not provide satisfactory results due to low quality of the data. The discordance within the country and its immunisation

services was discussed briefly, as well as issues surrounding the Roma population, who are not covered and widen the gap for obtaining full vaccination coverage.

3.2.3 Hungary

Hungary follows a tax-funded, single payer, social health insurance model for their healthcare system. Primary care services are funded by the National Health Insurance Fund. Services for paediatric primary care are offered by visiting nurses, GPs or primary care paediatricians (PCPs), school health system personnel (contracted school doctors), and school visiting nurses.

Typically, both types of visiting nurses focus on screening, checking mandatory vaccination status, and follow-up on socioeconomic status issues. GPs or PCPs provide acute and chronic care, and also carry out screening, and administer mandatory and opportunistic vaccinations. School doctors are responsible for daytime acute care, screening and for promoting mandatory vaccinations. Presently, there is no EHR with school health services in Hungary.

All these services report to the local policy administration services of public health, which in turn provides vaccines for the GPs and school doctors. Only doctors are authorized to give vaccinations in Hungary. The reported vaccination coverage is high, where reports from OECD show a measles vaccination rate of 99% in Hungary⁴.

To encourage data and information sharing between healthcare services, the Hungarian national eHealth platform (EESZT) was introduced in 2017. EESZT is a cloud-based domain, which electronically stores information about patients and connects all sectors within the Hungarian healthcare system. It allows all state-funded health institutions to be interconnected, which facilitates physicians from different institutions to access patient health information. A complete patient case history can be produced when all medical documents are sent to the system, to provide a detailed picture of the patient.

Additionally, citizens can use a specific portal to access their medical records, electronic prescriptions, and healthcare encounters. In order to protect sensitive medical data, they can restrict access to healthcare professionals and review the access log to their data.

3.2.4 Iceland

Healthcare in Iceland is universal, largely paid for by taxes through the Icelandic Health Insurance Fund and administrated by the Ministry of Welfare. Primary care is provided by health centres throughout the country. Data from consultations with doctors is stored in an EHR for every patient, who has their own unique record identifier (URI). The information from this EHR can be shared easily via HealthNet Hekla, a cloud-based system. This means that EHRs used in hospitals, healthcare centres, private practices, and nursing homes are interconnected to support vital patient information and data exchange seamlessly.

Therefore, all EHR systems in use within Iceland need to be able to connect to the HealthNet Hekla for continuous health information exchange. It is important that healthcare providers comply with regulations on quality and security of data in the health records, before they can participate

⁴ Organisation for Economic Co-operation and Development. Child Vaccination Rates (Indicator). 2018. Accessible on ([fohttps://data.oecd.org/healthcare/child-vaccination-rates.htm](https://data.oecd.org/healthcare/child-vaccination-rates.htm)). Access date: 27/09/18.

in interconnected health records. This is particularly important for vulnerable populations, such as children.

HealthNet Hekla presents the opportunity to monitor every child from birth throughout their life course, meaning every individual in Iceland is counted. Although this system is in place, it has not helped to achieve full coverage of childhood immunisations. However, it seems the problem does not lie with vaccination, rather it lies in how to reach those individuals who are not immunised. Explanations for lower vaccination rates in Iceland include incorrect documentation (i.e. the vaccine is given but not registered), if the child is unwell at the visit for vaccination and forgets to attend another appointment when better, and if children move between providers. Further reasons include immigrants and also children who are vaccinated abroad and have not recorded these vaccinations in Iceland.

Current on-going efforts to alleviate these problems include introducing an algorithm to identify all children in the 'Social Insurance Register' who are not fully immunised. Health centres are informed if the child is not fully immunised and a set of reminders are in place for healthcare provider and the parents. In addition to this algorithm, reimbursement programmes for health centres, who receive remuneration if they reach the target vaccination coverage, could also help increase vaccination coverage.

Finally, the presence of 'Heilsuvera', a web portal with health-related information, also provides parents remote access to their child's vaccination status. Hekla is a nationwide cloud-based system in Iceland. All health professionals feed directly into this system- there are some exceptions, but all vaccination data is recorded in this database.

3.2.5 Italy

Italy has a tax-funded predominately public, decentralised national health system. Concerning immunisation, the Ministry of Health develops an annual 'National Immunisation Plan' and then each region adopts this plan defining its own strategies and procedures. Therefore, there are heterogeneous vaccine schedules and heterogeneous management processes across the country. In Italy, there are 21 regions/autonomous provinces in which 120 local health units (LHU) are operational. According to a survey from 2016⁵, of these regions, 18 have an immunisation information system (IIS) in all the LHUs. Of these 18 regions, eleven use a fully interoperable IIS. These eleven regions have the same software, which offers additional functionality, such as appointment scheduling, recall, recording reasons for no vaccination, history, and risk factors. Currently, the main challenge is that there is no integration across regions, making it difficult to estimate immunisation coverage. There is also no integration between the IIS and the paediatric EHR. Up until 1998 in Italy, children were required to have four vaccinations in order to enrol to schools. When this policy changed in 1999, a decrease in vaccination rates was observed. In 2017, 3670 cases of measles were reported, leading to three measles related deaths. A new legislation introduced in 2017/2018 states ten vaccinations as mandatory and strongly promotes four other vaccinations. The new National Vaccination Plan 2017-2019 is based on the EU Plan 2015-2020. The plan includes an agreement on vaccine schedules and guidelines to develop regional IISs. Moreover, both initiatives foresee the development of a national registry.

⁵ Organisation for Economic Co-operation and Development. Child Vaccination Rates (Indicator). 2018. Accessible on ([fohttps://data.oecd.org/healthcare/childvaccinationrates.htm](https://data.oecd.org/healthcare/childvaccinationrates.htm)). Access date: 27/12/18.

The information flow proposed by the new legislation requires communication from the LHU immunisation registry to the regional immunisation registry that sends data to the national registry to estimate prevalence of immunisation coverage. In regions where an EHR is present, the paediatrician is also informed of the immunisations provided. Regional registries could link information to schools to determine the immunisation status of students.

3.2.6 Portugal

The National Vaccination Program (PNV) was introduced in Portugal in 1965 and has been continuously reviewed since, to improve national vaccination rates. The goal of the program is to vaccinate as many people as possible, with the most appropriate vaccines, as early as possible, and in a sustainable manner. The promotion of individual protection is considered an asset for public health. The PNV is delivered through a vaccine recommended scheme to the Portuguese population and is administered according to age. Until 2003 the PNV was entirely paper-based, after which transcription of vaccination data to local electronic databases occurred. Though this digital transformation was required, the execution led to partial loss of information for older patients during transcription and fragmented, incomplete records. Additionally, each regional or local health unit was only aware of patient information within their area, which resulted in multiple partial records for citizens with multiple residences over a period of time.

Consequently, in 2016, the Portugal Electronic Vaccination System was set up. The aim was to eliminate paper-based administrative and clinical healthcare data records and have a fully electronic immunization system. The user is registered at birth through a digital birth notice, children are issued an 'eBulletin' instead of a traditional paper-based home-based record, and the immunisation record is digitized (Digital Vaccination Bulletin). This digital immunisation record is accessible through the National Health Service (SNS) portal to citizens and professionals from the public and private sector.

The digitisation of health records has led to several advantages including: cost reduction, simplification of immunisation history, and improvement in the quality of information. This system also promotes the citizen as the nucleus of the healthcare system, encouraging vaccination uptake, and empowering citizens to participate in their healthcare. A reference set for vaccines has also been developed using SNOMED CT mapped to the National Code System. The SNOMED CT English terms were translated to Portuguese and the reference set was validated by national authorities and healthcare professionals. The SNS portal is also available in the mobile application (app) offered by SPMS, the health IT agency in Portugal, called 'MySNS Wallet'.

Vaccinations outside the vaccination schedule are also available and can commonly be accessed through community pharmacies. These pharmacies are ubiquitous and are a popular resource amongst the Portuguese population. To receive a voluntary vaccination at a pharmacy, a medical prescription is required. So, it is possible that a citizen could approach a pharmacy with a prescription and receive a vaccination outside the vaccination schedule by a specially trained pharmacist or a nurse. Pharmacies are privately run and therefore, there is no universal brand used for a certain vaccine. Rather, the citizen can choose their vaccination brand and pay for whatever they prefer, promoting empowerment and a patient-centred approach. These vaccinations are typically electronically recorded from the pharmacy to the recipients' EHR, where in 2017 all pharmacy administered vaccinations were recorded.

4 Workshop Discussion

As this was an expert and stakeholder working meeting, a key element was consideration of key issues within breakout sessions, followed by plenary reporting. This enabled critical review of the analyses and proposals from the groups, then cross-linkage into an overall situation review resulting into actionable proposals.

4.1 Workshop Discussions- Day 1

4.1.1 Child patient summaries: Vaccination Model – reasons for non-immunisation

Stakeholder discussions into child patient summaries and reasons for non-immunisation suggested that despite resistance to immunisation being a problem for a small population, overall coverage still remains problematic for wider reasons that are often overshadowed and not recorded. The points of 'slippage' for missing vaccinations were thought to vary across the lifespan of the child. For instance, vaccinations when a child is 0-5 years may be delayed, missed or avoided due to family issues, such as congruence or dissonance between family members or carers, or difficulty of a busy parent in bringing the child if this involves for instance time off work and lost income. School-aged children are likely to be healthier and therefore it is possible they have less contact with health services; in this way continuity of care is lost. When a child reaches adolescence, there are other problems and factors to be considered that may prevent vaccinations from occurring, including compliance and cultural concerns. Of note are children with complex care needs, whom in the absence of shared data records are entirely missed from vaccinations.

Other issues include access and education. Access issues include:

- Geographical limitations and challenges in visiting medical professionals;
- Timing of appointments that may cause inconvenience to working parents;
- Issues around communication and language barriers between the family and medical professionals;
- Economic issues surrounding not vaccinating the child;
- Phased immunisations that are spread out over time rather than delivered all at once.
- Multiple sets of engagement can be a deterrent, hence reducing full vaccine coverage.

Educational issues include:

- Complacency of health professionals and their knowledge surrounding immunisation. It is probable that there is variability in undergraduate medical courses and therefore it is unlikely that all doctors would have the same level of knowledge concerning immunology and vaccinations;
- Complacency of parents who see their child as predominately healthy and do not see the need to vaccinate their child if it is not unwell;
- Children's education and knowledge surrounding vaccinations and hesitancy.

The problems surround non-immunisation in children are visible, notably concerning data and processes for immunisation. A few considerations and proposed solutions, as next steps, included establishing an **algorithm that could detect a missed immunisation and the reason for this within a patient's pathway**. Further, an **IIS flagging geographical areas that have lower vaccination coverage** and could highlight problematic areas, providing a clearer picture of which areas to target with vaccination campaigns. It was noted that **the current IPS data set did**

not identify reason for non-vaccination, and thus targeted follow-up was not possible based on the child's patient summary. It was suggested that these three proposals could improve the quality of data on different indicators within the IPS.

4.1.2 Common Interface to Immunisation registries and patient summaries

When discussing a common interface for immunisation registries that could be used by patient summaries to retrieve up-to-date immunization information, it was concluded that simplicity is key. Throughout all stages of design and implementation, it is crucial to remember that the **target audience is both the patient and the clinician**. The importance of interoperability and standards was highlighted, and the introduction of a set of **value-based standards for sharing immunisation information across Europe** was discussed.

Discussions regarding the design of the **IPS once again centred around information being disease led, rather than immunisation-event led**. Other suggested design features included limiting free-text categories within the IPS and including information categories for immunisation data (e.g. adding the next booster date, duration of coverage for individuals for each vaccination, etc.).

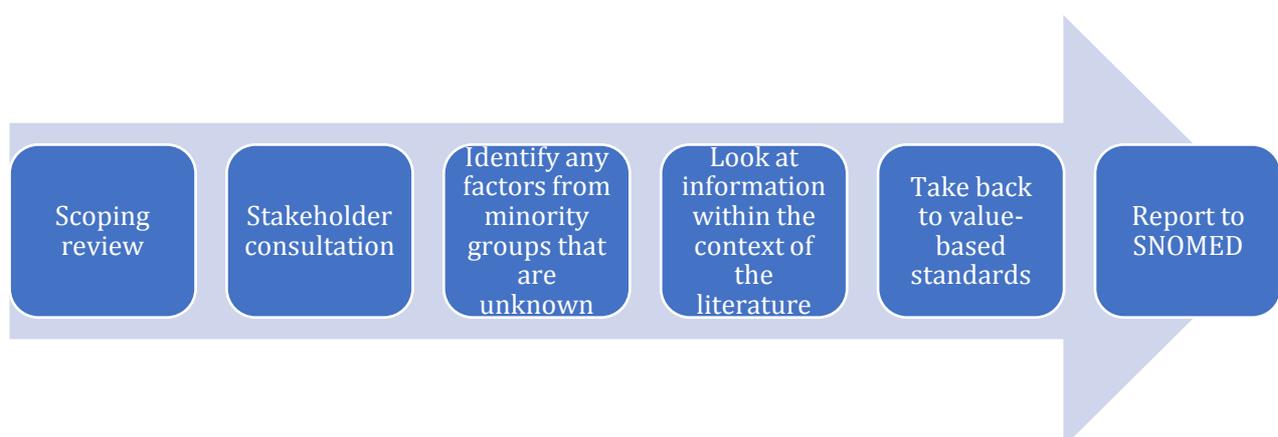
4.1.3 Functional requirements: patient summaries for child health

When discussing patient summaries for child health, the stakeholder group reflected on how the current structure of the IPS recorded when a vaccination was received and details surrounding the event. It was discussed whether a disease-centred approach would be more beneficial, in order to see progress towards achieving full immunisation for polio, for example. In this way, the focus is on life-course vaccinations rather than for specific age groups, and the process becomes more patient-centred.

Further discussions focused on refining the IPS itself. It was discussed that the IPS should only contain a brief overview of information required for the healthcare professional to treat their patient. Questions arose surrounding the presentation of information and the interface of the IPS. Clarification on the main purpose behind the IPS was also mentioned, where in the context of this meeting it was discussed whether it could be used to improve vaccination coverage and help individuals who miss out on immunisations be back on track.

4.1.4 Vaccination confidence and the patient summary: scenarios for awareness

During this discussion, there was a recap on points of vaccination 'slippage' (access, education, data quality), which led to further discussions on innovation, communication, and organisation. A framework was suggested that could aid the coding process and is shown below:



Similar to previous design pointers, it was stated that the interface should be simple for patient use. **Lastly, development of a code for vaccine delay to be used in the IPS was suggested since currently this is not accounted for in the relevant IPS value set.**

4.2 Workshop Discussions- Day 2

4.2.1 Digital health policies for child health – vaccination workflows

When discussing workflows for vaccination, it is important to define the workflow requirements. There should be clarity about what is the pathway modelled, whether it is a clinical or administrative pathway, whether the focus is on data or the child. Additionally, who are the actors that are involved? In this context, actors include people (healthcare professionals; parents; children), services (immunisation centres, GP surgeries, hospitals, schools), systems (registries, e-records, information systems), and outcomes (data, documents, paper-based records, electronic records). Other requirements to be defined include which part of the pathway should be modelled, which events trigger the workflow, and what functionalities of the new system need to be implemented. These considerations are important since there is much variability across and within countries, and also throughout the life course of an individual.

4.2.2 Health Data in Children with complex needs: role of the patient summary

Children with complex care needs have multidimensional health and social care needs in the presence of a medical condition. Two key issues are faced by children with complex care needs. First, primary/preventive care providers do not know who the healthcare providers for integrated care are and how best to approach them. Second, there are reportedly low levels of consultation between adolescents, parents, and healthcare providers within the EU/EEA 30 European countries.

Therefore, the IPS as a clinical snapshot is only good for children with complex care needs if it includes all the components of integrated care pathway and treatment plan. The key data issues are centred around individualised care; coordinated pathways to specialised care; and legal, policy, and governance structure. A further data issue, for parents who interact with and receive care and advice from charities or non-governmental organisations, there are no records available that could be shared within the healthcare sphere.

A further topic discussed was autonomy in children with complex care needs. As individuals who may be non-verbal or have limited communication, the issue of autonomy is somewhat heightened. Since there is no universal policy on the age at which children can make their own healthcare decisions, many functions are often based on age group rather than the child's capacity to engage.

An IPS for parents with children with complex care needs would be beneficial and supportive as a starting point, particularly to show their care needs and identify key current issues.

4.2.3 Recommendation of the EU council and European Vaccination Card

One attributed reason for insufficient vaccination coverage is the increasing fragility of vaccination programmes in the EU. Challenges such as low uptake of vaccines, vaccine hesitancy, increasing costs of new vaccines, and shortages in production and supply have worsened

problems. Therefore, the EU Council has set up aims to focus on strengthening cooperation and coordination between EU countries in order to improve vaccination coverage.

These aims include:

- Introducing a common vaccination card, which is compatible with electronic immunisation systems and can be recognised for use across borders without duplicating work at the national level;
- Introducing a common vaccination schedule;
- Assessing and monitoring attitudes to vaccination within the EU and methods to counter vaccine hesitancy in the EU;
- Forming a coalition between associations from all levels and backgrounds within the field to commit to delivering accurate information and best practice, in an effort to dispel myths surrounding the topic;
- Increasing awareness and strengthening current immunisation awareness events, such as the European Immunisation Week;
- Identifying barriers to access for disadvantaged and socially excluded groups by involving the community.

Methods proposed for fulfilling these aims include introduction of a European vaccine ISS, guidelines on a common vaccination schedule, an EU vaccination card, and a web-portal with updated information on the benefits and safety of vaccinations.

4.2.4 Towards a Functional model for child health records

After a brief description of the IPS, the discussion focused on systems. Even if a country has the best healthcare system, if the system cannot capture information in a usable data format, then this is a flaw. When considering the EHR, the system within which it is used can change depending on the level in which it is used (for example, personal system, regional system, national system, and so on). To overcome this, the HL7 EHR-S Functional Model defines a standardised model of the functions that may be present in EHR Systems. A clear distinction is made between the EHR as a singular entity and EHR Systems as a class that needs to support a set of functions.

5 Future Action Plans and Conclusions

The meeting, especially the topic-based small group discussions, had identified overlapping activity and discordances across European initiatives, additional to national regional and local variation. It was desirable to harmonise actions, and to seek commonality of goals and methods. Though WHO, individual Directorates of the European Commission, and specialist European agencies and programmes all had their expert role for specific aspects, there is no overall lead person or body.

In this context, the following broad areas of activity were agreed as desirable:

1. Boost the International Patient Summary immunisation (IPS) component (a simple new indicator of reason for non-immunisation would help clinicians figure out the problem and close gaps within the immunisation process). Send invitations to members to be part of an advisory committee.
2. Feedback to the European Commission regarding the duplication of European community initiatives. Promotion of harmonised activity, presentation of activity, and the interface of IPS, would be desirable.
3. Engaging WHO to aid in the promotion and overview of this work.
4. Further studies through literature reviews, focus groups, etc. to understand issues surrounding awareness of children to express themselves. Focus on important issues such as autonomy, consent, and use of patient summaries by children via mobile phones.
5. Health literacy work; providing access to reliable sources for immunisation education. Collaboration with the WHO initiative within the vaccines safety division.
6. Further work and discussion around topics not addressed to the stage of final recommendations in this meeting: gaps in health data standards for child health; autonomy and consent in patient summaries for adolescents; common interface to immunisation registries; and child patient summaries for children at school.

Specific short-term actions that were agreed upon were:

1. Explore validation of patient summaries in Portuguese community Pharmacies
2. Assess Digital Health Literacy for adolescents focusing on autonomy and use of IPS
3. Examine the feasibility of supporting the European Vaccination card as part of the roadmap for CEF eHealth DSI, addressing coding issues.
4. Explore the support of patient summaries to children with complex needs, developing further the care plan component for the IPS
5. Develop API to retrieve patient summary immunization component with Immunization Registries to extract up-to-date information.

6 Appendices

6.1 List of Participants

Aigul Kuttumuratova, WHO

Alex Berler, GNOMON, Greece

Anabela Silva, ANF, Portugal

Catherine Chronaki, HL7 Foundation (Trillium II)

Carrie Beth Peterson, WHO

Datta Siddharta, WHO

Daniela Luzi, CNR Italy (MOCHA)

Elena Petelos, CSFM, School of Medicine, University of Crete - HSR, CAPHRI, FHML, University of Maastricht

Eleni Siskou, EU DG Sante

Fabrizio Pecoraro, CNR Italy (MOCHA)

Geir Gunnlaugsson, University of Iceland, (MOCHA)

Giorgio Cangioli, Chair of HL7 Italia; HL7 TSC Member

Jane Millar, (International Health Terminology Standards Development Organisation (IHTSDO))

Jesper Kervin Franke, Head of Healthcare at GS1 Denmark

Marcello Melgara, LISPA, Italy

Maria Brenner, Trinity College Dublin (MOCHA)

Martin Weber, WHO Europe

Michael Rigby, Imperial College, UK (MOCHA)

Michael Tan, NICTIZ Product Manager, Netherlands

Mie Hjorth Matthiesen, MedCom, Denmark

Pascale Mauran, Vaccines Europe President

Paul Chenoweth, WHO

Peter Altorjai, Hungary (MOCHA)

Shalmali Deshpande, Imperial College, UK (MOCHA)

Stefano del Torso, EAP Executive Director

Tarik Derrough, European Centre for Disease Control (ECDC)

Tyra Krause, EU-JAV, Head of Dept. of Infectious Disease Epidemiology & Prevention at Statens Serum Institut

Vana Papaevangelou, Professor of Pediatric Infectious Diseases, National and Kapodistrian University of Athens



Trillium-II – MOCHA Stakeholder Consultation Meeting

Digital health policies for Children’s Health: Focus on Immunization **Strengthening child immunization in Europe through health data standards: Connecting holistic health records, patient summaries, EU vaccination cards, and immunization registries.**

Hosted by WHO Regional Office for Europe in Copenhagen on 21-22 November 2018

We are pleased to invite you as a key stakeholder representative to a cross-sectoral consultation on digital health policies to strengthen child immunization in Europe through health data standards.

This WHO Europe hosted consultation meeting aims to connect immunization programs to home-based records, patient summaries, EU vaccination cards along the child’s life trajectory from womb to adolescence. Common policy, standards, and implementation actions are largely overdue, and this meeting aims to identify actors, resources and projects to carry child immunization forward.

Childhood immunisation is a matter of concern for many health policy-setting organisations including WHO Europe, the European Centre for Disease Control (ECDC), the Council of Europe, the eHealth Network, and the EU Expert Panel on Effective Ways of Investing in Health, as well as immunization information systems (IIS), national eHealth programs, professional bodies, advocacy groups, and the industry. Several initiatives target immunisation uptake with strong information and awareness campaigns to counter vaccine resistance. However, these initiatives are largely uncoordinated not only in data recording, but also in the intended use of information underpinning critical use cases.

Most initiatives do not focus on delivery of immunisation to the individual child in the context of their primary care setting. Neither do they concern availability of up-to-date child-health information in settings beyond health care like the school system. Also, the degree to which initiatives consider child consent as the child grows to be health-aware, engaged and empowered, vary considerably. Finally, the possibility to transfer or access records as children move within Europe, and to aggregate immunization information at the Union level, is severely constrained by the fragmentation of information at regional and national level.

The Trillium II Project funded by DG CONNECT under the Horizon 2020 programme, aims to drive adoption of the International Patient Summary (IPS) considered as a window to person’s health information listing problems, medications, allergies, immunizations, and links to further information.

The Models of Child Health Appraised (MOCHA) Project is funded by DG Research to examine primary care systems for children in 30 countries. The MOCHA project collected data on Electronic Health Records (EHRs) and IIS use, including data on consent for HPV vaccination, and on how countries handle differences between the young persons and their parents over immunisation and access to their records. Identified gaps and differences signal the need for

aligned health data standards in immunisation records, an observation also confirmed by an ECDC study and Technical Briefing.

The joint Trillium-II MOCHA work suggests that health data standards for immunisation and related health data, could be a valuable way of aligning not just immunisation records, but also of improving immunisation uptake and ultimately other aspects of preventive health by addressing the needs of individuals informedly in their local context. Thus, the two projects have a commonality of interest in health data standards for children, and have committed to working together to advance understanding, implementation, and policy alignment.

The **eStandards Roadmap methodology** is employed to advance interoperability in digital health services for children. First, **trust and flow** of health data is seen as the basis of well-functioning health systems. Consistent child immunization information across holistic home-based records, vaccination cards, and the child's patient (health) summary is critical to building trust and securing dynamic flow of health data across settings to ensure safe informed care. Second, the **eStandards Compass** balances and respects the perspectives of health systems, workforce, citizen, and the market when educating about health data standards and incentives in collecting, understanding, and aligning needs around programming, delivery, and reporting of immunization information. Third, the **eStandards Roadmap Component Inventory** supports reuse of effective policies and components that help assess the extent to which child health scenarios drive uptake of child immunization along with trust and flow of high quality health data and indicators. Interlinked **Co-Creation, Governance, Alignment** circles bring data, actors, processes, methods together: **Co-creation** to make digital health real using standards, **Governance** to drive digital health adoption in large-scale, and **Alignment** to make digital health flourish in a measurable sustainable way through concrete actions.

A very useful exploratory workshop was held in Brussels on September 17-18 between experts of the two projects, leaders of some innovative national child immunisation e-health systems, and other bodies including WHO. A list of issues needing deeper discussion, and outline proposals for necessary work plans, was drafted and accompanies this invitation.

The **WHO Regional Office for Europe** is kindly hosting this follow-on consultation building on workshops in EFMI MIE2018 and CEN TC251 to seek the views of the wider stakeholder community to review, develop, and refine ideas to suggest further actions necessary to progress the health data and record keeping and sharing aspects of childhood immunisation in Europe in a systematic and child-centric way. The consultation will discuss work strands or projects that are needed, who would lead these projects, who would contribute under what coordination mechanism, and what funding or resources are available or needed to advance this agenda.

You represent an important stakeholder interest, and we do hope that you or one of your colleagues will be able to attend. This is a one-off opportunity for bringing so many interests together, and we very much hope you will be able to contribute. Note that no specific budget is allocated to this workshop. The WHO will provide the facilities; the organising projects will cover the planning and preparation; and we hope that each organisation invited will fund its delegate's travel and subsistence costs to enable a mutual commitment event.

Places are limited, and you are on our priority list. **Please RSVP as soon as possible and preferably before 4 November**, so we can use this place if you cannot attend. For any questions please do not hesitate to contact us. Looking forward to your participation,

Catherine Chronaki for Trillium II Project

Michael Rigby for the MOCHA Project



Trillium-II – MOCHA Stakeholder Consultation Meeting

Digital health policies for Children's Health: Focus on Immunization Strengthening child immunization in Europe through health data standards: Connecting holistic health records, patient summaries, EU vaccination cards, and immunization registries.

Hosted by WHO Regional Office for Europe in Copenhagen on 21-22 November 2018

Preliminary Programme

Wednesday 21 November, 2018

- 09:30 Registration
- 10:00 Welcome – Introductions – Position Statements
- 11:00 Break for Coffee/Tea
- 11:20 Overview of Immunization Initiatives and associated health data standards.
- 12:30 Plenary Discussion
- 13:00 Break for Lunch
- 14:00 Vaccination stories across a child's life trajectory for womb to adolescence: Use Cases
- 14:30 Plenary Discussion
- 15:00 Break for Coffee
- 15:30 Thematic Groups
- 17:00 Plenary Reports from Rapporteurs
- 18:00 End of Day #1

Thursday 22 November 2018

- 9:30 Recap Day #1
- 9:45 Report on Aligning home based records and patient summary for a European Vaccination Card
- 10:15 User Needs for Health Data prepared by experts
- 11:00 Break for Coffee/Tea

11:30 Discussion of Health Data Needs – Situations of Use

12:00 Discussion Groups

13:00 Break for Lunch

14.00 What next steps needed? Who volunteers? What funding? Research / Collation work / Coordination / Consultation

15.15 Closing statements from participating organizations and bodies.

15.40 Coffee/Tea Break

16.00 Action clusters and resourcing - Coordination Mechanism

17.00 Summing Up

Venue

General information

WHO Regional Office for Europe

UN City

Marmorvej 51

DK-2100 Copenhagen Ø

Denmark

Telephone: +45 45 33 70 00

Facsimile: +45 45 33 70 01

<http://www.euro.who.int/en/home>