doi:10.3233/SHTI240651

Childhood Cancer Survivorship Passport Challenges in the European Health Data Space

Roberta GAZZARATA[a,b,1], Michael STRÜBIN[a], Catherine CHRONAKI[a], Giorgio CANGIOLI[a], Davide SARACENO[c], Günter SCHREIER[d], Stefan BEYER[d], Florian TRAUNER[e], Gerald GREDINGER[e], Ruth LADENSTEIN[f], Ismay AE de BEIJER[g], Giacomo CAVALCA[h,n], Justas TRINKUNAS[i], Lucas CERVERO BELTRAN[j], Mark VANAUTGAERDEN[k], Ann-Kristin KOCK-SCHOPPENHAUER[l], Anke NEUMANN[l], Monica MURACA[h], Anna-Liesa FILBERT[m], Riccardo HAUPT[h], Desiree GRABOW[m] on behalf of the PanCareSurPass Consortium.

[a] *HL7 Europe, Brussels, Belgium*
[b] *Healthropy, Savona, Italy*
[c] *Cineca Interuniversity Consortium, Bologna, Italy*
[d] *AIT Austrian Institute of Technology, Wien, Austria*
[e] *Gesundheit Österreich GmbH, Wien, Austria*
[f] *CCRI, Wien, Austria*
[g] *Princess Máxima Center for Pediatric Oncology, Utrecht, The Netherlands*
[h] *IRCCS Istituto Giannina Gaslini, Genova, Italy*
[i] *Vilnius University Hospital Santaros Klinikos, Vilnius, Lithuania*
[j] *Hospital Universitario y Politécnico La Fe, Valencia, Spain*
[k] *University Hospitals Leuven, KU Leuven, Louvain, Belgium*
[l] *IT Center for Clinical Research, University of Lübeck, Germany*
[m] *German Childhood Cancer Registry, IMBEI, University Medical Center Mainz, Germany*
[n] *University of Bologna, Bologna, Italy*

ORCiD ID: Roberta Gazzarata https://orcid.org/0000-0002-7778-7601, Catherine Chronaki https://orcid.org/0000-0001-6638-8448, Giorgio Cangioli https://orcid.org/0000-0003-1918-376X

Abstract. Innovation in cancer therapy has increased childhood cancer survival rates. However, survivors are still at risk of developing late effects. In the digital transformation of the health sector, the Survivorship Passport (SurPass) can support long-term follow-up care plans. Gaps in seamless connectivity among hospital departments, primary care, combined with the time of health professionals required to collect and fill-in health data in SurPass, are barriers to its adoption in daily clinical practice. The PanCareSurPass (PCSP) project was motivated to address these gaps by a new version of SurPass (v2.0) that supports semi-automatic assembly from organizational Electronic Health Record (EHR) systems of the treatment summary data using HL7 FHIR, to create SurPass, and to link it to regional or national digital health infrastructures in six European countries. In this paper we present the methodology used to develop the SurPass technical implementation strategy with special focus on the European Health Data Space (EHDS). The

[1] Corresponding Author: Roberta Gazzarata; E-mail: roberta.gazzarata@hl7europe.org.

recently provisionally approved EHDS regulation instruments a digital health data ecosystem with opportunities for cost-effective SurPass implementation across Europe. Moving forward, a European HL7 FHIR SurPass Implementation Guide along with synthetic data sets, and validation tools can enrich the European Electronic Health Record Exchange Format (EEHRxF) with use cases on health & wellness of childhood cancer survivors.

Keywords. Cancer, oncology, survivor, digital health, EHDS, European Health Data Space, HL7 FHIR Implementation Guide, care plans, EHRxF

1. Introduction

Thanks to improvements in cancer treatment, the 5-year survival rates for childhood cancer have increased to over 80% [1]. Unfortunately, childhood cancer survivors (CCS) are at high risk of developing late effects due to the cancer treatment, resulting in excess morbidity and mortality [2]. Many survivors are unaware of their personal risk for specific late effects, and their treating healthcare providers (HCPs) lack information about care required for CCS, as they lack access treatment data from their childhood cancer. For this reason, the Survivorship Passport (SurPass) was introduced as an innovative, digital tool to overcome knowledge gaps and to improve person-centred long-term follow-up (LTFU) care [3]. Early implementation of SurPass (v1.2) identified that manual data entry of treatment data is time-demanding [4]. The PanCareSurPass (PCSP) project (pancaresurpass.eu), started in 2021 to explore the semi-automatic data entry by developing an interoperable version of SurPass (v2.0) and testing it in 6 European countries (Austria, Belgium, Germany, Italy, Lithuania, and Spain). While employing HL7 FHIR for semi-automatic creation of treatment summaries from organizational EHRs and seamless integration with digital health infrastructures, SurPass would show how to improve long-term person-centered CCS care. Following a pre-implementation study in the involved countries representing different health system structures in Europe [1,5,6], cost data from implementation would allow development of a prediction model to inform scaling adoption. Ethical, structural, organisational, economical and privacy issues must be considered in the context of digital transformation policies. An important implementation barrier identified includes the lack of consistency and interoperability among hospital EHR systems and regional/national digital health infrastructures. In fact, these exact considerations underpin and motivate the proposal of the European Health Data Space (EHDS) regulation in May 2022, which was recently provisionally accepted by the European parliament and council in March 2024. Among other provisions related to health data governance and access, the EHDS proposal establishes a new regulatory framework for manufacturers of EHR systems, including compliance with new European interoperability specifications, the European EHR Exchange Format (EEHRxF)[7]. Thus, the EHDS will create a new European digital health ecosystem to facilitate the effective use of electronic health data for healthcare, research and innovation. Therefore, SurPass use cases are clearly under the preview of EHDS. In this paper, we analyse the potential impact of the EHDS regulation on the SurPass v2.0 implementation strategy, taking the Austrian implementation as an example.

2. Methods

SurPass [5] is a digital tool for supporting LTFU care comprising: (1) a treatment summary (TS) with description of demographics, cancer type and stage, chemo/radiotherapy cumulative treatment doses (CTD), and surgeries; (2) a Survivorship Care Plan (SCP) with personalised surveillance recommendations automatically generated by built in algorithms linking the individual treatment history with risk factors identified by international guidelines for follow-up recommendations; (3) a follow-up event form allowing the registration of subsequent malignant and non-malignant events. The SurPass pre-implementation study used digital questionnaires and Open Space meetings to analyse barriers and facilitators to SurPass implementation and scale-up. The resulting general and country-specific recommendations and examples [1,5,6] led to a practical implementation strategy for each participating country promoting the adoption and integration of evidence-based practices, interventions and policies into routine health care and public health specific settings to improve impact in population health. Meanwhile, PCSP partners have been constantly monitoring the progress of the EHDS proposed regulation associated trialogues, eHealth Network guidelines, and initiatives supporting the EEHRxF, to make sure that the SurPass v2.0 implementation strategy is aligned with the upcoming EHDS rules. As a result, the IT technical specifications for SurPass v2.0 take into account the GDPR and the evolving EHDS recommendations to ensure interoperability, cybersecurity and to guide the implementation of the SurPass in the 6 healthcare systems involved. Although HL7 Clinical Document Architecture (HL7 CDA) was initially considered as the key standard, technology developments and political decisions mandated the move to HL7 FHIR. As a result, the HL7 FHIR PCSP Implementation Guide (IG) became a key element of the SurPass 2.0 technical implementation strategy.

3. Results

The SurPass v2.0 technical implementation strategy adopted an agile approach, continuously iterating with the 6 participating hospitals and CINECA engaging in co-creation, mutual learning, and peer support. For the technical implementation strategy design, the following principles have been followed: (1) common stable architecture; (2) flexible and scalable solution to fulfil the specificities of each pilot; (3) progressive implementation (Figure 1). An HL7 FHIR server was implemented as core element of the SurPass infrastructure and was connected with the EHR system of each participating hospital to semi-automatically assemble and exchange EHR data with the SurPass 2.0 platform through HL7 FHIR Resources. HL7 FHIR Release 4 (R4) profiles and international terminologies (e.g. ATC, ICD-O-3, ICCC3, etc.) are part of a HL7 FHIR IG for SurPass 2.0 (hl7.eu/fhir/ig/pcsp). This IG guided implementation in the 6 clinics, while incorporating feedback from implementation. With each implementation, HL7 FHIR resources mature and eventually, the HL7 FHIR PCSP IG could become a valuable instrument to scale-up adoption of SurPass v2.0 across Europe. As part of the care process, HCPs review health data in HL7 FHIR resources to share EHR data with the SurPass v2.0 platform and generate SurPass. The integration of SurPass v2.0 with the local digital health infrastructure relates to national/regional capabilities and policies for each state. Several strategies for SurPass integration have been adopted by the 6 clinics. Here, we consider the case of Austria, (sharing similarities with Lithuania and Belgium)

as an example. The preliminary SCP generated is integrated in the local EHR system in Austria or used to update existing medical documents, e.g., the International Patient Summary (IPS) or other medical documents used in Austria. The full process shown in Figure 2, is as follows: at the end of treatment, relevant treatment data is gathered in the Survivor Passport (SUPA) App for the submission of the paediatric outpatient report to ELGA, the National EHR Platform and the transfer to the SUPA Bioregistry for late effects. The data set required to generate the preliminary SCP is provided in a anonymised form to the SurPass v2.0 API, which generates the preliminary SCP. Next, the preliminary SCP is personalised, edited as needed by the HCP and presented to the survivor for validation using the SUPA App. The approved SCP is then used by the SUPA App to generate SurPass and complete the paediatric outpatient report, which is sent to the ELGA system to be stored and indexed for further consultation by HCPs and by the CCS. The SurPass is sent to the SUPA Bioregistry in a pseudonymised form for secondary use and research purposes. When applicable, a new preliminary SCP is requested through the SurPass v2.0 API. It is used to generate a new SurPass version and an updated Paediatric outpatient report for ELGA making SurPass available in the EHDS.

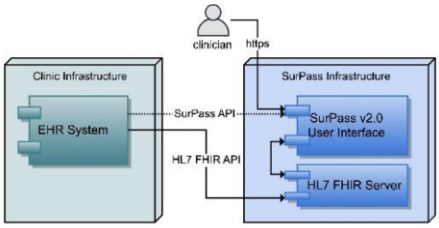

Figure 1. Exchange of data between Hospital EHR systems and SurPass v2.0.

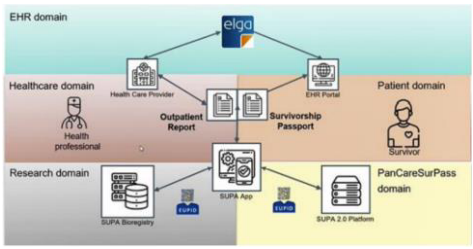

Figure 2. Austrian blueprint for the Austrian SUPA implementation for SurPass v2.0.

4. Discussion and Conclusions

Healthcare systems in Europe are fragmented due to different historical paths, organisational structures, and payment systems. In fact, healthcare and social systems remain a national (and often regional) responsibility and each state has been building its hospital EHR systems and digital health infrastructures at different speeds. Sparked in part by the pandemic, the EHDS marks a departure and a new era of EU collaboration, to develop a new ecosystem for health data use, addressing technical, legal and ethical/social barriers. The EHDS, building on Commission Recommendation (EU) 2019/243 on the EEHRxF [5], will comply with international specifications and mandatory standards, starting with EHR systems. Timelines are uncertain, yet the direction of travel is clear. The PCSP consortium is addressing how implementation can be optimized in different countries with different organizational Health System models. Austria's EHR system "ELGA" delivers an important case study for SurPass 2.0 implementation. During the conception and integration of the SurPass in ELGA, the technological differences between the currently used HL7 CDA format and HL7 FHIR proved to be challenging. Additionally, there was the need to map the HL7 FHIR IG contents to the existing outpatient report CDA format, as a new document type could not be defined within a realistic timeline, due to the prioritization of other projects on

ELGAs. With the EHDS, national authorities will also need to solve these mapping issues. The HL7 FHIR PCSP IG can serve this purpose enriched with national implementation feedback and supported with sample data and tools to accelerate SurPass v2.0 adoption across Europe. The tight integration into the SUPA Bioregistry will enable long-term research in Austria, where regular and automated updates through hospital EHRs and ELGA play a crucial role. This may serve as a model for other member states towards a European-scale late effects registry and as a use case to pioneer efficient transition between primary and secondary use of health data in the EHDS. PCSP is in-line with the core elements of the provisional agreement on EHDS: (1) opt-out: informed consent of a CCS is requested to create SurPass v2.0; (2) restricted information: if CCS choose to restrict information, HCPs will not be able to access restricted health data; (3) sensitive data: Member States may employ stricter measures governing access to sensitive data. Austria has stricter measures than Spain or Lithuania that permit generation of SurPass v2.0 in Italy; (4) Health data access bodies and trusted data holders: a European late effects registry could see PANCARE, the Pan-European Network for Care of Survivors after Childhood and Adolescent Cancer, as trusted data holder. Finally, concerning economic considerations, costs for implementation are dependent on the digitization level of the hospital information system. The already established standard use for the health data transfer plays a key role when it comes to costs within the implementation phase. Although the relatively cheapest option in the short term when implementing the infrastructure for operating a SurPass v2.0 is the one where data is not transferred automatically and all the necessary information has to be typed in manually, a higher digitization level will reduce costs and efforts in the long run. Additionally, a higher digitization level and the standard use will reduce costs for further similar projects in the respective health systems.

Acknowledgements: PanCareSurPass received funding from the European Union's H2020 research and innovation programme under grant agreement No 899999.

References

[1] van den Oever SR, et al. Barriers and facilitators to implementation of the interoperable Survivorship Passport (SurPass) v2. 0 in 6 European countries: a PanCareSurPass online survey study. Journal of Cancer Survivorship. 2023;1–13.
[2] van Deuren S, et al. Prevalence and risk factors of cancer-related fatigue in childhood cancer survivors: A DCCSS LATER study. Cancer. 2022;128(5):1110–21.
[3] Haupt R, et al. The 'Survivorship Passport' for childhood cancer survivors. Eur J Cancer. 2018;102:69–81.
[4] van Kalsbeek RJ,et al. The European multistakeholder PanCareFollowUp project: novel, person-centred survivorship care to improve care quality, effectiveness, cost-effectiveness and accessibility for cancer survivors and caregivers. Eur J Cancer. 2021;153:74–85.
[5] de Beijer IAE, et al. Barriers and facilitators to the implementation of a new European eHealth solution (SurPass v2. 0): the PanCareSurPass Open Space study. Journal of Cancer Survivorship. 2023;1–13.
[6] de Beijer IAE,et al. IT-Related Barriers and Facilitators to the Implementation of a New European eHealth Solution, the Digital Survivorship Passport (SurPass Version 2.0): Semistructured Digital Survey. J Med Internet Res. 2024;26:e49910.
[7] European Commission. Proposal for a regulation - The European Health Data Space [Internet]. Available from: https://health.ec.europa.eu/publications/proposal-regulation-european-health-data-space_en