

ECPDC Final Event

30-10-2023, 2 pm – 5 pm

53 participants:

ECPDC team (8), STC (10), RTD (7), SANTE (2), JRC-ISPRA (2), guests (24)

Harald Wagener introduces the European Cancer Patient Digital Centre (ECPDC):

- ECPDC is part of the EU Mission on Cancer implementation plan to provide patients with access to information, data and support which are unevenly distributed in the EU Member States.
- ECPDC is a European initiative for cancer patients and survivors.
- ECPDC is envisioned to be a use case of the European Health Data Space (EHDS), specifically targeting cancer patients' and survivors' needs.
- Three ECPDC concepts were developed by the team at Charité, BIH Center of Digital Health and the Health Data Science Unit at Heidelberg University Hospital who have a long record in cancer research and build health data exchange structures.

Address by Barbara Kerstiens, Head of the Unit “Combatting Diseases” (DG RTD) that is hosting the Cancer Mission Secretariat

The Cancer Mission proposed to develop the ECPDC to increase the quality of life of cancer patients during and after treatment and of cancer survivors. One of the challenges to address cancer is to get the right information in the right format at the right time to those at risk for cancer, to the cancer patients and to the caregivers and relatives of cancer patients. The vision of the ECPDC is to offer digital tools that are useful for patients, survivors, their families and caregivers. The concepts for the ECPDC were developed not only by the scientists but also by collecting the opinion of different stakeholders, such as patient organisations and young cancer survivors. The blueprint of the ECPDC will be assessed and further developed within the future Horizon Europe work programme.

Address by Guillaume Byk, policy officer in the “Digital Health” unit (DG SANTE) and involved in the development of the European Health Data Space (EHDS)

The EHDS is a common legal and organizational framework designed to promote the use and flow of electronic health data both for primary and secondary use. The ECPDC shows the need to develop the EHDS. The EHDS has the potential to open up a new opportunity for health data to be used to support the European Beating Cancer Plan. Also, the pooling and sharing of data and knowledge will develop practical solutions for cancer patients. ECPDC and EHDS share the common goal to provide patient-oriented access to their data. The ECPDC should use and complement the structure provided by the EHDS.

“Patients’ and Survivors’ needs for an ECPDC” by Gilliosa Spurrier-Bernard, Vice President of the Melanoma Patient Network Europe (MPNE)

The MPNE was involved from the beginning in the idea of the ECPDC. Patients are most concerned with the access to their own data first, altruism is secondary. Patients’ primary needs for data use are decision making, to check and maintain accuracy, to quickly and easily transfer to other centers, to feel involved and as driver of their own healthcare and also of relevant research. Altruism is secondary. Patients have a more nuanced view on data privacy and data sharing based on the return of engagement than researchers or citizens in general. As patients are the primary data source and owners of their data, a return on engagement for them is what they want to see in research. Dynamic and tailored informed consent is really important. A data vigilance framework for the correct and decent use of data is needed including transparent punishment of abuses. “You can’t have an ECPDC without European cancer patient experts on the coordination.”

Concept 1: ECPDC Information Portal, presented by Roland Eils, head of the Center of Digital Health, Berlin Institute of Health at Charité

The three ECPDC concepts are presented and discussed individually, but none of these concepts could stand without the other two.

In Concept 1 a standalone information portal is set up to provide evidence-based information in an understandable way to cancer patients, survivors and their families. The information portal aims to enhance literacy about the disease and to provide easy access to information, such as personal statistics on risk and outcome assessment and outcome prognosis. Expert knowledge and recommendations for actions need to be integrated as well as a community safe space for sharing information and data. Concept 1 is based on existing infrastructure, resources and practices both within the EU but also beyond e.g. the Knowledge Centre on Cancer (KCC) and the International Cancer Information Service Group (ICISG). Treatment guidelines from scientific societies and the Cochrane network should be integrated and tailored to patients through a trusted AI model.

In the panel discussion on Concept 1 the following questions were addressed:

- **“What is a good ECPDC? Where is the need highest?” Presented by Penilla Gunther and Christine Chomienne (Mission on Cancer Board)**
“A good ECPDC is the one that will be used.” Prerequisites are easy access and easy use but also usefulness with a clear exchange of knowledge between patients and patients’ groups. The patients’ community has a great responsibility to share the knowledge that the ECPDC exists.

The different rooms of the ECPDC house show the patients' needs. People at risk also request to have access to the portal. The ECPDC is a personalized tool, adapted to language, to the country and to the cancer type. So, it is not the same information for all patients, survivors, carers, patients at risk, and young cancer survivors. Each patient should be able to fill in quality of life and get information in the portal to understand their symptoms.

- **“How could KCC contribute to ECPDC and vice versa?” Presented by Magdalena Stepien (Knowledge Centre on Cancer, DG JRC)**

The Knowledge Centre on Cancer (KCC) provides evidence-based updated information on cancer burden, cancer prevention and cancer care and can so contribute to the information portal. The KCC offers the European Cancer Information System (ECIS), which works together with the European Network of Cancer Registries (ENCR), the European Cancer Inequalities Registry (ECIR), the Knowledge and Disease Prevention Gateway and EU guidelines and quality assurance schemes for cancer screening, diagnostics and care. Data interoperability and standardization is very important. The ECPDC could provide information especially on patient-recorded outcomes, which is currently missing in the ECIR. Vice versa the KCC could provide ECPDC users with KCC guidelines and information for support.

- **“How could collaboration between different Cancer Information Services be deepened?” Presented by Susanne Weg-Remers (German Cancer Information Service)**

The ECPDC is a quite important novel development and is very interesting because it is combining many different aspects, not only information but also the possibility to self-manage the disease, the patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs), and to exchange with other patients and with scientists.

There is a very competitive environment with a flood of digital offers around. The ECPDC needs to have high-quality content, which is reliable, comprehensible, easy to understand, evidence-based, up to date, and therefore needs constant updates. It also needs to be search engine optimized to show up on the first page of a Google search.

The Cancer Information Services (CIS) in the different European states could make a major contribution to the ECPDC by sharing, testing and adapting content to their national structures and health care systems. However, the content cannot simply be duplicated because this will be “punished” by Google. The CIS can work very nicely together to support the ECPDC. They need certain funding to do so, and they have the possibility to act as trustworthy entry points in their countries.

- **“Why do we use what is there?” Presented by Harald Wagener, ECPDC team (Berlin Institute of Health at Charité)**

We have a huge number of high-quality resources already. The main challenges are that these resources are not necessarily targeted at patients and survivors and that the high-quality information is unevenly distributed in Europe. One of the ideas of ECPDC is to take the best of everything and make that into a blueprint or a template for Member States to start building cancer-related systems for data sharing etc. into their electronic healthcare systems which will grow based on EHDS. We can also answer questions about sustainability and feasibility of building these systems. It is important to bring together the people that are already experts, i.e. scientists, science writers, and patients.

Discussion

- It is very important that country and EU data do not clash. It would be great if the need for high-quality information that is European-wide would drive templates and information needs in Member States.
- The ECPDC comes into a competitive environment where different stakeholders (pharma companies, politics, healthcare sector etc.) with different interests even provide different levels of information. What does the ECPDC require to be successful in this competition? The most challenging part is how to make sure that the data is not only quality checked etc. but also updated on a regular basis which will require an enormous effort
- There will also be a lot of information in the future so we need to have a flexible and dynamic way to which this information can be added and translated.
- A good starting point is to team up with the Cancer Information Services that already have a huge body of evidence and content and the experts in communication sciences who know how to communicate certain aspects of cancer diseases. It is interesting to combine all the different functionalities in one portal: managing your own disease data, exchanging data with other patients, exchanging data with scientists, getting feedback and input from scientists or healthcare providers.
- The patient community and the patient organisations should dare to update their own data according to the information given on the ECPDC platform. It is also important to compare information and to get help from somebody who can value it.
- The ECPDC must be better than Google but that is a hard task. For the patients it is crucial to know where the information is coming from, and which authority (EC or national) is allowed to monitor it so that it is safe.
- The added value of the ECPDC would be if it is an officially quality-checked and endorsed source of information on a national and European level and is accepted as authority in this field. This is not an easy to achieve goal.
- The ECPDC must have a strong educational component to judge and to identify the criteria to differentiate between the good and the not

trustworthy information. There is also a chance to increase the health literacy in the European Member States.

- People are overwhelmed by the data and information provided by Google, so it is important that the ECPDC presents well-tailored information for the cancer patients' specific needs.

Concept 2: ECPDC Personal Health Data Space, presented by **Harald Wagener**, ECPDC team (Berlin Institute of Health at Charité)

The ECPDC implementation plan is divided into three different concepts. Concept 1 – the information portal – will very heavily rely on Concept 2 which describes the ways to grant patients and survivors access to their clinical data and in addition to integrate their own data into the system leading to a Personal Health Data Space. Therefore, Concept 2 is extremely important.

Concept 2 describes the ECPDC's basic requirements for **data access**. It must comply with the European Health Data Space (EHDS) and the General Data Protection Regulation (GDPR). Also, it must ensure semantic and platform interoperability and the use of persistence, exchange and semantic standards. The ECPDC must be well connected to existing initiatives and programs and be set up in a sustainable way so that its existence outside the project level funding is secured.

The **status quo for data access** is looking at infrastructures that can be used for ECPDC like MyHealth@EU. The limitations, however, are that national ECPDC nodes as of today could not access MyHealth@EU central services on national contact points because those are focused on cross-border data transfer between doctors and health insurers. There are two different ways to provide direct access for the patients and survivors themselves: 1. through a portal whereby other projects like smartCARE or PATHeD might provide the ways to access this data or 2. via the national infrastructures which would allow the use of existing national electronic health data structures (best practice example: HEALTH-X dataLOFT). A strong and trustworthy digital identity is important, so that the request to access data can be traced back to the original patient. Further existing infrastructures and initiatives to build on are the Genomic Data Infrastructure (GDI), the European Cancer Imaging Initiative (EUCAIM, UNCAN), and the Health Outcome Observatory (H2O) for patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs).

Concept 2 also includes the idea of a **Personal Health Data Space** as a complement to the EHDS. It should answer the question of how the patients and survivors could find, manage and share their data under their own control. The architecture principles of ECPDC map well to those of the European SIMPL project. The following five parts would build the Personal

Health Data Space within the context of ECPDC: core services to keep data safe and secure, data access, access point and input of personal clinical data (also PROMs and PREMs), self-determination such as the power of attorney, and data from primary care and data altruism.

For the **primary and secondary use of health data** there are pilots like MyHealth@EU and HealthData@EU which are GDPR- and EHDS-approved ways to build a system that allows access to and sharing of data. Regarding the primary use of data, this could be the basis for the remote consent for data sharing with healthcare professionals and the cross-border data exchange. For the secondary use there are slightly different systems: ECPDC nodes could donate aggregated de-identified data of patients to the health data access bodies or the ECPDC could do study-specific consented, patient-centric data aggregation as a data trustee. The personal health data spaces can exist in the EHDS as an intermediary or complementary way where the patients can control their data on their systems, share it with family, friends or health professionals and can grant access to health data access bodies.

In the panel discussion on Concept 2 the following questions were addressed:

- **“How should ECPDC be designed as a use case of EHDS?” Presented by **Guillaume Byk (DG SANTE)****

The question is what kind of interaction there is between EHDS and ECPDC. The purpose of EHDS is to give patients access to their data, provide them with the ability to change and share their health data. The EHDS does provide the legal and technical tools to do these applications for patients. It is up to ECPDC in collaboration with patient organisations to see how the whole system will work out. The question is which additional elements could increase the added value for patients.

- **“How could MyHealth@EU and HealthData@EU interact with data access and data management in ECPDC?” Presented by **Guillaume Byk (DG SANTE), Zoltan Lantos (PATHeD / POTENTIAL)****

PATHeD is developing a new mobile backend service which will allow patients to access their health data through the EHDS infrastructure, so each Member State will have the opportunity to integrate this mobile toolkit. A new important project will define the European exchange format and will address the following aspects: identification matters, definition of standardized EHR requirements, and an interoperable data record. After implementation of the HL7 FHIR standard data and data selection will be retrieved from the Member States' infrastructure. The European Digital Identity Wallet will be a true game changer because a uniform identity and identification tool will be applied throughout Europe so the consent management will be much easier. A dynamic consent manager will allow patients together with the exchange format to grant access to researchers and to health professionals to their clinical, genomic and all kinds of omics

data. Access will be controlled by the patients. These infrastructural developments will enhance the technical capability and provide better services for the patients.

- **“Patient Reported Outcome Measures (PROMs), Patient Reported Experience Measures (PREMs) and EHDS: Why are they useful for patients / survivors?” Presented by Fabian Prasser (H2O) and Jack Latteur (smartCARD)**

PROMs are standardized and validated questionnaires that are completed by patients themselves and measure their perceived health status, quality of life, or functional status. The positive impacts for patients are: Facilitating and improving patient-physician communication by bringing in the patients’ perspective, adapting treatments and individualizing care, and benefiting from research such as identifying unmet needs. PREMs are about how patients perceive the care delivery process which can involve patients’ satisfaction and might improve services or resource reallocation. The perspective of the Health Outcomes Observatory (H2O) project is to bring together PROMs and PREMs with other clinical parameters throughout the patient journey so that they can develop their full potential and show the whole picture. The ECPDC data space and EHDS are perfect environments for implementing this and bringing those different types of data together to then have an effect on the primary and secondary side of data use. It is important to bring PROMs and PREMs into daily use across countries in Europe. They also help to measure impact on treatments in a large range of different areas, e.g. overall survival, treatment toxicity, pain, nausea etc.

- **“What features would a safe community space within ECPDC need to help mitigating social isolation and discrimination?” Presented by Jack Latteur (smartCARD)**

From the smartCARE perspective - a project aiming to develop a cancer / survivor smartCARD in form of a mobile app - PROMs and PREMs are very important because they help to capture the patient’s experience and so help to facilitate patient-centered care. There are more plausible options to connect this kind of data and to give a sharp and more precise insight and find unmet hidden medical needs which can then be brought into the spotlight.

The topic of community spaces was frequently mentioned in consultations with patient organisations and in workshops with patients. “Mitigating social isolation“ is very important for a community space and can be ensured by different measures: Moderation is critical to ensure that discrimination and the spread of disinformation are not allowed. This is linked to the ability to report or block heases by the moderation team. Another major point is that users have full control over their data, and this also includes their data on identity. Discrimination can come from insurance companies or from employers for example when they learn of diagnoses. The option to decide

which data to share with whom and using which standard is very important. ECPDC should continue listening to the patients and survivors and understanding what the end-users would like to have.

Discussion

- The EHDS gives access to a wide range of data, not only health data. ECPDC could be a user of this data and add data from outside the EHDS to which it has access to within a secure data processing environment to carry out additional and meaningful analyses. Some of the PROMs and PREMs data sets might not be within the EHDS but could be put together with data from the EHDS.
- To enhance the usefulness of ECPDC the technical capabilities need to be harmonized and aligned with patients' and survivors' lives. It is also needed to develop life situations-based knowledge graphs to improve services. PROMs and PREMs fit very well into this concept.
- ECPDC could be a source of aggregated data after patients consented to sharing their data via the health data access bodies (HDAB), i.e. the researchers submit their research questions via the HDABs. That is within the mechanisms of EHDS. ECPDC is not a data holder but a way for people who are willing to give their data via a neutral party.

Concept 3: ECPDC Co-decision, presented by **Roland Eils**, head of the Center of Digital Health, Berlin Institute of Health at Charité

Concept 3 cannot stand independently of Concepts 1 and 2. It will integrate all aspects enabling true engagement and informed decision-making and participation by cancer patients, survivors and their families.

Concept 3 includes the establishment of a **patient agency** which puts patients, survivors and their representatives at the point of action. The major goal of the patient agency is to empower patients for co-decision on treatment, for participation in research and to exchange data with affected groups within a safe community space. The safe community space would enable patients and survivors to exchange their experiences without fear of stigmatization, discrimination, or exclusion, would provide patient organisations' services online and mitigate effects of cancer ghosting. This requires moderation and expert support. Providing meaningful information is of utmost interest, and there is a lot of information that must be tailored towards the requirements but also the personal profile of the individual. **Artificial Intelligence (AI)** can be of help by providing AI-tailored information aggregation for Cancer Information Services and would thereby increase quality and reduce costs. Trusted AI in ECPDC needs to be safe, reliable, fair and accountable. There are several challenges when using trusted AI in a

healthcare context, e.g. the complex information on cancer, data bias and psychosocial consequences when providing outcome statistics in the patients' own personal context.

Patients should be informed as much as possible to be involved in the **co-decision on their own treatment**. They should have access to all relevant evidence-based and AI-tailored information and health data about their disease in lay terms so that communication with doctors and understanding of the situation improves and treatment is discontinued less frequently.

Participation rate in research studies remains low although nearly all cancer patients are willing to donate their data for specific research. Therefore, the ECPDC needs to be trustworthy and fully transparent with regard to data access, purpose of data use and removal of consent. This means that a fine-grained remote consent for data donation needs to be established and be equally transparent.

In the panel discussion on Concept 3 the following questions were addressed:

- **“How to achieve patient agency?” Presented by Gilliosa Spurrier-Bernard, Vice President of the Melanoma Patient Network Europe (MPNE)**

Our forums are all about quality data: teaching people to fortify and to rely on their own decisions because they get the information from the right places. Agency means that people feel capable of taking on their own decision making. It is more than the right information; it is also having high quality support of the community. We cannot run our health system anymore without having patient agency. ECPDC is a good way to get that started.

- **“Can we expect patients to making meaningful decisions on treatment? If no, what is missing?” Presented by Jan-Willem van de Loo (DG RTD)**

First thing for making meaningful decisions is the language. Another requirement is that the patients have a certain digital aptitude, and internet access is still an issue in large parts of the EU. Patients want to have peer-reviewed information based on lay language to make clinical decisions. It is a legal issue in which environment (e.g. hospitals) patients are permitted to make clinical decisions. There would be the need for a patient navigator as complementary to the above-mentioned editorial teams. Several organisations in Europe are offering this service. The high-level concept of a patient agency is reminiscent of the Patient-Centered Outcomes Research Institute (PCORI) in the US.

- **“Are researchers even prepared to explain their research to patients in a useful way? How can we help them?” Presented by Christine Chomienne (Mission on Cancer Board)**

Researchers are not prepared but it depends on the type of research. In interventional research they are moving faster. Fundamental researchers,

however, are still very perplexed when they are sitting in the room with a patient. But it also depends on the patients. Some patients also need to know how to speak with researchers. This is an important gap for participative research, so it needs to be compulsory, and training needs to be performed. One part of the Mission Board's actions is to make participation of patients upfront in co-design and co-construction.

- **“How can we make sure that research results contribute to the ECPDC info portal in a timely manner?” Presented by Salvador Capella (EOSC4Cancer)**

We want to create trust in patients. The answer lies in having community-driven standards that facilitate the rapid and timely uptake of research results and maybe show the results in the portal or in any other platform. The community comes first, the second is not a standard but creation of a capacity to make researchers aware of the importance of such standards. The researchers must explain the results of their research to the patients.

Discussion

- Were healthcare professionals, especially nurses working with cancer patients, consulted and which feedback was given regarding the usage of the platform and the treatment of their patients and also the potential difficulties with AI?
There were conversations with many stakeholders, scientists, clinicians and patients, but not with study nurses or nurses directly. That is a gap that needs to be closed in future work.
- The level of willingness from the healthcare providers to involve patients and their families in the treatment and decision-making process is very different. The healthcare providers who are working directly with the patients need to be convinced that the ECPDC and the patient agency coming with it is of benefit not only for the patients but also for them.
- It must be a win-win situation for everyone. If healthcare professionals must do double time for data entry it won't work. It also must be a return on engagement for everyone: the healthcare system, the healthcare professionals, the payers, and the patients.
- Co-creation is the place where the new mobile technical advances will provide new opportunities. There is the opportunity to develop user-centric applications which are based on the new digital identity and the wallet framework. Thus, it is time to start working on new solutions where we can use different AI solutions and push the healthcare professionals to take these tools into consideration.
- It is relevant how research flows back to the info portal. Within the portal we should follow the standards of how research will be reported and approved i.e. in the words of evidence, independent validation, and having a pipeline of how we can really trust in the research before it is transferred into the portal.

- It must be guaranteed that the results are properly generated and managed before they are shared with the community. Regarding the discussion on the standards, we have many opportunities as we have new technologies and new developments. We should ask ourselves: Do we already have standards? Do we already have solutions or solutions that can be extended? When developing new things there needs to be a community behind to facilitate adoption. We must ask: What is the way towards having a more sustainable and more interesting ecosystem for data that is being generated in care and then being transferred to research? This data should be verified, aggregated and utilized.
- All the different players involved in cancer diagnosis, treatment and care must be on the winning side if it comes to establishing and using the ECPDC. Otherwise, it would be very difficult to convince any of these communities to participate actively.
- There are scenarios where we can analyze how to communicate results to patients. There are clinical studies in hospitals and there are medical doctors in charge of that. Are there any exercises, how this interaction is happening? Can this be improved? We could start learning from this.
- There must be a lot of research and exploration going in this direction. Within the context of designing the ECPDC blueprint in the last 8-9 months this aspect has not been well integrated into our work. As a research community we are not well prepared to talk to patients although we are all very motivated and willing to do so. It is a very difficult process if you take it seriously. If it comes to healthcare providers, doctors, nurses etc. given the time constraints and the pressure they are under, it makes it even more difficult for them to get fully engaged. We should think very thoroughly how we can help those communities both in research but also in healthcare and how to promote their interaction and service to the patients.
- The patient wants the information and wants to be able to collect his/her data for his/her own use. When the patient has all his/her data the possibility that he/she can participate in research projects is the second step. The way the data is collected is important, but the way the patient is going to participate is the most complicated. Is a patient agency to solve this? How do we get the researcher to provide ideas of research to the patients? How do we get patients to define topics for research?
- We have these 3 concepts where we handle different aspects of the ECPDC and we also have some ideas about what is easier or harder to achieve. There are some dependency orders in there. You can't take a decision without the data; you can't use the data before understanding it. On the other side there will be patients and survivors who will definitely be able to do things with data, even before ECPDC implements some technology support. We will already improve the ability for patient agency and co-decision even just with the info portal.

Wrap-up by **Roland Eils**, head of the Center of Digital Health, Berlin Institute of Health at Charité

Thanks to everybody for participating in today's meeting and for the many helping hands, brains and idea givers in the past nine months who have supported us along the way to develop these three ECPDC Concepts. Now we have these three Concepts in our hands and put them in the hands of the Commission so that it can take proper action and decide on the next steps. It is important to bear in mind that those three EPDC Concepts are designed individually as projects which can be realized independently from each other. There is some form of modularity, but if you want to bring ECPDC to its full benefit we need to consider seriously how we can implement those three Concepts in parallel. In **Concept 1**, the information portal, it is clear what is to be done but it is equally clear that it is extremely challenging to place it at the right point in the information space to give it a value by itself, to create this data and also to make this data accessible in different formats for different stakeholders at different levels for the patients and survivors in different EU Member States and regions.

If it comes to **Concept 2**, it will be extremely important to add value to Concept 1 because if it is the "information portal" only we will be competing with the rest of the information space on cancer in the WWW. But if we add functionalities for the patients to add own data and to use their own personal signature of their cancer to retrieve information which is most important and most informative, we are at a level in which we help Concept 1 to flourish much faster and further.

Concept 3 is the outreach where we can fully integrate and fulfill the promise of integration of patients and survivors in the diagnostic, treatment and follow-up processes at full scale. If we do not have this in place all the promises for patient and survivor involvement would just remain very theoretical, but we need to put this into practice. So, my wish to the Commission would be to consider each of these concepts to be equally important and to consider that they need to be established and implemented at best in parallel. Only if we bring these three Concepts together, we will be able to bring the ECPDC to its fullest level of usability and usefulness and accessibility for all stakeholders in the cancer context but with the primary focus on patients and survivors.