



Trillium II- MOCHA meeting: ‘Digital Health Policies for Children’s Health’ workshop

17th & 18th September 2018

Strengthening children’s immunisation in Europe through health data standards: Connecting Patient Summaries to EU vaccination cards, Immunisation Registries, EHRs, and Home-Based Records.

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1. Background

Vaccination is one of the most cost-effective health interventions available, saving millions of people from illness, disability and death each year. However, recent statistics show a resurgence of vaccine-preventable diseases in children in Europe, suggesting sub-optimal levels of immunisation rates. Factors contributing to lower rates include: vaccine resistance; the increasing cost of new vaccines, and shortages in vaccine production and supply in Europe; reducing focus on the process of delivery of individual vaccinations to the child; and a lack of accessible, updated patient health records, based on common processes and standards, amongst many others.

The current picture is fragmented since there is an individual approach to vaccination across Europe¹. This complex problem has been recognised and acted upon by key international and global actors, but aspects still remain unsolved. The World Health Organisation Regional Office for Europe stated priority areas for action, so as to ensure that all countries are able to “provide equitable access to high-quality, safe, affordable vaccines and immunisation services throughout the life course in its European Vaccine Action Plan (EVAP) 2015–2020”². The European Centre for Disease Control (ECDC) has a remit to promote effective vaccination across all ages, including childhood but on into adulthood, and including also travel and occupation-related immunisation. ECDC promotes the concept of national Immunisation Information Systems (IIS) to enable a personal record of immunisation for each citizen (whether a stand-alone system or a functionality of a wider system) and has reported on the current situation³.

However, a further set of interests all in 2018 that in fact also create potential confusion are the promotion by the Council of Europe for a range of immunisation supportive information projects including a European Vaccination Card⁴; the Expert Panel on Effective Ways of Investing in Health (EXPH) recommending more activity to address vaccine hesitancy but not looking at investing in record or delivery systems⁵; and WHO globally issuing guidelines on home-based records to include immunisation data without specifying the data items⁶ (while the WHO-linked organisation TechNet-21 advocates home-based records primarily as an immunisation support but again without more detailed content specification⁷).

¹ Sheikh S, Biundo E., Courcier S., et al. A report on the status of vaccination in Europe. *Vaccine* 2018 36(33): 4979-4992

² World Health Organisation. European Vaccine Action Plan (EVAP); 2015-2020. (http://www.euro.who.int/__data/assets/pdf_file/0007/255679/WHO_EVAP_UK_v30_WEBx.pdf?ua=1). Accessed 25-09-2018.

³ ECDC Technical Report on Immunisation Information Systems in the EU and EEA – Results of a Survey on Implementation and System Characteristics, ECDC Stockholm, 2017. (<https://ecdc.europa.eu/en/publications-data/immunisation-information-systems-eu-and-eea>). Accessed 27-09-2018.

⁴ Council of Europe. Strengthening Cooperation against Vaccine Preventable disease” COM 2918, 244 Final, 2018, (<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018DC0244&from=en>). Accessed 27-09-2018.

⁵ Expert Panel on Effective Ways of Investing in Health. Draft Opinion on Vaccination Programmes and Health Systems in Europe, Brussels, 2018, (https://ec.europa.eu/health/expert_panel/sites/expertpanel/files/020_vaccinationpgms_en.pdf). Accessed 27-09-2018.

⁶ World Health Organisation. WHO recommendations on home-based records for maternal, new-born and child health; WHO Geneva, 2018, (<http://apps.who.int/iris/bitstream/handle/10665/274277/9789241550352-eng.pdf?ua=1>). Accessed 27-09-2018.

⁷ TechNet-21, Home-based Records. (<https://www.technet-21.org/en/topics/home-base-records>). Accessed 27-09-2018.

One area that requires particular focus is the use of data in healthcare and vaccination delivery for children, which could help find a balance between target setting, the day-to-day challenge of delivery in a child-centric way, and data collection throughout Europe. This could also help improve child health records, which is an important medium for co-production with child and parents as well as extracting child health data. Establishing clarity on the specific needs of child health records when moving between countries, within countries, or sending health data locally within countries to partner services outside the primary healthcare system, is essential.

Harmonising data-driven health services and establishing child health data requirements is a common area of interest, and therefore now the aim supported by the joint effort between Trillium-II⁸ and the Models of Child Health Appraised (MOCHA) project⁹. The Trillium-II project intends to increase usage of International Patient Summary (IPS) standards and expand the patient summary globally. Currently, this does not specifically focus on children or their specific healthcare needs. Meanwhile, MOCHA, a child-centric project focusing on the models of delivery of primary healthcare in 30 EU/EEA countries, brings specific attention to child health.

Connecting the IPS to child immunisation registries and home-based records could help to correctly populate, maintain, and increase accessibility of information when needed. This workshop focused on discussions surrounding improving the availability of updated child immunisation records, accessible for use in all healthcare situations.

⁸ Trillium-II (www.trilliumbridge.eu).

⁹ Models of Child Health Appraised (www.childhealthservicemodels.eu/).

2. Objectives

The following objectives were decided in advance, as the purpose of the workshop:

1. To identify the actors, processes and data involved in childhood immunisation:
 - a. Scheduling, immunisation programs, and delivery
 - b. Recording
 - c. Displaying- supply of summary
2. To identify the areas of need for standards
3. To identify current progress and unmet needs
4. To contextualise within holistic child health records
5. To relate to other European initiatives.

The meeting involved the use of five case studies. These studies explored relevant complex issues, information gaps and discrepancies across health systems in European regions and member states. The case studies cover data and exchange standards for using accurate and reliable immunisation information outside the health system – in schools, home based records, and elsewhere as needed linked also to cross-border or cross-jurisdiction movement within Europe (7.2 Reference Materials Used). The specific meeting objectives involving these case studies were to:

1. Examine and define issues and processes in delivering immunisation and recording immunological status, including also recording of consent, feeding of summary records, etc.
2. Identify where IT systems support vaccination processes, including stand-alone systems, imbedded components in EHR or delivery systems, and system interfaces and data exchange
3. Identify the types of data, and of processes, needed in such systems and relate this need to current European policy initiatives, agencies and other bodies
4. Establish compatibility with Patient Summaries, and Home-Based Records, policies and initiatives, and related data feeds including patient (parent and older child) access
5. Assess how current standards address these issues, and define gaps
6. Propose an action plan for submission to the EC, other competent bodies, and funding sources
7. Consider next steps in stakeholder consultation to endorse blueprint, analysis and action plan.

3. Discussions

The workshop began by briefly introducing the different organisations present and their interests in strengthening children's immunisation. This was followed by examples of a small sample of country positions and policies surrounding immunisation.

3.1 Positions of Organisations Involved

European Centre for Disease Prevention and Control (ECDC)

ECDC is an agency of the European Union aimed at providing evidence for decision-making, strengthening public health systems, and supporting response to public health threats. This includes antimicrobial resistance, food and waterborne diseases, and vaccine-preventable diseases. One specific project focuses on electronic immunisation registries to share experiences on how to better support immunisation services in Europe. The priority is to develop standards and standardised immunisation data to allow linkage to other countries or sectors outside of healthcare.

European Committee for Standardisation (CEN)- Technical Committee C251

CEN/TC 251 is a technical body within the European Committee for Standardisation. The aim is to achieve standardisation in Health ICT to achieve interoperability between systems. A project in agreement with HL7 (see below), called the International Patient Summary (IPS) Project, was established in 2017. This collaboration for a single, common, summary of core data items, that is readily usable by all healthcare professionals, is an effort to further the care for citizens across the globe. The IPS is a health record extract comprising a standardised collection of clinical and contextual information that provides a snapshot in time of health information and healthcare. The principles of the IPS are that it should be implementable, applicable for global use, extensible and open, and sustainable. The adopted approach is incremental and progressive, in order to achieve acceptance and adoption. The focus from CEN in this workshop was to identify the specific data needs for a child IPS, immunisation as a key data requirement, and the additional security or safety measures that would need to be implemented. CEN works with HL7 to consistently implement the IPS in HL7 FHIR and HL7 CDA.

Health Level Seven International (HL7)

HL7 is a not-for-profit, standards developing organisation. Its aim is to make electronic health information more accessible to support clinical practice and health services - their mission is "to provide standards that empower global health data interoperability"¹⁰. To improve interoperability and access to healthcare, the use of application programming interfaces (APIs) is at the core of its newest standards developments. APIs in healthcare could manage the flow of information between different systems and better serve end-user needs. Further to this, the Fast Healthcare Interoperability Resource (FHIR) standard, is an HL7 development that answers the need for agile standards development. The FHIR IPS implementation guide, also promoted by the Trillium-II project and aligned with CEN IPS standards aims to provide a high quality, safe, and standardised approach to aggregate and merge patient health data from separate EHR sources. The focus from HL7 was to emphasise vaccinations as a key feature in holistic child health records

¹⁰ Health Level Seven International. About HL7. Accessible on (<http://www.hl7.org/about/index.cfm?ref=nav>). Access date: 26/09/18.

and explore actions that would allow the IPS to be used as attestation of vaccination coverage outside the health system, as for example in schools.

Home Based Records (MOCHA and WHO)

Home-based records (HBRs) or 'Parent Held Records', are an initiative that has developed in many countries globally, and they are seen not least as a support to, and record of, the individual child's immunisation history and future schedule. The expert group TechNet-21 has identified the use of HBRs worldwide, including in most cases a pdf of the record (in indigenous language)¹¹. WHO supports the value of HBRs, however there are no standards for type or format of content, as each country's system has developed independently. With WHO encouragement, MOCHA has undertaken a detailed study of the processes and formats of HBRs in each EU and EEA country, and any current links with e-health (report in compilation).

Models of Child Health Appraised (MOCHA)

MOCHA is a Horizon 2020 funded project that focuses on the full spectrum of child health within primary care. The project is child-centric and aims to appraise the models of healthcare delivery. Within this, one work package is dedicated to electronic health records (EHRs) and the types of EHR systems available for children. Other fields of study within this work package include health record standards, mHealth, and home-based records. The focus from MOCHA in this workshop was on holistic child health records, with immunisation being an important part.

Trillium-II

Trillium-II is a Horizon 2020 project that aims to expand implementation and use of patient summary standards, and in particular, the use of these summaries in emergency care. In doing this, the aim is to establish a global community for digital health and to bridge patient summary initiatives. A patient summary provides information on a person's health at a glance, to aide clinical decision making. It includes information such as medications being taken, allergies, and vaccinations. In order to achieve the full potential of a patient summary, it is important to identify the required clinical data and establish standardised vocabulary and value sets. The focus from Trillium-II in this workshop was on child health and how to ensure the presence of updated child patient summaries within and outside the health system.

World Health Organisation European Regional Office- Child and Adolescent Health

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. Although most children in this region enjoy a high standard of health and well-being, disparities in child health between and within countries persist. A recent news item from WHO European Regional Office stated that over 41,000 children and adults have been infected with measles in the first half of 2018. Measles is a preventable disease and WHO recommends that "good health for all starts with immunisation"¹². Improving recording of immunisation data could help increase the prevalence of immunisations. WHO also recently launched recommendations on the use of home-based records, which are important tools for

¹¹ TechNet-21, Home-based Records. Available on: (<https://www.technet-21.org/en/topics/home-base-records>).

¹² World Health Organisation. Measles cases hit record high in the European Region. 20/08/2018. Accessible on (<http://www.euro.who.int/en/media-centre/sections/press-releases/2018/measles-cases-hit-record-high-in-the-european-region>). Access date: 26/09/18.

recording immunisation data¹³. The focus from WHO in this workshop was on the redesign of the Child and Adolescent Health strategy, incorporation of IMCI (an integrated approach to child health that focuses on the wellbeing of the whole child), and standards for child health data management.

3.2 Examples of country positions and policies

Workshop attendees from nine different countries presented an unofficial summary of the situation of healthcare systems, EHRs, and immunisation in their country.

Greece

In recent years, Greece has been actively trying to reform their 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 and is provided free of charge to all residents, including immigrants. Typically, paediatricians provide immunisation services to children, whilst GPs mainly cover adult health needs. Public health nurses have an important role in immunisation delivery in both the hospital and in primary care.

Greece is amongst a few countries who have experienced a surge of refugees. This has led to outbreaks of vaccine-preventable diseases, such as measles. This outbreak initially only affected Greek Roma children, who typically have lower vaccination rates. The disease then spread to healthcare workers and now Greece is experiencing the second largest measles outbreak in Europe¹⁴.

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 are no compulsory included fields for immunisation data making it difficult to record how many children are vaccinated. Other electronic services present in Greece are electronic prescribing, the pilot implementation of 'Condensed Health History' (a patient summary), and eHealth research programs.

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. Within this, services for paediatric primary care include visiting nurses, GPs or primary care paediatricians (PCPs), school health system personnel (contracted school doctors), and school visiting nurses.

¹³ World Health Organisation. Home-base records for maternal, new born and child health. 13/09/18. Accessible on (http://www.who.int/maternal_child_adolescent/news_events/news/home-based-records/en/). Access date: 26/09/18.

¹⁴ Maltezou HC., Dedoukou X., Vernardaki A., Measles in healthcare workers during the ongoing epidemic in Greece, 2017-2018. *The Journal of Hospital Infection* (2018).

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, also carry out screening, and administer mandatory and opportunistic vaccinations. School doctors are responsible for daytime acute care, screening and for promoting mandatory vaccinations. There is no school health services EHR present in Hungary presently.

All these services report to the local policy administration services of public health, which in turn provides vaccinations 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 Hungary¹⁵.

To encourage data and information sharing between these 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.

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 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

¹⁵ 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.

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.

Italy

Italy has a decentralised national health system. The Ministry of Health develops an annual 'National Immunisation Plan' and then each region decides how to adopt this plan. Therefore, there are heterogeneous vaccine schedules and management occurs at a local level. In Italy, there are 21 regions and 120 local health units (LHU). 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 allows additional functionalities, such as appointment scheduling, recall, recording reasons for no vaccination, history, and risk factors.

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, of which four are strongly promoted. 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 a regional IIS.

The proposed immunisation process will see information flow from the LHU immunisation registry to the paediatrician EHR and then to a regional immunisation registry. This regional registry could link information to schools to determine the immunisation status of students. It could also send data to the Ministry of Health to estimate prevalence of immunisation coverage. However, the main challenge currently 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.

Luxembourg

The healthcare system in Luxembourg is mainly financed through compulsory public contributions to social health insurance. Additional voluntary health insurance and co-payments are also available in Luxembourg. The system is based on three fundamental principles: compulsory health insurance, free choice of healthcare provider, and compulsory provider compliance. Vulnerable groups are not obliged to pay contributions, and students, the unemployed, and children are covered up until the age of 27 years.

Citizens are able to directly access any GP, or any medical specialist for primary care services, which are well distributed among cities and villages in Luxembourg. This is because there is no

gatekeeping system in Luxembourg and patients can visit any GP they wish. There is no school health system in Luxembourg.

Luxembourg has a mandatory two-year vaccine schedule, with financial incentives in place for completing the schedule on time. Infant vaccination is performed by paediatricians and GPs within primary care and rates for vaccination coverage are generally very high, with a reported measles vaccination coverage of 99% in 2017¹⁶. GPs are bound by law to keep medical records for all patients, which are stored electronically.

Netherlands

The healthcare system in the Netherlands is funded by compulsory health insurance contributions from every person who lives or works in the Netherlands. When a child is born or when a child enters the country after birth, data is collected and stored in a national IIS, available until the child is 18 years old. The IIS is also responsible for planning vaccinations, and for sending invitations to parents to attend appointments to vaccinate their child.

Information about immunisations and other child health data are stored in the 'Digital Dossier for Child Health Care' (DDJGZ). The DDJGZ is a digital, medical record that holds important data on the health and development of a child. This record is available to all child healthcare professionals, such as paediatricians, paediatric nurses, and child healthcare assistants. All other healthcare and care providers, and authorities do not have access to the DDJGZ, even if they are directly involved in the child's healthcare. Regarding vaccination, the DDJGZ acts as a local IIS and is digitally linked to the national IIS. The systems incorporate an interoperability model (Zorginformatiebouwsteen) and use HL7 messaging between the systems.

The National Immunisation Programme in the Netherlands is nationwide and uses one national registration system that is provided by the government. All immunised individuals are recorded in this database and those without vaccination are also recorded. The vaccination invitation and recall system is nationwide to ensure full coverage.

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, 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.

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 complete electronic system. The user is registered at birth through a digital birth notice, children are issued

¹⁶ 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.

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 them 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'.

United Kingdom

In the UK, the health system is state-funded, and healthcare is provided free at the point of service. This includes primary care services, which are the first point of contact in the healthcare system. Vaccinations are usually arranged and given by a practice nurse at a GP practice and are recorded in an EHR. Patients are able to access a summary care record from their GP practice and in most cases, parents are able to access their child's EHR.

The importance of immunisation is recognised by the British Medical Association (BMA) to achieve maximum population benefit. However, declining coverage rates for childhood vaccinations have been observed in some areas of the UK and there has led to significant measles outbreaks, particularly in South Wales (2013) and several parts of England (predominantly the North), in 2017¹⁷.

Protecting citizens against future outbreaks of vaccine-preventable disease requires maintaining and improving vaccine coverage rates. This could be achievable by up-to-date, complete records of the child's health. In the UK, the 'Personal Child Health Record' (PCHR) is a national standard health and development record, given to parents at the time of their child's birth. The PCHR provides space to record child immunisation status.

¹⁷ British Medical Association. Childhood Immunisation. 12/03/2018. Accessible on (<https://www.bma.org.uk/collective-voice/policy-and-research/public-and-population-health/childhood-immunisation>). Access date: 27/09/18.

4. Workshop Discussion

The meeting provided rich discussion, during the presentations, in plenary, and in break-out groups. This resulted in identification of a number of concerns and issues:

1. There is little or no coordination across the various European initiatives.
2. The immunisation delivery process, at an individual level, is seldom considered, yet is key to successful immunisation.
3. There is an understated difference between vaccine resistance (which is usually based on principles of belief or awareness of presented 'facts'), and vaccine hesitancy (which is individual and based on more individual concerns often based on lack of knowledge or difficulty of access). The administering health professional needs good information to counter either situation, but in hesitancy this needs to be based on understanding of the parents and child, and on their specific concerns, and for this the record can be key if appropriately complete.
4. Co-production of a child's health by the parent, and by the child as they grow up, through preventive health actions and activities is seldom considered in vaccination initiatives.
5. There is little consideration of the growing autonomy of the child, particularly with HPV vaccination (MOCHA has in press details for each country of how differences between child and parental views are handled).
6. While the choice of a child to receive an immunisation to which the parents are opposed would seem to be a mentally mature child's right, this may trigger unanticipated problems such as the child then not wishing the parents to see the child's medical record – and the false implications and resultant stresses which could follow.
7. The focus on cross-border health information exchange within Europe is well grounded in the sense that this is the European Commission's only competency in health (health delivery to residents being a national competence), but the data standards and processes resulting from it are likely to have greater volume and impact of application for within-country transfer of immunisation data.
8. There are across Europe innovative eHealth initiatives in immunisation, now including portal-linked systems and cloud storage, but there seems little exchange of innovation or experience.
9. The key aspect of immunisation records is at point-of-use. This use can be by the immunising health professional (or a support co-worker seeking to arrange an attendance with consent), in the emergency room, in school, or at an administrative point such as travel or relocation. There seems to have been little of any consideration of the data needed at these different points of use; or of the means of supply and role-based permissions needed.
10. There seems to be little consideration of the parental (and child) view of the content and format of the immunisation part of the immunisation record.
11. There is no indication of the necessary context information for immunisation, including (for example) consent (and by whom), reasons for hesitancy (e.g. sibling illness; difficulty of access to clinic due to work commitments, location, or multi-tasking of single parenthood; etc.), and reasons for non-administration (short term illness, holiday, etc.).
12. The issue of opportunistic immunisation (for instance at Emergency Room attendance if current records showing low protection are available in real time), yet with technical and ethical safeguards this could be a valuable means of boosting coverage.

13. There is little cataloguing of data and process scheduling standards. This includes standards on the antigen, batch number etc., but also on process (consent awaited, appointment issues, failed to attend not followed up, etc.).
14. Scope exists within the IPS protocol for addressing some issues, e.g. suppressing one area or one item of the record, but these are little known about or used.
15. In some respects, generic care planning standards from existing standards could be applied to immunisation scheduling, but this seems not to have been done.

5. Future action plan

It was agreed that there was a cohesive body of work needing to be done 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. Such work needed to seek to bring together aspects of the several well-intentioned but uncoordinated initiatives, and to acknowledge the key role of individual level delivery processes based on sound records.

An overall plan was needed, bringing together the various interest European Commission Directorates and agencies, ECDC, and other key stakeholders. Outside the Commission process, collaboration with WHO in particular was important and valued. For the necessary workstreams, leaders and funding sources were needed, and an ongoing coordination mechanism (it was noted that the MOCHA project comes to an end in November 2018, and the Trillium II project in 2019).

Stakeholders needed to be involved and their support sought. Such stakeholders included patient and civil society organisations and health professional bodies.

WHO had kindly agreed to host a stakeholder and planning meeting, on 21 and 22 November 2018 in Copenhagen. The arrangements, attendance, and content for this would be initiated by the current Trillium II and MOCHA team. One function of the meeting would be to agree future coordination.

Topics for discussion should include:

- 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?
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- What work strands or projects are needed?
 - Who would lead these, and who contribute?
 - What funding or resourcing is available?
 - What coordinating mechanism?

At the conclusion of the workshop, a group of workshop participants comprising Susana Sanches, Project Manager of Nacional System for Vaccination, Portugal; Dr Georges Ziade, Immunization Program Luxemburg; and Irmgard Zonnenberg, Manager Coordination of the Dutch National Immunization Program, agreed to propose an initial structure and scope for the European Vaccination Card which could be supported by The Netherlands, Luxemburg, and Portugal. Their findings and recommendations would be submitted to the stakeholder workshop in Copenhagen and compared to the International Patient Summary vaccination component and home-based records, for discussion there and agreement on next action.

6. Conclusions

Many health and European agencies are concerned about immunisation of children; many are recommending initiatives. However, there is no co-ordinating mechanism across all issues within the EU and EEA. WHO has a strong relationship but a wider responsibility and no formal function within the EU. Children, parents, and civil society seem not to be involved in discussions.

Data and records standards seem to be a common vocabulary and can link to and be endorsed by a range of European and international bodies.

The workshop concluded that there should be clarity and policy harmonisation for child immunisation data linkage. A stakeholder meeting as proposed should give significant opportunity to progress the issues in a context of informed mutual sharing.

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7. Appendices

7.1 List of Participants

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7.2 Reference Materials Used

Use Case study #1: Primary Immunisation

Henri is seven months old. He is the third child of David and Martha, having a sister Marie aged 7 years and a brother Dominic aged 5 years. David is an engine-room technician on a deep sea going vessel, and Martha struggles with managing the family single-handed for much of the time, working part-time as a cashier in a local supermarket, and arranging school runs. Dominic suffers from childhood eczema which flares up regularly when he is stressed.

Henri is now overdue for his first primary vaccination. Martha has not managed to find time to take him to the doctor, and she is putting it off partly because she is worried about a possible link between immunisation and flare-up of eczema.

How should the primary health care system manage Henri's immunisation? In particular, what needs recording, where and by whom?

Use Case study #2: HPV Immunisation

Tamsin is 14 years. She is the only child of Mabel and Denis, older parents who were aged 38 and 41 when Tamsin was born. Mabel is an accountancy assistant, and Denis an architectural assistant. The family enjoy cultural and outdoor activities, while Tamsin also has her own circle of friends, not least in a local youth band. She studies hard, and hopes to be a policewoman, with an interest in pursuing detective work.

This school year the public health service will be offering HPV immunisation to all girls in Tamsin's school year, and for the first time this will be offered to boys too. Consent letters are issued via the school to parents, to be returned to school ahead of the planned immunisation session for Tamsin's class.

Tamsin's family discuss the letter. Tamsin is keen to have the injection – she understands the value of immunisation, and the serious diseases it will protect her against over future years. However, her parents are undecided. Mabel wants the best for her daughter, but has heard things about reactions to the immunisation, though she cannot recall the details. She thinks the doctors are motivated partly by being paid per immunisation given, so they have a vested interest. Denis thinks the letter is too officious and not sensitive to the individual; he says that Tamsin leads the kind of responsible lifestyle which will not expose her to these sexually borne risks.

In the end Mabel and Denis do not sign the consent letter, but instead write on it that they are not convinced of the value of HPV vaccination for Tamsin when weighed against the risks of the procedure. Tamsin asks to see the doctor and asks for the immunisation.

What should happen, and what should be recorded by whom?

Use Case study #3: Tetanus Protection

Sunita is 12 years old. She came to her European country of residence with her parents when she was 2 years of age, when her parents were seeking employment. Her father is an engineer, and her mother a teacher. The family successfully applied for local nationality three years ago.

The family are happily settled, but do not socialise widely. They have a lifestyle largely based in the parents' Indian roots but modified by local living. Sunita enjoys school, both academically and in sport. She plays in the under-14 school hockey team.

On Thursday afternoon at 14.15 Sunita is playing in a practice match on the outdoor grass pitch when she loses her balance in a hard tackle. She falls badly, and suffers an arm injury. Her wrist rapidly swells and is painful and she has limited movement. As she fell she also badly cut her arm on a sharp object in the grass, with a four cm. laceration and steady bleeding.

As the hospital is only 12 minutes drive away, one of her teachers immediately drives her to the Emergency Room. There the triage team want to know her key medical history, including any current medication but also her tetanus protection status. In a state of shock-induced confusion, Sunita cannot remember when she last had an immunisation or for what.

What data should have been recorded, where, and what permissions should be needed to release this to the Emergency Room?

Use Case study #4: Child with Asthma in the Emergency Room

Dany is a 14 year old boy with a diagnosis of asthma made by his primary care practitioner when he was 5 years old. He has many acute attacks which are triggered by cold weather, pollen and house dust mite as well as viral respiratory tract infections.

He is reviewed regularly by the PHC team including the nurse who checks his inhaler technique and makes sure that his agreed written asthma plan is up to date. This plan clearly describes the medications he has to take regularly and also what his parents/carer should do if he has an attack.

She also measures his peak flow (a measurement of how hard the child can blow into a machine with normative values based on height). The units are in litres per minute.

His mother has ensured that the school teacher and school nurse support has a copy of this plan in their files. He has had two episodes when the ambulance had to be called at school after a chemistry lesson where the fumes triggered an asthma attack which was particularly severe.

Recently Dany was referred to the paediatric respiratory specialist who has suggested some new medications and has also gained the family consent to enter into a clinical trial of a new tablet designed to reduce sensitivity of the lungs to triggers. The notes must be tagged in some way to ensure that the trial participants are identifiable in usual clinical care circumstances.

Dany has attended a variety of Emergency departments in different parts of his town- on one occasion he was taken ill whilst staying overnight at a friend's house living 15 km from his usual hospital but only half a km from a local nurse led emergency department unit.

One of Dany's big concerns is how his treatment is going to be managed when he becomes an adult. He has not yet been introduced to the adult team and is concerned that his whole record system is with a different group of clinicians and therefore they won't know him so well.

HE would also like to have a summary record for his own purposes which describes over time his many different treatments and a record of his growth and previous peak flow measurements. He is computer literate and owns and smartphone as do both of his parents.

Danny had an exacerbation and is admitted to the emergency room – is patient summary information relevant? What parts? What about immunisation information?

Use Case study #5: Migrant/refugee case study

Fatima is a three-year-old girl who sees a GP as an urgent consultation because she fell in the woods near her home and cut her knee on a sharp point of a barbed wire fence. The bleeding has subsided but there is a gaping wound that needs a couple of stitches to enable neat skin healing. Fatima is a "temporary patient" because her family has recently been housed by the local authority into a multi-occupancy house which the GP knows to be frequently used to place refugees, migrants and travellers. Fatima is today accompanied by her mother, who does not speak the local language. There are no historic medical records but Fatima's mother has produced some identity documentation that has enabled the practice staff to complete a basic registration form. There is no background medical information included in this.

The GP is easily able to clean the wound and put in a couple of stitches to enable good skin closure. However, she is concerned not to know the tetanus immunisation status of Fatima. She is thankfully able to telephone a professional translator who is willing, through speakerphone, to help broker the consultation. Through the interpreter, who is not medically trained but has some healthcare experience, the GP is able to ascertain that Fatima had some immunisations through the local health centre, in the region close to where Fatima was born, probably for the first six months of her life in Syria. Since then the family has had to move several times, to avoid the risk of military violence, and no further healthcare has been possible.

The GP makes the decision to provide tetanus inoculation during the consultation, but she is worried about the other immunisations that would normally be expected to have already taken place in a three-year-old in this country. Through the interpreter she is able to document the likely immunisations that Fatima should have had in those first six months, but without firm assurance of what was actually administered. A further challenge that surfaces through the interpreter is that Fatima's mother does not wish to trust the GP, or her use of the computer on her desk, as she is very fearful that they may be deported back to Syria or somewhere else.

Adverse factors making it potentially hard to derive an accurate immunisation summary for refugees, migrant and travellers:

- cumulative healthcare and prevention deficit, leading to many healthcare issues needing attention at once
- fragmented disrupted care, so immunisation schedules may not have been followed
- often no written information, or fragmentary, may be inaccurate
- history from parent/guardian might be inaccurate - based on memory through confusing times, multiple locations and care providers, maybe the loss of the main parent who had the knowledge
- language and/or lack of health advocates may be a further barrier to obtaining a complete and accurate history from whoever can attend the clinical encounter
- there might be a lack of clarity about who can legally give consent to the administration of a new immunisation
- initial documentation in the summary might therefore be provisional, uncertain, needs to be transparently tagged as such and capable of later updating
- frequent moves mean that linkage of health records may always lag behind the child's attendance, so the home held record will be an important vector to inform health professionals and others

- travellers may distrust official systems, may at times fabricate their identity, not wish to support linkage (home held record may be the only joined up data we have, need it to be the best possible)

Implications for the immunisation information represented via a patient summary standard:

- to state the level of certainty in any documented immunisation information, including its source
- ability to later corroborate or change a clinical statement about immunisation based on more certain information
- any national or cross-border online summary must be capable of synchronisation with a home held record
- the home held record must be able to be printed, and ideally should be translatable into other languages (not just European ones).