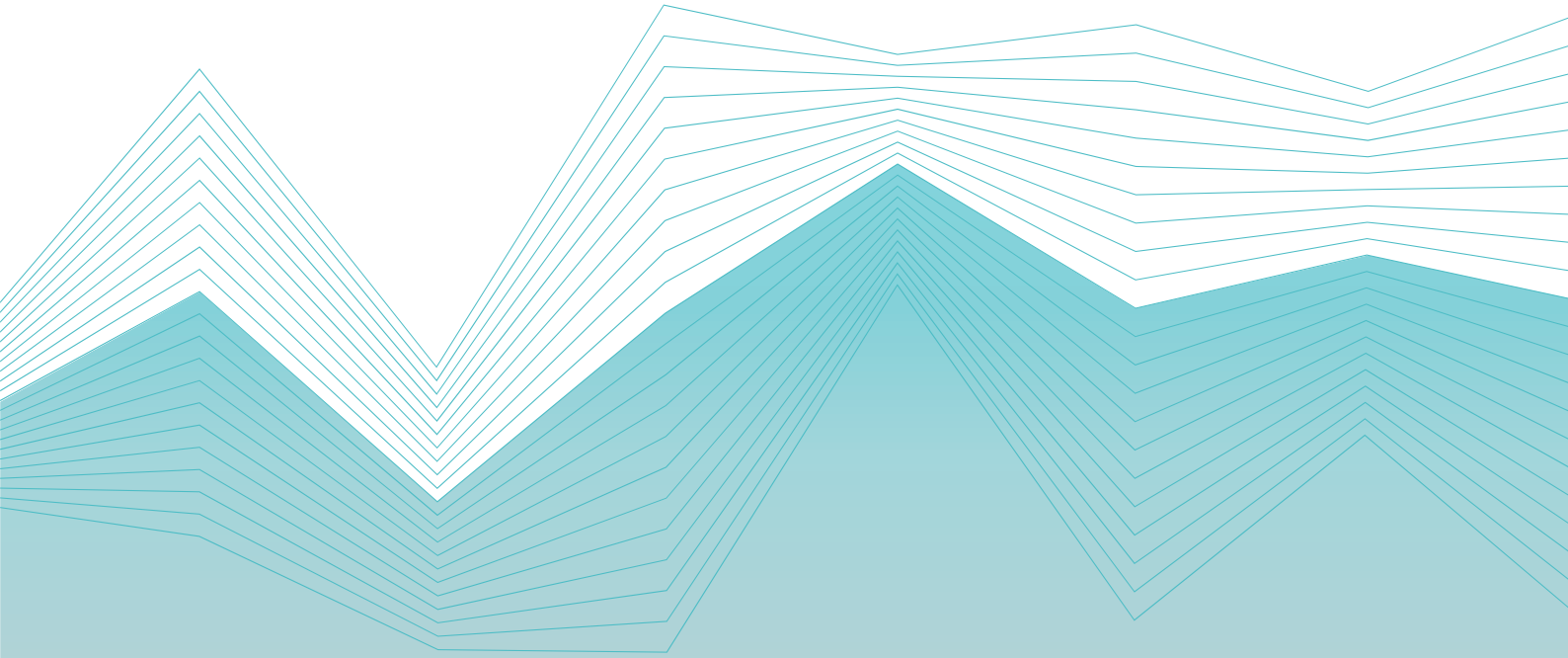
Quick scan of virtual networks of patient-controlled digital data

Report



Marianne Heins
Madelon Kroneman
Johan Hansen
Mieke Rijken

NIVEL
Kennis voor betere zorg

EUHealthSupport

Nivel, Netherlands institute for health services research, is the national institute for health services research in the Netherlands. Health services research is the multidisciplinary field of scientific investigation that examines how social factors, financing systems, organisational structures and processes, health technologies, and personal behaviours affect access to health care, the quality and costs of health care, and ultimately our health and well-being. Nivel is an independent organisation, which carries out high quality research with a demonstrable impact upon society.

This report was produced with funding from the European Commission, DG Research & Innovation, as part of a service contract by the EUHealthSupport consortium to support the EU Mission on Cancer (Specific Contract No SC-Cancer Mission/RTD.E2-2020 in the context of the Single Framework Contract Chafea/2018/Health/03).

January 2022

ISBN 978-94-6122-678-5

++31 30 272 97 00
nivel@nivel.nl
www.nivel.nl

Content

Acknowledgements

We thank the members of the Cancer Mission Board as well as officers of DG RTD for their guidance during the design and execution of this study. Moreover, we are grateful for the insights shared by representatives of the six initiatives described in this report. We also wish to thank two experts (Mr Dusan Milovanovic, Lead ICT architect at WHO and Mr Nicolas Garcelon, Head of the data science platform at Imagine Institute) who provided expert advice, which helped draft the main lessons of this study.

Executive summary

European Research and Innovation Mission on Cancer

As an integral part of the Horizon Europe Framework Programme for Research and Innovation (2021-2027), the European Commission has initiated the European Research and Innovation Mission on Cancer. The goal of this Mission is to save and improve the lives of millions of European citizens exposed to cancer and its risk factors. In designing the Mission, the European Commission appointed a Board of experts to specify the Mission's objectives and to propose a coherent set of actions to achieve the Mission's goal. In September 2020, the Mission Board handed its Mission Outline over to the Commission, including thirteen recommendations that had been developed in consultation with the Mission on Cancer Assembly, citizens, cancer patients and survivors and many other stakeholders in Europe.

European Cancer Patient Digital Centre

One of the recommendations described in the Mission Outline is to create a European Cancer Patient Digital Centre (ECPDC). This would be a virtual, federated network of patient-controlled (national) health data infrastructures, in which cancer patients and survivors can deposit their health data (both clinical data and patient-reported data) for their personal use. The ECPDC would provide cancer patients with a smart card including information on their treatment, care and follow-up recommendations; offer guidance and support to patients, survivors and their families and caregivers, including support to assert survivors' rights. Furthermore, the ECPDC would be a global centre of knowledge on cancer. Moreover, the rich data of the ECPDC would serve as a valuable resource for scientific research.

Quick scan

To prepare the implementation of this recommendation, the EUHealthSupport consortium was tasked by the European Commission's Directorate-General for Research and Innovation (DG RTD) to conduct a quick scan to identify existing (patient-controlled) health data centres or networks that might provide useful inputs for the future development of the ECPDC. Considering the complexity of understanding all ins and outs of such health data networks in the context of countries' health systems and EU and national (health) data protection legislation, we selected six initiatives out of the 44 health data centres or networks identified by our scan, for in-depth study: the Duchenne Data Platform, GerOnTe, Patientöversikt, POLA, Share4rare and the Survivorship Passport for paediatric cancer survivors.

Functionalities of initiatives studied

All six initiatives provide patients or survivors with a health passport, i.e. an overview of clinical information on their diagnosis and treatment. These passports also often include patient reported outcome measures (PROMs). Some include recommendations for screening based on clinical guidelines. Patients or survivors can access these passports through a (mobile) application or an online platform; for one of these initiatives, users currently receive a paper version of the passport, but an online version will be developed. Most passports allow patients to share their information with (other) health care professionals. Clinical data are mostly added manually by patients or health care professionals, although application programming interface technologies are being developed to derive clinical data automatically from patients' electronic health records.

Some initiatives offer general medical information on their websites and/or have an extensive Q&A section where patients or survivors can see the answers on frequently asked questions and can ask

questions themselves. Others offer patients or survivors the opportunity to compare themselves to aggregated data of other patients or survivors, providing insight to their situation with respect to their peers.
Several initiatives promote patient empowerment by offering support for patients, survivors and their families. For example, they offer a toolkit for patient advocacy, information about relevant patient organisations or a feature to apply for free legal consultation on patient rights. Other initiatives support patients to get in contact with each other through a forum or a private Facebook group.
Most initiatives also have a research aim. In some, data can be used to select users that fulfil specific criteria of eligibility for research purposes. Eligible patients or survivors are informed about new studies and could give their informed consent if they wish to participate. This may improve access to trials for patients or survivors living in countries where clinical trials are less often initiated. Other initiatives facilitate secondary use of patient data for research, after approval of a scientific advisory board and consent given by the patients or survivors.

Challenges
The challenges mentioned by the contact persons of the six initiatives cover a broad range of topics of technological, legal, organisational, structural and cultural nature. In the case of technology, an important challenge is handling the mixture of unstructured, semi-structured and structured data, which may differ by care provider and country. This can be done using warehouse methodology that could combine these types of data. Another issue is the handling of cross-country data from multiple sources. An option that could meet EU and national data and privacy protection legislation is to make sure that data remain at their original location and only be linked.

Conditions
If recommendations for follow-up care are part of the ECPDC, these need to be updated regularly and healthcare professionals will need to be educated on the guideline-based recommendations that patients receive.
Moreover, the contact persons of the initiatives mentioned that for the ECPDC to be successful, it is important that patients or survivors are motivated to use it. The ECPDC should therefore be easy to use, compatible with multiple devices and registration should be as simple as possible. There should also be an active and personalised customer service. Motivation of patients or survivors may also be increased by informing them about the importance of sharing their data for research. Communication and transparency on patient data security is pivotal to address any concerns patients or survivors may have.
The conditions mentioned above not only hold for the implementation and use of the ECPDC, but also for its development. Key stakeholders, including patient-experts and care providers, should be involved in the developmental process right from the beginning, to ensure that the ECPDC will meet their needs as well as their preferences for practical use.

Conclusion
The quick scan provides valuable lessons to be considered when developing the future ECPDC. The experiences with the six initiatives we studied reveal opportunities, challenges and conditions that may be important for the development and implementation of the ECPDC.

1 Background

1.1 EU Mission on Cancer

In April 2019 the Council of the European Union and the European Parliament reached a political agreement on the next EU research and innovation programme Horizon Europe (2021 – 2027), on the basis of which the Commission has started preparing Horizon Europe's implementation. Among the novelties of Horizon Europe are "missions", which aim to address important societal challenges by giving direction to EU research and innovation activities that can make a real difference in European citizens' lives and societies. One of the missions is the Mission on Cancer.

In designing the Mission on Cancer, the European Commission invited a Mission Board of European experts – covering cancer research, innovation, policy, healthcare provision and practice –to define an ambitious and measurable goal with a substantial impact on and relevance for society and citizens of Europe. The Commission also asked the Mission Board to propose a coherent set of actions to achieve this goal in a set timeframe. These actions will be implemented through Horizon Europe and other instruments of the European Union (EU) and its Member States, and aligned with other initiatives at EU and Member State level.

During the first phase of the Mission, which lasted until September 2020, the Mission Board developed a Mission Outline[1] in consultation with the Mission on Cancer Assembly and citizens and stakeholders in all EU countries. In this Outline the goal of the Mission was defined as: "By 2030, more than 3 million lives saved[2], living longer and better". To achieve this goal, the Mission Board identified five areas for action: 1. Understanding cancer, 2. Preventing cancer as far as possible, 3. Improving and optimising cancer treatment, 4. Better quality of life and survivorship support, and 5. Equitable access to cancer research, prevention, treatment, care and support. Within these areas thirteen recommendations were made. One of these recommendations is to to create a European Cancer Patient Digital Centre (ECPDC; see section 1.2 and Annex I).

The Mission Outline was handed over to the European Commission on 22 September 2020. The Commission decides on whether and how the recommendations will be adopted, taking into account the available resources and instruments to implement the Mission. The Mission Board will advise the Commission on the portfolio of research and innovation actions, but also on the broader spectrum of actions needed to implement the recommendations of the Board in the coming years.

1.2 European Cancer Patient Digital Centre

As mentioned above, one of the recommendations of the Mission Board is to "create a European Cancer Patient Digital Centre (ECPDC) where cancer patients and survivors can deposit and share their

[1] https://ec.europa.eu/info/publications/conquering-cancer-mission-possible_en

[2] The Mission on Cancer aims to avert more than 3 million additional premature deaths over the period 2021 – 2030, by accelerating progress of cancer prevention and control programmes and creating more equitable access to these programmes. This goal was set based on an analysis of avoidable deaths by the International Agency for Research on Cancer (IARC).

data for personalised care." The Mission Board has also described how the ECPDC could be created: "The creation of the ECPDC would rely on a patient-driven roadmap and governance document, drawing on existing expertise at the EU and national level and on EU- and Member State-tailored data sharing procedures." The Board also provided a description of what this ECPDC should look like:

> "a **virtual network** of **patient-controlled (national) health data infrastructures**, in which **cancer patients and survivors can deposit their health data provided by their medical care providers** (e.g. imaging, genetics, blood markers, clinical and lifestyle data) in a **standardised, ethical and interoperable manner**. The repository would include a **summary of treatments** and **integrate patient-reported outcomes** useful for the cancer patient own use and everyday life data **provided by patients and survivors themselves**."
>
> *Source: Conquering cancer, mission possible (Mission Outline 22-09-2020)*

The ECPDC should serve various purposes:

1. *For people living with and after cancer and their families*
    - A health passport, including information on treatments and follow-up recommendations, and a (long-term) personalised care plan.
    - A global centre of knowledge on cancer, cancer prevention and health promotion, diagnostics, treatment and supportive care.
    - A global point of contact, offering guidance and support on returning to work, addressing financial issues and asserting survivors' rights.
    - Give a voice to patients and survivors, enable them to enforce their rights (in line with the European Data Strategy put forward by the European Commission[3]).
    - Increase their confidence in sharing their data for cancer research, innovation and policy development.
2. *For researchers*
    - A valuable resource for research to improve understanding of cancer and its impact on patients' and survivors' lives, thus contributing to the development of improved diagnostics, treatment, care and quality of life support.

[3] https://ec.europa.eu/info/sites/info/files/communication-european-strategy-data-19feb2020_en.pdf

2 Quick scan

2.1 Aim

To prepare the implementation of the recommendation to create this ECPDC, the European Commission requested the EUHealthSupport consortium to conduct a quick scan to identify a number of existing patient-controlled health data networks that could serve as potentially useful examples for the ECPDC, and describe their features and users' experiences.

Considering the complexity of understanding all ins and outs of such health data networks in the context of Member States' health systems and the EU (health) data protection safeguards, it was decided to study six potentially useful examples more in-depth rather than providing an overview with a more exhaustive nature. These six examples would not necessarily reflect best practices, but rather reflect a broad variation of health data networks, this to enhance the learning potential of the study.

2.2 Methods

The quick scan consisted of a number of steps:

1. Deciding on the selection criteria for the patient-controlled health data networks to study
2. Identifying interesting examples of existing patient-controlled digital health data networks
3. Collecting information about these networks (i.e. data extraction)
4. Data synthesis and reporting.

Step 1: Selection criteria

Regarding the first step it was decided to search for digital health data centres or networks that:

- were initiated, driven or controlled by patients, ex-patients and/or family members of (ex-) patients. This means that a) these persons are providing health data themselves or agree explicitly with provision of their health data, and b) these persons are co-steering the use of the collected data.
- have run within or across EU Member States in the period 2018 - until now. This is to ensure that these health data centres or networks are operational under the EU General Data Protection Regulation (GDPR).

Health data centres or networks aimed at other health conditions than cancer were also considered of interest, in particular those that had been developed for rare diseases, as these could be good examples for the ECPDC. As many rare diseases typically have only few patients per country, there is a strong need to connect at European level. This may explain why for the rare diseases community, several international infrastructures exist that may have (partly) similar aspects as the proposed ECPDC. The focus of the lessons to be learned from these initiatives was on how they deal with the challenges of internationally exchanging data and drafting the governance structure of an international network.

Step 2: Identification

Existing patient-controlled digital health data centres or networks were identified via three searches: 1) a search in PubMed, 2) via our contacts within the rare diseases community, and 3) by means of an inventory with the help of Board and Assembly members. Regarding the latter, the consortium asked the Mission Board and Assembly members to provide examples of relevant patient-controlled health data centres or networks themselves and/or to share our request within their professional network ('snowballing').

Step 3: Data collection

Initiatives that were considered of interest to study were contacted and an online meeting with EUHealthSupport, and in some occasions also Board Members, was planned. During the meeting the contact persons/coordinators introduced and explained the initiative, and first data were gathered.

A data extraction form was developed in collaboration with the Mission Board. This form was pre-filled by EUHealthSupport based on the information gathered during the online meeting and additional information received from the initiatives. The contact persons/coordinators of the initiatives checked the pre-filled information and provided additional information where relevant.

Step 4: Data synthesis and reporting

The checked data of the six selected initiatives were synthesised by EUHealthSupport, following the structure of the data extraction form, and reported in this report.

3 Description of selected initiatives

A total of 44 patient-controlled health data networks were identified (see Annex II). As mentioned previously, our aim was not to give an exhaustive overview of such initiatives, but to study a selection of interesting initiatives in more detail.

From the identified initiatives, six were chosen for further study. Preference was given to patient-controlled health data centres or networks that show most similarity with the intended ECPDC. Besides, variety as to the involvement of EU Member States, and characteristics and functionalities of the data networks was sought. This resulted in the following initiatives for further study *(in alphabetical order)*:

- **Duchenne Data Platform** (https://duchenne.nl/duchenne-data-platform/)
- **GerOnTe** (www.geronteproject.eu)
- **Patientöversikt** (https://www.cancercentrum.se)
- **POLA** (www.pola.lt)
- **Share4rare** (https://www.Share4rare.org/)
- **Survivorship Passport** (http://www.survivorshippassport.org/)

In this chapter we provide a brief description of each of these initiatives, based on the data we extracted, which were confirmed by contact persons of the initiatives. Detailed information on these initiatives can be found in Annex III.

3.1 Duchenne Data Platform (DDP)

Organisation	
Countries involved	NL, ES
Organisations involved	- Parent organisation Duchenne Parent Project Netherlands (DPP NL) - Non-profit health IT organisation 'Foundation 29'
Boards	- Boards of Duchenne parent project and 'Foundation 29' - Scientific advisory board
Funding	EU 3rd Health Programme
Implementation	
No. patients contributed	70
Disease	Duchenne Muscular Dystrophy
Countries	NL

Functionalities	
Health passport?	Patients and parents can deposit and access their data through an app or the online portal of 'Foundation 29'. Clinical data and PROMS are provided by patients themselves. Healthcare providers are also able to add data through an app, but the controller remains the patient. Patients and parents are reminded to visit their clinicians according to the Standards of Care.
Centre of knowledge?	DDP contains an FAQ section with information on, e.g., treatments, vaccinations, equipment, education. If their question/answer is not already answered there, the question will be answered and added on the platform if appropriate for general use. Patients and parents can also find general information about their disease on the website of DPP NL and World Duchenne Organization for parents and children.
Point of contact for patients and/or families?	The website of DDP offers advice to parents to get care and has a private Facebook group for parents.
Research?	DDP is FAIR (data are Findable, Accessible, Interoperable and Re-usable) by design and allows secondary use of data for care, research and regulatory queries. Researchers can request information from DDP. Data sharing is regulated by a dynamic informed consent.

3.2 GerOnTe

Organisation	
Countries involved	FR, BE, NL, IE, NO, IT

Organisations involved	The GerOnTe consortium is constituted of:
	- five hospitals and universities specialised in geriatrics and/or oncology
	  - Université de Bordeax, France (coordinator)
	  - Stichting Diakonnessenhuis, Netherlands
	  - Oslo Universitetssykehys HF, Norway
	  - University College Dublin, Ireland
	  - Katholieke Universiteit Leuven, Belgium
	- two universities with expertise in socio-economic studies of health systems
	  - Universita Commerciale Luigi Bocconi, Italy
	  - Dublin City University, Ireland
	- two experts in health informatics
	  - MyPL SAS, France
	  - University College Dublin, Ireland
	- two associations skilled in stakeholders' engagement
	  - E-Seniors: Initiation des Seniors aux NTIC Association, France
	  - International Society of Geriatric Oncology, Switzerland

Funding	EU Horizon 2020

Implementation	
No. patients contributed	Has not started yet
Disease	Older patients with cancer and concomitant chronic conditions
Countries	Plans for FR, BE, NL
Functionalities	
Health passport?	Patients will have access to their personal information through a dashboard. This will include essential information on their diseases, treatment and tolerance. Clinical data will be automatically derived from patients' Electronic Health Records (EHRs) through an ICT module. The dashboard will also include PROMs and disease- or treatment-related symptoms, which will be collected on a weekly basis.
Centre of knowledge?	Self-management tutorials will be available through the web-app and specifically tailored and pushed to the patient according to their specific geriatric baseline evaluation.
Point of contact for patients and/or families	No
Research?	There are plans to apply machine learning once enough patient data has been collected throughout Europe.

3.3 Patientöversikt

Organisation	
Countries involved	SE
Organisations involved	Regional cancer centres Sweden
Funding	Regional cancer centres Sweden, non-profit organisation Swedlife and Swedish government
Implementation	
No. patients contributed	23,600
Disease	8 cancer types
Countries	SE
Functionalities	
Health passport?	Information can be accessed through the national 1177 Vårdguiden (patient portal). Patientöversikt visualizes the individual cancer patient's care data seen on a graph over time. This includes data about the patient's medical history, disease status, laboratory data, examinations, treatments, side effects, symptoms and quality of life (described in PROMS). Data is entered manually by health professionals, but automatic retrieval is planned. Questionnaires for patients are also available through the portal.
Centre of knowledge?	There is some general information on the site of the cancer centre on different types of cancer, mainly on the care process. Individual information and recommendations will be found in the personal care plan "Min Vårdplan".

Point of contact for patients and/or families?	No
Research?	Patientöversikt can be used by clinicians to select patients for research purposes.

3.4 POLA

Organisation	
Countries involved	LT
Organisations involved	Patient organisation POLA
Funding	Patient organisation POLA and 5 private companies
Implementation	
No. patients contributed	300
Disease	Cancer
Countries	LT
Functionalities	
Health passport?	Patients can access data on their diagnosis, treatment or side effects through the POLA app. Data is provided by patients themselves directly into the app, via anonymised user accounts.
Centre of knowledge?	On the POLA app "news" column – POLA shares recommend-dations on self-management. The app is sending disease specific reminders on upcoming health events, opportunities, trials related to diagnosis. Patients can statistically compare whether their symptoms also occur in other patients of the same diagnosis.
Point of contact for patients and/or families?	The POLA app has a feature to apply for free legal consultation on patient rights as well as psychological and nutritional support that are offered for free. POLA also uses the data collected by the app to write policies based on social-economic needs of the population and represent the patient needs.
Research?	No

3.5 Share4rare

Organisation	
Countries involved	ES, UK, NL, SE, BE
Organisations involved	- Fundació Sant Joan de Déu and Hospital Sant Joan de Déu - Asserta Global Healthcare Solutions SL - Cliclab Transformative Agent - John Walton Muscular Dystrophy Research Centre – Newcastle University - Melanoma Patient Network Europe - Òmada Interactiva - The Synergist - Universitat Politècnica de Barcelona (UPC)

Funding	EU Horizon 2020
Implementation	
No. patients contributed	2,000
Disease	Rare cancers, neuromuscular disorders and undiagnosed diseases
Countries	Worldwide
Functionalities	
Health passport?	Patients and parents can deposit and access their data through the online portal of Share4rare. They can provide clinical data and PROMS.
Centre of knowledge?	Patients can find information about a large number of rare tumours and neuromuscular disorders and medical books on different conditions written by medical experts.
Point of contact for patients and/or families?	The website of Share4rare offers a toolkit for patient advocacy and patients can find information about relevant patient organizations. Patients can also get into contact with each other through a forum.
Research?	Share4rare allows researchers to request data for projects that comply with the goals of the registry. After approval of the data access committee, the adult patient or the caregiver needs to consent the use of the data through a digital (re)consent process.

3.6 Survivorship Passport

Organisation	
Countries involved	EU-wide
Organisations involved	- SIOP Europe (representing Paediatric Oncologists) - CCI-E (representing patients and parents) - PanCare (research on late effects) - Cineca
Funding	EU FP7 and Horizon 2020
Implementation	
No. patients contributed	800
Disease	Childhood and adolescent cancers
Countries	IT (plans for DE, CR and LT)
Functionalities	
Health passport?	Survivors receive a paper passport from their physician after the elective end of treatment therapies. This passport contains detailed information about the cancer history and therapy and advice and guidance on long-term follow-up of possible late effects. Data are entered manually by health professionals. In the future, data will be extracted automatically and survivors will be able to view and/or print the electronic documents in any of the available languages through a personal account. Patients will then also provide data trough patient reported outcome measures (PROMS) and clinicians through clinician reported outcome measures (CROMS).

Centre of knowledge?	The survivorship passport contains detailed patient specific advice and guidance on long-term follow-up of possible late effects.
Point of contact for patients and/or families?	No
Research?	No

4 Synthesis of selected initiatives

In this chapter we describe the structure, characteristics and functionalities of the six selected initiatives from the perspective of usefulness for the development and implementation of the proposed ECPDC.

4.1 Health passport

All six initiatives contain a health passport, i.e. an overview of clinical information about a patient's diagnosed condition(s) and treatment(s), sometimes also including recommendations for screening and follow-up. Information from patient reported outcome measures (PROMS) may also be included. Patients or survivors can access their passport through a (mobile) application or an online platform or receive it on paper. In most initiatives, patients or survivors can also share information in their health passport with (other) healthcare providers.

4.1.1 Clinical data

All health passports include clinical data of patients. This may range from a short description of the diagnosis and treatment to extensive information including hospital visits and results of lab tests and imaging. Raw imaging data are often not included because of the size of image files.

In most cases, clinical data is entered manually by patients themselves (Duchenne Data Platform, POLA, and Share4rare). This can be done with the same application that patients use to access their health passport, either by filling in information fields or uploading clinical reports that patients have access to. In other initiatives, clinical data are uploaded by healthcare providers (Patientöversikt, Survivorship Passport).

Application programming interface technologies are being developed to derive clinical data automatically from patients' electronic health records (EHRs) (GerOnTe, Patientöversikt, Survivorship Passport). Some of these interfaces are able to connect with various EHR software packages that hospitals use and can process and combine unstructured, semi-structured and structured data that are included in an EHR. There are several data standards for exchanging data between healthcare applications. GerOnTe, for example, complies with Fast Healthcare Interoperability Resources (FHIR) standards, developed by the Health Level 7 (HL7) organisation.

4.1.2 Patient reported data

Almost all health passports include, or will include, patient reported data. These are for example patient reported outcome measures (PROMS). Patients or survivors are, or will be, invited to complete questionnaires, often through the same application that they use to access their health passport. Results can be used by patients or survivors themselves, to monitor symptoms and side-effects and to get insight into their functioning and wellbeing. The results can also be discussed with healthcare providers.

To motivate patients to enter their data, POLA uses a gamification feature. For each action and active use of the app, POLA points are awarded, which are available for additional services or gifts based on the number of points collected.

4.1.3 Wearables and other smart devices

The POLA app can automatically add data that are collected by wearables or smart devices to the health passport; for example, data on physical activity, weight, sleep or nutrition. This is an easy way for patients to share data about their lifestyle with their healthcare providers.

4.1.4 Recommendations for follow-up

The Survivorship Passport provides survivors of paediatric cancer with organ-specific screening recommendations for possible late complications of treatment. These recommendations were developed by PanCareSurFup in collaboration with the International Guideline Harmonization Group (IGHG) (https://www.ighg.org/international-guideline-harmonization-group/methods/publication/).

Survivors at risk are identified by using automated algorithms built into the system. The system provides the strength of the screening recommendation with a colour code: strong (green), moderate (yellow) or weak (orange) or a recommendation not to do (red). The treating physician can also assign other screening recommendations, based on the survivor-specific medical history (e.g. complications during treatment).

Patientöversikt provides patients with a personal care plan. These include diagnosis-specific and personal descriptions and recommendations for care professionals and self-care. There are national, diagnosis-specific formats which are adapted and activated when a cancer diagnosis investigation starts for an individual. During the different stages in the investigation and in the treatment, more parts of the formats are being activated.

DDP reminds patients to visit their clinician(s) according to the Standards of Care. This is based on the information about healthcare visits that patients enter.

4.1.5 Accessing the health passport

For most initiatives a special app or online portal was developed, which patients can access on their personal computer, smartphone, tablet or another mobile device. An exception is Patientöversikt, which can be accessed by patients through the portal of 1177 Vårdguiden, the online medical file that is operated by the Swedish health regions. Most platforms are available in one or a limited number of languages. The Survivorship Passport is provided to the patient on paper.

Several initiatives provide user support. On the website of DDP, patients/parents can find instruction videos, there is an automatic chat function and a FAQ section. POLA app customer service is provided by the POLA team via email, telephone, public events and social media (e.g. Facebook).

For Share4rare dedicated staff of the platform is available to guide users through the registration and validation process. Guidelines and material support (such as videos) have been made available on the Share4rare website, as well as community questions, which develop in further information in the ecosystem. Patientöversikt provides instruction videos for healthcare professionals. The portal also contains an extensive manual.

4.1.6 Sharing the health passport with healthcare providers

Most health passports can be shared with healthcare providers. The simplest form is the current version of the Survivorship Passport, which can be printed and then shared by the patient. With the POLA app patients can show the information on their mobile device when they visit a healthcare provider. On the DDP platform patients can download their information in a computer-readable format. Patients involved in Share4rare can request their information, and subsequently share it with their healthcare providers.

Other initiatives (DDP, Patientöversikt, GerOnTe and the future version of the Survivorship Passport) offer physicians the possibility to access the information through an online platform or mobile app. Access is often restricted to certain healthcare providers; for example, healthcare providers can only access data from Patientöversikt if they are involved in the care for a patient, although emergency access is possible. Access is also logged. GerOnTe will use blockchain technologies and artificial intelligence for tracing and securing data so that only trusted people can access it.

4.2 Centre of knowledge

A second aim of the ECPDC is to be a centre of knowledge. The websites of DDP, Patientöversikt and Share4rare have this function by offering general information about the disease itself, treatments and living with the disease. Besides, the DDP portal has an extensive Q&A section where patients can read the answers on frequently asked questions and ask questions themselves. On the website of Share4rare, patients can find extensive information on several rare conditions written by medical experts. These 'medical books' include information about the disease itself, risk factors, symptoms, diagnosis, treatment and disease management.

POLA and Share4rare offer patients the opportunity to compare themselves to other patients. In both initiatives, the data for comparison are entered by the patients themselves. In POLA, patients can compare (anonymously) their disease, stage, age, location as well as side effects with population data. Share4rare developed a specific Module for Automated Individual Reports (MAIR). MAIR generates two versions of plots. In one version the graph represents the aggregated responses on a given question. In the second version the graph represents the same aggregated data but highlights (in different ways depending on the type of plot) the response of the individual patient, as such providing insight to patients in their situation compared to the situation of peers.

4.3 Point of contact and support for patient/families

The Cancer Mission also proposes the ECPDC to serve as a point of contact and support for patients and their families. Several of the examined initiatives for other patient groups offer support. The website of Share4rare offers a toolkit for patient advocacy and patients can find information about relevant patient organisations. Patients can also get into contact with each other through a forum. The POLA app has a feature to apply for free legal consultation on patients' rights as well as to receive psychological and nutritional support that are offered for free. POLA also uses the app to send out questionnaires that they use to write their policies and represent patient needs. The website of DDP offers advice to parents on where to get care and has a private Facebook group for parents. The care plan provided through Patientöversikt contains information about patients' rights.

4.4 Research

This section describes whether and how the six initiatives offer facilities to contribute to scientific research, which is also considered an option for the ECPDC. DDP, Share4rare and Patientöversikt can be used to select patients that fulfil specific criteria for research purposes. Patients fulfilling specific criteria receive information about studies in which they could participate. These may be surveys, of which the questionnaires can be completed within the application. Patients may also be invited for

clinical trials, which may be an interesting approach for studies that require the enrolment of patients with rare (subtypes of) diseases. It may also improve access to trials for patients from countries where clinical trials are less often conducted. Within the DDP platform, patients can also register clinical trials in which they participate.

Other initiatives allow secondary use of patient data for research. For instance, DDP is FAIR by design, meaning that data are Findable, Accessible, Interoperable and Re-usable according to the FAIR Guiding Principles for scientific data management and stewardship (https://www.go-fair.org/fair-principles/), which facilitates the use of the data for research. Access to data is regulated by a dynamic informed consent: At the time of registration, patients or their parents/legal representatives (depending on the age of the patient) give informed consent to be contacted when researchers want to use their data. In case of a relevant study, they are informed about the specific study and need to give an additional consent before their data can be shared with the researchers. All data requests require approval of the Scientific Advisory Board of DDP. Share4rare also allows researchers to request patient data for studies that comply with the goals of the registry. Researchers can ask for data already collected on Share4rare. A dedicated data access committee (the Share4Rare Data Access Committee; S4RDAC) evaluates all requests. After this committee has approved the request, the patient or parent/legal representative needs to consent the use of the data for this specific purpose, through a digital (re)consent procedure. In the GerOnTe initiative, the architecture of the app will be adapted for future machine learning.

4.5 Data storage and security

Because a large amount of storage capacity is usually required, data storage of most initiatives is cloud based. For GerOnTe it was chosen to:

- Develop the core architecture using a cloud based technology, ensuring robustness and allowing international development while being compliant with hosting health data rules;
- Store the data in a lakehouse. A lakehouse is a combination of both a data lake combining structured, semi-structured and unstructured clinical data, and a data warehouse, which is a system used for reporting and data analysis that optimises processing power.

When handling health data, confidentiality and security are of utmost importance. Therefore, in all initiatives, several security measures have been implemented, such as two-factor verification and data encryption.

GerOnTe applies Fast Healthcare Interoperability Resources (FHIR) standards, which includes a Security and privacy module. This module describes how a server should be protected (through access control and authorisation), how to document what permissions a user has granted (consent), and how to keep records about what events have been performed (audit logging and provenance). Furthermore, GerOnTe uses blockchain technologies and Artificial Intelligence to aggregate clinical and health data and show only validated data, tracing and securing so that only trusted people can access the data.

4.6 Legal issues and informed consent

Data ownership and use has to be regulated in compliance with the General Data Protection Regulation (GDPR), which went into effect on 25 May 2018: individual centres/patients retain data ownership; the

software provider must be nominated as data processor and guarantees the correct management of the data.

For most initiatives, patients have to give informed consent to store and use their data. Exceptions are Patientöversikt and POLA. Patients cannot refuse their data to be registered and saved in Patientöversikt, as it is a system supporting their clinical care. However, patients can actively say no to data being transferred to the national quality register. When registering with the POLA app, patients are informed that their personal data are not collected or stored. It is also stated that anonymised encrypted data may be used by POLA for publication in scientific papers and for public policy initiatives.

5 Challenges and lessons learnt

Although most initiatives we studied have not been fully developed and implemented yet, they may provide useful information for the development of the ECPDC, including information on several challenges and lessons already learnt. These cover various elements of a technological, legal, organisational, structural and/or cultural nature.

As to technology, an important challenge that was mentioned for digital patient data centres/ infrastructures is standardisation of health data. Electronic health records often contain a mixture of unstructured, semi-structured and structured data, and may differ by hospital and country. If data is to be managed in a secure and efficient way - and made available to patients digitally so that they really own their data - this challenge needs to be addressed.

Furthermore, the contact persons of the initiatives emphasised that it would be necessary to have patients' clinical data be either provided or validated by healthcare professionals. This process may be time-consuming and complicated, given the many individual healthcare professionals involved. Automatic extraction of data from patients' electronic health records may provide a solution. This seems feasible, as applications are (being) developed that are compatible with many clinical information systems.

Also mentioned were suggestions for data storage. This may be done in a pan-European cloud, but such a cloud should be in compliance with the GDPR and different regulations among Member States may hamper cross-border transfer of personal data. Alternatively, a future European Health Data Space[4] may provide options to store patient data for the purpose of research as intended with the ECPDC. Another possibility is that patients' clinical data stay at their original location and are only linked. Patients could then decide who could access their data and which data exactly. A platform in which several types of documents/data (e.g. discharge letters, lab results, imaging results, PROMS) can be searched in a 'google' like way would be an option to access the data. For research purposes, the data may be anonymised or a Personal Health Train[5] approach may be used, in which instead of transferring data, algorithms are transferred.

The contact persons of the six initiatives also mentioned that, to make the ECPDC successful, it is important that patients are motivated to use the ECPDC. The ECPDC should be easy to use (intuitive). It should be accessible on multiple platforms, e.g. smart-phones, tablets, laptops, desktop computers, and registration should be easy and simple. An idea is to add incentives for users to come back frequently (medication reminders, stress-relieve tips, gamification, etc.). It is also important to have an active and personalised customer service, including email, social media, and phone. This is a challenge for a European platform, as preferably, patients should be able to communicate in their own language. Communication and transparency on patient data safety is also important to address any concerns patients may have. Besides, motivation may be increased by educating patients about the importance of sharing their data for research.

For the implementation phase, the contact persons recommended to bring together a multidisciplinary team to design the ECPDC, including users such as patients and healthcare professionals. User

[4] https://ec.europa.eu/health/ehealth/dataspace_en#:~:text=The%20creation%20of%20a%20European%20Data%20Space%20is,policy%20making%20purposes%20%28so-called%20secondary%20use%20of%20data%29.

[5] https://pht.health-ri.nl/

experience experts should be part of the team. Multiple stages of testing should be performed before releasing. The process should be flexible and there should be many possibilities to customise the platform. Open source development can increase the flexibility and the possibilities to customise the platform, allowing the development and adjustment of the platform and its tools according to project needs and organic evolution.

Accessing personal health data and receiving information about possible future health problems could be stressful for cancer patients and survivors. A future initiative should be aware of this and preferably provide options for (psychological) support to users, at least when accessing the information for the first time. An option may be to access the data together with a properly trained healthcare professional, or at least offer the option to do so.

A final challenge is the integration of clinical guidelines, as these need to be regularly updated based on new scientific insights. Recommendations given to patients based on these guidelines should therefore also be updated regularly. Healthcare professionals also need to be continuously informed on the guideline-based recommendations that patients receive through the initiative.

In conclusion, this quick scan of patient-controlled digital data infrastructures has shown interesting examples for the development of the ECPDC. The six initiatives studied in more detail also provide useful information for its development and implementation. They point to the need to support further research and innovation in this area, including sharing and scaling up good practices from other settings and disease areas.

Annex I: Recommendation as formulated in the Cancer Mission Outline

Recommendation 8: Create a European Cancer Patient Digital Centre where cancer patients and survivors can deposit and share their data for personalised care

This recommendation involves the creation of a European Cancer Patient Digital Centre (ECPDC), i.e. a virtual network of patient-controlled (national) health data infrastructures, in to which cancer patients and survivors can deposit their health data provided by their medical care providers (e.g. imaging, genetics, blood markers, clinical and lifestyle data) in a standardised and interoperable manner. The repository information network would include linked data of each individual patient, including biomedical, a summary of treatments and other healthcare-related information stored within their medical care providers' data centres as well as integrate patient-reported self-observations, outcomes and everyday life data.

The creation of the ECPDC would rely on a patient-driven roadmap and governance document, drawing on existing expertise at the EU and national level and on EU- and Member State-tailored data-sharing procedures. The ECPDC (with due regard for the GDPR) will provide people living with and after cancer with a health passport, including information on treatments and follow-up recommendations, and foster a (long-term) personalised care plan. For patients and carers, the ECPDC will be a global centre of knowledge on cancer, cancer prevention and health promotion, diagnostics, treatment and supportive care. For survivors and their families, the ECPDC will also be a global point of contact, offering guidance and support on returning to work, addressing financial issues and asserting survivors' rights.

Data within the ECPDC will serve as a valuable resource for research to improve understanding of cancer and its impact on patients' and survivors' lives, thus contributing to the development of improved diagnostics, treatment, care and quality of life support (recommendations 1 and 2, 4 to 7, 9, 13). In line with the European data strategy put forward by the European Commission, the ECPDC will give a voice to patients and survivors, enable them to enforce their rights, and increase their confidence in sharing their data for cancer research, innovation and policy development.

Annex II: Identified examples of patient-controlled health data networks

Name	URL
Alivia foundation	www.alivia.org.pl
Are you okay today	https://eithealth.eu/spotlight-story/silver-starters/
Arthritis power	https://arthritispower.creakyjoints.org/
Cancerbase	https://www.cancerbase.org/
Care Across	https://www.careacross.com/
CATCH ME	http://www.catch-me.info/catch-me-health-care-provider-app-atrial-fibrillation
China close contact detector	https://ij-healthgeographics.biomedcentral.com/articles/10.1186/s12942-020-00202-8
covidnearyou.org	www.covidnearyou.org
CURIA	https://curia.app/#
Daily corona questionnaire Israel	https://coronaisrael.org/
DATA-CAN	https://www.data-can.org.uk/
DIGICORE	https://www.apre.it/media/659706/demaria_mbc_16_settembre.pdf
Duchenne Data platform	https://duchenne.nl/duchenne-data-platform/
ECDC COVID-19 dashboard	https://qap.ecdc.europa.eu/public/extensions/COVID-19/COVID-19.html#global-overview-tab
European Platform on Rare Disease Registration	https://eu-rd-platform.jrc.ec.europa.eu/_en
EVITA platform	http://www.evitacancro.org/
Flatten.ca	flatten.ca
France Connect	https://franceconnect.gouv.fr/
GerOnTe	https://geronteproject.eu/
H2O Health outcomes observatory	https://health-outcomes-observatory.eu/
Harmony alliance	https://www.harmony-alliance.eu/
HealthMap	https://healthmap.org/
IHAN	https://www.sitra.fi/en/topics/fair-data-economy/
Johns Hopkins University dashboard	https://coronavirus.jhu.edu/map.html
KANTA	https://www.kanta.fi/en/citizens
Min Vardplan	www.cancercentrum.se
NF Patients United	https://www.nf-patients.eu/
Oncokompas	https://www.oncokompas.nl/
OTH	https://www.oth.io/
Owise	https://www.owise.nl/
Pathcheck	www.pathcheck.org

Patientöversikt	https://www.cancercentrum.se/samverkan/vara-uppdrag/kunskapsstyrning/patientoversikter/
PLCRC	https://plcrc.nl/
POLA app	www.pola.lt
Prologica	https://www.prologica.pt/
Projectbaseline.com	www.projectbaseline.com
RUDY	https://research.ndorms.ox.ac.uk/rudy/
Share4rare	https://www.Share4rare.org/
SPECTA	https://www.eortc.org/specta/
Survivorship Passport	http://www.survivorshippassport.org/
TreatNMD	https://treat-nmd.org/
War on cancer	https://waroncancer.com/
WHO Dashboard COVID-19	https://covid19.who.int/
Withings	https://www.withings.com/us/en/research

Annex III: Descriptions of selected patient-controlled health data networks

The following descriptions were drafted based on information provided by the main contacts of the initiatives during or after interviews conducted by EUHealthSupport with these persons in November 2020, and on information available from the websites of these initiatives. Contact persons of all initiatives, except the Duchenne Data Platform[6], checked and consented on the description.

Duchenne Data Platform

History

The Duchenne Data Platform (DDP) was started in 2019 by Duchenne Parent Project Netherlands (DPP-NL) and Foundation 29. DPP NL is a Dutch organisation of parents that have a child with Duchenne. DPP NL promotes research in the search for a cure for Duchenne Muscular Dystrophy. DPP NL sponsors promising research projects and fellowships, fast exchange of data and stimulates international collaboration. Foundation 29 is a non-profit organisation that leverages cutting-edge technology to help patients dealing with rare diseases combat the feeling of helplessness and take control of their health data, while empowering clinicians to leverage that data to make accurate diagnoses for those patients.

Governance and funding

The DDP is a collaboration between the Dutch parent organisation DPP NL and the Spanish non-profit organisation Foundation 29. Both organisations have their own boards. DPP NL also has a Scientific Advisory Board.

The DDP is part of the European Reference Network EURO-NMD registry project, funded by the 3rd EU Health Programme; Grant Agreement: 947598 EURO-NMD Registry — HP-PJ-2019. This project aims to connect several registries for neuromuscular diseases.

Implementation

The DDP is aimed at (parents of) patients with Duchenne Muscular Dystrophy. Up until now, 70 patients with Duchenne Muscular Dystrophy from the Netherlands have provided data

Data provision

Patients and parents can deposit their data through an app or the online portal of Foundation 29 in a personal 'locker'. Healthcare providers are also able to add data and can validate PRO and PROMs, but the controller remains the patient.

Data include symptoms, (motor) milestones, pulmonary outcomes and treatments, cardiac outcomes, genetic information, medication, socio economic (education, participation), treatments, hospital admissions etc. Imaging data cannot yet be provided due to the size of these files, but reports of imaging are deposited.

[6] From the Duchenne Data Platform we did not receive a response on our request to check the description, despite several attempts.

Data storage and security

Data is stored with Foundation 29 in a secured environment. Two-factor authentication is used to keep data secure. The patient locker system is a secure web based software system that enables patients to collect all their "clinical research data" in one single place of their choice, and fully exercise their "right to data portability" (GDPR art. 20). The Patient Locker application is part of a larger trusted digital space with high interoperability, security and confidentiality features;

The Patient Locker application has been presented to the European Medicines Agency and DPP describes the initiative as the state of art digital initiative driven by the patient community. According to DDP their initiative is the "Reference Point" for other future Patient Locker solutions.

Informed consent

Patients or their parents/legal representatives (depending on the age of the patient) give informed consent when they register with the platform. If researchers want to use the data, patients have to give consent again (a dynamic consent system).

Data sharing

According to DDP is the initiative FAIR by design and allows secondary use of data for care, research and regulatory queries.

Researchers can request information from DDP. Patients/parents decide with whom they want to share their data. Data sharing is regulated by a dynamic informed consent. For a specific data set they are asked: do you agree to share these data with XYZ institution?

Data is accessible online and as an app in a patient's smartphone to support optimal care. Patients/Parents can find instruction videos about DDP online. There is a chat function and an FAQ section

Health passport

Patients/parents can access their own information through an app and on their personal computer. Within the Data Platform they can see their own information. They are reminded to visit their clinicians/specialist according to the Standards of Care.

Centre of knowledge

Patients/parents can find information on the Duchenne Data Platform on, for example, treatments, vaccinations, equipment, education and if the question/answer they look for is not already answered there, the question will be answered and added on the platform if appropriate for general use. For personal questions we refer to their clinician. They can also find general information about their disease on the website of DPP NL and World Duchenne Organization for parents and children. In the FAQ's we also refer to these international guidelines.

Support and patient empowerment

Patients can get answers to FAQs on the Data Platform. They can get support through Duchenne Parent Project Netherlands.

Lessons learnt

User experience experts (which is a discipline often not included in the data collection) should be part of the team.

Plans for the future

Currently, data have been collected from Dutch patients and some UK patients (testers). From January 2021 onwards an international version (English) will be available and optional patient organisations from other countries can apply for participation. Together the patient organisations will form a user group. The FAIRification of the platform is ongoing. DDP's development is continuing and this solution will be complemented with all the required interoperability features to enable "machine to machine" automated data collection directly from clinical research systems (such as EDC, ePRO, eCOA, eConsent systems) and EHR systems (at investigational sites or academic sponsors). Foundation29 is open to discuss the use of this technology for other diseases.

GerOnTe

History

GerOnTe is an initiative of the Université de Bordeaux, France. The project started in 2021.

Governance and funding

The GerOnTe consortium is constituted of five hospitals and universities specialised in geriatrics and/or oncology from five different European countries (Université de Bordeaux, France (coordinator); Stichting Diakonessenhuis, Netherlands; Oslo Universitetssykehus HF, Norway; University College Dublin, Ireland; Katholieke Universiteit Leuven, Belgium), two universities renowned in socio-economic studies of health systems (Universita Commerciale Luigi Bocconi, Italy; Dublin City University, Ireland), two expert organisations in health informatics (MyPL SAS, France; University College Dublin, Ireland) and two associations skilled in stakeholders' engagement (E-Seniors: Initiation des Seniors aux NTIC Association, France ; International Society Of Geriatric Oncology, Switzerland).

GerOnTe is funded by the EU Horizon 2020 Framework.[7]

Implementation

GerOnTe is aimed at elderly cancer patients with concomitant chronic diseases. The project yet has to start.

Part of the project is two randomised clinical trials in France and Belgium/the Netherlands in at least 16 clinical sites and will enrol at least 634 patients. Patients older than 70 with at least two morbidities including cancer will be included. Other main inclusion criteria are: one of the four common types of cancer (breast, prostate, colorectal and lung cancer), cancer treatment is planned and life expectancy is above one year.

Data provision

GerOnTe will build on existing ICT modules from partner MyPL to develop Holis™ GV, an interoperable secured digital solution adapted to all types of European health organisation systems. Holis™ GV, co-designed with patients, informal care givers and health professionals, will integrate health system data and self-assessment as well as real-time feedback.

One part of Holis™ GV is a web-based tool will be available at home for patients for their weekly collection of PROMs and disease- or treatment-related symptoms, including a library of self-management guidelines for patients. This module will be specifically designed with and for older people, and will be adapted to all kinds of socio-economic status, age, way of living (alone or with

[7] https://cordis.europa.eu/project/id/945218

others) and place of living. Based on a first proposal of content by health professionals, final items included in web-based Holis™ GV for collection of patient-reported outcomes will be discussed with patients taking into account results of Focus Groups in a co-design approach, older patients and health professionals.

Health system data will be retrieved automatically using a powerful application programming interface technology (Iris Data Platform – InterSystems), especially chosen for its capacity to connect to +2000 different IT hospitals systems, and a patient identification reconciliation. Clinical data retrieved from the health system and data about symptoms/functioning/quality of life will be collected. These data will include both hospital-based data extracted from the EHR and patient-reported data collected during follow-up through a web-app. Standard consensus minimal dataset (including baseline data and follow-up data) will be defined, then specified according to each morbidity (including each tumour type) and finally validated by consensus in each participating country. Patients will be an integral part of the design process, especially for patient-reported outcomes.

Data ontology, more commonly defined through Unified Medical Language System (UMLS) integrates and distributes key terminology, classification and coding standards, and associated resources to promote creation of more effective and interoperable biomedical information systems and services, including electronic health records. Uniform coding of patients' health problems will be used through the OSIRIS consensus dataset.

Existing self-management guidelines will be gathered or co-developed when necessary, to fit to individual patient specificity, then validated in each participating country by consensus with health professionals and patients to get shared guidelines to disseminate at the European level at the end of the study. They will be incorporated into Holis™ GV web-app.

Data storage and security

According to GerOnTe partners, MyPL is striving to build a holistic and quality approach of the clinical patient data since 2017, and has already developed a unique core solution. It integrates technical bases for GerOnTe clinical use case development project:

- Core architecture has been developed using a cloud based technology (Amazon Web Services), allowing robustness, an easy international development while being compliant with hosting health data rules;
- Blockchain technologies and artificial intelligence will be used to aggregate all clinical and health data and show only validated data, tracing and securing it so that only trusted people can access it. Data is handled according to HL7.
- The solution is developed using Fast Healthcare Interoperability Resources (FHIR) standards, which aim to simplify implementation without sacrificing information integrity. This leverages existing logical and theoretical models to provide a consistent, easy to implement, and rigorous mechanism for exchanging data between healthcare applications;
- Data are stored in a lakehouse. Lakehouse is the combination of both data lake (combination of structured, semi-structured and unstructured clinical data) and data warehouse (a system used for reporting and data analysis that optimizes processing power).

Informed consent

Patients give informed consent to share their data with their health care providers. The Trial Steering Committee will consult with patient representatives to contribute to the elaboration of the informed consent and other trial documents for participants.

Data sharing

GerOnTe will link in an Health Professional Consortium all health professionals involved in a cancer patients multimorbidity management. Data from medical records and patient-reported data will be shared with professionals through the Holis^{TM} GV digital decision support tool. This tool will integrate automatic generation of the main Quality Key Performance Indicators. These data can be used by the multidisciplinary health professional consortium to efficiently understand the patient situation, validate the diagnosis, and propose the best personalised treatment strategy.

Data generated by health professionals, patients and Holis^{TM} GV will be shared by stakeholders following data protection and ethics rules and respecting the privacy by design principle. Baseline data generated by Holis^{TM} GV (multimorbidity, tumour and geriatric data) will be made available to the Advanced Practice Nurse who will manage patients, while data generated by the web-based ICT tool will be available to improve the minimum dataset generated by Holis^{TM} GV for further health professional consortium meetings.

Once the development of Holis^{TM} GV app is completed, its architecture will be adapted for future machine learning which will be performed once enough patients' data, validated by healthcare professionals in Holis^{TM} GV has been collected throughout Europe.

Sharing of data will be granted to end-users by patients through their informed consent they will sign before inclusion in the clinical trials. Data from medical records and patient-reported data will be shared with professionals through the Holis^{TM} GV digital decision support tool.

GerOnTe partners plan several training activities: End-users will be trained for the use of the app at baseline, then regularly and on demand. As part of the RCTs, the overhead trainee (APN) will be trained at the hospital directly, who will then be the contact point for training and use by RCT patient volunteers. A training session will be organised for the clinicians with adequate material (Pdf, tutorials, web service pages to access online tests). A support toolkit for senior patients will be created. This toolkit will include a users' guide as well as a series of tutorial videos (in French, Dutch and English) presenting the most common problems faced by the users, and how to overcome these problems.

The APN at each hospital will then manage training for every one of its patients with the help of hospital partners in France, Belgium and the Netherlands. A hotline will be set up in order to help end-users deal with issues on their device and an appointed Community Manager will liaise with hospitals to ensure they have the necessary background & training. All open tickets will be handled directly by the hospital teams after the problem has been described.

Health passport

Patients will have access to their personal information through a dashboard which content will be co-designed with health professional and patient representatives. This will include diagnosis and essential information of their diseases as well as data about treatment and tolerance. Self-management tutorials will be available through the web-app and specifically tailored and pushed to the patient according to their specific geriatric baseline evaluation.

Centre of knowledge

This is not planned specifically, but may raise as an important issue during the first year (co-design).

Support and patient empowerment

Patients will be supported by an advanced practice nurse who may guide them to further guidance and support according to the available facilities (may depend on the health system of each country.

Lessons learnt

Not yet since the protocol has not been launched. Organisational issues will certainly be central and will justify specific attention to facilitate coordination of members of the health professional consortium.

Plans for the future

After (but also during) evaluation of the GerOnTe care system in France, Belgium and the Netherlands, analysis of the health organisation system of at least 10 European countries will be scrutinised in order to build and provide country-specific recommendations for implementation of GerOnTe. Extension to other diseases is not planned during the 5-year project but later on.

Patientöversikt

History

In Sweden, the hospital health care is organised in 21 regions. Since 2009 there is an organisation within the regions of Sweden – Regionala Cancercentrum – (RCC) working both on the national and on the regional level – to support Cancer health care.

RCC is developing several tools to support cancer health care. One of the tools is Patientöversikt – a clinical decision support system. The system is currently developed and nationally implemented for eight cancer diagnosis within the scope of a project.

Governance and funding

The development of Patientöversikt is organised as a project during the years 2018-2021

The organization of the project for the introduction of Patientöversikt is based on the model developed in the project's feasibility study and guarantees broad support for governance and management via the steering group, working committees and working groups.

The steering group consists of patient representatives, government officials, industry representatives, operations manager group representatives, research representatives, financial representatives, and representatives of the Regional cancer centres.

The working committee includes representatives from the eight diagnoses included in the project. It handles cross-diagnostic issues in the work with development and implementation of the Patientöversikt. Two member of the working committee are also part of the steering group.

Each diagnosis also has its own working group, consisting of professionals and patient representatives who have developed the criteria for the diagnosis specific Patientöversikt (adaptation of the generic model).

The project is developed within the organisation of RCC and is using several of the resources within the organisation. In addition, the project is funded by Swelife (governmental funding) and the Sjöberg Foundation. The Sjöberg Foundation was founded in 2017 by Bengt Sjöberg and wants to give its contribution to the future research of cancer and environment to protect the human life and the environment. In 2017, the Sjöberg Foundation granted funding for all higher education institutions with faculties of medicine, university health authorities and RCC to participate in the research program Partnership for precision medicine in cancer.

Implementation

Patientöversikt is aimed at patients with breast cancer, CNS cancer, lung cancer, melanoma, myeloma, kidney cancer, prostate cancer and ovarian cancer. Up until now, data of 13,000 patients with lung cancer, 9,000 with prostate cancer and 1,600 with kidney cancer are included.

The introduction/implementation of the Patientöversikt must be done step by step so that experience can be gained after each step in order to make the Patientöversikt as valuable a tool as possible. The number of patients included in the system will increase rapidly as more clinics implement the system and all eight diagnoses have received their Patientöversikt, starting at the end of 2020 and forward.

Data provision

Clinical data about the cancer diagnosis and treatment are uploaded by healthcare providers. As most data in EHRs are not structured, some data in the patient overviews need to be entered into the system manually. Some of the structured data (treatment with chemotherapeutics and lab tests) will during 2021 be automatically retrieved from the hospital EHR. There are several different Electronic Health Systems (EHSs) in the different regions of Sweden, and procurements and implementations of new systems are currently underway in several regions. There are several ongoing discussions between the project and the regions, as well as with the suppliers of EHS, to enable the need for common structures of data to enable automatic transfer between systems.

As part of the work with Patientöversikt, the development and implementation of patient-reported data (PROM- Patient Related Outcome Measures) is also included. The Questionnaires of the PROMs are available on the national portal 1177 Vårdguiden (the patient portal) and is built on the same technical platform as Patientöversikt. The answers of the questionnaires will be visualised as part of the Patientöversikt.

Data storage and security

Data is stored on INCA, the platform of national quality registers for many diagnoses (all of the cancer diagnoses).

As part of the project, a management system has been developed, to be able to meet to the requirements of a national medical information system (NMI), which is based on the perspective of making the system patient-safe. The system is registered as an NMI-system at the responsible authority, Läkemedelsverket. Data in the Patientöversikt are structured and will be mapped to Snomed CT.

Informed consent

Before the start of the project, the legal perspectives and possibilities were investigated by one of the one of Sweden's leading lawyers in the field. As a patient, you cannot decline that your data is registered and saved in the Patientöversikt, as it is a system used for your care. You have the right to actively say no to data being transferred to the national quality register.

Data sharing

Data is transferred through the National service platform to INCA, the platform of Patientöversikt and of the national quality registers of cancer. Structured data from the Patientöversikt are transferred automatically to national quality registers (after opt-out possibility for the patient). These quality register data can be used as a source for research.

It is possible to link data from Patientöversikt to other registers, e.g. causes of death register, In-patient register, databases on socio-economic-status, drug prescription register, and sick leave register.

Health passport

Patients have access to Patientöversikt through the patient portal “1177 Vårdguiden”. The patient overview visualizes the individual cancer patient's care data seen on a graph over time. The information that is visualised is cancer diagnosis specific, based on a generic model and involves data about the patient's medical history, disease status, laboratory data, examinations, treatments, side effects, symptoms and quality of life (described in PROMS).

On the portal 1177, patients will also find diagnosis specific and personal descriptions and recommendations for the professional and self-care delivered in the form of a “Min Vårdplan”. There are national, diagnosis-specific formats for “Min Vårdplan” which are adapted and activated when a cancer diagnosis investigation starts for an individual. During the different stages in the investigation and in the treatment, more parts of the formats are being activated.

Centre of knowledge

There is some general information on the site of the cancer centre on different types of cancer, mainly on the care process. As mentioned, individual information and recommendations will be found in “Min Vårdplan”.

Support and patient empowerment

“Min Vårdplan” includes information on patients´ rights.

Lessons learnt

The challenges of this type of project are found at many levels; technological, legal, organisational, structural and cultural. The initiative is considered to fulfil a need for strengthening and driving the challenge of standardisation of health care data. If data are to be managed in a secure and efficient way - and made available to the patient digitally, so that data can also be moved/transferred - this challenge needs to be addressed.

Plans for the future

As both patients and healthcare staff see how Patientöversikt becomes an important and accessible tool, the interest in developing the system for more diagnoses also increases. There is also an increased interest in making the system more user-friendly (for patients as well as for professionals) and the opportunity to include more data sets in it.

POLA app

History

The idea to create a mobile app for cancer patients in Lithuania originated in 2018, with the increasing demand for mobile health applications in the oncology world. By initiating this project, the Lithuanian Cancer Patient Coalition (POLA) aims to empower and connect cancer patients, to ensure the collection of representative information about Lithuanian patients and healthcare system problems, and to provide realistic and statistically proven data. POLA has tried several platforms before creating their own.

Governance and funding

POLA is responsible for collecting, securing and analysing the POLA app data. POLA is a non-governmental umbrella organisation uniting 30 oncology-related NGOs, including cancer patients'

societies and organisations, providing assistance to people affected by cancer. POLA represents a community of 17,000 cancer patients, who applied for POLA card membership and are registered in the POLA database.

This project is co-sponsored by 5 private companies, in equal parts and also financed from POLA reserves.

Implementation

On 4 November 2019, four registries of oncological diseases (breast cancer, prostate cancer, melanoma, lung cancer), through the Andaman7-based app, started functioning. At the end of December 2019, about 300 patients were registered.

In 2020, the second stage of the POLA mobile app project was launched. The app is available on android, iPhone and windows platforms to the entire POLA patient community. Anyone (any cancer patient) can register and use it, although specific disease questionnaires will apply to six oncological diagnoses (breast cancer, prostate cancer, ovarian cancer, colon cancer and melanoma). The number of disease-specific questionnaires will increase in the future.

Data provision

At the moment data is provided by patients directly into the Andaman7-based app. The app provides patients with the ability to bring all of their medical records into the app, and thus have all of their diagnostic results and medical records in one place. As an added functionality, it provides the ability to collect patient data on nutrition, physical activity, sleep cycle from other smart devices in one place, and provides a feature to participate in POLA surveys to express their opinions and expectations about the needs of cancer patients.

Based on the feedback received from app users, POLA has decided to create a second version of the POLA mobile app, by creating an autonomous platform with ability for patients to monitor and evaluate their health data, as well as taking advantage of opportunities belonging to the POLA community. In the initial phase of the POLA mobile app, users of the POLA mobile application are able to register and regularly update side effects caused by the specific cancer diagnosis and its treatment. They can statistically compare whether their symptoms also occur in other patients with the same diagnosis.

A "Profile" window has been created, where patients are able to fill in initial information about themselves, including location (city, region) and their disease. For the beginning, disease-specific “Health” questionnaires have been developed for six different disease groups (breast cancer, lung cancer, prostate cancer, colon cancer, ovarian cancer, and melanoma) with ability to describe side effects, provide information about the treatment they are receiving, the medications they are taking. Users will be asked to describe their social-economic challenges e.g., monthly out of pocket payment, waiting times, and other related questions. Patients are able to receive disease-specific notifications on various opportunities, trials, health events, etc. (e.g., trainings for breast cancer patients).

The app integrates an electronic version of the POLA card (with a unique number and barcode). It also provides information about all the beneficial discounts applied with the POLA card in the app's user area with the possibility to filter discounts by your location and service type. For each action and active use of the app, POLA points (gamification feature) are awarded, which are available for additional services or gifts based on the number of points collected.

Data storage and security

All users register using their individual POLA card code (unique 10 digits code) and create secured account with passwords. A personal identification system is installed during registration process to link a person to a POLA card, but personalised data is not being transferred, collected or analysed by POLA.

All data is stored encrypted in the cloud. In order to ensure privacy and data protection of individuals, POLA only collects aggregated data from app users that are anonymous. Once the data is downloaded it remains encrypted and shows only anonymized disease specific or socio-economic survey data. Third parties do not have access to any data collected in the app.

Informed consent

Ethical and legal information is declared on the website pola.lt. The website contains a FAQ section. Patients are informed that their personal data, which is inputted in the app, is not collected or stored. It is also stated that anonymised encrypted data may be used by POLA for the publications in the peer-reviewed literature and for public policy initiatives.

Data sharing

Currently, only POLA has access to the POLA app data. Aggregated data can be downloaded on clearly pre-defined criteria, e.g. 6 months side effect management data on patients with a specific cancer diagnosis. During the registration process, patients are asked if they allow their data to be used for policy and research purposes anonymously. Data will be used for POLA research, health technology assessment process and policies.

At this stage, third parties may not request the data from the registry. In April 2021, a secured platform for extraction of anonymised data from the app will be created. POLA is then considering sharing the aggregated anonymised data with researchers who will be willing to co-author research with POLA.

Patients can download their data on side effects management or data from disease-specific questionnaires and compare their data with other users using the same platform. They can freely decide to share this data with their treating physicians or caregivers.

POLA app customer service is provided by POLA team via email, telephone, public events and social media (e.g. Facebook).

Health passport

Patients can access and edit all information about diagnosis, treatment and side effects that they provided. On the POLA app “news” column –recommendations on self-management are shared. The POLA app is sending disease specific reminders (notifications) on upcoming health events, opportunities, trials related to diagnosis.

Centre of knowledge

Using the app, patients are able to compare (anonymously) their disease, stage, age, location as well as side effects within the patient population. Evidence based information can be found on app “news” section and also on POLA website pola.lt.

Support and patient empowerment

Based on data collected by the POLA app, POLA is writing policies based on social-economic needs of population, thereby representing patient needs. The POLA app has a feature to apply for free legal consultation on patient rights as well as psychological support, nutritional support. This support is

offered for free by POLA to all POLA card holders, but these services are coordinated and arranged outside of the app.

Lessons learnt

- The app should be "user-friendly" and relatively easy to use (intuitive) – we have tailored the app to be understood for patients over 50 years of age
- Registration to the app should be as simple as possible and as fast as possible, otherwise patient will lose interest to use the app.
- The app should be accessible on multiple platforms e.g., not just smart-phones, but also tablets, laptops, desktop computers, etc.
- Communication and transparency on patient data safety is extremely important.
- The app should have incentives for users to come back frequently (medication reminders, stress-relieve tips, gamification, etc.)
- The app should have an active and personalised customer service, including email, social media and phone.
- It is important to collaborate with multidisciplinary team while creating the platform e.g., caregivers, data analytics and patients, also to perform multiple stages of testing before releasing.

Plans for the future

For the next 12 months, POLA is planning to release new functionalities every 1-2 months, including different disease – specific questionnaires, calendar, medication reminders, incorporating data from external gadgets (e.g. heart rate, step count, oxygen level). Also, the app will be translated to at least two more languages – Russian and English. The ultimate goal is to integrate the POLA app into the Lithuanian eHealth system and help patients to share their data from the app with their treating physicians, while incorporating data from their eHealth records into the app.

Share4rare

History

The Share4Rare platform is a result of the Share4rare H2020 project (GA: 780262). It was initiated by Fundació Sant Joan de Déu (FSJD) and Universitat Politècnica de Barcelona (UPC), both located in Spain. The main purpose of the platform is to link patients and enable a communication network where they can find peers with similar conditions and symptom. Moreover, it aims to build a safe space controlled by patients where they can choose to contribute to research and they will have a feedback on the findings where they have contributed, as well as comparison with the rest of the participants.

Governance and funding

FSJD and UPC are the partners responsible of the data processing, storage and security.

Specific requests of aggregated data are evaluated and supervised by an ad hoc Data Access Committee (S4RDAC). This committee is formed by:

- One representative of the coordinating institution of the project
- One representative from the Ethics Committee of FSJD (Spain)

- Two patient representatives. Whenever possible, one of the patient representatives will be directly related to the specific condition and to the patient community. The second patient representative will be directly related to the Share4rare Consortium appointed by Stichting United Parent Projects Muscular Dystrophy (UPPMD; The Netherlands) and Melanoma Patient Network Europe (MNPE; Sweden)
- One data scientist
- Two members from the clinical research area
- One legal advisor from FSJD as legal responsible of the Share4rare data.

This project has received funding from European Union's Horizon 2020 programme under Grant Agreement 780262.

Implementation

The Share4rare platform was initially created as a tool for patients with rare diseases and their carers. At the moment, there are 5 research studies being conducted on:

- Paediatric rare tumors
- Neuromuscular diseases
- Acute Lymphoblastic Leukemia
- Undiagnosed patients
- Effects of the COVID-19 on patients with rare diseases.

More than 2,100 users related to rare diseases have provided data (Data up to 01/12/2020). Patients from all countries can provide data to Share4rare. Until now, most users live in Spain, with also substantial user groups in the United Kingdom and Argentina. The most represented disease groups are: undiagnosed patients, patients with neuromuscular diseases and patients with acute lymphoblastic leukaemia. According to Share4Rare, the platform has the potential to cover a wider scope of diseases, due to the flexibility and power of the tools it uses to perform these studies.

Data provision

At registration, patients receive a baseline questionnaire about the natural history of their disease and other relevant aspects such as clinical data, genetic data, quality of life or patient-reported outcomes. They can adjust their data at any time they want.

Further data will be collected depending on the patients' participation to the different research projects and the questionnaires they will be asked to fill in.

Clinicians can also include data from their patients (with the corresponding informed consent in place). Moreover, the platform has the potential to invite patient's clinicians to complete medical questionnaires specifically addressed to them to collect their expertise. This feature has not been developed yet but is on the platform scope.

Data storage and security

All data is physically stored within FSJD premises in HSJD information department systems, where physically is located the hosting system. The system is in a secured environment and is audited every year.

The platform's strategy for data standardisation will differ depending on the structure of the data stored within Share4rare. We can differentiate:

- Raw data, stored as UTF-8 that will be enriched through the Linked Data approach (with help of RDF and tools developed by Linda Project).
- Genetic data, stored in the following formats (as far as possible): Human Genome Variation Society (HGVS) Nomenclature, Human Gene Nomenclature Committee (HGNC), Reference Sequences NCBI (RefSeq) and Logical Observation Identifiers Names and Codes (LOINC).
- Clinical data will use HL7 to ensure transferability between systems, and will be enriched with Human Phenotype Ontology (HPO).
- Quality of life data will be enriched with help of a Quality of Life Ontology initially referenced from WHO ICF structures.

The platform architecture is described as being flexible and able to store other types of data. In particular, the initiative plans to implement the technical features necessary to enable the inclusion of imaging data, although this is still in the analysis phase. For further integrations with other platforms the option is to host the server and data on the cloud, facilitating the process of cross-collaboration with other initiatives. A data management plan is in force, reviewable and regularly updated to adapt to the needs of the project and the platform.

Informed consent

Patients have to give digital informed consent when they register with Share4Rare. Whenever they are involved in a research study, informed digital reconsent will be asked.

All data processing is in compliance with the Spanish Organic Law on the Protection of Personal Data (LOPD) and Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR).

The platform has been approved by HSJD's clinical research ethics committee CEIm, and all the research studies are required to be submitted to and approved by this committee too. CEIm has appointed a DPO who supervises the data processing in all the platform research studies. The platform and its safety is audited annually and there is a contact address,

Access, rectification and deletion of data, as well as other rights, as detailed in the Spanish Organic Law on the Protection of Personal Data (LOPD) and Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR), has to be exercised through a written communication or email to Fundació Privada per a la Recerca Sant Joan de Déu. Data can be removed from any analysis but not from the database, following the indications of the Spanish law and the GDPR.

Data sharing

Patients can ask for all the data they donated to Share4rare. They will receive files which they can share with their physicians. Share4rare is working to implement an access option for physicians that want to complete questionnaires about their patients. The adult patient/caregiver can invite the physicians, as the approval of the patient/caregiver to contact the physician is needed to comply with the GDPR. The platform will then send a private message to the physicians, inviting them to complete the registration process that will allow them to report the data about their patient.

Stakeholders (policy makers, clinicians, researchers, patient organisations, etc.) can request data for their research, provided they comply with the goals of the platform. For any regulatory use of the data donated by patients a cross check/validation with their doctors is mandatory.

A standard operational procedure (SOP) was enacted to define in detail and with transparency the overall process of third parties accessing aggregated and anonymised data. Shortly, all data requests will have to fill in a request template form. These forms will be reviewed by S4RDAC, and approved upon patients consent (please see answer to question 2 for further details).

Before sharing data with researchers, it has to be approved by the Data Access committee, the Medical Ethics committee at the hospital and consented by patients themselves.

Data project access is available in two approaches: a) bulk download; b) data access following REST (REpresentational State Transfer) architectures. REST APIs will be maintained by the technical partners from the project (UPC, OMADA and FSJD). REST APIs will be described and versioned within the platform. Older API versions will be maintained jointly with the current API definition for the full lifetime of the project. Therefore, shared data is always aggregated and anonymised.

Dedicated staff of the platform is available to guide users through the registration and validation process and to support researchers through the study workflow.

Guidelines and material support (such as videos) have been made available on the website, as well as community questions, which develop in further information in the already rich ecosystem.

Health passport

Patients can always see the data they provided. Additionally, when participating on a research study, they can compare their answers to aggregated data of other respondent in the Module for Automated Individual Reports (MAIR). Graphs highlight (in different ways depending on the type of plot) the response of the patient in the general context of the answers to that question, providing insight to their situation with respect to its peers.

One of the core assets of the platform is the People Like Me (PLM) algorithm: PLM uses a mathematical processing of the information provided by the users, such as the description of the symptoms declared, information about the disease and the country of origin of the user. With those three dimensions (symptoms, disease, and location) PLM builds a network of users, connecting most related users under the light of the three sources of information, even when some of this information is missing (e.g. disease or location).

This mapping enables to customise the information shown in the users interface in different positions according to the information provided, facilitating the access to relevant content and the visualisation of other patients and patient organisations according to the three dimensions above mentioned.

Centre of knowledge

As previously mentioned, patients can compare themselves to other respondents in the MAIR module. This will provide insight into their own situation in comparison to their peers.

The Share4rare website contains a public library of medical books where several chapters on different diseases are shared. These chapters are written by medical expert and reviewed by patients, to ensure it can reach the wide public. They include information on diagnosis, treatment and quality of life.

Additionally, there is a forum for the user where there can share their questions and be answered by an expert and patients, if needed.

Support and patient empowerment

On the website there is a toolkit for patient advocacy and patients can find relevant patient organizations. Several webinars have been organised to educate users on the tool kit and facilitate the overall exploring process.

Lessons learnt

Patients need to be educated about the importance of sharing their data for research.

Not working on a commercial environment increases the flexibility and the possibilities to customise the platform, allowing the development and adjustment of the platform and its tools according to the project needs and organic evolution.

Plans for the future

The approach of Share4rare is translatable to any disease and nationality, and Share4rare is willing to provide the infrastructure to make it possible.

Share4rare has had several webinars involving ERNs, where they have expressed their interest on the research layer and to explore possible connections and synergies. Patient organizations and (international) hospitals are willing to use the research tools of Share4Rare.

Survivorship passport

History

The development of the Survivorship Passport started during the ENCCA project, which ran from 2011-2017. Several upgrades/modifications of the platform were further developed during the ExPOrNet, PanCareSurFup and PanCareFollowUp studies. The v1.2 of the Survivorship Passport is currently implemented in Italy.

A four-year new project called PanCareSurPass[8] started early 2021. This project will investigate the possibility and methodology for implementing the Survivorship Passport platform (Treatment Summary, personalized Survivorship Care Plan) and follow-up form into Electronic Health Information Systems of 6 countries representing 3 different organizational Health Systems models.

Governance and funding

The Survivorship Passport project is coordinated by a joint action between:

- SIOP Europe (representing Paediatric Oncologists)
- CCI Europe (representing patients and parents)
- Pan Care (network of health care professionals, survivors and researchers of late effects and survivorship care)
- the Italian IT consortium Cineca (which developed the survivorship platform).

These partners signed an MoU to work together on the development and implementation of the Survivorship Passport (with Cineca). A Steering Committee was formed.
The development of the Survivorship Passport was funded by several grants from the European Union's Seventh Framework Programme for research, technological development and demonstration. In particular under the project ENCCA, grant agreement no. HEALTH-F2-2011-261474, the platform

[8] https://cordis.europa.eu/project/id/899999

was developed and the treatment summary variables identified. In the PanCareSurFup project (grant agreement no. 257505) the first recommendations for follow up were implemented into the platform; while under the ExPo-R-Net (SANTE, Health Programme, grant agreement no. 2013 12 07) translations of the treatment summary variables as well of plain language brochures describing reasons and details of screening recommendations were implemented into the system. In the ongoing PanCareFollowUp (PCFU) project, the Survivorship Passport platform has been upgraded with the revision of the treatment summary variables and the Survivorship Care Plan (SCP) has been completed with a total of 41 recommendations. The paper version of the passport including the SCP is being used within the PCFU project in Lund (Sweden), Brno (Czech Republic) and Leuven (Belgium).

Grants for test-wise implementation of the survivorship passport were received from parents associations (in Germany and Croatia) and EU funds (TREL project in Lithuania).

Implementation

The survivorship passport is aimed at survivors of childhood and adolescent cancer. It is currently implemented in 7 centres in Italy and more than 800 patients have agreed to received it with their personal data. Overall 35% of the survivors who received the survivorship passport were previously affected by ALL, 13% by Hodgkin Lymphoma, 8% by Wilms' tumour, 7% by neuroblastoma, 5% by CNS tumour, 5% by bone sarcoma, 3% by soft tissue sarcoma and the remaining 25% by other types of cancer.

The Survivorship Passport will start test wise implementation of v1.2 in early 2021 in Germany, Croatia, Lithuania. Within the new PanCareSurPass project, a new version (v 2.0) of the survivorship passport will be implemented in Italy, Germany, Croatia, Lithuania, Belgium, Austria, Spain.

Data provision

In the current Survivorship Passport, data is provided after the elective end of treatment therapies. The treating physicians and/or authorised personnel access the secured website http://www.survivorshippassport.org): and login with their personal credentials. The first step is to insert the personal data of the survivor to create his or her personal record. Then, treatment data should be inserted following the predefined forms of the web-based platform. The online system performs automatic checks.

In the Italian experience, thanks to the fact that Cineca is based in the same country and already acts as data centre for several AIEOP initiatives, data on diagnosis and treatment can be uploaded either manually by retrieving data from clinical records or electronically by downloading data from databases used during the treatment period (e.g. electronic clinical records, databases of clinical trials in which the former patient was enrolled or cancer registries). The electronic download of data was tested in Italy, using the AIEOP-I-BFM ALL 2009 protocol. After mapping of the variables in common between the two databases, it was possible to download 61% of the requested data (72% if only mandatory fields were considered), thus reducing the average time of 1.5 h to just 30 min for preparing the Survivorship Passport for a standard risk leukemic patient.

In case of a relapse or of a subsequent malignant neoplasm (SMN) after the end of first-line treatment, the new information about site and type of relapse or SMN and related salvage treatments can be inserted in the follow-up form. In this case, the Survivorship Passport is "kept on hold" until the new elective end of treatment and it may then be updated by the treating physician. After calculation of the cumulative doses of treatments received (for front line therapy + salvage therapy) the built-in algorithms will generate an updated Survivorship Care Plan based on the new total doses received by the survivor.

The Survivorship Passport data can be modified only by the healthcare providers with the appropriate credentials (at this stage, only the treating physicians). It is however planned that survivors themselves will be able to add some more information in a dedicated section of the online platform (e.g. visits, examinations, patient reported outcome measures and other tests).

In the new PanCareSurPass project the Survivorship Passport platform will be "integrated" into the local NHS electronic platforms. Because of this, the method of data provision/sharing might differ by country, in some countries data is retrieved from the homogeneous, national health record (Austria, Lithuania), in others data from institutional medical records are linked to the national Cancer Registry (Germany, Belgium) data from institutional medical records are linked to regional Electronic Health Record (Italy, Spain) or data are added manually by physician (Croatia).

In this new version, patients will also provide data trough patient reported outcome measures (PROMS) and clinicians through CROMS.

The Survivorship Passport contains a total of 168 variables, divided into five sections:

- demographic data
- tumour description and other concurrent diseases, either cancer predisposition syndromes (e.g. ataxia telangiectasia) or other clinical conditions not cancer associated (e.g. diabetes) if any
- front-line treatment for the primary main tumour and salvage treatment in case of progression/relapse before the first elective end of treatment, with details on
    - chemotherapy
    - stem cell transplantation
    - radiation therapy
    - major surgery
    - other relevant clinical events that occurred during treatment (e.g. ICU admission or seizures)
    - medical prescriptions at the time of elective end of treatment
- screening recommendations
- follow-up.

Relevant stakeholders of various European institutions and communities actively participated, and paediatric oncology late effect experts, parents' and survivors' organisations (Childhood Cancer International (CCI) and the Pan-European Network for Care of Survivors after Childhood and Adolescent Cancer (PanCare) were actively involved in the selection of these variables.

When available, internationally approved nomenclature and coding schemes were adapted for each variable (e.g. ICD-O-3, ICCCC-3, ATC, ICD-9, ORPHANET). Otherwise, a specific coding system was developed. Details about surgery are entered either as free text or with a drop-down menu in particular for surgeries which are included in algorithms activating suggestions for organ-specific follow-up program.

Variables were translated from English into several European languages, including Croatian, Czech, Dutch, French, German, Italian, Lithuanian and Spanish, within the scope of the European project ExPO-r-Net (www.expornet.eu).

Data storage and security

Cineca experts designed the electronic infrastructure for data collection and insertion, taking into consideration security and privacy issues, the possibility of data transfer from already available clinical datasets and multilanguage support. The resulting electronic platform had to be fully compliant with the latest national and international data privacy regulations.

The web-based platform provides a secure online database that enables the collection and storage of all the data and images in a standard format. The web-based platform can be delivered from the Italian Cineca-certified data centre in SaaS (Software as a Service) mode or can be installed at any local data centre that should guarantee compliance to security and quality standards if it is requested according to the country related needs. In addition, personalisation can be done to activate the platform in a dedicated environment.

Personal data are encrypted, and the platform is compliant with the highest security standards (using HTTP and SSL encryption standards) and data quality procedures, according to ISO 270001 certification[9]. Privacy is enforced with role based user security (survivor, health professional and data manager), authentication, identification and authorisation mechanisms to share and store data.

For the PanCareSurPass project, data storage in the future maybe organized either by using the CINECA facilities or local infrastructures in different countries; the hypothesis of a pan European cloud might be investigated. Transfer of data between different platforms will be done according to HL7 standards. HL7 and its members provide a framework (and related standards) for the exchange, integration, sharing, and retrieval of electronic health information. These standards define how information is packaged and communicated from one party to another, setting the language, structure and data types required for seamless integration between systems.

Informed consent

Informed consent from the survivor, or for those underage or lacking capacity their parents, is given before data are entered in the platform. Ethics committee approval was granted for the implementation in Italy.

Data ownership is regulated in compliance with the European Directive 2016/679, which went into effect on 25 May 2018 (GDPR): individual centres/survivors retain data ownership; the software provider must be nominated as data processor and guarantees the correct management of the survivors' data.

Data sharing

Survivors receive their paper passport from their physician after the elective end of treatment therapies. This document can be shared by patients. After survivor's consent, Healthcare Providers may have access to the electronic version of the Survivorship Passport.

In the future PanCareSurPass project, survivors and physicians, after survivor's consent, will have the possibility to access the information via a dedicated secured website. A mobile app is planned. Survivor and physicians can view and/or print the electronic documents (summary treatment, brochures and any other documents uploaded on the platform such as radiotherapy files) in any of the available languages. Documents can thus be shared at any time with the survivor's physicians or hospitals where they were admitted.

The Survivorship Passport is currently not used for research purposes, but it may be integrated in institutional/national registries. If survivors would consent, it might be possible, either at institutional

[9] https://www.cineca.it/en/content/certifications

or even larger level, to collect statistics about who has done what in terms of screening and the corresponding results. Statistics could then be provided about prevalence and/or incidence and analysis performed on risk factors of chronic conditions detected following evidence-based screening recommendations.

Health passport

After the elective end of treatment therapies, patients receive a self-generating paper document containing detailed information about the cancer history and therapy and advice and guidance on patient-specific long-term follow-up of possible late effects.

The organ-specific screening recommendations for possible late complications of treatment were developed by PanCareSurFup in collaboration with the International Guideline Harmonization Group (IGHG)[10]. Each organ-specific guideline defines the following:

- who needs surveillance
- what is the most appropriate test for screening
- when and at what frequency screening should be initiated and or ended
- what should be done if abnormalities are identified.

Currently outcomes include:

- cardiomyopathy
- subsequent breast cancer
- male or female gonadal toxicity
- thyroid cancer.

Subjects at risk for each outcome are identified by using automated algorithms built into the system, which are based on the risk group definitions reported in the respective guidelines. The system provides the strength of the screening recommendation. According to IGHG criteria, four levels of strength of recommendations to enter a specific screening program are reported and highlighted with a colour code: strong (green), moderate (yellow) or weak (orange) or a recommendation not to do (red) because of the expectation of more harm than benefit of such testing. The treating physician can also assign other screening recommendations, based on survivor-specific medical history (e.g. complications during treatment). A shared decision to enter the screening program for each organ at risk identified by the system will be made by the treating physician together with the survivor and/or their parents based on the strength of recommendations, survivor's wishes, any other possible risk factor (e.g. family history) and local circumstances.

Information regarding timing and results of screening tests performed after delivery of the Survivorship Passport can be uploaded by the treating physician or late-effects clinic staff into the follow-up form and stored. At each visit, the system reports the clinical summary of the previous evaluation and requests updated medical and socioeconomic history, results of physical examination and of other evaluations performed during the visit. A new summary will then be prepared by the physician, after evaluation of all new information. Any chronic condition (either newly or already diagnosed) can be reported and categorised through identification of 1) system affected (e.g. cardiovascular); 2) organ or system affected (e.g. heart, vessels) and 3) details (e.g. cardiomyopathy, arrhythmia and hypertension)

In case of a relapse or of a subsequent malignant neoplasm after the end of first-line treatment, the survivorship passport may be updated by the treating physician once the new information about site

[10] "http://www.ighg.org/international-guideline-harmonization-group/methods/process"

and type of relapse or subsequent malignant neoplasm and related salvage treatments becomes available. Individualised screening recommendations may be affected by the additional salvage treatments. Therefore, updated and adapted new screening recommendations are generated and may be integrated into the updated survivorship passport.

In the future both doctors and survivors will have the possibility to access the information via a dedicated secured website and a mobile app.

Centre of knowledge

Based on the medical history of each individual as summarized in the passport, follow-up recommendations are included. The PanCare Society is planning to upload on its website (www.pancare.eu) all the recommendations as well organ specific brochures.

The recommendations are based on guidelines developed as part of the international EU funded project PanCareSurFup in collaboration with the International Guidelines Harmonization group (www.ighg.org). Each guideline is defined after extensive literature review and discussion among experts and identifies: who needs surveillance; what is the most appropriate test for screening; when and at what frequency screening should be initiated and or ended; and what should be done if abnormalities are identified?

Organ-specific brochures with the survivor name and survivorship passport number can be printed. Each brochure is originally prepared in English and then translated into several European languages by native speakers in the affiliated consortia and/or translators of the UN Volunteers Programme (https://unv.org). Brochures on secondary breast cancer, cardiomyopathy and premature ovarian failure are currently available in the following languages: Croatian, Czech, Dutch, English, French, German, Italian, Lithuanian and Spanish. Translations into Greek, Hungarian, Polish, Portuguese, Swedish and Hebrew are in progress. Under PanCareFollowUp the remaining brochures addressing the rest of the 41 recommendations are being developed.

Support and patient empowerment

Not included.

Lessons learnt

The way to access platform by local hospitals may differ by country. The prototype was developed in Italy, but due to differences in the local situation (i.e. availability of regional/national health records) it is not always transferable to other European countries.

Data should be validated by a health professional and this process might be time consuming. You want shared use of the platform by both patients and health professionals, but clinical data about diagnosis and treatment should be provided by health professionals; follow-up data should be kept separated if from clinical visit or by self-report/questionnaire.

Then there is the issue how to store data. This may be done in a pan-European cloud, but issues related to GDPR and cross border transfer of personal data might be differently approached/interpreted by national authorities.

The moment of the delivery of the passport might be stressful for some survivors. Particular attention, possibly with psychological supervision should be paid at the moment of the Survivorship Passport delivery and of shared decision about the care plan.

Guidelines are living instruments and need to be updated based on new information available in the literature. IGHG has already delivered the first revision for secondary breast cancer screening. Physicians also need to be educated on the guideline-based recommendations that patients receive, so patients will not get contradictory information.

Plans for the future

The Memorandum of Understanding between PanCare, SIOPE, CCIE and Cineca is also about dissemination of the survivorship passport in other European countries. Non oncologic diseases might be included (e.g. survivors treated with Hematopoietic stem cell transplantation because of non-malignant conditions). The platform would then need an update to code those diagnoses and to modify some terminology (e.g. second malignant tumour for children previously not affected by cancer (e.g. but by Fanconi anaemia).

Recommendations and related algorithms will be updated as soon as new evidence based guidelines will become available.

In the PanCareSurPass project, the survivorship passport will be further developed to allow semi-automatic data transfer from and to electronic medical record. PROMs and CROMs will be added in the follow-up form.