

# **G7 International Patient Summary** Roadmap

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# 1. Purpose of this report

This International Patient Summary roadmap (G7-IPS) supports the G7 commitment to deliver on the rights of patients to have access to their health information, and through using open and interoperable standards it enables this information to be used at the point of treatment or care.

The roadmap outlines the component parts required for implementation and the standards which will be used to ensure alignment and interoperability across the G7 community. Although developed by the G7 countries, other countries, should they wish to, will be able to adopt the same principles and use the open and interoperable resources.

# 1.1. Summary

The G7 Health Communique makes commitments on collaboration on several health initiatives, including a commitment to develop internationally shared principles for enabling patient access to health data, based on the principle of informed explicit consent or patient permission.

The G7 countries agreed five principles and ambitions that describe the desired direction of travel for increasing patient access to records as a means of patients taking more responsibility for and control of their own health and care. These are:

- online access to records
- use of own information to manage their health
- patients contributing to their health record
- offer online access to health information by healthcare providers
- audit trail of who accessed the patient's record

The implementation of these principles in individual G7 countries will depend on local laws, healthcare structures and culture, but there is a genuine desire to make progress in this area for the benefit of patients, and to learn and get support from each other.

### 1.2. G7 commitment on digital health

The health ministers of the G7 countries met on <u>3-4 June in Oxford and signed a communiqué</u> agreeing to collaborate on four health track themes. Ministers made the following commitments on digital health:

Recognition of the importance of digital health solutions in transforming healthcare and of the need for appropriate data governance, system security, regulatory, and data protection standards in order to benefit from advances in digital health.

Commitment to working towards adopting a standardised minimum health dataset for patients' health information, including through the International Patient Summary (IPS) standard; developing internationally shared principles for enabling patient access to health data; and promoting the use of open standards for health data.

Recognition of the need for multilateral collaboration on a standards-based, minimum data set for COVID-19 testing and vaccination verification and commitment to work within existing WHO processes to develop this and to work as G7 countries towards a process of mutual acceptance of COVID-19 certificates.

Recognition that governance of artificial intelligence (AI) systems in the health sector must be strengthened in order to keep pace with technology development.

Commitment to working together to define and develop a shared understanding of phases for how we clinically evaluate health Al algorithms and develop and share best practices for benchmarking the suitability of a health Al algorithm developed in one G7 country for potential deployment in another.

#### 1.3. Patient access to health data

The following paragraph shows the full wording of the commitment:

38. We commit to work towards adopting a standardised minimum health dataset for patients' health information, including through the International Patient Summary (IPS) standard, with the shared objectives of facilitating health interoperability within and between countries, developing internationally shared principles for enabling patient access to health data, based on the principle of informed explicit consent or patient permission and in keeping with countries' and regional existing legislative frameworks; and facilitating and promoting the use of open standards for international health data to encourage the widest possible adoption of standards and greater interoperability. To achieve this goal, we will work with the Global Digital Health Partnership (GDHP) as they are already advancing IPS efforts.

# 2. Introduction

The G7-IPS Roadmap has been developed to enable countries to implement the components of IPS in a manageable way that fits in with their existing health economy, health technology and legal requirements.

It is not a one solution to fit all, rather a flexible and incremental approach which progresses from a small amount of information with limited user functionality, through to all the IPS data and the facility to transfer information between systems across national borders. To prevent the creation of parallel structures, the IPS Roadmap builds on previous approaches, such as the European work on electronic health records.

Our aim is to make a start and work incrementally towards an end point, using new and emerging technologies and ensuring that solutions meet the needs of patients and clinicians.

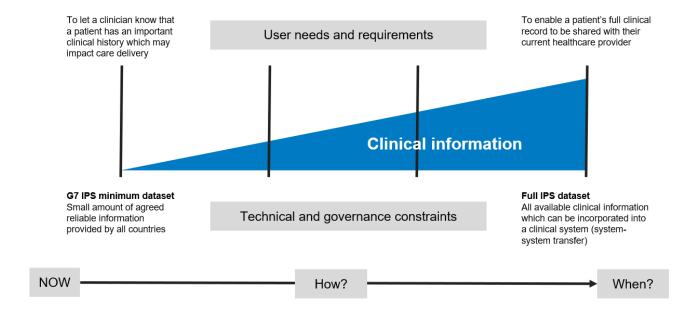


Figure 1: IPS implementation with incremental gains

# 3. Objective

At present, when a patient seeks care from a new clinician (particularly but not exclusively in a foreign country) there is no consistent way that the clinician can access relevant and potentially vital clinical information about the patient.

Currently, in many instances, this relies on the patient's memory. Adopting a structured and safe IPS record, and related service infrastructure will enable patients to access and share reliable information with their clinician.

#### Provision of information to clinicians during unplanned care

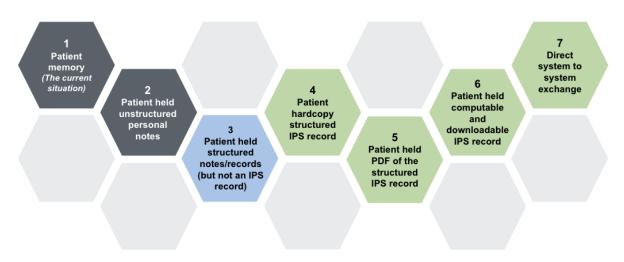


Figure 2 - how patients share their information with clinicians

The G7 health ministers agreed that through the implementation of IPS, information could be more complete and reliable. This would result in better healthcare experiences and outcomes for patients.

Figure 2 shows the different methods patients could share information with their clinician.

The first two options (grey hexagons) rely on the patient's memory and what they think is important for the clinician to know, this is likely to result in incomplete information for the clinician.

Some countries have the facility to provide their patients with access to their structured clinical records or notes (see option 3 - blue hexagon). These records may or may not be complete and may or may not originate from a single healthcare provider or sector.

Options four to eight (green hexagons) move the information provision and sharing into IPS, which provides both provenance and an understanding of which data items are

available. This could start with the patient physically showing the clinician a copy of their IPS record on their smartphone or passing them a printed copy (options 4 and 5). This progresses to the patient generating an access code, sharing it with their clinician and their clinician being able to view the information in their viewer, and potentially import this data to their clinical systems (option 6).

The final goal of IPS (option 7) is to enable system-to system transfer of information.

#### 3.2. ISO IPS ambitions

The <u>International Standards Organization</u> (ISO) maintains and publishes the international patient summary (IPS) standard for the dataset.

<u>ISO IPS</u> was originally designed to be used in 'unplanned, cross-border care'. It consists of a minimal and non-exhaustive dataset. However, it is recognised that the ISO IPS information will be beneficial to planned care.

The ISO IPS is an ecosystem of standards emerging from collaboration across multiple standards development organizations (SDOs), including <a href="Health Level 7 International">Health Level 7 International</a> (HL7), the <a href="European Committee for Standardisation">European Committee for Standardisation</a> (CEN), <a href="Integrating the Healthcare">Integrating the Healthcare</a> <a href="Enterprise">Enterprise</a> (IHE), <a href="International Standards Organization">Integrating the Healthcare</a> <a href="Enterprise">Enterprise</a> (IHE), <a href="International Standards Organization">Integrating the Healthcare</a> <a href="Enterprise">Enterprise</a> (IHE), <a href="International Standards Organization">Integrating the Healthcare</a> <a href="Integrational SNOMED International">International</a>. <a href="Integrational SNOMED International">International</a>. <a href="Integrational SNOMED International SNOMED International">International</a>. <a href="Integrational SNOMED International SNOMED I

The ISO IPS standard is not an implementation guide and does not address jurisdictional concerns. It does not address directives, formats, terminologies, and classifications. However, HL7 has published an implementation guide of the IPS using the <a href="#Fast">Fast</a> <a href="#Healthcare Interoperability Resources">Healthcare Interoperability Resources</a> (FHIR) standard. This publication was first published in 2020 and includes examples of how the IPS could be constructed using common vocabularies and terminologies. Additional information is available on the <a href="#HL7">HL7</a> IPS FHIR Implementation guide and through the HL7 website.

Further information is also available on the **ISO** website.

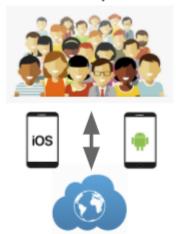
# 4. G7-IPS principles

A series of principles were agreed which have informed the development of the G7-IPS model and the G7-IPS roadmap:

- 1. Each country will develop their own IPS which meets the G7-IPS standards and requirements.
- 2. Each country's G7-IPS will conform to their own legislature and governance requirements.
- 3. Patients control access to their information in the G7-IPS data point(s).
- 4. G7-IPS data is personal identifiable information which will be uploaded or collated in real time, for the patient to view and share.
- 5. Print and non-editable file download (i.e. pdf) options will be available to patients.
- 6. A patient mediated IPS data point facilitates the sharing of clinical information for direct patient care.
- 7. Patients will be informed how their G7-IPS information will be used before they agree to the use of their data.
- 8. Creation of a person's IPS record will not depend on a person's registration within a country's health system.
- 9. The G7-IPS will contain human readable and computer processable data.
- 10. This is a digital first service and requires setting up by the user (or their authorised representative) on a computer or via an app.

# 5. G7-IPS model

# Individual patients



# Multiple IPS data points - linked to multiple sources

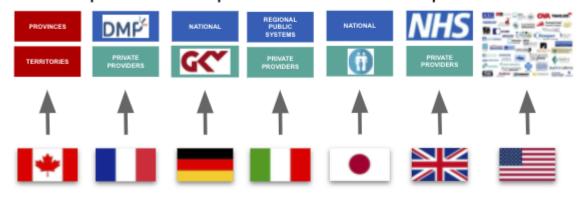


Figure 3: G7-IPS model

The G7-IPS model emphasises the following attributes:

- each country determines how IPS will be implemented for them. They determine their data access model for their data point(s)
- all patients hold and share access to their own data
- each country has its own IPS data point(s); these could be one per country or multiple to reflect their healthcare provision and infrastructure
- they (or their delegated organisations) determine the information which will be made available via their IPS account

- they manage access to it
- they make sure it complies with their national laws and governance

### 5.1. Individual patients

The approach used for access to the IPS data point(s) is patient mediated exchange. This means that the patient is responsible for deciding who their information will be shared with and for the physical act of sharing it.

Patients will open their IPS account, unless it is automatically provided to them, and this will provide them with access to their information and the functionality to share it.

At all times, patients can access their own data and control access to it by others.

For further information about patient access and the roles and responsibilities in managing patient clinical information please refer to the 'patient access report'

### 5.2. National IPS data points and uploads

Each G7 country has its own IPS data point(s), for countries such as Canada, the USA and the UK due to the devolved nature of their healthcare system each data point(s) may be at a sub-national rather than national level, in the USA this could be at state or organisational level. This could be a physical data store or a way of gathering information, using APIs or similar functionality, to collate the patient's information when they access IPS.

Each country develops and implements a <u>FHIR</u> and <u>ISO 27269:2021</u> compliant data model for their data point(s). This is essential as each healthcare system and the source(s) of information differ, so bespoke functionality will be required.

The UK has produced two proof of concept prototypes using different technologies and approaches, which can be further developed.

# 5.3. Sub-national jurisdictions

Canada has 13 provinces and territories, the USA has 50 states, and the UK has four home nations. In these countries developing a single national IPS data point(s) may neither be possible nor desirable. Nevertheless, the portability of data across these internal borders will improve care, accessibility, and choice for the public.

For some G7 countries, using IPS FHIR standards will be an effective way to share information across their sub-national borders. However, other countries, such as the USA with their <u>Consolidated Clinical Document Architecture</u> (C-CDA), have established processes for information sharing, and it is expected that they will continue to use these.

The G7-IPS roadmap has built-in flexibility to enable countries to adapt implementation to work within their own healthcare environments and facilitate the sharing of patient information across these sub-national jurisdictions.

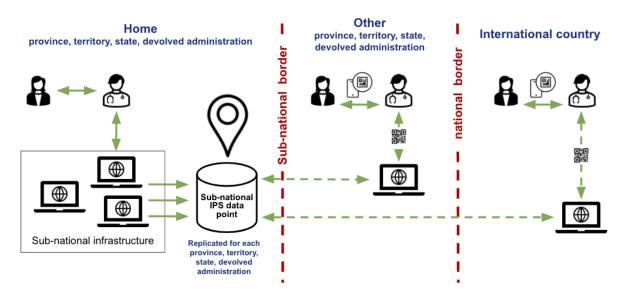


Figure 4: Example - sub-national G7-IPS model

#### 5.4. Data

Each G7 country will upload a minimum dataset of information, consisting of patient demographics, allergies and intolerances, immunisations and vaccinations, current medication and health problems. This dataset

- has been developed based on the needs of clinicians and patients and includes the most commonly used clinical information
- has considered the complexities associated with consistency of data recording across different countries' healthcare systems
- has the ability to be presented in a human readable format

Each G7 country will determine their schedule for uploading additional data blocks. This phased approach will enable each country to add more data when they are able to, but not exclude them from participating in the G7-IPS initiative.

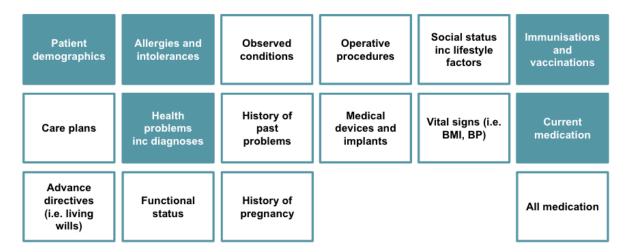


Figure 5: ISO 27269:2021 IPS data blocks

The data must be in a <u>FHIR</u> and <u>ISO 27269:2021</u> compliant format to support the presentation of information to patients and clinicians, and for future data transfer.

#### Recommendation

It is essential that users understand the context of any empty data field and whether that means there is no clinical history or that a country is not providing it. As such, all empty data blocks and items must indicate whether

The information is not included in the country's IPS upload

There is no clinical information in the patient's record

### 5.5. Terminology and language translation

### 5.5.1 Coded terminology and classification

The datasets specify the type and format of information to be included in the IPS, but do not specify the terminologies or classifications to be used. However, preferred terminology bindings are documented in the FHIR IPS standard.

At present, there is no single common coded terminology or classification in use across the G7 countries, in all their clinical systems. This complicates the transfer and use of information.

#### 5.5.1.1. Clinical information

Agreeing a common recording standard has been under discussion for some time. The <u>Global Digital Health Partnership</u> (GDHP) encourages the use of <u>SNOMED CT</u> or its subset <u>SNOMED GPS</u> terminologies for information transfer. This is under discussion among the GDHP members with a final path to be determined.

Although all G7 countries have SNOMED CT licences, this terminology is not consistently used in all clinical information systems. Neither is it universally in use across devolved jurisdictions in some countries. Timescales for the universal adoption of SNOMED CT are in years, so a solution facilitating the use of information from multiple terminologies and classifications is necessary.

The ISO IPS and FHIR standards enable each data item to have more than one allowable input format, so for a diagnosis, acceptable inputs could be SNOMED CT, SNOMED GPS, ICD-10 and/or ICD-11.

#### 5.5.1.2. Medication

The issue is further complicated with the recording of medications. There are multiple classifications, terminologies and standards in use, and different regulations around prescribing within countries. However, the primary purpose for sharing information about medications is so that the clinician treating the patient has a full list of prescribed medications at the point of care. It is NOT so they can automatically re-prescribe. Any required prescriptions will be made using their own clinical system.

#### Recommendation

The use of a common coding standard would undoubtedly make the transfer of information easier.

We recommend that the G7 countries consider the practicalities, cost and timescales involved in this ambition, against the benefits which would be derived, including safer patient care, from achieving this.

### 5.5.2. Language translation

It is agreed that the best option is for the patient and clinician to access any information in their preferred language. It would be advantageous to include this in the user IPS viewer.

Societally we are familiar with translation tools in internet browsers, however accuracy rates vary, and important nuances may be lost.

Coding terminologies and classifications are often provided in multiple languages. The World Health Organisation supports 42 languages for its ICD classification. SNOMED international publishes SNOMED CT and GPS in US English, UK English, and Spanish. In 2018, a SNOMED CT Starter set (6,300 concepts) was translated into French, German and Chinese. Canada leads the French international effort for a Common French set that is made available to other countries. Other translations have been achieved by member countries in, Spanish, Danish and Swedish, German, Dutch, Estonian, Lithuanian, Norwegian. However, additional language versions have been developed by member nations.

#### Recommendation

Where a translation is provided the original text must be included alongside it.

Where available, the code description or rubric should be offered in the user's preferred language.

Computer-based language translation technologies are becoming increasingly sophisticated and are in frequent use in daily life through a variety of cloud-based voice services.

Where existing translations are not available, we recommend that these are reviewed and assessed prior to any use in production systems, and when they are suitably capable that they are adopted into the IPS to enable the user to access information in their preferred language, where this is available. Written and spoken approved translations should be available to the user.

#### 5.6. Access

Each G7 country will manage patient access to their national IPS data point(s). The country is also responsible for verifying patients' identities and ensuring that access to their IPS data point(s) is safe and secure.

#### **England and Wales example**

NHS England has developed identity checking services for both clinicians and patients

NHS login allows English and Welsh patients to access health and care websites and apps with a single set of login credentials. The patient can securely access many digital health and care services with one email address and password.

NHS Care Identity Service 2 is a secure authentication service used by health and care professionals in England to access national clinical information systems.

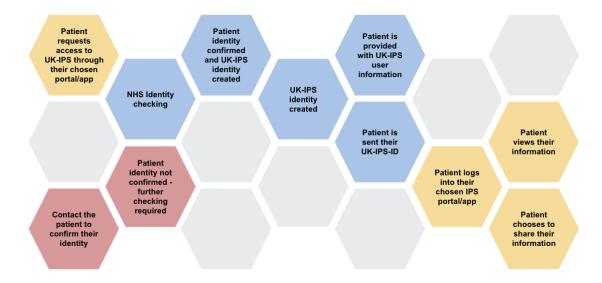


Figure 6: Example - patient journey and verification pathway

#### 5.7. International standards

Refer to the G7 Open standards and interoperability report.

#### 5.7.1. International IPS standards

Implementation of the <u>IPS standard ISO 27269:2021</u> | Health informatics - International Patient Summary. Produced by the <u>ISO/TC 215</u> Health informatics technical committee.

#### HL7-FHIR R4

#### **HL7-FHIR IPS**

<u>ISO 9241-210</u> | Ergonomics of human-system interaction — Part 210: Human-centred design for interactive systems produced by the <u>ISO/TC 159/SC 4</u> Ergonomics of human-system interaction

### 5.8. Legislation and governance

Each G7 country, and in some instances their sub-national jurisdictions such as provinces, territories, states, or home nations, have their own legislation and information governance requirements. Each must ensure their IPS complies with these.

#### 5.8.1. Data for direct patient care

Principle 6\_states that the information generated by an IPS data point(s) is intended for direct patient care. Principle 7 ensures that all patients know how their information is being used, with Principle 3 ensuring that the patient controls access to their own information. Adhering to these principles ensures that patients have the information they need to understand how their information will be used by the clinician and decide whether to share it or not.

It is essential that the information gathered into an IPS data point(s) is not confused with the local clinical information system from which the data was uploaded. These systems will continue to be used as per their original purpose, which may include for planning and research.

#### **G7** variations

France, Germany, Italy and the UK use the General Data Protection Regulation (GDPR) as the foundation of their information governance and patient rights to their clinical information. These are detailed and specify how their citizens' information is kept confidential and how it can be used, processed and stored.

Canada, Japan and the USA have different legislation which does not seamlessly dovetail with GDPR. These legislations will impact on the system-to-system cross-border transfer of information

#### Recommendation

Before G7 countries agree to using information from an IPS data point for anything other than direct patient care, information governance regulations must be addressed.

The Trillium Bridge Project assessed the differences between the EU and USA.

# 5.8.2. G7-IPS information use - informing the patient

Principle 7 enshrines the importance of patients understanding how their information will and will not be used by the individual and the organisation they are considering sharing it with. Importantly, the patient will need to choose whether or not to go ahead and share their information.

# 6. Data access and transfer

ISO IPS was developed to support the exchange of clinical information between healthcare systems and across international borders. Technically this is complex, but a greater hurdle is information governance. For example, the UK and EU countries have strict governance requirements on where information can be stored, how it must be stored and the security around this. However, different regulations are in place in Canada, Japan, and the USA.

# 6.1. Patient mediated exchange

To enable the G7-IPS to work the patient will be in control of their own healthcare data and will have the ability to securely share their data. This makes the data management in IPS the responsibility of the patient and not the originating healthcare provider. This aligns with the GDHP approach.

In the simplest format this could be through showing and sharing information on a smart device (phone or tablet), or the patient printing a copy of their record and handing it over to a healthcare professional in a human readable format.

The roadmap includes the adoption of technical solutions, such as the patient generating a 2D Barcode and sharing this with clinician(s), which will enable the clinician to view the patient's information in a clinical viewer which could be standalone or part of the clinical system they use. Ultimately information could be transferred directly between systems (see below).

This approach enables the clinicians treating a foreign national patient to view the clinical information they need to provide safer care and improve the experience of the foreign national patient. It also provides the patient with the opportunity to share information about their treatment abroad with their regular clinicians when they return home.

### 6.2. Access to view read-only or fixed copy information

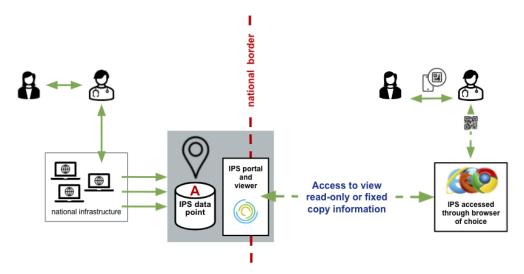


Figure 7: Access to view read-only or fixed copy information

In this scenario there is no transfer of information between systems. The patient authorises the clinician to access read-only information and uses a one-time passcode or QR code to enable this.

Using web browser functionality, the clinician can access the patient's information through an IPS portal and viewer, which is linked to the IPS data points.

# 6.3. Transfer of information from IPS data point to clinical system

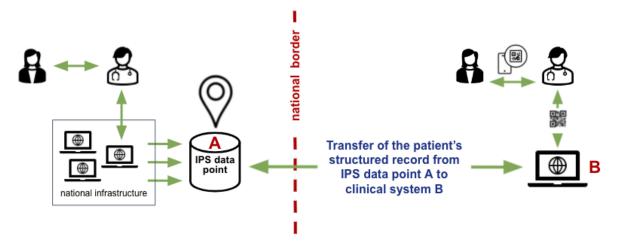


Figure 8: Transfer of a structured record from IPS data point A to clinical system B

In this scenario the system-to-system transfer of information takes place. As with the previous access to read-only information scenario, the patient is the person that gives permission to the clinician to access their record.

If the clinician is using a clinical system which is recognised and meets national governance and security standards, they will be able to request a download of the patient's IPS record into that system.

As the system is an authorised part of the G7-IPS ecosystem, and the clinician is an authorised user of the system, this will constitute the identity verification of the clinician.

The GDHP is involved with the testing of data exchange using the FHIR IPS standard, which could be used in system-to-system exchange.

Before a system-to-system exchange can happen, the complex cross-border governance issues must be resolved. Patient mediated exchange could still be used to grant access to a record, but there will still be data ownership and processing governance issues to be addressed.

There may be fewer governance issues where the data exchange is across sub-national boundaries in a single country, or where a community has common standards such as the EU with its member states are signed-up to the <u>General Data Protection Regulation</u> (GDPR) protocol.

#### MyHealth@EU data processing example

The EU member states are implementing MyHealth@EU which transfers information between countries using <u>eHDSI</u>. All countries are expected to have implemented it by 2025.

Each country has a National Contact Point which aggregates the information from its provider systems and cross references the codes, where necessary, into the codes specified in the Master ValueSet Catalogue. Translation is through using the code set descriptions into the preferred language. Translation for free text is not available.

The Master ValueSet Catalogue currently specifies <u>SNOMED CT</u>, <u>WHO ICD-10</u>, <u>WHO ATC</u>, <u>EDQM</u>, <u>UCUM</u>, <u>LOINC</u>, <u>HL7</u>, <u>ISO 3166</u>, <u>ISO 639-1</u>, <u>ISCO</u>.

Each country clearly defines the legal basis, and informs its patients, and the methods and principles for the processing and transferring of information for direct patient care.

When a patient needs to be treated in another member state, their information can be requested from the NCP from each country of affiliation. The information can be cross-referenced to local standards and translated into the local language.

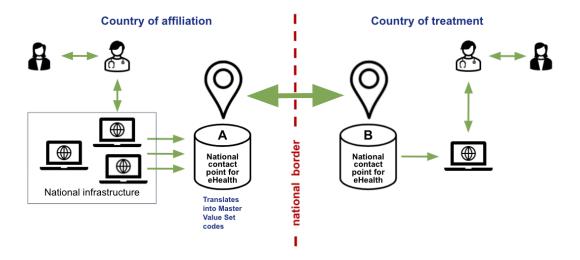


Figure 9: MyHealth @EU - Data transfer between EU member states

#### UK use case

The UK has committed to separating data from the user systems. In effect, having a single information source accessed by the multiple systems used by the health care providers. This will mean that all healthcare providers will have access to and maintain a single comprehensive health record for individual patients.

#### Recommendation

The G7 countries agree on a common governance standard or arrangement for sharing IPS data.

FHIR and ISO IPS standards must be adhered to when developing a single IPS data point.

Transfer of information between systems is both technically complex and legally challenging. The G7 countries should consider the viability of developing and enabling international read-write access to a single and complete patient record via IPS.

# 7. Roadmap

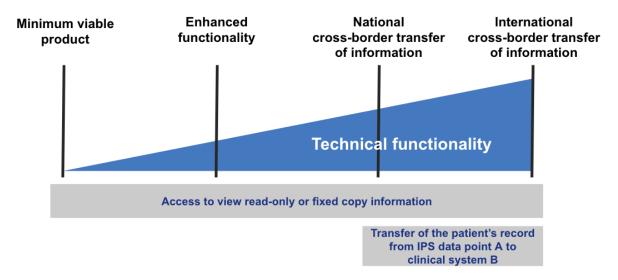


Figure 10: Roadmap - technical functionality

The roadmap is a collection of elements which represent the political, data and technological requirements to implement the G7-IPS and support the sharing of patient information across national and international borders.

As outlined in the introduction the process will start with some technical functionality and some data (G7-IPS minimum dataset). This is the minimum viable product that must be implemented. Each country or jurisdiction can implement additional technical features and increase the amount of data available in their own time.

#### 7.1. File structure

Using the latest <u>ISO IPS FHIR standards</u> (currently using FHIR R4), each country will need to share the complete ISO IPS dataset. However, for data items which they are not sharing, they must state this. This ensures that the clinician treating the patient has full understanding of the limits to the information they have available to them.

#### 7.2. Patient identifiers

G7-IPS data point(s) will develop its own mechanism for identifying patients in it. Most countries have a combination of healthcare providers, it is highly unlikely that the mix of public funded and private healthcare will have a single unified patient identifier.

ISO IPS FHIR has a patient identifier standard, which we expect to be implemented in their IPS data point(s) to ensure individual patients have globally unique identifiers.

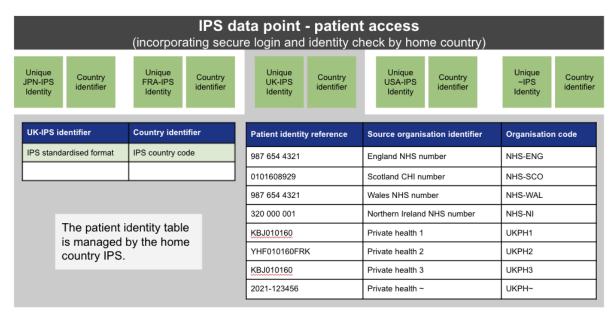


Figure 11: Example - patient identifier mapping

# 7.3. Roadmap groups

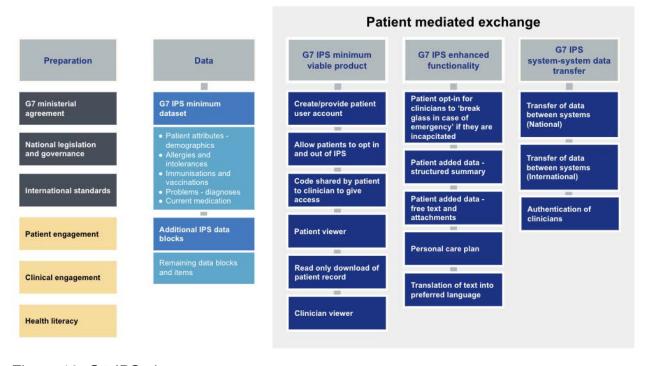


Figure 12: G7-IPS elements

# 7.4. Preparation

Objective	Governmental agreement to implement the G7-IPS roadmap.
Data	See the sections on <u>Data</u> <u>Data items</u>
International standards	ISO 27269:2021   Health informatics - International Patient Summary.  HL7-FHIR R4  ISO 9241-210   Ergonomics of human-system interaction - Part 210:  Human-centred design for interactive system.
Technical features	Each country's health service and its supporting infrastructure is different.  Transfer of information must align with the international ISO IPS Data and ISO IPS FHIR standards. Each country will need to develop a process (where necessary) to align and transmit data using these standards. This could be through embedding these standards and/or updating their systems to IPS/FHIR or translating and mapping data to match the IPS/FHIR standards.  It is recommended that these systems are Internet facing and are API driven architectures to allow the interoperability of the country's IPS.
Best practice	Patient engagement User centred design Improving health literacy
Governance	Factoring a country's governance requirements, which may include international requirements i.e. GDPR, that must be followed with regards to data recording and sharing and patient access to information.
User experience	User requirements must be considered (patient and Healthcare worker) as part of the development. Each country should consider how best to engage with both clinical and patient use of IPS.
Implementation deadline	31 December 2021
Notes	Each country is to develop their own implementation roadmap and timescales. In addition to international standards, each country may have standards which they will need to conform to. These should be identified at this point. Which terminologies and classifications will be used should be identified at this point.

# 7.5. Data items

For further information see the section on <a href="Data">Data</a>.

# 7.5.1. G7-IPS minimum dataset

Objective	All the remaining data blocks and items as listed in the <u>ISO</u> <u>27269:2021</u> IPS specification.
Data blocks	Patient attributes - demographics Allergies and intolerances (inc. adverse reactions) Immunisations and vaccinations (see note) Problems - diagnoses Current medications
International standards	ISO 27269:2021   Health informatics - International Patient Summary. HL7-FHIR R4
Technical features	All available data is to conform to the FHIR version 4 standard.
Implementation deadline	To be confirmed, but in line with the G7-IPS minimum viable product
Notes	Immunisations and vaccinations are not mandatory items in the <a href="ISO 27269:2021">ISO 27269:2021</a> IPS specification. However, because of the COVID-19 coronavirus pandemic, this was specifically included in scope by the G7 countries health ministers.

# 7.5.1. Additional IPS data blocks

Objective	All the remaining data blocks and items as listed in the <a href="SO">ISO</a> <a href="27269:2021">27269:2021</a> IPS specification.
Data blocks	Observed conditions History of past problems History of pregnancy Operative procedures Medical devices and implants Social status inc. lifestyle factors Vital signs All medications Care plans Advance directives
International standards	ISO 27269:2021   Health informatics - International Patient Summary. HL7-FHIR R4
Technical features	All available data to conform to the FHIR R4 standard.
Implementation deadline	To be confirmed.

#### 7.5.3. Non-ISO-IPS data items

These data items are not a standard part of the <u>ISO 27269:2021</u> IPS specification. However, there is flexibility within the technical structure to accommodate these requirements.

Objective	Additional information which patients consider of great value and would not usually be recorded in their clinical record, but which they would want to share with any clinician treating them. For example: hard of hearing but can lip-read; will not accept blood transfusions on religious grounds
Data blocks	Patient added information Detailed care plans
International standards	ISO 27269:2021   Health informatics - International Patient Summary. HL7-FHIR R4
Technical features	See <u>patient added data - structured summary</u> and <u>patient added data - free text and attachments</u> .  All available data is to conform to the FHIR version 4 standard.  Facility to add and store patient-added information, which could be in summary form (picking lists), free text, and/or attachments.
User experience	To enable patients to actively participate and inform clinicians of their care needs and other requirements.
Implementation deadline	To be confirmed.
Notes	This functionality was high on the wish list of the NHS England patient co-production group. Lived personal experience had resulted in optimal care not being provided as this information was not readily available. For example, a patient being taken to a hospital which did not have the facilities to reset his pacemaker, when he could have been taken directly to the one which could if this information had been known.

#### 7.5.4. Medication

Medications are prescribed and recorded in a variety of ways in each of the G7 countries. There is no international 'language' for medication. This makes the sharing and exchange of information between clinical systems and countries extremely complex.

However, G7-IPS records are a conduit to inform clinicians of which medication(s) a patient is or has taken, rather than the G7-IPS system enabling clinicians to reissue or repeat prescribe; they will continue to do this in their native clinical system.

Objective	To provide access to a list of current and historically prescribed medication for the patient.
Data	Prescribed medication which a patient is currently taking on a regular basis or when it is needed.
International standards	ISO 27269:2021   Health informatics - International Patient Summary. HL7-FHIR R4
Technical features	All available data is to conform to the FHIR version 4 standard. Prescribed medication and dosage is required as a minimum.
Governance	Due to the complexity and difference in the way each country prescribes and records prescriptions, the G7-IPS infrastructure is not suitable for the reissue or repeat prescription of medications.
User experience	Patient - list of medication they have been prescribed. Clinician - List of prescribed medication which they can use to inform treatment decisions.
Implementation deadline	To be confirmed.
Notes	There is no international language for medication. The EU are developing and implementing ISO Identification of Medicinal Products (IDMP) which aligns to the WHO International Nonproprietary Names (INNs) for pharmaceutical substances.

# 7.6. G7-IPS minimum viable product

The G7-IPS minimum viable product is the basic functionality which will enable G7-IPS interoperability and for a patient's clinical history to be available at the point of care, in any G7 country.

The minimum viable product providing access to the G7-IPS minimum dataset is the starting point. For all benefits to be achieved, enhanced functionality and system-to-system transfer of information should be implemented.

# 7.6.1. Create/provide patient user account

Objective	Create or reuse an existing account which will enable the patient to access their record(s) in G7-IPS infrastructure.
Technical features	Create user account (unless provided automatically) Authenticate the user (best practice)
International standards	ISO 27269:2021   Health informatics - International Patient Summary.

Objective	Create or reuse an existing account which will enable the patient to access their record(s) in G7-IPS infrastructure.
	HL7-FHIR R4 ISO 9241-210   Ergonomics of human-system interaction - Part 210: Human-centred design for interactive system.
Governance	There is no international standard for cyber security. Each country will use their own.
User experience	A simple failsafe mechanism for patients to open/setup their account and access their G7-IPS clinical information.
Implementation deadline	To be confirmed.

# 7.6.2. Allow patients to opt in and out of IPS

Objective	Patients must be able to join and leave IPS in a straightforward simple way.
Technical features	Allow users to opt in/out of using the G7-IPS infrastructure, including closing and completely removing their account.
International standards	ISO 27269:2021   Health informatics - International Patient Summary.  ISO 9241-210   Ergonomics of human-system interaction - Part 210: Human-centred design for interactive system.
Governance	There is no international standard for cyber security. Each country will use their own.
User experience	Allow user to opt-in/opt-out to the IPS Single viewer demonstrating how coded and free text information could look in IPS
Implementation deadline	To be confirmed.

# 7.6.3. Access code sharing - patient to clinician

Objective	For the patient to share an access code with the clinician, enabling them to access the patient's IPS record.
Technical features	Create 2D Barcode for data access One Time Passcodes (OTP) Printout of 2d (QR) barcode for non-smartphone users
International standards	ISO 27269:2021   Health informatics - International Patient Summary. HL7-FHIR R4

Objective	For the patient to share an access code with the clinician, enabling them to access the patient's IPS record.
	ISO 9241-210   Ergonomics of human-system interaction - Part 210: Human-centred design for interactive system.
Governance	There is not an international standard for cyber security. Each country will use their own.
User experience	Simple user interface to produce access code.  OTP sent by standard message allowing those without a smartphone to access it.  Clinicians to be able to access record using either the alphanumeric code or the 2d (QR) barcode.
Implementation deadline	To be confirmed.

# 7.6.4. Patient viewer

Objective	A simple viewer which presents clinical information in a structured way, which supports the patient to understand the information in their record.
Technical features	Open account Access account Close account View clinical information in a structured format Manage user preferences Create and revoke access codes Download a date stamped read-only copy of their record (see read only download of patient record)
Data	See the section on data items.
International standards	ISO 27269:2021   Health informatics - International Patient Summary.  ISO 9241-210   Ergonomics of human-system interaction - Part 210: Human-centred design for interactive system.
Governance	There is not an international standard for cyber security. Each country will use their own.
User experience	Allow the patient to opt-in/opt-out to the IPS Manage their G7-IPS preferences View their clinical information in a structure way
Implementation deadline	To be confirmed.

# 7.6.5. Read only download of patient record

Objective	To enable the patient and the clinician to download a fixed, non-editable copy of the patient's record. This could be printed or in electronic format.
Technical features	Print a date stamped copy of the patient's IPS record Download patient's IPS record as a date stamped read-only print file.
Data	See the section on data items.
International standards	ISO 27269:2021   Health informatics - International Patient Summary.  ISO 9241-210   Ergonomics of human-system interaction - Part 210: Human-centred design for interactive system.
Governance	There is not an international standard for cyber security. Each country will use their own.
User experience	Patients can 'carry' their clinical information in a format that is most suitable for them. Clinicians can upload this into their clinical system where functionality is available.
Implementation deadline	To be confirmed.
Notes	Having the functionality to make a physical copy of the record, enables patients who do not have smartphones or do not have internet connectivity to share their clinical record when required.

# 7.6.6. Clinician viewer

Objective	A simple viewer which presents clinical information in a structured way, which supports the patient to understand the information in their record.
Technical features	Provide access to a patient's IPS record using access code and one-time passwords (OTP) Present data in a structured viewer Break glass in case of emergency functionality
Data	See the section on data items.
International standards	ISO 27269:2021   Health informatics - International Patient Summary.  ISO 9241-210   Ergonomics of human-system interaction - Part 210: Human-centred design for interactive system.
Governance	There is no international standard for cyber security. Each country will use their own.

Objective	A simple viewer which presents clinical information in a structured way, which supports the patient to understand the information in their record.
User experience	Data presented in a structured viewer allowing ease and speed of access to relevant information during a consultation.
Implementation deadline	To be confirmed.
Notes	Data views for the clinician 'Break glass in case of emergency' access for clinicians

# 7.7. G7-IPS enhanced functionality

The enhanced functionality lists elements which will improve the user experience of both patients and clinicians.

# 7.7.1. 'Break glass in case of emergency' access for clinicians

Objective	IPS will be an opt-in model with the patient being responsible for giving permission for a clinician to access their international patient summary record. If a patient is unconscious, they will not be able to give that permission. This break-glass function will enable a clinician to access the patient's G7-IPS record providing the patient is identifiable and has opted-in sharing a G7-IPS record. This access will only be available on clinical systems linked to the national infrastructure, with appropriate safeguards.
International standards	None
Technical features	Patient As part of the patient IPS sign up process the break-glass option will be explained, and they will select either "allow break-glass access" or "do not allow access and keep the record sealed".  Clinician Break-glass option for clinicians which uses the patient preferences.
Best practice	Ensure that patients retain control of their IPS record. Ensure that clinicians can access information for treatment where permission has been granted.
Governance	Each country will have their own rules for patient and clinician access to records, these must be adhered to by default.
User experience	Test the functionality and how easy it is to use in a range of clinical

Objective	IPS will be an opt-in model with the patient being responsible for giving permission for a clinician to access their international patient summary record.  If a patient is unconscious, they will not be able to give that permission.  This break-glass function will enable a clinician to access the patient's G7-IPS record providing the patient is identifiable and has opted-in sharing a G7-IPS record.  This access will only be available on clinical systems linked to the national infrastructure, with appropriate safeguards.
	settings.
Implementation deadline	Each G7 country will develop their own timescales.

# 7.7.2. Patient added data - structured summary

Objective	Discussions with patient groups have identified that there is some information, which is very important to the patient, but would not be routinely captured in a clinical record. This functionality will enable patients to record this.
Data	See <u>non-ISO IPS data items</u>
International standards	ISO 27269:2021   Health informatics - International Patient Summary.  HL7-FHIR R4 ISO 9241-210   Ergonomics of human-system interaction - Part 210:  Human-centred design for interactive system.  Also see recommendation.
Technical features	Facility to add and store patient added information in a structured format which could be in summary form (picking lists), free text, and/or attachments.
Best practice	User centred design.
Governance	Each country will have their own rules for patient and clinician access to records, these must be adhered to by default.
User experience	To enable patients to actively participate and inform clinicians of their care needs and other requirements.
Implementation deadline	Each G7 country will develop their own timescales.
Notes	This functionality was high on the wish list of the NHS England patient focus group. Lived personal experience had resulted in optimal care not being provided as this information was not readily available. For example, a patient being taken to a hospital which did not have the facilities to reset his pacemaker, when he could have been taken directly to the one which could if this information had been known.

#### 7.7.3. Patient added data - free text and attachments

Objective	Discussions with patient groups have identified that there is some information, which is very important to the patient, but would not be routinely captured in a clinical record. This functionality will enable patients to record this.
Data	Patient entered information; this could be free text or uploaded copies of documents, scans, x-rays etc. This could also include structured data from recommended and optional sections as outlined in ISO and FHIR IPS guidance which has not been developed in prior phases.
International standards	ISO 27269:2021   Health informatics - International Patient Summary.  HL7-FHIR R4 ISO 9241-210   Ergonomics of human-system interaction - Part 210:  Human-centred design for interactive system.  Also see recommendation.
Technical features	Structured format for patients to add information in and to make it easy for the clinician to use. Patient entered information; this could be free text or uploaded copies of documents, scans, x-rays etc.
Best practice	User centred design.
User experience	To enable patients to actively participate and inform clinicians of their care needs and other requirements.
Implementation deadline	Each G7 country will develop their own timescales.
Notes	This functionality was high on the wish list of the NHS England patient focus group. Lived personal experience had resulted in optimal care not being provided as this information was not readily available. For example, a patient being taken to a hospital which did not have the facilities to reset his pacemaker, when he could have been taken directly to the one which could if this information had been known.

#### Recommendation

FHIR and ISO IPS standards do not have a specification for patient added data. The G7 should make representation to ISO IPS and FHIR and request that a specification is added.

# 7.7.4. Personal care plan

Objective	Many patients with complex conditions have personal care plans. These are detailed documents and are relevant to both emergency and ongoing care.
Data	This is additional information, sometimes in free text, but could include data items from other ISO IPS data blocks. It does not completely align with the ISO IPS Plan of Care data block.
International standards	ISO 27269:2021   Health informatics - International Patient Summary.  HL7-FHIR R4 ISO 9241-210   Ergonomics of human-system interaction - Part 210: Human-centred design for interactive system. Also see recommendation.
Technical features	The facility to upload detailed care plans which could include coded segments, free text, supporting documentation.
User experience	Patient and clinician involvement in the development of the structure and processes.
Implementation deadline	Each G7 country will develop their own timescales.
Notes	This functionality was high on the wish list of the NHS England patient focus group. Lived personal experience, had resulted in optimal care not being provided as this information was not readily available. For example, a patient being taken to a hospital which did not have the facilities to reset his pacemaker, when he could have been taken directly to the one which could if this information had been known.

#### Recommendation

FHIR and IPS standards have not fully developed personal care plan resources. The G7 should make representation to IPS FHIR and request that additional specifications be developed.

# 7.7.5. Translation of text into preferred language

Objective	This objective is to enable the user, patient, or clinician to view the written text, either code rubric/description or free text, in their preferred language.
Data	All IPS data.
Technical features	A simple way of selecting and remembering preferred language when accessing patient information via G7-IPS.

Objective	This objective is to enable the user, patient, or clinician to view the written text, either code rubric/description or free text, in their preferred language.
Best practice	The source information along with the translation must be provided.
User experience	To be able to select their preferred language when accessing patient information via G7-IPS.
Implementation deadline	Each G7 country will develop their own timescales.
Notes	Some jurisdictions are required to provide information in multiple languages, for example, Canada has two official languages: English and French, and Wales must provide English and Welsh.

# 7.8. G7-IPS system-system data transfer

# 7.8.1. Transfer of data between systems (national)

Objective	All G7 countries have a complex network of clinical systems, many are standalone, and it is not possible to share information.  This objective is to enable the transfer of information using the IPS and FHIR standards across sub-national jurisdictions such as provinces, territories, states or home nations. As the data transfer is internal to the country, information use could be delivered without the additional issue of international governance and data transfer regulations.  This element will not be applicable for all G7 countries.
Data	G7-IPS minimum dataset progressing to all IPS data.
International standards	ISO 27269:2021   Health informatics - International Patient Summary.  HL7-FHIR R4 ISO 9241-210   Ergonomics of human-system interaction - Part 210:  Human-centred design for interactive system.
Technical features	Importing information shared in IPS/FHIR into the receiving system's data structure.
Best practice	User centred design.
Governance	It is envisaged that all governance, relevant to the healthcare provision in each country will be applied. This could be national, or devolved at sub-national, state or organisational levels.
Implementation deadline	Each G7 country will develop their own timescales This element will not be applicable for all G7 countries.

Objective	All G7 countries have a complex network of clinical systems, many are standalone, and it is not possible to share information.  This objective is to enable the transfer of information using the IPS and FHIR standards across sub-national jurisdictions such as provinces, territories, states or home nations. As the data transfer is internal to the country, information use could be delivered without the additional issue of international governance and data transfer regulations.  This element will not be applicable for all G7 countries.
Notes	In the UK this could be used to ensure that clinical information is available at the point of care whether the patient is being treated in England, Scotland, Wales or Northern Ireland.  In Canada this could similarly be used inter-province/territory.
	In the USA, the IPS may be used in conjunction with other care summary standards that are already being shared among healthcare providers.

# 7.8.2. Transfer of data between systems (international)

Objective	This objective is to enable the system-to-system transfer of information using the IPS and FHIR standards across international boundaries.
Data	All IPS data.
International standards	ISO 27269:2021   Health informatics - International Patient Summary. HL7-FHIR R4
Technical features	Importing information shared in IPS/FHIR into the receiving system's data structure.
Best practice	Information campaign to ensure patients understand what, why and how this is happening. Focusing on the opt-in and security of information, and international guarantees that this will not be used for research, medical trials or that a patient of one country will not be barred entry to another unless they have and declare the contents of their IPS.
Governance	The governance processes used in the G7-IPS are mitigated through the approach that the patient chooses whether to share their information or not. As it is their information, they control the access to it and cannot be forced by a nation state or other actor to share this information.
	However, there is a complexity of national and international

Objective	This objective is to enable the system-to-system transfer of information using the IPS and FHIR standards across international boundaries.	
	requirements regarding the transfer of information between countries. For example, the EU only allows information to be stored and processed in the EU community. In the USA governance is devolved to individual states.	
	Data transfer, management and processing policies MUST be agreed between the G7 countries and other stakeholders (such as the EU) before the system-to-system transfer across international boundaries can take place.	
Implementation deadline	Each G7 country will develop their own timescales.	

# 7.8.3. Authentication of clinicians

Objective	Clinicians will need to be authenticated where there is the transfer of information between clinical systems. This is to ensure that information is only transferred between approved systems.  It is also essential where 'break glass in case of emergency' access is being used.
Data	All IPS data.
International standards	None.
Technical features	Each country will manage an approved list of clinical systems which can upload information from a G7-IPS data point(s). Clinical staff with secure access to a system on the approved list(s) will be able to request access to a patient's record through functionality embedded in that system.
Governance	There is a complexity of national and international requirements regarding the transfer of information between countries. For example, the EU only allows information to be stored and processed in the EU community.
	Data transfer, management and processing policies MUST be agreed between the G7 countries and other stakeholders (such as the EU) before the system-to-system transfer across international boundaries can take place.
Implementation deadline	Each G7 country will develop their own timescales.

# 8. Use cases

This section will include a series of potential use cases, which will demonstrate how IPS could be used and benefit patients and clinicians in these scenarios.

We have produced a series of use cases, which consider how IPS could be used and benefit patients and clinicians in each scenario.

#### 8.1. The traveller

This use case illustrates how IPS could be used while holidaying, travelling, and working abroad.

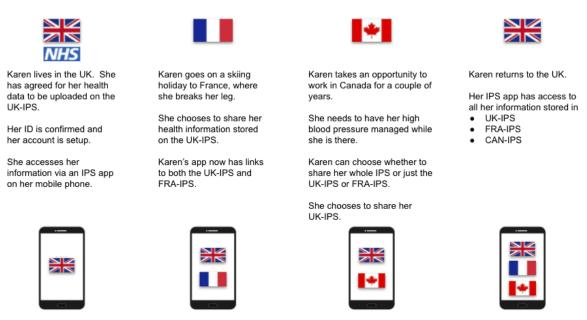


Figure 13: Use case - the traveller

#### 8.2. Vaccinations

This use case illustrates how IPS could be used to provide evidence of vaccination status while at home and abroad. Please note that it does not imply any national or international policy.

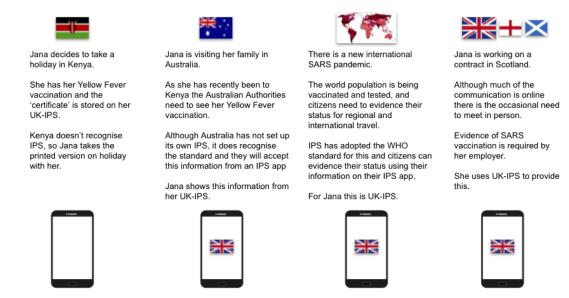


Figure 14: Use case - vaccinations

### 8.3. Displaced persons - internal

In the case of a natural disaster or other event which places a region or country in a state of emergency, it is essential that an individual's healthcare needs are known about and met.

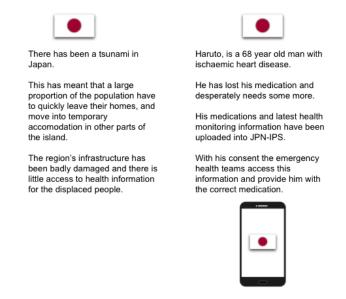


Figure 15: Use case - displaced persons internally within a country

# 8.4. Displaced persons - internationally

This use case looks at how IPS can support people who have had to leave their own country due to natural disasters or wars. As these people are displaced it is essential that

they trust IPS and can use it to ensure that they get correct and continuous healthcare for themselves and any dependents.

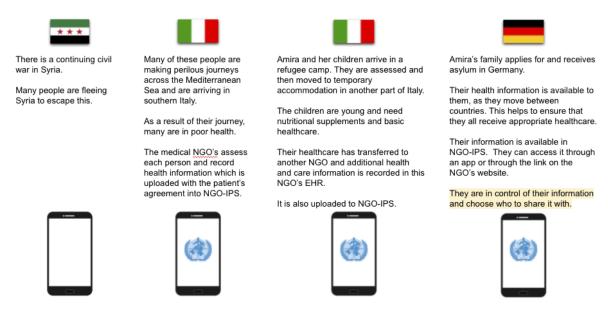


Figure 16: Use case - displaced persons travelling across international borders

### 8.5. Other potential use cases

Elective surgery internationally or cross-borders

Migrant workers

Displaced persons vaccination status

Sub-national jurisdictions care, such as provinces, territories, states or home nations

Veteran mental and physical health

Homeless people

Dual abodes, e.g., students based away from home

Dental care and other healthcare providers

Emergency preparedness, resilience and response (EPRR) in the case of natural disasters, significant accidents (e.g., plane crash) and terrorist incidents

# 9. References and further reading

Reference	Author	Date published or accessed
ART-DECOR®	Art-Decor	Website accessed 13 December 2021
Complete guide to GDPR compliance	GDPR.eu	Website accessed 03 November 2021
EHN Guideline on the electronic exchange of health data under Cross-Border Directive 2011/24/EU. Release 2	eHealth Network	21 November 2016
FHIR® – Fast Healthcare Interoperability Resources	HL7.FHIR	01 November 2019
General Data Protection Regulation (GDPR)	Intersoft Consulting	Website accessed 03 November 2021
Global Patient Set (GPS)	SNOMED International	Last release, September 30
Health informatics — The International Patient Summary: Guideline for European Implementation	CEN	2019
HL7 CDA® Release 2 Implementation Guide: Data Provenance, Release 1	HL7 International	Website accessed 13 December 2021
HL7 Standards based product grid	HL7 International	Website accessed 13 December 2021
IHE Patient Care Coordination Technical Framework	Integrating the Healthcare Enterprise (IHE) International	Website accessed 13 December 2021
International Patient Summary Implementation Guide	HL7.FHIR	19 May 2020
Introduction to ISO Identification of Medicinal Products, SPOR programme EMA/732656/2015	European Medicines Agency (EMA) Information Management Division	29 November 2016
ISO 27269:2021 Health informatics —	ISO/TC 215 Health	April 2021

Reference	Author	Date published or accessed
International patient summary	informatics technical committee	
ISO 9241-210   Ergonomics of human- system interaction — Part 210: Human- centred design for interactive systems	ISO/TC 159/SC 4 Ergonomics of human- system interaction	July 2019
ISO Identification of Medicinal Products (IDMP)	European Medicines Agency (EMA)	Website accessed 03 November 2021
JIC Standards Set - Patient summary	Joint Initiative Council for Global Health Informatics Standardization	Slide presentation January 2016
Joint Initiative Council (JIC)	Joint Initiative Council for Global Health Informatics Standardization	Website accessed 13 December 2021
New CEN standard TS 17288 'The International Patient Summary: Guideline for European Implementation	CEN-CENELEC	16 February 2021
NHS Care Identity Service 2	NHS Digital	Website accessed 04 November 2021
NHS login	NHS England and Improvement	Website accessed 04 November 2021
Patient health records: access, sharing and confidentiality	House of Commons briefing paper, number 07103 Elizabeth Parkin, and Philip Loft	15 May 2020
The epSOS Project	European Commission	Website accessed 13 December 2021
The Global Digital Health Partnership	HealthIT.gov	18 August 2021
The International Patient Summary	Joint Initiative Council for Global Health Informatics Standardization	Website accessed 13 December 2021
The International Patient Summary Structure	HL7 International	19 May 2020
The Sequoia Project	The Sequoia Project	Website

Reference	Author	Date published or accessed
		accessed 13 December 2021
The Trillium Bridge Project	Trillium II	Website accessed 13 December 2021
Transatlantic eHealth/health IT Cooperation Roadmap	United States and the European Union	July 2016

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