Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health Information and Standards

Draft standard for public consultation — information requirements for a national patient summary

August 2018

Safer Better Care

Version control

This section lists the previous and current versions of the document, summarising the major change in each version.

Date	Change
May 2018	Draft created
August 2018	Draft standard for public consultation

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent authority established to drive high-quality and safe care for people using our health and social care services in Ireland. HIQA's role is to develop standards, inspect and review health and social care services and support informed decisions on how services are delivered.

HIQA aims to safeguard people and improve the safety and quality of health and social care services across its full range of functions.

HIQA's mandate to date extends across a specified range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children and Youth Affairs, HIQA has statutory responsibility for:

- **Setting Standards for Health and Social Services —** Developing person-centred standards, based on evidence and best international practice, for health and social care services in Ireland.
- **Regulation —** Registering and inspecting designated centres.
- **Monitoring Children's Services —** Monitoring and inspecting children's social services.
- **Monitoring Healthcare Safety and Quality —** Monitoring the safety and quality of health services and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health Technology Assessment —** Providing advice that enables the best outcome for people who use our health service and the best use of resources by evaluating the clinical effectiveness and cost-effectiveness of drugs, equipment, diagnostic techniques and health promotion and protection activities.
- **Health Information —** Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care services.

Overview of the health information function of HIQA

Healthcare is information-intensive, generating huge volumes of data every day. Health and social care workers spend a significant amount of their time handling information, collecting it, looking for it and storing it. It is therefore imperative that information is managed in the most effective way possible in order to ensure a high-quality, safe service.

Safe, reliable healthcare depends on access to, and the use of, information that is accurate, valid, reliable, timely, relevant, legible and complete. For example, when giving a patient a drug, a nurse needs to be sure that they are administering the appropriate dose of the correct drug to the right patient and that the patient is not allergic to it. Similarly, lack of up-to-date information can lead to the unnecessary duplication of tests — if critical diagnostic results are missing or overlooked, tests have to be repeated unnecessarily and, at best, appropriate treatment is delayed or at worst not given.

In addition, health information has a key role to play in healthcare planning decisions — where to locate a new service, whether or not to introduce a new national screening programme and decisions on best value for money in health and social care provision.

Under section 8(1)(j), HIQA is charged with evaluating the quality of the information available on health and social care and making recommendations in relation to improving the quality and filling in gaps where information is needed but is not currently available.

Information and communications technology (ICT) has a critical role to play in ensuring that information to drive quality and safety in health and social care settings is available when and where it is required. For example, it can generate alerts in the event that a patient is prescribed medication to which they are allergic. Further to this, it can support a much faster, more reliable and safer referral system between the patient's general practitioner and hospitals.

Although there are a number of examples of good practice, the current ICT infrastructure in Ireland's health and social care sector is highly fragmented with major gaps and silos of information which prevents the safe, effective, transfer of information. This results in people using the service being asked to provide the same information on multiple occasions.

In Ireland, information can be lost, documentation is poor, and there is over-reliance on memory. Equally, those responsible for planning our services experience great difficulty in bringing together information in order to make informed decisions. Variability in practice leads to variability in outcomes and cost of care. Furthermore, we are all being encouraged to take more responsibility for our own health and wellbeing, yet it can be very difficult to find consistent, understandable and trustworthy information on which to base our decisions.

As a result of these deficiencies, there is a clear and pressing need to develop a coherent and integrated approach to health information, based on standards and international best practice. A robust health information environment will allow all stakeholders, the general public, patients and service users, health professionals and policy makers to make choices or decisions based on the best available information. This is a fundamental requirement for a high-reliability healthcare system.

Through its health information function, HIQA is addressing these issues and working to ensure that high-quality health and social care information is available to support the delivery, planning and monitoring of services.

HIQA is now defining information requirements for a national electronic patient summary standard. Information requirements are a minimum set of data items that are recommended for implementation in information systems that create and transfer information to support the delivery of safe and quality care to patients. The inclusion of data items in the minimum set of data is determined by the clinical relevancy of the data item and the potential for the data item to improve patient safety in a collaborative care environment. The draft information requirements presented in this document are based on international evidence and ongoing interest and initiatives that are being undertaken globally. They have been developed in conjunction with HIQA's eHealth Standards Advisory Group.

Contents

Document Outline **7**
Chapter 1. Introduction **8**
Chapter 2. Background **11**
2.1 Definition of an electronic patient summary 11
2.2 Benefits of electronic patient summaries 11
2.3 International initiatives on patient summaries 14
2.4 Summary 18
Chapter 3. Draft information requirements for an electronic patient summary **20**
3.1 Information Requirements for a national patient summary 21
Appendix A eHealth Standards Advisory Group **31**
Appendix B Consultation questions **32**
How to submit feedback 33
How we will use your comments 33
Appendix C Sources of information **34**
References **39**

Document Outline

Chapter 1 – Introduction

This chapter outlines the background to the project, the scope of the project and the methodology being followed.

Chapter 2 – Background

This chapter provides a definition of electronic patient summaries, explores the benefits of electronic patient summaries and provides detail on international initiatives on implementing electronic patient summaries.

Chapter 3 - Draft information requirements for information requirements for a national patient summary

This chapter presents the draft information requirements being presented for consultation.

Chapter 4 Conclusion

This chapter summarises the introduction, background and methodology being followed.

Appendix A — Advisory Group

This appendix lists the groups and organisations who participated as members of HIQA's eHealth Standards Advisory Group.

Appendix B — Consultation questions

This appendix lists the consultation question being asked during this public consultation.

Appendix C — Sources of information

This appendix lists the documents that were referenced when developing the draft information requirements.

Chapter 1. Introduction

An electronic patient summary is a succinct document, usually containing a minimum set of the most relevant, up-to-date and useable clinical information that is fit for purpose and can help clinicians to make more informed clinical decisions at the point of patient care. An electronic patient summary can support clinical process and improve patient care by providing timely, accurate information needed to enable better communication among clinicians, patients and other healthcare staff. It can support the continuity of patient care between healthcare settings.

The Department of Health's eHealth strategy 2013 identified that the development of patient summaries should be an early priority project and indicated that it would be delivered by eHealth Ireland. The eHealth Ireland organisation is responsible for realising the vision of the eHealth Strategy, and one of its strategic projects is the development of a national electronic health record. eHealth Ireland is also leading on a project to share electronic patient summaries with other EU countries. This project is known as the OPEN NCP project, and Ireland is committed to making patient summaries available, with a patient's consent, to healthcare professionals across participating member states by March 2020. In order to develop both a national electronic health record and to fulfil the requirement to share electronic patient summaries internationally, a national electronic patient summary is required.

HIQA has undertaken a significant amount of work in this area, including carrying out an international review of summary care records and developing clinical datasets for diagnosis, allergies and procedures. HIQA published an international review of summary care records in 2016,[(1)] and this is available at www.hiqa.ie. It documented international evidence and best practice around developing patient summaries in seven countries: England, Scotland, Northern Ireland and Wales, Australia, New Zealand and The Netherlands.

Overall findings from the review highlighted that having accurate patient summaries can lead to many benefits for both individuals and clinicians, can improve patient experience, patient safety and the effectiveness of patient care by facilitating timely access to the relevant patient records. The review also highlighted that the introduction of patient summaries requires attention being given to issues such as governance, the necessity for good quality information from those source systems that generate the information for the electronic patient summary, the need for evaluation studies on the use of patient summaries following deployment and the need for appropriate consent models.

HIQA has developed a suite of clinical datasets which standardise how patient information is recorded and can facilitate easier sharing of patient information, including:

- National *Standard Diagnosis Dataset and Clinical Document Architecture (CDA) template* (2016)[2]
- *National Standard Adverse Reaction Dataset and Clinical Document Architecture (CDA) template* (2016)[3] and
- *National Standard for a Procedure Dataset including a Clinical Document Architecture specification* (2017)[4].

HIQA is now developing the information requirements required to support the implementation of a national electronic patient summary. This draft standard for consultation defines the information requirements for a national electronic patient summary. Information requirements are minimum set of data items that are recommended for implementation in information system that create and transfer information to support the delivery of safe and quality care to patients.

The inclusion of data in the minimum set of data is determined by the clinical relevancy of the data and the potential for the data to improve patient safety in a collaborative care environment. Those exchanging the information are primary care healthcare providers such as general practitioners, nurses in primary care and nursing and other health and social care professionals in community and acute care settings.

Methodology

Under Section 8(1)(k) of the Health Act 2007, HIQA is charged with setting standards as HIQA considers appropriate for the Health Service Executive (HSE) and service providers in relation to data and information in their possession about services and the health and welfare of the population.

The sources of evidence used to inform the information requirements include the international review undertaken by HIQA and the work currently being undertaken internationally between standards development organisations on patient summaries. Previous standards developed by HIQA — including clinical datasets for diagnosis, procedures and adverse reactions — informed these information requirements. HIQA has established an eHealth Standards Advisory Group from a range of interested and informed organisations. These organisations are listed in Appendix A. The role of the eHealth Standards Advisory Group is to advise HIQA about technical standards for health information and to ensure a coherent and consistent approach to developing

technical standards. The eHealth Standards Advisory group reviewed a draft of the information requirements prior to this consultation.

Reflecting HIQA's commitment to consultation and engagement, each project includes a public consultation to seek and incorporate feedback from external stakeholders. Our public consultation ensures that the final information requirements have taken account of existing processes nationally and internationally, and includes any appropriate requirements identified by stakeholders.

The draft standards will be made available for public consultation on Monday 13th August 2018. The public consultation will run for six weeks, closing on Friday 21st September 2018. A number of consultation questions have been prepared for your consideration when reviewing the draft standards. Appendix B documents the consultation questions and provides information on how to make submissions to the consultation. These questions are not intended in any way to limit your feedback, and other comments relating to the draft national standards are welcome.

As part of the standards development process, HIQA will also undertake consultation on the draft standard through focus groups and one-to-one interviews with both people using services and healthcare professionals to seek their requirements for a national patient summary.

Once these consultations are complete, the standard will be updated and HIQA's Advisory Group will be consulted. The final draft standard will then be submitted for approval to HIQA's Executive Management Team and Board of HIQA — before being submitted to the Minister for Health and being published on the HIQA Website.

Chapter 2. Background

Before defining the high-level information requirements for electronic patient summaries, it is important to understand what the term 'electronic patient summary' means, the benefits that a national electronic patient summary programme can realise, and the initiatives that are underway in Ireland and internationally.

2.1 Definition of an electronic patient summary

Healthcare is under increasing pressure to harness the benefits of good quality health information. Patients expect their health information to be recorded, processed and used appropriately for their benefit. Healthcare professionals require access to complete, valid and up-to-date health information in order to make more informed decisions about patient care, for example, deciding on the most appropriate medication treatment for a patient. In order to meet these demands, a number of international initiatives have focused on the area of electronic patient summaries.

An electronic patient summary is a succinct document, usually containing a minimum set of the most relevant, up-to-date and useable clinical information that is fit for purpose and can help clinicians to make more informed clinical decisions at the point of patient care. Informed by research on international best practice, the core information that should be available to a clinician in a patient summary should include the demographic information, allergies, current medical problems (diagnosis) and procedures, alongside a list of the medication that a patient is currently taking.

The definition of a patient summary that will be used throughout this document is sourced from European guidelines on patient summaries and states that:

> A Patient Summary is an identifiable dataset of essential and understandable health information that is made available at the point of care to deliver safe patient care during unscheduled care (and planned care) with its maximal impact in the unscheduled care.[2]

2.2 Benefits of electronic patient summaries

Where patient summaries exist, there are significant benefits for patients, health and social care providers and organisations. An electronic patient summary can support clinical processes and improve patient care by providing timely, accurate information needed to enable better communication among clinicians, patients and other healthcare staff. It can support the continuity of patient care between healthcare

settings. Internationally, patient summaries have been used to improve patient care in out-of-hours and emergency care settings and in the area of medication safety.

The existence of an electronic patient summary can enhance communication between healthcare providers when a patient presents to an out-of-hours care setting, be these based in the community or in acute hospitals. The existence of a patient summary created by the patient's usual general practitioner (GP) provides the out-of-hours healthcare practitioner with timely access to quality information about the patient. It is also beneficial where a patient's medical history is unknown to the treating clinician. The electronic patient summary is particularly useful when a patient arrives at an emergency department and is unresponsive or is unable to recall important clinical information about their medical problems.

An electronic patient summary can provide a list of the patient's current medication, which is useful for clinicians in an emergency or out-of-hours situation to treat patients who may have been prescribed multiple medications and have a complex medical history. For example, elderly patients who have difficulty remembering the combination of medications they have been prescribed, or for incoherent patients who have no patient chart available or for patients with a history of drug abuse. In such cases, an electronic patient summary would be a timely source of information available to support clinicians to provide the best possible patient care.

Electronic patient summaries have proved to be very beneficial in the area of medication safety. In the UK, electronic patient summaries are accessible to hospital and community pharmacists. In has been shown that the availability of patient summaries in the UK has led to significant efficiencies during the medication reconciliation process[1] which takes place when a patient is admitted to hospital. There was a clear reduction in the time taken to complete the drug history at the time of admission, with an average reduction of 29 minutes per patient. The associated reduction in phone calls (31%) and faxes (19%) is likely to have contributed to the reduction in time taken. Additionally, results indicated that more medication discrepancies are identified during the reconciliation process when patient summaries are used compared to when patient summaries were not available.(5)

Access to patient summaries has also been made available to community pharmacists in the UK. NHS Digital in the UK states that having instant access to patient information speeds up care, reduces the need for phone calls to GP practices, and reduces referrals to other services, particularly out-of-hours, because summary care records are available 24 hours a day — including at times when the

[1] Medication reconciliation is a formal process for creating the most complete and accurate list possible of a patient's current medications and comparing the list to those in the patient record or medication orders.

patient's GP practice may be closed.[6] Specific benefits for patients and staff identified by NHS Digital include the ability to:

- check allergies to prevent prescribing errors
- check current medications prescribed for emergency supply purposes
- check eligibility for services such as a free flu jab.

There are considerable benefits to patients if an accurate and up-to-date electronic patient summary is available at the point of care, and, conversely, there are the associated risks for the patient if such information is unavailable. For example, the absence of an electronic patient summary in an emergency situation can be detrimental to a patient's outcome if a clinician has to spend valuable time collecting information and understanding a patient's history or in the worst case scenario have to act without any patient information being available to them.

From an organisational perspective, an electronic patient summary can bring about substantial benefits, such as reducing duplication of effort when ordering unnecessary tests and asking the patient for information they have already given elsewhere. Benefits identified by the international review include these benefits for patients:

- improved efficiency of care by reducing time, effort and the resources required to share patient's information across different organisations
- improved quality of patient care through more timely and informed clinical decisions in emergency and out-of-hours care
- improved patient safety by reducing the risk of prescribing errors and adverse reactions to prescribed medication
- better patient care by giving healthcare staff relevant information to make appropriate decisions about patient care
- improved patient experience as patients do not need to organise or remember a list of their medications
- reduced number of times that a patient has to repeat his or her clinical information to healthcare staff
- better support for people with difficulty communicating.

The benefits of an electronic patient summary for health and social care providers include:

- empowering health professionals by providing access to consistent, accurate, accessible clinical information about a patient 24 hours a day
- improving patient safety by providing timely access to accurate information which supports safer and more informed prescribing
- improving the efficiency of care delivery to patients by reducing the time, effort and resources required to obtain key information from the patient's GP
- improving the effectiveness of patient care by supporting the delivery of appropriate care to patients.

2.3 International initiatives on patient summaries

There has been widespread interest in the topic of patient summaries globally given the substantial benefits they can deliver. This section of the draft standards summarises the international review on patient summaries that was undertaken by HIQA in 2016. The section then briefly documents some of the international collaborative initiatives that have taken place or are currently underway which are relevant to electronic patient summaries.

2.3.1 International review on patient summaries

HIQA's *International Review of Summary Care Records*[1] documents how electronic patient summaries have evolved in other countries. The review covered the national electronic patient summary implementations developed in the UK (England, Scotland and Wales, and Northern Ireland), Australia, New Zealand and The Netherlands. A number of factors were examined such as the structure of the healthcare system, the source of information, the content and usage of an electronic patient summary.

England, Scotland, Wales and Northern Ireland each began a programme to introduce a summary care record between 2004 and 2008. In 2013, Greenhalgh et al., conducted an evaluation study on the summary care record in the UK inclusive of England, Scotland, Northern Ireland and Wales.[7] The study concluded that clear benefits can be derived from the use of summary care records, such as improved patient experience, patient safety and the effectiveness of patient care. However, implementing a nationally shared electronic summary record, as with the introduction of any new health technology, is challenging given that implementing organisational change in healthcare systems is complex and can be difficult to manage.

There is much in common between the four programmes of work in the UK. All countries generated information for the electronic patient summary from the record held by the patient's National Health Service (NHS) general practitioner. All countries developed their national electronic patient summary for the purpose of emergency, unscheduled and out-of-hours care. Initial implementation in England, Scotland and Northern Ireland have the same core minimum summary of information that includes medications, adverse reactions and or allergies and information to uniquely identify a patient. Wales have similar information requirements as the other three countries but also includes medical problems and test results. In July 2013, the UK summary care record was expanded to include patients' end-of-life care information, immunisations, reason for medication and significant past problems and procedures. There is widespread use of summary care records in England, Scotland, Northern Ireland and Wales.

Building on the success of the summary care record programme in England, the NHS decided to trial its use in community pharmacy, which started in 2014. The aim was to support community pharmacists in a range of services such as providing patients with consistent information about their usual medications, offering more accurate advice to patients and assisting with dispensing emergency supplies of medication. The information available to pharmacists includes the core information from the summary care record, alongside allergies and adverse reactions, repeat medications, acute and discontinued medications. Importantly, the summary care record only contains medication prescribed by the general practitioner and does not include other sources, such as hospital prescribing. The use of the summary care record demonstrated improvements in patient safety, whereby the pharmacist is able to access a patient's summary when they suspect a prescribing error has occurred, allowing them to help clarify a prescriber's intention. The summary care record for community pharmacy was rolled out nationally in 2015.[8]

The national patient summaries in Australia, New Zealand and The Netherlands also source information from general practitioners' practice management systems. There are common categories of information that the three countries use as the core content for their summary care records, including demographics information, health problems, medicines, allergies, adverse reactions and immunisations. In addition, New Zealand also includes data on laboratory results, and in The Netherlands, the electronic locum summary record includes the most recent records of a patient's visit to hospital.

Overall findings from the international review in 2016 highlighted that a national electronic patient summary can increase patient safety by providing a tool for clinicians to securely access structured, core information about patients. The quality of care that patients receive can be enhanced by fast, easy access to the most

accurate and relevant patient information available. A study conducted in Scotland on the evaluation of the impact on the Key Information Summary Record, an extension of the Scottish emergency care summary, confirmed that clinicians working in emergency care and in out-of-hours services highly value the Key Information Summary and regard it as a critical data source for conducting their work effectively. The study found that the electronic patient summary had a positive impact on preventing medication errors.(9) Clinicians also reported on the benefits of the electronic patient summary, particularly for sub-groups of patients, such as the cognitively impaired, the elderly and those on multiple, complex medication regimes.(10)

Having summarised the international review on national electronic patient summary implementations, the following sections outline global initiatives that have been undertaken by international standards development organisations in the area of patient summaries.

2.3.2 European Patient Smart Open Services (epSOS)

Running from 2008 to 2013, the European Patient Smart Open Services (epSOS) project was an EU-wide pilot project that developed and tested an eHealth framework and an ICT infrastructure for secure cross-border access to patient health information between different European healthcare systems, including patient summaries. The epSOS pilot was designed to test the legal, organisational, semantic and technical aspects of cross-border information exchange.

It was intended to demonstrate a measurable improvement in cross-border medical services. Participating countries were at different stages of implementing patient summaries, making it necessary to define both a minimum dataset and a maximum dataset for the transfer of patient summaries across EU borders. This resulted in the EU member states agreeing a number of communication standards for patient summaries.(11,12,13)

2.3.3 EU guidelines for patient summaries

Based on the work completed by the epSOS pilot project, the EU published guidelines on patient summaries in 2013. In 2015, the 'Joint Action to Support the eHealth Network' (JAseHN)[2] report found that the implementation of the electronic patient summary guidelines was at a different stage across most EU countries.

[2] JAseHN is led by the EU member states and co-financed by the European Commission through a Joint Action. JAseHN functions as a platform for operational and strategic cooperation between member states, including their relationship with EU eHealth stakeholder groups and standardisation organisations. It provides support and guidance for the implementation, deployment and use of eHealth services throughout national healthcare systems to enable better use of healthcare resources.

Although some countries already had in place many of the components necessary for supporting the implementation of electronic patient summary guidelines, in most member states, putting this into practice in some public services had not yet been completed. A revision of the guidelines, through the work of JAseHN, was published in 2016 and entitled the 'Guideline on the electronic exchange of health data under Cross-Border Directive 2011/24/EU Release 2 Patient Summary for unscheduled care'.(14)

The European Commission subsequently supported an initiative called OPEN NCP for the cross-border exchange of patient summaries. It is tasked with providing infrastructure for sharing patient summaries across Europe. Ireland is participating in this initiative and is committed to making electronic patient summaries and electronic prescriptions available, with a patient's consent, to healthcare professionals across other participating member states by March 2020.

The United States and European Union signed a Memorandum of Understanding on eHealth in 2010. One of the main outcomes was the European Trillium Bridge project (2013-2015)(15) which conducted a feasibility study for the electronic exchange of patient summaries between the United States and Europe. Starting with a gap analysis, the study compared the Health Level 7 Continuity of Care Document specification cited in the US Meaningful Use programme in the US(16) and the epSOS Patient Summary Implementation Guide (2011),(12) cited in the EU Patient Summary Guideline. The study demonstrated the technical feasibility of the exchange of patient summaries across the Atlantic. Recommendations and a roadmap for the next steps were elaborated and submitted to the eHealth community and the European Commission for future development.

Informed by the Trillium Bridge Project, a collaboration between the Health Level 7 International[3] and CEN/TC251[4] was started in 2016 to develop an International Patient Summary(17) which aims to provide a minimal and non-exhaustive electronic patient summary which is not specific to any particular medical condition or medication problem and is usable by clinicians for cross-border unscheduled care of a patient. Both organisations are working towards agreeing on the same information requirements and are targeting implementations and associated guidance by 2019.

[3] Health Level Seven International (HL7) is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services

[4] CEN/TC 251 (CEN Technical Committee 251) is a technical decision making body within the European Committee for Standardization (CEN) working on standardization in the field of Health Information and Communications Technology (ICT) in the European Union.

2.3.4 Joint Initiative Council

In January 2018, the Joint Initiative Council (JIC), a consortium of eight international digital health standards development organisations, released a standards set[5] on patient summaries. The Joint Initiative Council was formed to enable a coordinated, common and timely approach among different standards development organisations to develop health information standards. The intent of the standards set is to provide health information standards, scenarios and information flows for specific healthcare settings . The electronic patient summary standards set [(18)] outlines details of the information requirements for the content of patient summaries. The documents are directed at vendors, healthcare organisations and governments and policy-makers who want to develop and implement patient summaries.

2.4 Summary

In summary, international evidence shows that the deployment of accurate and timely patient summaries can lead to increased patient safety outcomes and can deliver improvements for both patient experience and the effectiveness of patient care. The core information or content required for an electronic patient summary was consistent across countries reviewed and at a minimum included health identifying information, diagnosis, current medications, allergies and immunisations. All countries populated the electronic patient summary directly from general practitioner practice management systems.

From the review, it was evident that the deployment of patient summaries, in the first instance, was for the purpose of emergency, unscheduled and out-of-hours services. Following on from the success of implementing the core electronic patient summary, some countries extended the content of the electronic patient summary and increased its scope to include different healthcare settings. For example, in England, the summary care record has been extended for the purpose of end-of-life care, community pharmacy and for medication reconciliation on admission to hospital.

Studies have demonstrated that patient summaries can improve patient safety, improve the quality and effectiveness of care and save healthcare staff and their organisations time and money.[(19)] However, successful deployment of a national electronic patient summary demands attention around issues such as governance (for example, maintaining continuously updated summary care records), evaluation

[5] The JIC describe the term Standards Set itself as 'not a set of standards, but is a process to be followed to allow an informed and consistent approach to identifying, selecting and deploying standards and related artefacts.'

of their use, appropriate consent models, effective business management, engagement of clinicians and active participation of patients.[20]

An electronic patient summary that is shared between healthcare practitioners can facilitate effective communication between clinical teams. Importantly, patients are more empowered as those with cognitive difficulty, low literacy levels or limited English can receive as high a standard of care as others.[21] The introduction of a national electronic patient summary can ensure clinicians are better informed to make clinical decisions for the patient at the point of care potentially resulting in fewer medical errors, more efficiency of care and lower healthcare costs.

Having discussed the definition, benefits and international initiatives on patient summaries, we will now describe the draft information requirement for a national electronic patient summary in Ireland.

Chapter 3. Draft information requirements for an electronic patient summary

This section describes the information requirements required to support a national electronic patient summary. As stated earlier in this document, information requirements define the minimum set of data items that are recommended for implementation in information systems that create and transfer information to support the delivery of quality collaborative care. The inclusion of data in the minimum set of data is determined by its clinical relevancy and the potential for it to improve patient safety in a collaborative care environment.

This section defines the information that should be contained within a national electronic patient summary whenever information is generated by a primary care or general practitioner practice management system and shared with other health and social providers. Though additional information about the patient's visit may be recorded by clinicians in primary or secondary care, HIQA is identifying the information that is required to be shared in an electronic solution in order to ensure patient safety.

Sources which have been used in the development of the information requirements are listed below. Appendix C of this document sets out the links between these sources and each data item in the national electronic patient summary record.

- Australian Digital Health, Shared Health Summary Information Requirements, v1.1[(22)]
- European Patients Smart Open Services (epSOS), Work Package 3.9 – Appendix B1/B2 epSOS Semantic Implementation Guidelines (2011)[(12)]
- Guideline on the electronic exchange of health data under Cross-Border Directive 2011/24/EU Release 2 Patient Summary for unscheduled care.[(14)]
- CEN/TC 251 European standard (EN) 17269: *The Patient Summary for Unscheduled, Cross-border Care* (the CEN/TC 251 EN 17269)[(23)]
- HL7 International Patient Summary Implementation Guide Implementation Guide Release 0.1.0[(17)]
- Joint Initiative Council, Patient Summary Standards Set, Guidance Document, January 2018 v1.0[(18)]

3.1 Information Requirements for a national patient summary

The draft information requirements are outlined below and include the following areas:

- subject of care
- health condition
- current medication
- allergies
- procedures
- vaccinations.

Each table is structured to include the number of the requirement, the name of the data item, a statement for the requirement and a description for how the requirements could be used in practice. The optionality for a data item is described as either SHALL or SHOULD. The definitions of SHALL and SHOULD are as follows:

SHALL	When appearing in a requirement, the verb **SHALL** indicates a mandatory requirement. Its negative form **SHALL NOT** indicates a prohibition.
SHOULD	When appearing in a requirement, the verb **SHOULD** indicates a recommendation. Its negative form **SHOULD NOT** indicates an option that is not recommended.

1.0 Subject of care

The patient's demographic details for the purpose of an electronic patient summary.

Table 1. Subject of care

No.	Data item	Requirement statement	Usage
1.1	**Title**	The patient summary **SHOULD** contain the title relevant to the subject of care.	A patient's preferred title, for example, Mr, Doctor, Mrs.
1.2	**Forename**	The patient summary **SHALL** contain a patient's first name or given name(s) as stated on the birth certificate.	A patient's first name or given name (s) as stated on the birth certificate.
1.3	**Surname**	The patient summary **SHALL** contain the second part of a patient's name which denotes their family or marital name.	The second part of a patient's name denotes their family or marital name.
1.4	**Address**	The patient summary **SHALL** contain the location to be used to contact or correspond with the patient. This would normally be the patient's usual home address.	The particulars of the place where the patient lives.
1.5	**Date of birth**	The patient summary **SHALL** contain the date of birth indicating the day, month, and year when the patient was born.	The date of birth should be supplied in dd/mm/yyyy format.
1.6	**Sex**	The patient summary **SHALL** contain gender identity.	Gender identity is a person's sense of identification with either the male or female sex, as manifested in appearance, behaviour and other aspects of a person's life.
1.7	**Health identifier**	The patient summary **SHOULD** contain a number or code assigned to an individual to uniquely	Both the code and the code type that the code relates to should be provided, for example, 0987654321 Individual Health Identifer.

	identify the individual within an organisation.	Other identifiers which may be carried in this field include the General Medical Scheme, Drug Payment Scheme, Long Term Illness Scheme and Hardship Scheme identifier.

2.0 Health condition

The patient's current health condition which includes health problem or diagnosis.

Table 2. Health condition

No.	Data item	Requirement statement	Usage
2.1	**Current health condition**	The patient summary **SHALL** identify the condition or diagnosis.	The name of the condition.
2.2	**Clinical description**	The patient summary **SHOULD** contain a narrative description or comments about clinical aspects of the condition.	Additional narrative about the condition.
2.3	**Date of onset**	The patient summary **SHOULD** state the estimated or actual date of onset, in the opinion of the healthcare practitioner.	The estimated or actual date on which the health condition was first detected or suspected or entered.
2.4	**Status**	The patient summary **SHALL** contain the status of the health condition.	The status of the condition categorised as provisional, working, confirmed, refuted, resolved or inactive.
2.5	**Date resolved or inactivated**	The patient summary **SHOULD** contain the date or estimated date that the condition was resolved.	The date or estimated date that the condition resolved or went into remission, as indicated or identified by the healthcare professional.
2.6	**No health conditions identified**	The patient summary **SHOULD** contain a record to indicate that the patient has **no known health conditions**.	An indication that the patient had no known health conditions.

3.0 Current medication

A list of the current medications prescribed for the patient.

Table 3. Current medication

No.	Data item	Requirement statement	Usage
3.1	**Medicinal product**	The patient summary **SHALL** include the name of the medicinal product or package. It may be a trade name or a generic name.	The medicinal product that is prescribed. This field covers where package-level dispensing occurs or where a formulation takes place in the pharmacy in order to produce the substance dispensed to the patient.
3.2	**Dose form strength**	The patient summary **SHOULD** state the content of the active ingredient expressed quantatively per dosage unit, per unit of volume or per unit of weight, according to the pharmaceutical dose form.	This field consists of a size value and unit, a combination of both to define the strength, for example, 250mg or 1g.
3.3	**Dose form type**	The patient summary **SHOULD** include a description of the dose type, such as tablet or vial.	This field describes the dose type, such as tablet or vial.
3.4	**Number of units per intake**	The patient summary **SHOULD** state the number of instances of the medicinal product to be taken by the patient at a given time.	This field is used to describe the number of units(s) to be taken at a given time.
3.5	**Frequency of intake**	The patient summary **SHOULD** state how the medication is to be administered, often expressed in number of times per day but may also include information such as '1 hour before or after meals'.	This field is used to describe the frequency of the dose that should be taken by the patient.
3.6	**Duration of treatment**	The patient summary **SHOULD** state the duration of time for the regime to be taken.	This field is used to describe the duration of the dose described should be taken by the patient.
3.7	**Date of start of treatment**	The patient summary **SHALL** state the date on	Date field which indicates when the treatment commenced. For

		which treatment becomes effective.	example, the date on which the healthcare practitioner instructs the patient to begin the treatment.
3.8	**No medication taken**	The patient summary **SHOULD** contain a record to describe that the patient is not taking medication.	An indication to suggest that the patient has no medication prescribed.

4.0 Allergies

An allergy that a patient experiences to a substance such as medicines, food allergies, bee venom and so on.

Table 4. Allergies

No.	Data item	Requirement statement	Usage
4.1	**Substance**	The patient summary **SHALL** identify the substance that the patient has a susceptibility to an allergy upon exposure to the substance.	The substance that caused the allergy to occur. Example of a substance could include peanut, penicillin and so on.
4.2	**Reaction**	The patient summary **SHOULD** describe the type of reaction event as determined by the healthcare practitioner.	A subjective assessment of the type of reaction event as evaluated by the healthcare practitioner. Examples include rash, diarrhoea, and anaphylaxis.
4.3	**Severity of reaction**	The patient summary **SHOULD** include the severity of the symptom as determined by the healthcare practitioner.	An assessment of the severity of the reaction event as evaluated by the healthcare practitioner. Examples include: severe, serious, moderate or minor.
4.4	**Reaction onset date**	The patient summary **SHOULD** contain a record of the date or time (or both) of the onset of the reaction.	This field is used to capture the date or time (or both) of the onset of the allergic reaction.
4.5	**No known allergies**	The patient summary **SHOULD** include a record if **no known allergies**.	A indication that the patient has no known allergies.

5.0 Procedures

A procedure is defined as a clinical activity carried out for the therapeutic, evaluative, investigative, screening or diagnostic purposes.

Table 5. Procedures

No.	Data item	Requirement statement	Usage
5.1	**Procedure**	The patient summary **SHALL** include a description of the procedure.	Captures a narrative description of the procedure. Examples can include a description about performance, findings, failed attempt or cancellations.
5.2	**Procedure date**	The patient summary **SHOULD** state the date and or time on which the procedure was or is intended to be performed.	This field is used to capture the date and or time on which the procedure was performed.
5.3	**No procedures undertaken**	The patient summary **SHOULD** include a record if **no procedures undertaken**.	An indication that a patient has not had any procedures undertaken to date.

6.0 Vaccinations

Details of immunisations or vaccinations that have been administered to the patient.

Table 6. Vaccinations

No.	Data item	Requirement statement	Usage
6.1	**Names of vaccinations**	The patient summary **SHALL** state the name of the vaccinations given to the subject of care.	The name of the vaccination given to the patient.
6.2	**Vaccination date**	The patient summary **SHOULD** state the date that the vaccination was administered to the Subject of Care.	The date and or time when the vaccination was administered to the subject of care
6.3	**No vaccinations administered**	The patient summary **SHOULD** include a record that no vaccinations were administered.	An indication that a patient has not had any vaccinations or immunisations administered to date.

Chapter 4. Conclusion

An electronic patient summary is a succinct document, usually containing a minimum set of the most relevant, up-to-date and useable clinical information that is fit for purpose and that can help clinicians to make more informed clinical decisions at the point of patient care. Electronic patient summaries can support the clinical decision-making process and result in safer and better care. In order to develop both national electronic health records in Ireland and to fulfil the country's requirement to share electronic patient summaries internationally, with the patient's consent, a national electronic patient summary is required for Ireland.

HIQA is developing information requirements for an electronic patient summary. The sources of evidence used to inform the information requirement include the international review undertaken by HIQA and the work currently being undertaken internationally between standards development organisations on electronic patient summaries. Previous standards developed by HIQA — including clinical datasets for diagnosis, procedures and adverse reactions — informed these information requirements.

They have been developed in collaboration with the eHealth Standards Advisory Group, with participant membership listed in Appendix A. The information requirements for an electronic patient summary is now being made available for public consultation. This will be available for a six-week public consultation, running from 13th August to 21st September 2018. Appendix B documents the consultation questions and provides information on how to make submissions to the consultation. These questions are not intended to limit your feedback in any way, and we would welcome other comments.

As part of the standards development process HIQA will also undertake consultation on the draft standard through focus groups and one-to-one interviews with both service users and healthcare professionals to see what their requirements are for a national electronic patient summary record. All feedback will be carefully reviewed and where necessary and appropriate, the draft standards will be revised. Once the various consultation approaches are complete, the standards will be updated and the Advisory Group will be consulted.

Appendix A eHealth Standards Advisory Group

The following groups and organisations participated in the eHealth Standards Advisory Group:[6]

- Department of Health
- Council of Clinical Information Officers (HSE)
- Knowledge Management/Health Intelligence (HSE)
- National Standards Authority of Ireland
- General Practice Information Technology Group
- Office of the Chief Information Officer (HSE)
- Irish Pharmacy Union
- Royal College of Surgeons in Ireland
- Royal College of Physicians of Ireland
- Faculty of Nursing & Midwifery (RCSI)
- Enterprise Ireland.

[6] HIQA is in the process of revising the membership of the eHealth Standards Advisory Group, and future membership will include patient representation.

Appendix B Consultation questions

A key issue for Ireland is to determine the high-level information requirements, as part of the definition of a national standard for a patient summary in Ireland. This document is available for public consultation for a six-week period. In this way, the public, service users and service providers will have the opportunity to provide feedback and participate in the development process. We invite all interested parties to submit their views on this document.

Question 1:

Have you any alterations or additional items to include in the subject of care information requirements?

Question 2:

Have you any alterations or additional items to include in the health condition information requirements?

Question 3:

Have you any alterations or additional items to include in the current medications information requirements?

Question 4:

Have you any alterations or additional items to include in the allergies information requirements?

Question 5:

Have you any alterations or additional items to include in the procedures information requirements?

Question 6:

Have you any alterations or additional items to include in the vaccinations information requirements?

Question 7:

Have you any general comments you would like to make about this document?

How to submit feedback

There are several ways to tell us what you think.

Your comments can be submitted by downloading and completing the consultation feedback form available from www.hiqa.ie and e-mailing your completed forms to technicalstandards@hiqa.ie.
You can print off a copy of the feedback form from our website and once completed, post it to us at:

Health Information and Quality Authority
Draft Standards for Consultation (Electronic Patient Summary)
George's Court
George's Lane
Smithfield
Dublin 7
D07 E98Y.

For further information or if you have any questions, you can talk to the consultation team by calling (01) 8147685. The closing date for receipt of comments is 1pm on 21 September 2018.

How we will use your comments

Following the consultation, all submissions will be carefully considered and used as appropriate to inform the work of HIQA and of the eHealth Standards Advisory Group in the development of a National Standard for an electronic patient summary for Ireland. We would like to thank you in advance for taking the time to review this document and for submitting your comments to us.

Appendix C Sources of information

The sources used to inform the information requirements for a national patient summary are outlined in Tables 7 to 12 below.

Table 7. Subject of care

1.0 Health Condition		
No.	**Data Item**	**Source**
1.1	**Title**	HIQA: National standard demographic dataset and guidance for use in health and social care settings in Ireland
1.2	**Forename**	HIQA: National standard demographic dataset and guidance for use in health and social care settings in Ireland
1.3	**Surname**	HIQA: National standard demographic dataset and guidance for use in health and social care settings in Ireland
1.4	**Address**	HIQA: National standard demographic dataset and guidance for use in health and social care settings in Ireland
1.5	**Date of birth**	HIQA: National standard demographic dataset and guidance for use in health and social care settings in Ireland
1.6	**Sex**	HIQA: National standard demographic dataset and guidance for use in health and social care settings in Ireland
1.7	**Health identifier**	HIQA: National standard demographic dataset and guidance for use in health and social care settings in Ireland

Table 8. Health condition

2.0 Health condition		
No.	**Data Item**	**Source**
2.1	**Current health condition**	HIQA Diagnosis Standard EU Directive Joint Initiative Council (JIC)* HL7/CEN IPS‡ Australian Digital Health Agency
2.2	**Clinical description**	HIQA Diagnosis Standard Joint Initiative Council EU Directive HL7/CEN IPSAustralian Digital Health Agency
2.3	**Date of onset**	HIQA Diagnosis Standard Joint Initiative Council EU Directive HL7/CEN IPS Australian Digital Health Agency
2.4	**Status**	HIQA Diagnosis Standard
2.5	**Date of resolution/inactive**	HIQA Diagnosis Standard Joint Initiative Council EU Directive Australian Digital Health Agency
2.6	**No health conditions identified**	HIQA eHealth Standards Advisory Group Australian Digital Health Agency

* Joint Initiative Council, Patient Summary Standards Set, Guidance Document, January 2018 v1.0

‡ HL7/CEN International Patient Summary Implementation Guide Implementation Guide Release 0.1.0

Table 9. Current medication

3.0 Current Medication		
No.	**Data item**	**Source**
3.1	**Medication**	HIQA ePrescribing Standard Joint Initiative Council EU Directive HL7/CEN IPS Australian Digital Health Agency
3.2	**Dose form strength**	HIQA ePrescribing Standard Joint Initiative Council EU Directive HL7/CEN IPS Australian Digital Health Agency
3.3	**Dose form type**	HIQA ePrescribing Standard Joint Initiative Council EU Directive Australian Digital Health Agency
3.4	**Number of units per intake**	HIQA ePrescribing Standard Joint Initiative Council EU Directive Australian Digital Health Agency
3.5	**Frequency of intake**	HIQA ePrescribing Standard Joint Initiative Council EU Directive HL7/CEN IPS Australian Digital Health Agency
3.6	**Duration of treatment**	HIQA ePrescribing Standard EU Directive Australian Digital Health Agency
3.7	**Date of start of treatment**	HIQA ePrescribing Standard Joint Initiative Council EU Directive HL7/CEN IPS EU Directive Australian Digital Health Agency
3.8	**No medication taken**	HIQA eHealth Standards Advisory Group

Table 10. Allergies

4.0 Allergies		
No.	**Data Item**	**Source**
4.1	**Substance**	HIQA Adverse Reaction Standard Joint Initiative Council EU Directive HL7/CEN IPS Australian Digital Health Agency
4.2	**Reaction**	HIQA Adverse Reaction Standard Joint Initiative Council EU Directive HL7/CEN IPS Australian Digital Health Agency
4.3	**Severity of reaction**	HIQA Adverse Reaction Standard Joint Initiative Council EU Directive HL7/CEN IPS Australian Digital Health Agency
4.4	**Reaction onset date**	EU Directive HL7/CEN IPS Joint Initiative Council
4.5	**No known allergies**	HIQA eHealth Standards Advisory Group

Table 11. Procedures

5.0 Procedures		
No.	**Data Item**	**Source**
5.1	**Procedure**	HIQA Procedures Standard EU Directive HL7/CEN IPS Joint Initiative Council
5.2	**Procedure date**	HIQA Procedures Standard EU Directive HL7/CEN IPS JIC
5.3	**No procedures undertaken**	HIQA eHealth Standards Advisory Group

Table 12. Vaccinations

6.0 Vaccinations		
No.	**Data item**	**Source**
6.1	**Names of vaccinations**	EU Directive
6.2	**Vaccination date**	EU Directive
6.3	**No vaccinations administered**	HIQA eHealth Standards Advisory Group

References

1. Health Information and Quality Authority. *International Review of National Summary Care Records*. Dublin: Health Information and Quality Authority; 2016. Available online from: https://www.hiqa.ie/sites/default/files/2017-02/International-Review-Summary-Care-Records.pdf.

2. Health Information and Quality Authority. *National Standard Diagnosis Dataset and Clinical Document Architecture (CDA) template*. Dublin: Health Information and Quality Authority; 2016. Available online from: https://www.hiqa.ie/sites/default/files/2017-01/Standard-Diagnosis-Dataset-and-CDA-specification.pdf.

3. Health Information and Quality Authority. *National Standard Adverse Reaction Dataset and Clinical Document Architecture (CDA) template*. Dublin: Health Information and Quality Authority; 2016. Available online from: https://www.hiqa.ie/sites/default/files/2017-05/Standard-Adverse-Reaction-Dataset-and-CDA-specification.pdf.

4. Health Information and Quality Authority. *National Standard for a Procedure Dataset including a Clinical Document Architecture specification*. Dublin: Health Information and Quality Authority; 2017. Available online from: https://www.hiqa.ie/sites/default/files/2017-02/National-Standard-for-a-Procedure-Dataset-including-a-Clinical-Document-Architecture-specification.pdf.

5. Lay A, Cotton L. A benefits study of Summary Care Records use in hospital medicines reconciliation and their impact. *Journal of Medicines Optimisation*.2015. Available online from: https://www.pharman.co.uk/imagelib/pdfs/Journal_articles_by_issue/JoMO_Dec_2015/Summary_Care_Records.pdf

6. National Health Service Digital. *Summary Care Record (SCR) in community pharmacy.* 2018. Availble online from: https://digital.nhs.uk/services/summary-care-records-scr/summary-care-record-scr-in-community-pharmacy

7. Morris L, Greenhalgh T, Wyatt Jc, Thomas G, Gunning K. Introducing a nationally shared electronic patient record: Case study comparison of Scotland, England, Wales and Northern Ireland. 2013. *International Journal of Medical Informatics.* 2013 82(5):e125-38. Available online from: https://www.ncbi.nlm.nih.gov/pubmed/234343622013;82:125-38.

8. Gibson D. How to use the summary care record in community pharmacy. *The pharmaceutical Journal.* 2016. Available online from: https://www.pharmaceutical-

journal.com/learning/learning-article/how-to-use-the-summary-care-record-in-community-pharmacy/20201008.article?firstPass=false.

9. Stramer K, Greenhalgh T, Bramer T, Byrne E, Russell J, Potts H. Adoption and Non Adoption of a shared electronic summary record in England:a mixed-method case study. *British Medical Journal*. 2010. Available online from: https://www.ncbi.nlm.nih.gov/pubmed/20554687

10. Morris L, Craig J, Cameron J, Setters J, Varley D, Lay A, Thompson I. An evaluation of the impact of the key information summary on GPs and out-of-hours clinicians in NHS Scotland. *Scottish Medical Journal*. 2015. Available online from: https://www.ncbi.nlm.nih.gov/pubmed/25805773

11. European Patient Smart Open Services. *D2.2.7 - Recommendations from the epSOS Project*. 2014. Available online from: http://www.epsos.eu/uploads/tx_epsosfileshare/D2.2.7_Recommendations_v1.5.pdf.

12. European Patients Smart Open Services. *Work Package 3.9 – Appendix B1/B2 epSOS Semantic Implementation Guidelines*. 2011. Available online from: http://www.epsos.eu

13. European Patients Smart Open Services. *About epSOS*. 2018. Available online from: http://www.epsos.eu/home/about-epsos.html.

14. Joint Action to Support the eHealth Network (JAseHN). *Guideline on the electronic exchange of health data under Cross-Border Directive 2011/24/EU Release 2 Patient Summary for unscheduled care.* 2016. Available online from: https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co30_en.pdf.

15. European Commission. *Trillium Bridge II - Reinforcing the Bridges and Scaling up EU/US Cooperation on Patient Summary*. 2015. Available online from: https://cordis.europa.eu/project/rcn/206099_en.html

16. Health Level Seven (Hl7). *HL7/ASTM Implementation Guide for CDA® R2 - Continuity of Care Document (CCD) Release 1*. 2017. Available online from: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=6.

17. Health Level Seven (Hl7). *International Patient Summary*. 2018 Available online at: http://international-patient-summary.net/mediawiki/index.php?title=Main_Page

18. Joint Initiative Council. *Patient Summary Standards Set Guidance Document Version* 1.0. 2018. Available online from:http://www.jointinitiativecouncil.org/registry/Patient_Summary_Standards_JIC_Jan_2018.pdf

19. Jones E. How summary care records can improve patient safety. *Emergency Nurse.* 2015. 23(1):20-2. Available online from: https://www.ncbi.nlm.nih.gov/pubmed/25854741

20. Greenhalgh T, Wood GW, Bratan T, Stramer K, Hinder S. Patients' attitudes to the summary care record and HealthSpace: qualitative study. *British Medical Journal* 2008, 336(7656):1290-5 Available online from: https://www.ncbi.nlm.nih.gov/pubmed/18511764

21. Stramer K, Greenhalgh T, Bratan T, Byrne E, Russell J, Hinder S, Potts H.The Devil's in the details Final report of the independent evaluation of the Summary Care Record and HealthSpace programmes. *University College London*. 2010. Available online from: http://discovery.ucl.ac.uk/151127/2011.

22. Australian Digital Health. S*hared Health Summary Information Requirements, v1.1* 2015. Available online from: https://www.digitalhealth.gov.au/implementation-resources/clinical-documents/EP-2397-2017/NEHTA-1837-2015

23. CEN/TC 251 European Standard (En) 17269. *The Patient Summary for Unscheduled, Cross-border Care* (CEN/TC 251 EN 17269). 2017. Available online from:https://www.cencenelec.eu/standards/Sectors/healthcare/eHealth/Pages/default.aspx

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