Report from the meeting of the 'Task Force on Interoperable data-sharing within the framework of the operations of ERNs'

Thursday 18th February, Albert Borschette Conference Centre, Brussels

Summary of Key Issues (from final session)

- The expertise of this Task-Force (TF) is well-placed to address RD-specific issues concerning data-sharing within ERN framework.
- It was explained that an interoperability framework will not be in place for the first 'release': this would be a long-term goal. Although it is not realistic to think of interoperability between ERN centres and hospitals at large (at least for now) ERNs will be relatively interoperable within themselves, in the sense that they will all use the same platform.
- Clarification was sought as to the origins of this TF and its user-community. The group was reminded that the TF was established because DG Santé supported the opportunity of learning from eHealth initiatives such as EXPAND and translating this knowledge to create added value in the RD field, specifically in ERNs. There is a concern that ERNs will otherwise pursue their own directions. The TF could be committed by the EC to bring the needs and expertise of the RD field together, to support the EC in the development of the core platform.
- There are high expectations for this platform. The first ERNs will be approved at the end of December and should be operational early in 2017. If they have little to work with -or are ultimately only provided with tools which are less effective, sophisticated, legally-sound and research-friendly than their coordinators use at present in their *smaller* networks- this will potentially be very damaging to the entire concept of ERNs and will be a missed opportunity for sharing structured and standardised data on RD.
- Colleagues have laboured for many years to persuade would-be coordinators of the added value they will find under an ERN, and it would be disappointing if their expectations are not met.
- The day's group discussions were very helpful, in terms of allowing the expertise from the health sphere – and from the *RD* health sphere, in particular- to support IT colleagues in understanding the realities that will need to be faced by the ERNs.
- It was confirmed that the mandate of the TF within the *mandate and capacity of the RD Action* will be exhausted with the delivery of a detailed report based on the outcome of the meeting and including a conceptual description of the above-mentioned Roadmap. RD Action will also validate and disseminate this report within its Network of clinical leaders engaged in the preparation of ERNs.
- Although the focus is on RD ERNs, **the benefits of tailoring the ePatient Summary for RD patients requiring unplanned care were agreed**.
- The EC was requested to consider appropriate support for the continuation of this activity. Such support would provide the requisite resources and an appropriate framework for the exploitation of the results of this work

Co-funded by the Health Programme of the European Union

Presentation: Outline of the Task Force scope and activities to-date (V. Hedley presenting on behalf of Chair K. Bushby)

This Task Force (TF) was initiated following long consultation with DG Santé colleagues and the Commission Expert Group on Rare Diseases (CEGRD) in order to formalise collaboration between the RD (in particular the Joint Action) and eHealth (especially epSOS/EXPAND) communities. As the need for immediate action on preserving and improving interoperability in the field of RD was well established, the establishment of an eHealth ERN TF under the policy WP of RD Action was agreed. The launch of the TF was presented to the Commission Expert Group on Rare Diseases on 12th November 2015 and to the eHN on 23rd November 2015. The TF was initially anchored in EXPAND (whilst operational) and the Joint Action for RD, RD-ACTION, inheriting the mantle of the EUCERD Joint Action. The scope of the work of the TF was defined to be two-fold:

The Task Force should deliver, by the time of the launch of the first wave of ERNs, the elements needed to provide a long term vision in the form of a European Interoperability Roadmap for data sharing in the framework of operations of ERNs. The main deliverables of this TF will be a proposal for a European interoperability Roadmap for sharing data in the framework of the operation of ERNs for rare diseases, which will provide

(i) Policy and decision-making support on immediate priorities to be addressed as extensions of the Connecting Europe Facility (CEF) eHealth Digital Service Infrastructure.

(ii) A longer term vision that will be consolidated at some stage in a Roadmap describing a stepwise approach, subsequent milestones, the incremental achievements and a realistic timeframe.

The expertise of the TF is well-placed to address issues of data-sharing within ERN framework:

Chair Kate Bushby is a RD expert on the CEGRD and has many years of experience coordinating a network of excellence dedicated to a group of RD; furthermore, her UNEW team has robust links to the prospective leads of the future ERNs and is assembling a core group of these people. Ana Rath as Coordinator of RD-ACTION and Director of Orphanet has excellent knowledge of data-linking needs in RD, as well as the clinical and research complexities of these conditions. EURORDIS colleagues spearheaded the concept of ERNs, and advocated for their inclusion in the CBHC Directive article 12. They were active partners in the EJA and in the current RD-ACTION and lead the PACE-ERN consortium. Zoi Kolitsi, Jeremy Thorp, Henrique Martins, Michelle Thonnet, Dipak Kalra have extensive experience in eHealth initiatives and in preparing assets for deployment in CEF. Victoria Hedley has prepared a number of policy guidance documents related to the topic of RD ERNs, has organised 3 successful workshops to support the field in realising the opportunities afforded by ERNs, and is currently leading the match-making task within WP6. RD-Connect colleagues can provide expert advice, in order that the resources of this EC-funded platform now available to link RD data for research is accessible also by Members of an ERN, to assist them in diagnosing patients and furthering research. R. Choquet and Michelle Thonnet have extensive experience of the national realities of achieving interoperability in RD data. Persephone Doupi is an expert in the field of registries and interoperability.

The general services of the ERNs are in fact well-described in the Delegated Acts – the legislation is detailed. Each of these core services (e.g. providing care for patients in a virtual environment, conducting research, developing clinical practice guidelines, training and education) revolve around *sharing data*. A safe, secure, efficient IT platform is essential to allow members of an ERN to function as outlined in the legal Acts. Having supported the field in preparing for ERNs since 2012, the IT platform is often cited as perhaps the most important draw and the most crucial element. Would-be ERN coordinators have high expectations of this platform, and this TF has a robust understanding of the needs of this RD community regarding data-sharing in ERNs. For instance, people seek the following:

- A system with appropriate eHealth tools to enable improved diagnosis and care of patients, ideally in a virtual environment, to prevent patients moving unnecessarily.
- For this, HCPs require a system which allow the exchange of patient information amongst a group of relevant experts, along with scans, MRIs, test results, videos etc. This system needs to be 100% safe and legally sound – people do not want to worry about the legalities of this sort of virtual consultation. In some fields, such meetings should be held in real-time, in others this is less relevant.
- Would-be coordinators are requesting guidance from the JA on several topics. Ultimately, such an IT system must ensure demonstrable benefit to the clinicians in the ERN – time is limited and duplication of data entry is undesirable. Interfaces for sharing data for care and research must be user-friendly. Many of these needs have been understood since a workshop in March 2014. The scope of this TF was reconfirmed at the 1st Lisbon convergence workshop where various perspectives of ERN interoperability needs were presented, work content and next steps were defined. **The TF meeting today seeks to build on the analysis of the results of the Lisbon workshop towards the two lines of action defined above.**

Presentation: Update on ERNs and Timelines (Enrique Terol)

Enrique presented the overview and timelines for the various platforms, which may be divided into 3 stages – first the Communications/ Management platform (1) which is essentially ready. Then there is the basic clinical platform & common tools (2) which will be available to all Networks. All hospitals use PACS systems, for instance, these are not divided into specialist PACS for rare renal and rare neurology. Finally, there will be the more disease-relevant stage (3).

Discussion

The prospects to seek further IT funding via the CEF were discussed. There is a potential to dedicate costs for Generic Services, to complement the Core Service (i.e. the platform itself). To put this into the next CEF budget an estimation of costs to HCPs in terms of connecting to this IT platform and its tools, would be necessary. The TF efforts were welcomed and substantiated proposals were invited which would help the EC services in discussing eHealth priorities in the 2017 CEF work plan.

The EC colleagues confirmed that data can be shared within the ERN framework – i.e. between member HCPs- without a need to anonymise a patient, where this is for care purposes. This is defined in the legal acts. This is important, to understand that no further legal action is needed for ERNs to perform this basic and vital function. The Group confirmed that to share a patient's

information with other experts in the ERN, the patient would simply sign an informed consent form (which should ideally be harmonised across the ERNs) – in RD, it is essential that this form also has a section allowing the patient to consent to the long-term maintenance/storage of this data, in an anonymized form, for research purposes (using broad consent, ideally).

It is necessary to define a roadmap towards interoperability of data-sharing in the framework of ERNs, which indeed was one of the initial goals of this TF. The solutions developed via epSOS and EXPAND may be more complex than are needed here, but nonetheless, to prevent ERNs being silos of their own creation, a roadmap is important. It was agreed that an 'Instrument' to hand-over CEF services to ERNs would be necessary.

Presentation: European Commission Plans for the Communication Platform (Markus Kalliola)

Markus presented the Communication/Management platform. The EC has purchased a license for Adobe Connect and installed it to the EC hosting facilities, to ensure more security and control (if you use monthly subscriptions the documents uploaded can never be deleted completely, as they are cloud-based.) Various communication tools can be added to the main page, and if a HCP is a member of more than one network that is fine. Colleagues can share documents, follow news updates etc. This is very useful for compiling documents, for instance, and will enable HCPs to organise meetings etc. However, this platform is not designed for clinical data – it is not patient-oriented, neither for identifiable nor anonymised data. Before moving to production DG Sante will perform security and stress testing.

Discussion:

The TF sought clarification on the intended process and timeline for building the IT platform, as described in the CEF 2015 workplan:

- Will this be developed internally or will a Tender be developed?
- If a Tender is to be pursued, do specifications exist already?
- Is there a logical architecture already defined for the ERNs?
- Have colleagues already discussed how work can be distributed between core services and generic services?

The TF members could not be informed of any plans relating to a Tender. With regards to the last point, the most recent workplan for the CEF includes only Core, not Generic services – as already mentioned , if Generic services will be needed then this must go into the 2017 call. The needs of ERN members will be explored and it was explained that the TF plays an essential role, as it provides not only the eHealth expertise but also a vital link to the RD community and the JA.

Identifying Use Cases from Patient data-sharing scenarios (Group Work)

As a working approach, it was agreed to start from discussing realistic patient stories, to consolidate these stories into a small number of generic (all ERNs) use cases which should then be prioritized according to transparent criteria such as maturity, readiness of national infrastructures, status of interoperability assets, re-use of CEF BBs and the eH DSI etc. This would allow the TF to recommend

a number of immediate CEF extensions and identify necessary additional maturation actions that will be needed prior to deployment in CEF. It will also allow the TF to propose a process for co-creating a long term vision and a roadmap for eHealth, supporting the sustainable development of ERNs and associated CEF future implementations. The TF decided to divide into two groups to populate some 'patient data-sharing scenarios' to assess the needs and existing tools which might address these. Mapping patient journeys is a useful step towards a roadmap (for example, this was how Calliope originated). The proposed templates were amended slightly prior to the group work. 'Therapy', as one of the three headings, was replaced by 'Care Management'. It was agreed that the three boxes will each need two layers, to reflect the care and the research elements. The other boxes are Diagnosis and Unplanned Care.

Initial Conclusions: The group work led to the following overarching conclusions:

- ERNs will benefit from an ICT enabled, virtual, integrated healthcare environment, connecting facilities, enabling secure & trustworthy data flow and sharing health care data and expertise virtually. Simultaneously, they must build-up the evidence base to advance care and research in an area of scarce clinical evidence. Enabling such a (patient-centred) environment will require that clinicians can share data and clinical documents across borders in standardized formats, can discover and access such data and information residing in different repositories (e.g. registries) and often in different ERNs, and that they can interpret the content of these documents in a trustworthy and safe way in order to support their clinical decision making. The contractor developing the IT platform will need some interoperability specifications to implement this effectively, whether in the first instance or at a later point in the timeline. (Use case 1).
- There are important issues concerning the legal identification/anonymisation of patients and consent in RD ERNs. An eID framework, including patient consent, compliant to EU Regulations and meeting the requirements of enabling sharing of data within a shared care framework, is needed (Use case 2).
- Emergency care for Europe's 30 Million RD patients would improve greatly if they could be identified during the unplanned encounter as patients with a specific rare condition, and if decision-making support and guidance for handover to the appropriate national centre could be provided to the emergency care physician (Use case 3).

These brief descriptions of use cases would need to be further elaborated after being:

- Assessed in terms of feasibility and status of maturity, via consultation with projects working on interoperability challenges in the RD field and in developing and piloting eID solutions for eHealth.
- Scoped and stratified in terms of a step-wise approach to their implementation and scalability to meet the needs of the ERN communities as part of an interoperability long term vision and Roadmap.

It was asked if there is potential to influence the work ongoing in eSens - The technical leads are asking for an expert analysis of the situation and are seeking a workshop on eSens and ERNs, to examine requirements/opportunities for eID.

Colleagues agreed that defining the use cases is essential as without these, work cannot proceed under CEF. Work on the structure and standard of data would be required, and pseudonymization would be useful. How could a stepwise approach enable the end-goal of 'fully-interoperable' ERNs? The TF can benchmark through the ERN contacts and through projects addressing /having addressed topics relevant for interoperability issues, to support the EC in fulfilling the most urgent commitments. *But it is important to know what resources are available for this work* (e.g. would the EC fund a workshop with the ERNs leads?) Three levels of possible funding for ERNs were described: 1) there will be research needs associated with ERNs, and H2020 may in time offer grants for which the ERNs can apply; 2) the health programme could provide funding to conduct certain activities; 3) an additional source of potential funding is the CEF (however, the concentration of resources for health is not yet clear). The EC colleagues raised the possibility of seeking Generic Funding in CEF to provide virtual meeting rooms for HCPs. However, the costs soon increase when one considers the number of member HCPs per ERN, and the fact that more can join each year. It is difficult to see what CEF can finance in terms of the Generic services here, as it cannot fund the centres themselves. If there is the option of funding Generic services, this would be to allow HCPs to implement what they need to connect to the other centres, not to specify the tools of one ERN or another.

The conclusions of the final session are presented at the beginning of this document.

Participants of the Meeting

Valentina Bottarelli	Task-Force Member
Anna Carter	European Commission
Remy Choquet	Task-Force Member
Meta Geibel	European Commission
Marc Hanauer	Task-Force Member
Victoria Hedley	Task-Force Member
Matt Johnson	Task-Force Member
Zoi Kolitsi	Task-Force Member
Markus Kalliola	European Commission
Roger Lim	European Commission
Sevala Malkic	European Commission
Licinio Mano	Alternate Task-Force Member
Tapani Piha	Task-Force Member
Ana Rath	Task-Force Member
Patrick Stevens	European Commission
Enrique Terol	European Commission
Michele Thonnet	Task-Force Member

Meeting Agenda

09:00 – Coffee, Welcome and outline of the Task Force scope and activities to-date (Vicki/Zoi)

09:30 – Update on ERNs and Timelines (Enrique Terol)

09:45 – Demonstration of current EC plans for the ICT platform (Markus Kalliola)

10:15 – Group Discussion of data-sharing scenarios within the ERN framework

(Output: patient data-sharing scenarios with accompanying assets, barriers and needs)

12:00 – Example presentation of a (non-disease specific) eHealth & research asset: for demonstration and discussion (Vicki)

12:30 – 16:00 - Necessary building blocks for sharing data in ERNs: what is there already, what is planned, what remains to be addressed

- Identification and anonymisation of patients in the ERN framework, to support care and research
- Privacy and data protection (e.g. consent, auditing)
- Adding RD specificities to the ePS, for use in epSOS framework
- Potential/value in building on the ePatient Summary for to standardise RD datasets in the ERN framework

(13:00 – 14:00 Lunch)

16:00 Coffee

16:30 - Agree short and medium terms tasks for this TF, according to needs identified and according to expertise of TF members (Chair Zoi and Ana)

Output – list of action points for each individual task with goals, the initiatives with which to make synergies, deliverables

18:00 Workshop ends