Information Technology (IT)-related barriers and facilitators to the implementation of a new European eHealth solution: the digital Survivorship Passport (SurPass) v2.0

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Abstract

Background: To overcome knowledge gaps and optimise long-term follow-up care for childhood cancer survivors, the concept of the Survivorship Passport (SurPass) has been invented. Within the European PanCareSurPass project, the semi-automated and interoperable SurPass (v2.0) will be optimised, implemented and evaluated at six LTFU care centres representing six European countries and three distinct health system scenarios: I) national electronic health information systems: Austria and Lithuania; II) regional/local electronic health information systems: Italy and Spain; III) cancer registries/hospital-based electronic health information systems: Belgium and Germany.

Objective: To identify and describe barriers and facilitators for SurPass v2.0 implementation with respect to semi-automation of data input, interoperability, and data protection/privacy and cybersecurity.

Methods: Information and Technology (IT) specialists from the six long-term follow-up care centres participated in an online, semi-structured survey targeted at IT-related barriers and facilitators to SurPass v2.0 implementation.

Results: 13/20 invited IT specialists (65%) participated. The main barriers and facilitators across all three health system scenarios related to (semi-)automated data input and interoperability included (un)aligned electronic health information systems infrastructure and the use of interoperability frameworks and international coding systems. The main barriers and facilitators related to data protection/privacy and cybersecurity included pseudonymisation of personal health data and data retention.

Conclusions: The current study provides essential insights into the Information and IT-related influencing factors that need to be taken into account when implementing the SurPass v2.0 in clinical practice. We recommend the adoption of Health Level Seven Fast Healthcare Interoperability Resources and data security measures such as encryption, pseudonymisation, and multi-factor authentication to protect personal health data where applicable. The results of this study are not only applicable to SurPass implementation, but also the implementation of other eHealth solutions.

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Information Technology (IT)-related barriers and facilitators to the implementation of a new European eHealth solution: the digital Survivorship Passport (SurPass) v2.0

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Keywords: Pediatric oncology; long-term follow up care; survivorship; cancer survivors; Survivorship Passport; SurPass, eHealth; Information and Technology

ABSTRACT

Background. To overcome knowledge gaps and optimize long-term follow-up care for childhood cancer survivors, the concept of the Survivorship Passport (SurPass) has been invented. Within the European PanCareSurPass project, the semi-automated and interoperable SurPass (v2.0) will be optimized, implemented and evaluated at six long-term follow-up (LTFU) care centers representing six European countries and three distinct health system scenarios: I) national electronic health information systems (EHIS): Austria and Lithuania; II) regional/local EHIS: Italy and Spain; III) cancer registries/hospital-based EHIS: Belgium and Germany.

Objective. To identify and describe barriers and facilitators for SurPass v2.0 implementation with respect to semi-automation of data input, interoperability, and data protection/privacy and cybersecurity.

Methods. Information and Technology (IT) specialists from the six long-term follow-up care centers participated in a semi-structured online survey focusing on IT-related barriers and facilitators to SurPass v2.0 implementation. We used the Fit-Viability Model (FVM) to assess the compatibility and feasibility of integrating SurPass into existing EHIS.

Results. 13/20 invited IT specialists (65%) participated. The main barriers and facilitators in all three health system scenarios related to (semi-)automated data input and interoperability included (un)aligned electronic health information systems infrastructure and the use of interoperability frameworks and international coding systems. The main barriers and facilitators related to data protection/privacy and cybersecurity included pseudonymization of personal health data and data retention. According to the FVM, the first health system scenario provides the best fit for SurPass implementation, followed by the second and third scenarios.

Conclusions. This study provides essential insights into the information and IT-related influencing factors that need to be considered when implementing the SurPass v2.0 in clinical practice. We recommend the adoption of Health Level Seven Fast Healthcare Interoperability Resources and data security measures such as encryption, pseudonymization, and multi-factor authentication to protect personal health data where applicable. In sum, this study offers practical insights into integrating digital health solutions into existing EHIS systems.

INTRODUCTION

More and more children and adolescents successfully survive cancer into adulthood due to improvements in childhood cancer treatment [1,2]. There are currently around 500,000 childhood cancer survivors (CCSs) in Europe [1-3], with around 8,000–10,000 new survivors each year [4]. However, despite the increasing survival rates, CCSs remain at risk of impaired quality of life and extensive morbidity and mortality due to disease relapse or late health complications caused by cancer treatments (late effects) [5-7]. Late effects can include physical as well as psychological and social conditions, ranging from subsequent neoplasms and cardiotoxicity to chronic pain and poor psychological well-being [4-16]. To improve and/or preserve the quality of life of CCSs, long-term follow-up (LTFU) care focusing on late effects surveillance and timely intervention is essential [17]. However, comprehensive LTFU programs are lacking in many pediatric cancer centers [18]. In particular, the coordination of LTFU care between healthcare providers (HCPs), care managers and CCSs, as well as the available knowledge about late effects and the transition from pediatric to adult healthcare services, often call for improvement [18-20].

Previous studies have highlighted the need for a treatment summary and care plan for CCSs as part of successful LTFU care [21-23]. To increase knowledge among HCPs and CCSs and optimize long-term survivorship care, the Survivorship Passport (SurPass) was developed by the Pan-European Network for Care of Survivors after Childhood and Adolescent Cancer (PanCare), a multidisciplinary and international association of professionals, CCSs and their families, with the aim of reducing the impact of late health effects for CCSs [24-26]. The SurPass summarizes cancer and treatment-related data of CCSs and, thanks to built-in algorithms, suggests personalized follow-up recommendations based on evidence-based surveillance guidelines developed by the International Guidelines Harmonization Group (IGHG) and consensus-based recommendations formulated within several PanCare projects (PanCareSurFup, PanCareFollowUp) [17,26]. In addition, the SurPass provides plain language information on late effects and self-care. All in all, the SurPass supports personalized follow-up care and can improve understanding of late effects among HCPs and CCSs. Over the years, multiple versions of SurPass have been developed. At the Istituto Giannina Gaslini, Italy, the SurPass v1.2 was found to have an overall positive impact on survivors and their families [24]. Ultimately, the SurPass has the potential to be employed throughout Europe and beyond to improve LTFU care and empower CCSs to take charge of their own health [24].

Previously developed versions of the SurPass require manual entry of individual treatment data to be entered manually into the SurPass database, making its use in daily clinical practice rather time-consuming [24]. As a result, SurPass is currently being upgraded to a semi-automated and interoperable version (SurPass v2.0) as part of the European Horizon 2020-funded PanCareSurPass (PCSP) project [27]. Like previous versions of SurPass, v2.0 will generate a survivor-specific treatment summary and survivorship care plan (SCP) using algorithms that link treatment data with available follow-up recommendations. Unlike previous versions, SurPass v2.0 (hereafter referred to as SurPass) will facilitate semi-automated data entry from Electronic Health Information Systems (EHIS) and/or integration of SurPass into national/regional Electronic Health Records (EHR). A high level of interoperability and data protection/security are essential to achieve (semi-)automated data transfer. The development and harmonization of interfaces is required to enable data exchange between systems and the storage of information in different systems (eg, hospital systems, clinical trials and cancer registries). Interoperability between EHIS and EHR and the SurPass platform is facilitated by the Health

Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR) interoperability standard [28]. HL7 FHIR supports the exchange of data between healthcare software systems and combines the hallmarks of the established HL7 version 2, 3 and Clinical Document Architecture (CDA) standards while leveraging current web standards such as Extensible Markup Language (XML), JavaScript Object Notation (JSON), Hypertext Transfer Protocol (HTTP) and the Open Authorization Standard (OAuth) [29]. In addition, HL7's International Patient Summary (IPS) standard specifies an EHR extract containing essential health information intended for use in cross-border care scenarios. IPS models support continuity of care for patients and coordination of care across health systems [30]. Specifically, the treatment summary variables in SurPass are linked according to the IPS. Finally, SurPass has been certified as a Class 1 medical device and must guarantee data security in terms of availability, confidentiality and data integrity in accordance with the General Data Protection Regulation (GDPR) [31] and national data protection and privacy requirements.

Upon successful implementation of SurPass throughout three European health system scenarios (national EHIS, regional EHIS, and cancer registries/hospital-based EHIS), the PCSP project must focus on the three main challenges described above: 1) semi-automation of data input, 2) interoperability, and 3) data protection/privacy and cybersecurity. To support the most appropriate implementation strategy for SurPass throughout the three health system scenarios and overcome the three main challenges, an online survey study was designed. The results of the first part of the survey, which addressed barriers and facilitators related to the care process and ethical, legal, social, and economic aspects of implementation, are described elsewhere [32]. This report describes the results of the second part of the survey, with which we aimed to identify IT-related barriers and facilitators to SurPass implementation. Subsequently, we aimed to derive insights that could be broadly applied to countries with similar types of health system interested in implementing SurPass

METHODS

Study design and participants

The PCSP project representatives were asked to provide the email addresses of all the IT specialists working in their center who are responsible for the management of IT systems used to document the treatment of cancer patients and the future implementation of SurPass (*n*=20). Specifically, the IT specialists invited were based in six LTFU care centers (hereafter referred to by their country name): one IT specialist from Austria (Children's Cancer Research Institute St. Anna Kinderkrebsforschung), one from Belgium (Katholieke Universiteit Leuven & University Hospitals Leuven), five from Germany (University Medical Center Mainz (German Childhood Cancer Registry (GCCR)) and Universität zu Lübeck), seven from Italy (Istituto Giannina Gaslini), two from Lithuania (Viesoji Istaiga Vilniaus Universiteto Ligonine Santaros Klinikos) and four from Spain (Fundación para la Investigación del Hospital Universitario la Fe de la Comunidad Valenciana). The participating centers represented the three European health system scenarios, including 1) nationally based EHIS or EHR (Austria, Lithuania), 2) institutional/regional EHIS or EHR (Italy, Spain), and 3) national cancer registries and hospital-based EHIS or EHR (Germany, Belgium).

Survey development

The survey was designed using the input from six earlier, semi-structured interviews with IT specialists from each of the participating centers, conducted by researchers from HL7 Europe [33]. The interviews were conducted in order to build up a picture of the relevant issues to be explored in the survey. In turn, the survey aimed to collect detailed data on the health system scenarios represented by the centers. First, we inquired about individual respondent characteristics, such as

country of residence and organization of the IT department, followed by questions about which systems could be accessed by survivorship care staff; whether the information could be downloaded, entered and/or updated; whether the information was integrated transparently, via common identifiers, or by other means; and whether the systems could exchange information using application programming interfaces (APIs). Second, respondents were asked to indicate which Health Data Exchange (HDE) standards and/or interoperability frameworks were used or currently implemented in their institution. Third, the availability of CCS information (eg, medical history, diagnostic imaging, or pathology labs) and its format (eg, hardcopy, PDF, or HL7 CDA) and accessibility were examined. Similar questions about availability and format were asked about cancer diagnosis and treatment (eg, histology-cytology reports, cumulative doses of chemotherapy or radiotherapy, and types of immunotherapy) and non-cancer medical information (eg, comorbidities, surgical procedures, and hereditary syndromes). Lastly, respondents were asked about data protection, data storage, and available resources related to the implementation of SurPass. The survey concluded with open-ended questions about barriers and facilitators to the implementation of the interoperable SurPass. The full survey is presented in Multimedia Appendix 2.

Ethical approval and data collection

Ethical review board approval was required and obtained in Belgium, Italy, Germany and Spain. Ethical approval was not required in Austria and Lithuania. Institutional approval for pseudonymized data collection, analysis and storage was provided by the Princess Máxima Center in the Netherlands. Survey distribution and data collection were conducted using the cloud-based central data management platform Castor Electronic Data Capture (Castor EDC), a GDPR-compliant online survey tool. The survey was conducted in English. On-site language assistance was provided to participants with limited English proficiency. The survey was launched on 16 August 2021 and closed on 4 October 2021. The results were sent to the centers for validation, which took place from December 2021 to March 2022.

Data analysis

Pseudonymized survey data were exported from Castor EDC and processed and analyzed using SPSS statistical software(version 25.0. Armonk, NY: IBM Corporation). The survey results were categorized and analyzed per health system scenario and according to the three main challenges: 1) semi-automation of data input, 2) interoperability, and 3) data protection/privacy and cybersecurity. Additionally, the availability of sufficient resources (ie, staff, funding, and knowledge) to implement SurPass was considered separately for each center

Predefined barriers to semi-automated data input and interoperability included: unaligned EHIS infrastructures without the availability of a personalized EHR or structured centralized clinical trial databases from which (clinical) data could be transferred; the availability/accessibility of less than half of the requested health data information sources and patient data; the non-use of HL7 FHIR; and the use of proprietary (non-interoperable) coding systems. Barriers to data protection/privacy and cybersecurity included not being able to privacy-protect SurPass record linkage (in line with GDPR); less than half of the IT specialists (per center) being able to guarantee data protection; and less than half of the IT specialists (per center) being familiar with data retention regulations. Finally, the unavailability of sufficient resources as indicated by at least half of the IT specialists (per center), was also considered a barrier.

Predefined facilitators for semi-automation of data input and interoperability included: having a standardized and structured HDE process; the availability of a personalized EHR or structured centralized clinical trial databases from

which (clinical) data could be transferred in the case of non-aligned EHIS; the availability/accessibility of at least half of the requested health data information sources and patient data, ideally with the possibility to download, enter, update, and integrate the data using APIs; the use of HL7 FHIR; and the use of international coding systems such as the Anatomical Therapeutic Chemical (ATC) code system, the International Classification of Diseases for Oncology (ICD-O-3), and the International Classification for Childhood Cancer (ICCC-3) as used in SurPass. Facilitators for data protection/privacy and cybersecurity included pseudonymization of personal health data in accordance with the European Regulation 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, at least half of the IT specialists (per center) being able to ensure data protection, and at least half of the IT specialists (per center) being familiar with data retention regulations. Similarly, the availability of sufficient resources, as indicated by at least half of the IT specialists (per center), was considered to facilitate the implementation of SurPass.

Furthermore, we used the Fit-Viability Model (FVM) as described by Liang et al. [34] to assess the successful implementation of SurPass across the three unique health system scenarios. Specifically, the FVM evaluates the technological factors and organizational readiness essential for implementing an information technology. Liang et al. defined ‘fit’ as the match between task requirements and technology capabilities and ‘viability’ as the economic feasibility, IT infrastructure maturity, and organizational support. In the current study, we used the FVM to assess how well SurPass fits into the three health system scenarios and the extent to which SurPass is feasible, sustainable and likely to be successfully integrated into the existing EHIS in the different health system scenarios, taking into account the system-specific barriers and facilitators.

RESULTS

Survey participants

A total of 13 IT specialists (one from Austria and Belgium, two from Lithuania and Spain, three from Germany, and four from Italy) responded to the survey invitation. Three IT specialists represented the first scenario (national EHIS), five IT specialists represented the second scenario (regional/local EHIS), and four IT specialists represented the third scenario (cancer registries and hospital-based EHIS). The overall response rate was 65%. The response rates per country were 100% for Austria, Belgium, and Lithuania; 60% for Germany; 57% for Italy, and 50% for Spain.

Barriers and facilitators per health system scenario

Inherent to the three health system scenarios, there are barriers and facilitators relevant to the implementation of SurPass. The characteristics of these scenarios, categorized according to the three main implementation challenges, are described below. The availability of data systems and resources in each center is discussed accordingly (see also Table 1-4). The center-specific HDE standards, interoperability frameworks and coding systems for each center are described separately by Chronaki et al. [33]. A general overview of all the identified barriers and facilitators to the implementation of the SurPass is provided in Table 5.

Table 1. Information system sources in each health system scenario and center.

	Scenario 1	Scenario 2	Scenario 3

	Lithuania	Austria	Italy	Spain	Belgium	Germany
Accessible data systems						
National EHR	Yes	Yes	Yes	Yes	Yes	No
Possibility to download data	Yes	Yes	Yes	Yes	Yes	No
Possibility to enter data	Yes	*m*	Yes	No	Yes	No
Possibility to update data	Yes	Yes	Yes	No	No	No
Integrated transparently	No	*m*	Yes	No	No	No
APIs available to integrate	Yes	Yes	Yes	No	Yes	No
Regional EHR	?	*m*	~	Yes	No	No
Possibility to download data	?	*m*	Yes	No	No	No
Possibility to enter data	?	*m*	Yes	Yes	No	No
Possibility to update data	?	*m*	Yes	Yes	No	No
Integrated transparently	?	*m*	?	~	No	No
APIs available to integrate	?	*m*	Yes	~	No	No
Cancer registry	Yes	Yes	Yes	Yes	Yes	Yes
Possibility to download data	No	Yes	Yes	?	Yes	No
Possibility to enter data	No	Yes	Yes	Yes	Yes	Yes
Possibility to update data	No	Yes	Yes	Yes	No	Yes
Integrated transparently	?	*m*	?	Yes	No	?
APIs available to integrate	No	Yes	?	No	Yes	No
Hospital EMR	Yes	*m*	Yes	Yes	Yes	Yes
Possibility to download data	Yes	*m*	Yes	Yes	Yes	No
Possibility to enter data	Yes	*m*	Yes	Yes	Yes	?
Possibility to update data	Yes	*m*	Yes	Yes	Yes	?
Integrated transparently	Yes	*m*	Yes	Yes	Yes	?
APIs available to integrate	Yes	*m*	Yes	Yes	No	?
Patient records at LTFU care center	Yes	*m*	Yes	Yes	Yes	?
Possibility to download data	Yes	*m*	Yes	Yes	Yes	?
Possibility to enter data	Yes	*m*	Yes	Yes	Yes	?
Possibility to update data	Yes	*m*	Yes	Yes	Yes	?
Integrated transparently	*m*	*m*	Yes	No	Yes	?
APIs available to integrate	*m*	*m*	Yes	No	No	?
Patient records at other outpatient center	Yes	*m*	No	No	Yes	?
Possibility to download data	Yes	*m*	No	No	Yes	?
Possibility to enter data	Yes	*m*	No	No	No	?
Possibility to update data	Yes	*m*	No	No	No	?
Integrated transparently	Yes	*m*	No	No	Yes	?
APIs available to integrate	Yes	*m*	No	No	No	?
Appointment scheduling system	Yes	Yes	Yes	Yes	Yes	Yes
Possibility to download data	Yes	*m*	Yes	Yes	Yes	?
Possibility to enter data	Yes	Yes	Yes	Yes	Yes	?
Possibility to update data	Yes	Yes	Yes	Yes	Yes	?
Integrated transparently	?	*m*	Yes	Yes	Yes	?
APIs available to integrate	Yes	*m*	Yes	Yes	No	?
Pharmacy	Yes	*m*	Yes	Yes	Yes	Yes
Possibility to download data	?	*m*	Yes	Yes	Yes	?

Possibility to enter data	?	*m*	Yes	Yes	Yes	?
Possibility to update data	?	*m*	Yes	Yes	Yes	?
Integrated transparently	Yes	*m*	Yes	Yes	Yes	?
APIs available to integrate	?	*m*	Yes	Yes	Yes	?
Labs	Yes	Yes	Yes	Yes	Yes	Yes
Possibility to download data	Yes	Yes	Yes	Yes	Yes	?
Possibility to enter data	No	No	Yes	Yes	Yes	?
Possibility to update data	No	No	Yes	Yes	Yes	?
Integrated transparently	?	*m*	Yes	Yes	Yes	?
APIs available to integrate	?	*m*	Yes	Yes	Yes	?
Radiology	Yes	Yes	Yes	Yes	Yes	?
Possibility to download data	Yes	Yes	Yes	Yes	Yes	?
Possibility to enter data	Yes	No	Yes	Yes	Yes	?
Possibility to update data	Yes	No	Yes	Yes	Yes	?
Integrated transparently	?	*m*	Yes	Yes	Yes	?
APIs available to integrate	?	*m*	Yes	Yes	Yes	?
Clinical trial systems	Yes	*m*	No	No	Yes	Yes
Possibility to download data	Yes	*m*	No	No	No	?
Possibility to enter data	Yes	*m*	No	No	No	?
Possibility to update data	Yes	*m*	No	No	No	?
Integrated transparently	Yes	*m*	No	No	Yes	?
APIs available to integrate	Yes	*m*	No	No	No	?
The primary health care information system	Yes	Yes	No	Yes	No	Yes
Possibility to download data	*m*	Yes	No	Yes	No	No
Possibility to enter data	*m*	Yes	No	Yes	No	?
Possibility to update data	*m*	Yes	No	Yes	No	?
Integrated transparently	*m*	*m*	No	Yes	No	?
APIs available to integrate	*m*	*m*	No	Yes	No	?

Abbreviations: EHR, electronic health records; EMR, electronic medical records; LTFU, long-term follow-up; API, application programming interface. *Note.* ? = respondent(s) did not know; *m* = answer(s) missing; ~ = unclear, eg, 1x 'yes' and 1x 'no'.

Table 2. Patient data electronically available in each health system scenario and center.

	Scenario 1	Scenario 2		Scenario 3	
	Lithuania	Italy	Spain	Belgium	Germany
Patient data type					
Patient summary/medical history	Yes	Yes	Yes	Yes	Yes
Hospital admissions	Yes	Yes	Yes	Yes	Yes
Diagnostic imaging (images)	Yes	Yes	Yes	Yes	Yes
Diagnostic imaging (reports)	Yes	Yes	Yes	Yes	Yes
Biochemical labs	Yes	Yes	Yes	Yes	Yes
Pathology labs	Yes	Yes	Yes	Yes	Yes
CC treatment summary	Yes	Yes	Yes	?	Yes
LTFU care visit report	?	Yes	No	?	?
SurPass[a]	No	Yes	No	No	No
LTFU center appointments	Yes	?	?	?	?
Other medical databases	?	?	No	Yes	Yes

Abbreviations: CC, childhood cancer; LTFU, long-term follow-up; SurPass, Survivorship Passport; LTFU, long-term follow-up. *Note.* [a] An earlier version of SurPass has been implemented and evaluated previously in Italy. ? = respondent(s) did not know. Austria was intentionally left out the table because all answers were missing.

Table 3: Overview of accessible patient data formats in each health system scenario and center.

	Scenario 1	Scenario 2		Scenario 3	
	Lithuania	Italy	Spain	Belgium	Germany
Patient data type					
General medical history					
Comorbidities	****	****	?	?	***
Allergies	****	****	****	***	****
Medication (non-cancer related)	****	****	****	***	**
Surgical procedures (non-cancer related)	****	****	****	***	**
Admissions	***	****	***	**	***
Trauma	****	****	**	**	No
Hereditary syndromes	***	No	**	***	No
Cancer diagnosis					
Cancer diagnosis	****	?	***	****	**
Cancer diagnosis date	****	*	***	[b]	****
Histology-cytology report	***	***	****	**	***
Imaging reports	**	***	****	**	**
Lab reports	****	****	***	**	**
Cancer treatment					
Surgical intervention(s)	**	****	****	**	**
Stem cell / bone marrow transplantation(s)	***	**	?	**	No
Chemotherapy start/end date	?	**	***	***	**
Chemotherapy type	?	***	***	****	**
Chemotherapy cumulative dose	**	***	***	?	?
Chemotherapy treatment complications	?	**	***	***	?
Immunotherapy start/end date	?	?	?	**	?
Immunotherapy type	?	?	?	**	?
Immunotherapy cumulative dose	?	?	?	?	?
Immunotherapy treatment complications	?	?	?	?	?
Hormonal therapy start/end date	?	?	?	**	?
Hormonal therapy type	?	?	?	**	?
Hormonal therapy cumulative dose	?	?	?	?	?
Hormonal therapy treatment complications	?	?	?	?	?
Radiotherapy start/end date	**	*	***	**	?
Radiotherapy type	?	*	***	**	?
Radiotherapy cumulative dose	?	*	***	?	?
Radiotherapy site	?	*	***	?	?
Radiotherapy treatment complications	?	*	***	?	?

Note. * = yes, hardcopy available; ** = yes, electronically available; *** = yes, electronically available and coded; **** = electronically available, coded and interconnected (*awarded when at least one respondent mentioned 'yes'). ? = respondent(s) did not know. [b] Electronically available, free text and interconnected. Austria was intentionally left out the table because all answers were missing.

Table 4: Scarcity of resources in each health system scenario and center.

	Scenario 1		Scenario 2		Scenario 3	
	Lithuania (*n*)	Austria (*n*)	Italy (*n*)	Spain (*n*)	Belgium (*n*)	Germany (*n*)
Resource type lacking						
Staff	-	Yes (1)	Yes (1)	Yes (1)	-	Yes (2)
	No (2)	-	No (3)	No (1)	No (1)	No (1)
Time	-	Yes (1)	Yes (2)	Yes (1)	-	Yes (2)
	No (2)	-	No (2)	No (1)	No (1)	No (1)
Funds	-	Yes (1)	Yes (2)	Yes (1)	-	Yes (1)
	No (2)	-	No (2)	No (1)	No (1)	No (2)
Knowledge	-	Yes (1)	Yes (2)	-	-	Yes (1)
	No (2)	-	No (2)	No (2)	No (1)	No (2)

Note. The table shows the number of IT-specialists per country that indicated either having (yes) or not having (no) sufficient staff, time, funds, and knowledge.

Table 5: Summary of the identified barriers and facilitators to the implementation of the SurPass v2.0 throughout all three health care system scenarios.

	Barriers	Facilitators
Scenario 1 **National EHIS**		
Austria[a]	• Uncertainty about data retention • Lack of resources	• Standardized and structured data exchange • Straightforward GDPR compliance using pseudonymization • Data protection can be guaranteed • Use of ATC code system for medication • Use of ICD-O-3 for histology
Lithuania	• Uncertainty about data retention	• Standardized and structured data exchange • Majority of the data systems is accessible • Majority of patient data is available • Use of HL7 FHIR • Data protection can be guaranteed • Sufficiency of resources • Use of ICD-O-3 for histology
Scenario 2 **Regional EHIS**		

Italy	• EHIS infrastructures discrepancies • Uncertainty about data protection • Uncertainty about data retention • Uncertainty about sufficiency of resources	• Availability of personalized EHR (Fascicolo Sanitario Elettronico) • Majority of the data systems is accessible • Majority of patient data is available • Use of HL7 FHIR • Use of ATC code system for medication
Spain	• EHIS infrastructures discrepancies • Unavailability of HDE standards • Uncertainty about data retention • Uncertainty about sufficiency of resources	• Availability of personalized EHR (Historia de Salud Electrónica) • Majority of the data systems is accessible • Majority of patient data is available • Data protection can be guaranteed
Scenario 3 **Cancer registries and hospital-based EHIS**		
Belgium	• Data origination from different sources • EHIS infrastructures discrepancies • Uncertainty about data protection • Uncertainty about data retention • Uncertainty about sufficiency of resources	• Majority of the data systems is accessible • Majority of patient data is available • Use of HL7 FHIR • Use of ATC code system for medication
Germany	• Data origination from different sources • EHIS infrastructures discrepancies • Majority of the data systems is accessible but not downloadable • Uncertainty about data protection • Uncertainty about data retention • Lack of resources	• Availability of structured centralized clinical trial databases • Majority of patient data is available • Use of HL7 FHIR • Use of ICD-O-3 and ICCC-3 for cancer diagnosis and histology

Note. [a] Accessibility of data systems and patient data availability unknown due to missing answers from the IT specialist from Austria. Abbreviations: GDPR, General Data Protection Regulation; HL7 FHIR, Health Level 7 Fast Healthcare Interoperability Resources; EHIS, electronic health information system; EHR, Electronic Health Records; HDE, Health Data Exchange.

National EHIS (Austria, Lithuania)

In this scenario, the data required for the patient-specific oncological treatment summary will be provided by HCPs through a national EHIS, such as the Austrian National Electronic Healthcare Record Systems (ELGA) or the Lithuanian Electronic Health Services and Infrastructure Cooperation System (ESPBI IS). The patient-specific oncological treatment summary, which takes into account the cumulative treatment burden and extends to the end of treatment of the first pediatric cancer,

will be systematically generated in CDA format. This scenario thus provides a standardized and structured way of exchanging data. In addition, the accessibility of digital data is fundamental to enable semi-automated data input from EHIS and to facilitate interoperability using HL7 FHIR. In Lithuania, these conditions are met as all data systems and the majority of patient data are accessible (Table 1-3) and HL7 FHIR is used. In addition, the IT specialists from Lithuania indicated that they have sufficient resources (staff, funds, knowledge) available to implement SurPass v2.0 in their center (Table 4). On the other hand, the IT specialist from Austria indicated that he did not have sufficient resources at hand. In addition, no information was available on the accessibility of the Austrian data system. In terms of interoperability, Austria currently uses HL7 CDA in ELGA and is working towards the adoption of HL7 FHIR in the future. For medication, Austria uses the ATC code system. For cancer diagnosis, Lithuania employs the ICCC-3. For histology, both Lithuania and Austria use the ICD-O-3. Other coding systems varied substantially between the two centers.

With regard to privacy and security, the structured data in this scenario will be pseudonymized where necessary, for example by using the European Patient Identity Service (EUPID)[1], and transferred to the SurPass platform to generate the CCS SurPass. EUPID will certainly be used in Austria, but there is no consensus yet in Lithuania. In the future, the use of EUPID for the HDE process will ensure GDPR compliance. In this study, survey results indicated that IT professionals in Austria and Lithuania have existing solutions that ensure SurPass data protection. Once the pseudonymized SurPass is generated, either the entire SurPass (in the case of Lithuania's ESPBI IS) or the SCP (in the case of Austria's ELGA) will be returned to the HCP and the CCS's local care team, where the SCP within the SurPass can be tailored to the CCS's individual needs and national care pathways in the local health IT system. The SurPass will be accessible to both CCSs and HCPs through the national EHIS or EHR. However, the IT specialists from Austria and Lithuania were uncertain about SurPass data retention. In the Austrian ELGA, data retention is currently limited to 10 years, which is likely to be too short for the SurPass concept.

In terms of the FVM, this scenario shows a high fit for SurPass, particularly in Lithuania given their current use of HL7 FHIR and the accessibility of data systems. In Austria, where a transition to HL7 FHIR is underway, SurPass compatibility is growing. Viability is strong with evident economic feasibility for Lithuania and effective data protection strategies present in both countries. Thus, prospects for SurPass adoption in this scenario are promising, especially in Lithuania, where ample resources contribute to a favorable implementation environment. Provided that uncertainties about data retention are resolved and Austria allocates sufficient resources, the implementation of SurPass is likely to be successful.

Regional EHIS (Italy, Spain)

In the second scenario, the main pediatric cancer institution(s) in each region have local registries/treatment protocol databases with demographic information and treatment data. Here, EHIS infrastructures are not fully aligned between regions or local hospitals in the same region, limiting semi-automated data exchange and interoperability. Similarly, EHIS may have been adopted at different times and therefore differ in terms of completeness and/or level of sophistication of the system, limiting interoperability. However, SurPass implementation can be aided by the availability of personalized EHR (Fascicolo Sanitario Elettronico in Italy, Historia de Salud Electrónica in Spain), which contain medical information that

[1]Pseudonymization and privacy-preserving record linkage tool to facilitate secondary use of datasets in biomedical research and healthcare [35]; see also https://services.eupid.eu/.

is accessible to all HCPs in the region/country and which also allow patients to access their data. However, it is worth noting that the FSE in Italy is currently undergoing a significant reorganization, transitioning from a regional to a national homogeneous system that will use HL7 FHIR. This transition may lead to changes in the way medical information is accessed and exchanged between HCPs, but it will allow SurPass to be integrated into the Italian EHR. Furthermore, the survey results showed that in both Italy and Spain, the majority of data systems and patient data are accessible to survivorship care staff (Table 1-3). Apart from the cancer registry, all data systems in Italy are also transparently integrated, including APIs, supporting interoperability between these systems together with the use of HL7 FHIR. Spain, on the other hand, has not yet adopted HL7 FHIR. For medication, Italy uses the ATC system. Other coding systems varied substantially between the two centers.

In this scenario, the SurPass v.2.0 is intended to be integrated into the EHIS of the treating institution for follow-up care, as well as into the EHR for use in possible emergency admissions to other hospitals and during the transition from pediatric to adult LTFU care. Similar to the first scenario, the cross-border data transfer could be pseudonymized by using a GDPR-compliant double pseudonymization system such as EUPID. Personalization of the SurPass data would only take place within the treating institution itself, or in other local databases with permission to hold identifying personal data. The results of the survey results showed that, in contrast to the Italian respondents, the majority of IT specialists from Spain indicated that they were able to guarantee the protection of SurPass data. Neither center's IT specialists knew how long SurPass records had to be stored. Besides, IT specialists in both centers were unsure about the availability of sufficient resources to implement SurPass (Table 4).

In the context of the FVM, this scenario shows a moderate fit for SurPass implementation within regional EHIS structures. Viability is impacted by EHIS infrastructures that are not fully aligned between regions and local hospitals, hindering seamless semi-automated data exchange and interoperability. Despite these barriers, the availability of personalized EHRs offers potential support for SurPass integration. Furthermore, viability is dependent on data protection concerns and GDPR compliance. Provided these challenges are addressed and sufficient resources can be secured, the adoption of SurPass in centers representing this scenario appears promising.

Cancer registries and hospital-based EHIS (Belgium, Germany)

The third scenario is the least favorable in terms of (semi-)automated data input, interoperability, and data protection. Unlike the scenarios with nationally or regionally organized health data, this scenario requires the integration of data from a multitude of sources to generate a SurPass. Epidemiological data will need to be obtained from cancer or bone marrow transplant registries such as the GCCR, while disease and treatment-specific clinical data will need to be retrieved from hospital databases. In addition, although it is possible to access and transfer clinical data from central clinical trial databases in Germany, this process adds complexity and is not as streamlined as data collection in the other two scenarios. Both Belgium and Germany store SurPass data at CINECA, the largest data center in Italy (cineca.it). The resulting SurPass will be returned digitally to the centers in PDF format. Currently, in both Belgium and Germany, most data systems and patient data are accessible, although in Germany without the possibility of downloading or further exploiting the data (Tables 1-3). Yet, if the data systems are already accessible, the possibilities to download, enter, update, and integrate the data can be explored in the near future as applicable during the PCSP project. Moreover, both

centers in Belgium and Germany are using HL7 FHIR, which improves interoperability between local health data systems. For cancer diagnosis and histology, Germany employs the cancer-specific coding systems ICD-O-3 and ICCC-3, and Belgium uses the ATC code system for medication. Other coding systems varied substantially between the centers. Lastly, at the time of completing the questionnaire, IT specialists from Belgium and Germany were uncertain about guaranteeing data protection, data retention, and the availability of sufficient resources in their centers (Table 4).

In this scenario, the FVM underscores significant barriers to SurPass implementation. SurPass fit is challenged by the need to integrate data from diverse sources. However, viability is reasonable, with accessible data systems and HL7 FHIR adoption improving interoperability. SurPass adoption/implementation supported by accessible data systems is feasible but will depend on overcoming challenges related to data transfer, data protection and resource availability.

DISCUSSION

Using an online survey, we assessed Information and IT-related barriers and facilitators to the implementation of the digital SurPass throughout three health system scenarios (national EHIS - Austria, Lithuania; regional/local EHIS - Italy, Spain; and cancer registries/hospital-based EHIS - Belgium, Germany). The survey involved 13 IT specialists from the participating centers. The application of the FVM to the three distinct health system scenarios provides valuable insights into the feasibility of implementing SurPass in pediatric cancer survivorship care. Scenario 1 (national EHIS) shows a positive outlook for a successful SurPass implementation, especially in Lithuania, where current HL7 FHIR usage and accessible data systems contribute to a high fit and good viability. In Austria, ongoing efforts to transition to HL7 FHIR indicate growing compatibility. Viability is strong in both countries, setting the stage for promising SurPass adoption, provided that uncertainties around data retention in Austria are addressed and sufficient resources are allocated. Scenario 2 (regional/local EHIS) presents a more nuanced picture with a moderate fit. Viability is hampered by misaligned EHIS infrastructures, impacting semi-automated data exchange and interoperability. Despite these barriers, personalized EHRs offer support for SurPass, provided that data protection concerns are dealt with. However, uncertainties among IT professionals regarding data protection, storage, and resource availability suggest that careful consideration is needed in the adoption process. Finally, scenario 3 (cancer registries/hospital-based EHIS) presents significant barriers to good SurPass fit due to the complexity of integrating data from multiple sources. Nevertheless, a reasonable viability, characterized by accessible data systems and HL7 FHIR adoption, suggests successful SurPass implementation in the future, provided that challenges related to data transfer, data protection, and resource availability are effectively handled. These findings highlight the importance of context-specific barriers and facilitators to the implementation of SurPass in the three different healthcare scenarios.

SurPass implementation requires the exchange of medical data between various data sources, especially in the second and third health system scenarios. National EHIS, as in Austria and Lithuania, are best suited for (semi-) automated data transfer from the EHIS of the treating institution to the SurPass platform, followed by the regional/local EHIS infrastructures, as in the second and third scenarios. Ultimately, (semi-)automated data input is paramount to making clinical care processes more efficient. Besides the EHIS infrastructure, the use of HL7 FHIR is of major importance for connecting SurPass to EHIS, registries and national/regional EHR. Due to its international recognition and adoption following the open API paradigm, FHIR is an ideal choice for promoting interoperability and the standardized exchange

of healthcare data. In addition to the IPS, FHIR's flexibility, extensibility, and wide adoption within the healthcare industry support our decision to recommend FHIR. All centers except Spain and Austria are already using HL7 FHIR. Austria is currently using HL7 CDA in ELGA, but is also working towards the adoption of HL7 FHIR. Relatedly, a systematic literature analysis on barriers and facilitators for the implementation of eHealth services found that having well-established HDE standards is an important success factor for eHealth services [36]. Furthermore, the lack of time for HCPs to create and update the SurPass is an important barrier in the survivorship care process [32]. Since the time needed to prepare and update SurPass depends on the level of interoperability that can be achieved between existing EHIS and SurPass, we recommend the LTFU care center in Spain and any other institution with the ambition to implement SurPass to adopt HL7 FHIR in all EHIS.

Complications with data accessibility and data privacy/security are listed in the top 10 barriers mentioned in 38 articles on the implementation of eHealth solutions [36]. On the one hand, this study illustrated that the majority of information sources and patient data types is accessible and downloadable in all health system scenarios, except in Germany (scenario 3), where the data are accessible but not downloadable. On the other hand, only in the first scenario (Austria and Lithuania) and in Spain (scenario 2) did IT specialists report being able to ensure SurPass data protection. With regard to data retention, IT specialists exhibited uncertainty and inconsistency in all scenarios. It is important to consider the context of the survey when interpreting these results. For example, in Germany, IT specialists were responsible for software development, but were not involved in detailed data protection discussions, which were handled by the official data protection officer. Each of the IT specialists involved is aware of the necessary prerequisites to ensure data protection. They may need to establish a specific framework to effectively integrate SurPass data and comply with data protection standards. It remains imperative for all centres to have a data protection solution in place, as compliance with GDPR and national requirements for data protection and privacy is an essential prerequisite for the successful implementation of SurPass in all health system scenarios. Data encryption, pseudonymization, and multi-factor authentication - a security process in which a user provides two or more authentication factors to verify their identity before accessing a protected resource or system - could form appropriate data protection measures for all health system scenarios.

The insights gained from SurPass implementation have broader applicability, offering valuable lessons for the introduction of similar eHealth solutions in various healthcare settings. SurPass serves as a practical example illustrating the integration of digital health tools into existing EHIS systems, and the application of the FVM framework provides essential technological considerations for implementing such solutions beyond the SurPass context. In addition, our study is of strategic importance in light of the upcoming European Health Data Space (EHDS) regulation, which refines the GDPR and requires electronic health systems to be able to exchange data in the European Electronic Health Record Exchange Format [37]. SurPass has many common elements with the IPS, which is one of the priority data categories in the EHDS regulation. In light of this, our study, despite its specific focus, sheds light on some of the hurdles of digital transformation in Europe as it explores the health data economy in realistic care pathways. As such, SurPass lays the groundwork for pragmatic adoption of key regulations and upcoming directives such as the EHDS, the Medical Device Directive and the Artificial Intelligence Act [37-39].

Limitations

Limitations of this study include missing data from Austria regarding accessibility of data systems and availability of patient data, and inconsistent or uncertain responses within individual centers. This may be due to the fact that SurPass is a newly developed tool and many IT specialists were unfamiliar with SurPass and its requirements. In addition, there were many unknown responses from German centers regarding information system sources, which may be attributed to the complexity of the IT systems in place and the lack of involvement of German IT specialists in detailed discussions on data protection. We therefore acknowledge that the overview of computing infrastructures and IT landscapes across the six centers may be incomplete. Furthermore, the number of IT specialists participating in this study may appear relatively small. The selection process was based on their direct involvement in the project to ensure a relevant perspective on the SurPass implementation. The study design including one center per country was based on resource allocation and practical considerations, as outlined in the PCSP project agreement. Despite initially inviting IT specialists from each of the six participating centers (n=20), only 13 provided complete responses. This limited participation reflects the challenges of understaffed and less engaged hospital IT departments across Europe. We acknowledge the potential for selection bias, as their individual expertise was not systematically assessed. However, it is important to note that after analyzing the survey results, we conducted a thorough verification of the IT specialists' responses with all participating centers. While we recognize the study's limitations, we emphasize that our findings are of substantial value in shaping an effective implementation strategy for SurPass in all three health system scenarios. To facilitate wider adoption of SurPass, we plan to publish an implementation toolkit at the end of the PCSP project.

Conclusions

This paper described the findings from an online survey study that assessed IT-related barriers and facilitators to SurPass implementation in three European health system scenarios, that is nationally based EHIS or EHR (Austria, Lithuania); institutional/regional EHIS or EHR (Italy, Spain); and national cancer registries and hospital-based EHIS or EHR (Germany, Belgium). In all scenarios, barriers and facilitators were related to three main challenges including (semi-)automated data input, interoperability, and data protection/privacy and cybersecurity. For all scenarios, we recommend the adoption of HL7 FHIR to support interoperability. In addition, we emphasize the importance of GDPR compliance in all scenarios, such as using encryption, EUPID pseudonymization, and multi-factor authentication where applicable. Our results will support the SurPass implementation strategies for all three health system scenarios. Ultimately, SurPass implementation provides lessons for introducing similar eHealth solutions across diverse healthcare settings, offering practical insights into integrating digital health solutions into existing and future EHIS systems and paving the way for the pragmatic adoption of key regulations such as the EHDS, the Medical Device Directive and the Artificial Intelligence Act.

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Author contributions

All authors contributed to the conception and design of this study and design of the surveys. Ethical approvals were obtained and data were collected by authors affiliated with the six participating institutions. Data were analyzed by Ismay A. E. de Beijer, Selina R. van den Oever, Leontien C. M. Kremer, Helena J. H. van der Pal, Saskia M. F. Pluijm, Catherine Chronaki and Eliana Charalambous, and results were interpreted by all authors. The manuscript was drafted by Ismay A. E. de Beijer and critically revised by all authors. All authors approved the final version of this manuscript.

Data availability

Study participants did not consent to data sharing outside the PanCareSurPass project. Access to participant data is therefore limited to national and international supervisory authorities. Upon request, the study protocol can be made available (please send an email to i.a.e.debeijer-3@prinsesmaximacentrum.nl).

Ethics approval

Ethical review board or institutional approvals were required and obtained in Belgium (Ethics Committee Research UZ Leuven), Italy (Comitato Etico Regionale della Liguria), Germany (Ethik-Komission Universität zu Lübeck) and Spain (Comité de Ética de la Investigación con medicamentos). Institutional approval for pseudonymised data collection, analysis and storage was granted by the Princess Máxima Center, the Netherlands (Clinical Research Committee Princess Máxima Center). This study was performed in line with the principles of the Declaration of Helsinki.

Consent to participate

Written informed consent was obtained from all participants included in this study.

Consent to publish

All responses to the survey were pseudonymized. Participants were informed that by participating in this study, they consent to publication of their pseudonymized responses.

Conflicts of Interest

None declared.

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Abbreviations

CCSs	Childhood cancer survivors
CDA	Clinical document architecture
EDHS	European Health Data Space
EHIS	Electronic health information system
EHR	Electronic health record
FHIR	Fast healthcare interoperability resources
FVM	Fit-Viability model
GDPR	General data protection regulation
HCP	Healthcare provider
HDE	Health data exchange
HL7	Health Level Seven
IPS	International Patient Summary
LTFU	Long-term follow-up
PCSP	PanCareSurPass
SCP	Survivorship care plan
SurPass	Survivorship Passport

Supplementary Files

Multimedia Appendixes

PanCareSurPass Consortium members.
URL: http://asset.jmir.pub/assets/154bbf63e2b8f26511d91fe072fea228.pdf

Full Survey.
URL: http://asset.jmir.pub/assets/aa976e0173055bc29f91e8b3206ab10f.pdf