Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health Information and Standards

Statement of outcomes report on focus group discussions and public consultation on a *National Standard on information requirements for a national electronic patient summary*

December 2018

Safer Better Care

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 has developed information requirements for a national electronic patient summary standard. The implementation of accurate patient summaries can lead to many benefits for both individuals and clinicians, and can improve patient experience, patient safety and the effectiveness of patient care by facilitating timely access to the relevant patient records. 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 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.

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Chapter 1 Introduction and background

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 and accurate information needed to enable better communication among clinicians, patients and other healthcare staff. It can also support the continuity of patient care between healthcare settings.

The Department of Health's eHealth Strategy[(1)] 2013 identified that the development of electronic patient summaries should be an early priority project and indicated that it would be delivered by eHealth Ireland. eHealth Ireland 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.

The Sláintecare Implementation Strategy[(2)] published in August 2018 states that ICT"has the potential to be the biggest and most effective driver of change and improvement for better patient outcomes across the health system". The design and roll-out of a range of primary and community-based ICT services that will improve the lives of patients — including ePrescribing, summary care records and telehealthcare solutions to support care in the community — was identified as a priority.

The Sláintecare Implementation Strategy lists patient summaries and the ePrescribing service as part of the implementation of community care solutions, one of the ten key strategic actions that underpin the Sláintecare vision. The approach outlined in the Strategy 'centres around strong health service governance, leadership, accountability, a focus on clear outcomes, providing support to the frontline to drive change, and sustained stakeholder engagement…'.

eHealth Ireland is currently leading on a project to share electronic patient summaries with other EU countries. This 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 published an international review of summary care records in 2016,[(3)] 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, 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, and 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 need for good-quality information from the 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 previously 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)[4]
- *National standard adverse reaction dataset and clinical document architecture (CDA) template* (2016)[5]
- *National standard for a procedure dataset including a clinical document architecture specification* (2017)[6].

HIQA has developed the information requirements required to support the implementation of a national electronic patient summary. This standard defines the information requirements for a national electronic patient summary. Information requirements are a 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 data included in the minimum set of data is determined by how clinically relevant the data are, as well as the potential for the data to improve patient safety in a collaborative care environment. Examples of healthcare providers who might exchange such information include general practitioners, nurses in primary care and other nursing and health and social care professionals in community and acute care settings.

Chapter 2 Overview of the process

Under Section 8(1)(k) of the Health Act 2007,[7] HIQA is charged with setting standards it 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. Standards previously 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. The membership of the eHealth Standards Advisory Group is 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.

When developing standards, the Health Information and Standards Directorate does so in consultation with subject matter experts, service providers, people using services, the general public and other key stakeholders. The project team consulted with people who use health and social care services and staff providing services including doctors, nurses, administrators, quality managers, pharmacists, allied healthcare professionals and general practitioners. The purpose of the focus groups and interviews were to discuss their experience and to obtain their opinion as to what type of information should be included in a national electronic patient summary for Ireland. The project team conducted one-to-one interviews with 23 staff working in emergency departments. One-to-one interviews took place with six general practitioners and two focus groups were conducted with nine service users.

The outputs from the focus groups and one-to-one interviews were summarised and used to inform the development of the draft standard.

HIQA engaged with staff working in emergency departments through a series of semi-structured interviews. The project team conducted one-to-one interviews with 23 hospital staff from emergency departments across two sites — Naas General Hospital and Our Lady of Lourdes Hospital in Drogheda. Participants who gave their views at the interviews included emergency staff from the following diverse roles:

- Consultants in emergency medicine

- Medical staff including Non-Consultant Hospital Doctor, Senior Registrar in Emergency Medicine
- Nursing staff including Assistant Director of Nursing, Advanced Nurse Practitioners, Clinical Nurse Managers, Nurses from the Acute Medical Assessment Unit, staff nurses and a GP liaison nurse
- Allied healthcare professionals — physiotherapists, radiographer
- Emergency department administration staff
- Pharmacists
- Quality Risk and Patient Safety Manager

The project team also conducted interviews with five general practitioners, three of whom also work in the out-of-hours service. Additionally, the team conducted two patient focus groups — one in Naas General Hospital and one in St James's Hospital Dublin — with a total of nine service users to determine what type of requirements the standard should include and to discuss their experiences.

A briefing document was sent to all participants in advance of the interviews and focus groups. This outlined the purpose of the interviews and focus groups, key questions for consideration and how the interviews and focus groups would be facilitated. Two members of the project team attended each focus group; one facilitated the focus group and the other took notes. Appendix C documents the questions which were asked during focus groups and interviews. It was explained that the notes taken would only be used to inform the development of the national standard and points would not be attributed to any individual. All of the feedback gathered at the interviews and focus groups was reviewed and considered by the project team and incorporated into the development of the National Standard.

Reflecting HIQA's commitment to consultation and engagement, each project includes a public consultation to seek and incorporate feedback from external stakeholders. HIQA's 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 standard was made available for a six-week public consultation, running from Monday, 13 August 2018 to Friday, 21 September 2018. In this way, the public, service users and service providers had the opportunity to provide feedback and participate in the development process.

HIQA asked for feedback through an online survey and an online feedback form, both of which included seven questions to prompt feedback:

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

- Have you any alterations or additional items to include in the health condition information requirements?
- Have you any alterations or additional items to include in the current medication information requirements?
- Have you any alterations or additional items to include in the allergies information requirements?
- Have you any alterations or additional items to include in the procedures information requirements?
- Have you any alterations or additional items to include in the vaccinations information requirements?
- Have you any general comments you would like to make about this document?

HIQA received a total of 45 submissions. Twenty one submissions were made on behalf of organisations listed in Appendix B, while 24 submissions were made by individuals. All submissions received were analysed. The draft standard was updated with all accepted comments. The updated draft standard was then presented to the eHealth Standards Advisory Group.

Chapter 3 Analysis of focus group discussions

Two focus groups were held during the consultation stage in order to get feedback from people on the draft national standard. HIQA also engaged with staff working in emergency departments through a series of one-to-one, semi-structured interviews with 23 hospital staff from the emergency departments of Naas General Hospital and Our Lady of Lourdes Hospital in Drogheda. Five general practitioners were interviewed through a small group interview, one telephone interview and one face-to-face interview.

A summary of the points raised during the interviews and focus groups are detailed below. In advance of the interviews and focus groups, all participants were sent a copy of the draft national standard. A briefing note was sent to participants informing them of what would be involved and the purpose of the interviews and focus groups, key questions for consideration and how the interviews and focus groups would be facilitated. At the interviews and focus groups, all participants were asked for their views on the draft standard and what information should be included in a national electronic patient summary for Ireland. The project team analysed and collated all of the feedback received from the focus groups under the themes outlined below.

3.1 Feedback from interviews and patient focus groups

There were six themes used to organise the feedback from the interviews and patient focus groups about information requirements relating to a patient's national electronic summary including: subject of care, health condition, medication prescribed, allergies, procedures and vaccinations. Additionally, there were three key themes that emerged from participants' feedback: business processes, data quality, and information governance.

Overall, there was significant support for the introduction of a national electronic patient summary. In particular, it was agreed by participants that a national electronic patient summary could ensure significant benefits for particular groups of patients including the elderly, trauma patients, people with intellectual disabilities and for cases where a patient does not speak English or has communication difficulties.

The key benefits of a national electronic patient summary that were emphasised by participants included:

- Improvements in patient experience, patient safety and patient care.
- Better trust in the healthcare system.

- Ensures a more efficient way of working, quicker access to up-to-date, accurate information whereby:
  - patients do not have to repeat the same information to different healthcare practitioners as often
  - healthcare practitioners will not have to rely solely on a patient's memory to describe their current health situation or past medical history or medications
  - it is easier to access a national electronic patient summary than the patient's paper chart.
- Encourages good record keeping from primary care and improves continuity of care and communication between primary care and out-of-hours and secondary care.

Some comments from participants in relation to the benefits of a national electronic patient summary included:

- *"Invaluable if person presents without GP's knowledge for where they are at."*
- *"Easier to look for information."*
- *"Patient can be vulnerable and nervous and forget."*
- *"We can decide and treat as soon as possible."*
- *"Emergency situation – stroke and unable to talk – are they on Warfarin?"*

Other important areas that were raised by participants included issues around business processes, data quality and information governance, which are discussed in the following section.

Business processes

A common theme that emerged across the focus groups and interviews was how existing business processes would affect the implementation of a national electronic patient summary. In particular, it was asked how the national electronic patient summary would coexist with the patient's paper chart and whether a national electronic patient summary would integrate with other existing IT systems in use in emergency departments, such as the National Integrated Medical Imaging System (NIMIS). The change in work practice and the time commitment for staff to use a national electronic patient summary was highlighted.

Comments were made on how the national electronic patient summary would work with the current referrals and discharge processes. Participants questioned how the information from the patient's visit to the emergency department would be sent back to the GP and if this information would be incorporated into a discharge summary. It was acknowledged by participants that the GP would generate the national

electronic patient summary and the information for the national electronic patient summary could be sourced from the GP practice management system. Participants commented that there could be challenges with this process as patients can attend multiple GPs, some patients may not have a GP and some GP practices are not computerised. It was also noted that the key stakeholders need to be involved from the start of the project and GPs need to engage fully with the process in order for it to work.

Some comments from participants in relation to the business processes that could affect the introduction of a national electronic patient summary include:

- *"What if patient doesn't have a GP?"*
- *"Referral letters and discharge letters interventions are not clear."*
- *"Hospital sends discharge summary, GP send referral letter, can be confusing, hard to read template they send – current complaint, PMH, Allergies, confusing layout."*
- *"GPs need to buy in."*

Data quality

Quality data and information refers to data and information that are relevant, accurate and reliable, timely, punctual, coherent, comparable, and accessible and clear. The quality of data that is required to populate a national electronic patient summary was discussed by participants. The need for good-quality information sourced from the GP practice management system was stressed by participants to ensure that healthcare practitioners can use the patient summary confidently and that patient's find the national electronic patient summary trustworthy.

Some comments from participants in relation to the data quality needed for a national electronic patient summary include:

- *"For GP – encourage good record keeping, minimal quality of notes usually recorded on systems, would improve quality of healthcare."*
- *"Only as good as the information, need access on need to know."*
- *"Will provide trustworthy information."*
- *"Keep simple with good information, keep it easy to read."*
- *"Big ownis on GP to maintain."*

Information governance

Information governance ensures that personal information is dealt with legally, securely, efficiently and effectively. Information governance issues were strongly emphasised by participants. Some of the comments that emerged from the interviews and focus groups concerned patient consent, patient privacy, security and accessibility of information. In particular, there was strong consensus on the need for accurate information to be made available. Questions were raised such as who is responsible for updating the information and how often patient information would be updated. There was discussion on the security and privacy aspects of the national electronic patient summary and who would have access to it. Finally, patient consent was commented on specifically around a patient's right to decide if they want a national electronic patient summary created and shared.

Some comments from participants in relation to the information governance for a national electronic patient summary include:

- *"The Governance word – who is responsible, is it going to be audited, not just something we are good at for three months and then falls down."*
- *"Issues around profiles for read and write access of GP lists."*
- *"How frequently will it be updates and who is responsible."*
- *"Wrong information about wrong patient – identifiers."*
- *"Only as good as person populating it."*
- *"Needs to be up-to-date."*
- *"If I don't trust the info I will get out the chart."*
- *"Security is important for patients to trust this."*

Information requirements

Participants commented on the type of information that should be included in a national electronic patient summary. Participants suggested changes to the information requirements that were included in the draft standard for consultation and suggested new requirements. In some instances, participants agreed with information requirements that were included in the draft standard and did not suggest any changes. The changes to the information requirements suggested during the focus groups and interviews are listed below.

Subject of care

- *Name — use common name rather than birth certificate name.*
- *Sex — support transgender and intersex status.*
- *Identifier — make the Individual Health Identifier mandatory.*
- *Add in phone number of patient.*
- *Add in socio economic status.*
- *Add next of kin and contact details.*
- *Add do not resuscitate.*
- *Add patient's insurance status.*

Health condition

- *Optionality — review the definition of medical condition.*
- *Change optionality from SHOULD to SHALL for data items date of onset, status, date resolved or inactivated.*
- *Add pregnancy status.*
- *Add infection control status.*
- *Add family history.*
- *Add working diagnosis.*
- *Add social history details.*
- *Add treatment for the diagnoses — was it a home by the GP or was it in hospital.*
- *Add presenting complaint.*
- *Optionality for no known conditions should be SHALL and not SHOULD if there are none, it should not be left blank.*
- *Add evidence that a patient understands reason for treatment.*

Current medication

- *Change optionality from SHOULD to SHALL for dose form strength, dose form type, number of units per intake, frequency of intake and duration of treatment.*
- *Add route of administration.*

- *Add do not substitute.*
- *Add non adherence information.*
- *Add discontinued medication.*
- *Add medication review date.*
- *Add drug interactions and contraindications.*
- *Add relevant blood tests.*
- *Add source of medications.*
- *Add dose adjustment over time.*
- *Add indications for medication.*

Allergies

- *Include a footnote in document on definition/difference between allergy and adverse reaction.*

Procedures

- *Review definition used for a procedure.*
- *Include time period for a procedure.*
- *Add implanted devices information.*

Vaccinations

- *Overall comment — More beneficial for children than adult patients.*

Other

- *Add investigations and ability to access previous test reports and x-rays.*
- *Add blood results.*
- *Add weight.*
- *Add information about smoking and drinking.*
- *Add blood group.*
- *Add referrals.*

Chapter 4 Analysis of public consultation

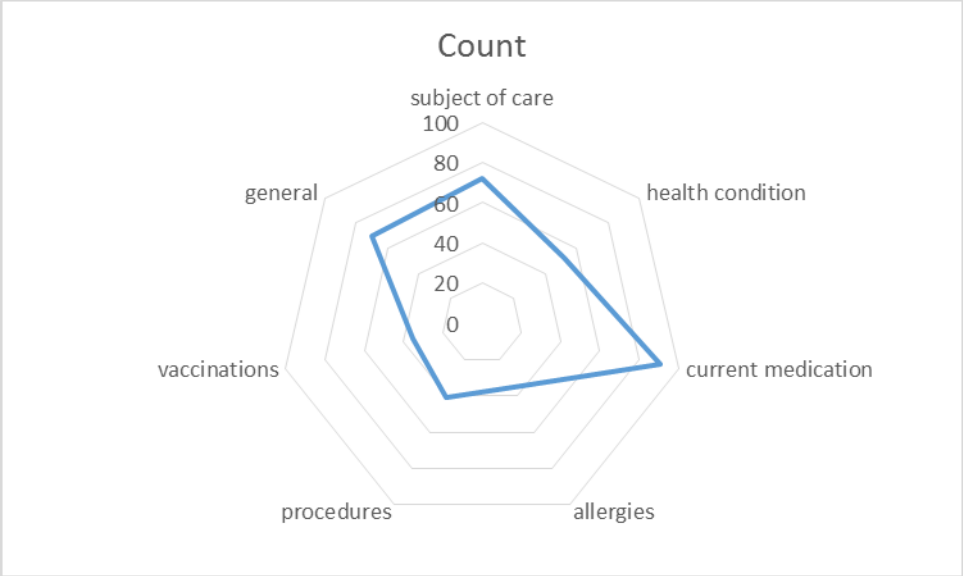
This section provides a high-level summary of the submissions received during the public consultation. Following this, an analysis of the responses to each of the questions asked is provided along with changes made to the standard and sample comments from the submissions.

4.1 Description of responses

During the public consultation on the draft National Standard, 45 separate submissions were received – 26 through the online survey, 18 by email, and one by post. Twenty one submissions were made on behalf of organisations (listed in Appendix B), while 24 were made by individuals.

Each submission was read in its entirety and broken down into individual comments. A total of 396 comments were received, each of which was reviewed and its relevance to the information requirements assessed.

Figure 1 below illustrates the final count of comments for each question and for the general comments category.



The following table shows the distribution of comments:

Question	Number of comments	Question	Number of comments
Current medication	91	Procedures	41
Subject of care	72	Allergies	35
General	70	Vaccinations	35
Health condition	52		

An overview of the comments received for each question is provided below. For each question, a brief summary is provided, followed by a sample of the comments and HIQA's response — where appropriate, corrections have been made to punctuation and grammar of comments quoted in this report.

4.2 Question 1: Have you any alterations or additional

4.3 items to include in the subject of care information requirements?

A total of 72 comments were received during the public consultation related to the subject of care details. The comments were very similar to the feedback received during focus groups and interviews with healthcare professionals.

Details (including contact details) of next of kin was consistently identified through all methods of consultation as being a requirement for the subject of care details. Other themes which emerged included:

- the need to add infection control status
- the need to support both gender and sex
- the need to support the use of the patient's preferred name
- the need to make using the individual health identifier mandatory
- the need to to add a patient's language preference
- the need to list the patient's blood type.

It was also suggested that a person's end of life decisions status be included.

What respondents said:

"I suggest additions to the standard information as follows: The patient summary SHALL contain a patient's first name or given name(s) as stated on the birth certificate and preferred name(s). I think this is more inclusive to those who have not changed the name on their birth certificate to reflect their current gender identity."

"Suggestion to use 'Contact Details' instead of 'Address' where a patient can chose the mode through which they would like to be communicated with e.g., postal address, Phone No., email. Postal correspondence can be slow so the option of other modes would be useful."

"I believe a place to capture contact details of a meaningful contact person or next of kin would be appropriate in this section."

"Suggest the addition of a mandatory infection prevention and control section in order to document each patient's status with regard to MDRO/AMRO, e.g., CPE, MRSA, VRE etc."

"Is there a Do Not Resuscitate (DNR) request for this patient?"

"The patient's blood type."

"Sex: there is confusion as to whether this refers to sex or gender. This should be clarified."

"Sex - Gender identity should include transgender."

"NOK - for life/death decisions and also for legal implications of death certificates."

"Nationality - may assist with language barriers if translation service required urgently."

"In order to maintain the veracity of identity of the patient, the Individual Health Identifier should be mandatory. i.e. SHALL rather than SHOULD."

"The demographic information SHOULD indicate the date at which the information was correct."

"Religion: the patient's religion SHOULD be included as it can pose constraints on management (e.g. Jehovah's witnesses)."

HIQA's Response

Following review of the submissions with the eHealth Standards Advisory Group it was decided that the next of kin and their contact details should be added to the information requirements.

As part of the HIQA standards development process, evidence from international standards and specifications on patient summaries were analysed and the most essential information requirements needed to constitute a patient summary were identified. The scope of a national electronic patient summary should contain the minimum dataset for a specific purpose, in this instance, emergency care and out-of-hours care. The additional requirements identified from the public consultation and during focus groups were carefully considered. It was decided the requirements for a national electronic health record are broader in scope than a national electronic patient summary and would be more suitable to incorporate some of the additional requirements identified.

4.4 Question 2: Have you any alterations or additional items to include in the health condition information requirements?

A total of 52 comments were received during the public consultation related to the health conditions information requirements. The comments were very similar to the feedback received during focus group and interviews with healthcare professionals. A significant number of respondents thought the information requirement were complete and required no changes.

Items which were suggested for inclusion in the health condition details included alcohol misuse, tobacco sage, obesity, past medical history, infection status, intellectual or cognitive disability, blood pressure values, results of investigations, family history and other comorbidities. The continued relevance of diagnoses which had occurred long in the past was questioned. Additionally some people thought the all of the fields should be SHALL rather than SHOULD.

What respondents said:

"I presume all relevant health conditions will be considered in this. In addition, conditions should include serious determinants of health such as alcohol, substance misuse, tobacco addiction, obesity."

"New requirements - Blood Pressure (Hypertension), HbAIC for diabetes, Cholesterol Levels."

"Just to flag the need to document if patient has any known intellectual or cognitive difficulty or difficulty in communicating/hearing…….It is very important for a health professional to know this information in an unscheduled care setting as it may affect the patient's ability to give an accurate history or verify their information which could affect the safety and quality of care they receive."

"We are satisfied with existing data items."

"Recommended an additional field to this section….entitled 'Infection Prevention Control or IPC status'."

"The patient summary should contain Family History: to trace out hereditary diseases."

"Current health condition should also include 'health conditions identified'. Comorbidities are very relevant to delivery of care and links with current medication."

"[We] support the inclusion of data relating to the health condition of the patient / service user within the patient / service user summary. We believe the definition of 'health condition' should be holistically described and include the person's mental health condition."

"Patients may have multiple conditions / co-morbidities each of which may be 'active' to varying degrees. Stating that a condition is either 'Current' or became 'Inactive / resolved' on a particular date is not a sufficiently accurate reflection of the condition."

"2.3-2.6 It may be unnecessarily onerous on GP practice time to retrieve the level of detail required, which may be of limited use".

HIQA's Response

In collaboration with the eHealth Standards Advisory Group, it was decided that the definition of 'medical condition' needed to change.

As part of the HIQA standards development process, evidence from international standards and specifications on patient summaries were analysed and the most essential information requirements needed to constitute a patient summary were identified. The scope of a national electronic patient summary should contain the minimum dataset for a specific purpose, in this instance, emergency care and out-of-hours care. The additional requirements identified from consultation processes were carefully considered. It was decided that the requirements for a national electronic health record are broader in scope and would be more suitable to incorporate some of the additional requirements identified for a patient's health condition in submissions.

4.5 Question 3: Have you any alterations or additional items to include in the current medications information requirements?

A total of 91 comments were received during the public consultation related to the current medications details. A significant number of respondents thought the information requirements were complete and required no changes.

The most common theme from the responses was the need for dose form, strength and type, number of units per intake and duration of treatment to be made mandatory. Route of administration was identified as a required field but was not in the information requirements. Several respondents identified the need to share generic rather than branded medicinal product information. Other comments suggested that the contraindications, previous adverse events, and the number of repeats, do not substitute instructions, medication review date, source of medication and indication for medication should be included.

What respondents said:

"I recommend adding: Known contraindications, past adverse reactions etc. in this section."

"The Must have ability to order via generic or brand name with linking or matching between these medications being maintained."

"Route not currently listed. Need the ability to specify route e.g. SC/IM/IV if injection or specify if drops are for eye or ear"

"Need ability to include the total number of units prescribed (e.g. 30 tablets for benzodiazepine/ CD prescription)."

"Need to include number of repeats of the prescription."

"Need the ability to indicate if something is no longer active i.e. stopped or changed to something else when the prescription would still be legally active. Important to know this at transitions of care as something may have been stopped due to serious adverse event."

"The GP should be able to indicate 'Do not Substitute'?"

"The GP should be able to record medical devices prescribed."

"The patient summary shall state a possible drug interaction column. For example, the patient should not take any statins while on antibiotic clarithromycin."

"The patient summary SHOULD include a section for discontinued medications (and reasons why)."

"[We] consider that there could be real value in having details of indication. This information is missing from the otherwise excellent Scandinavian registries and is a constraint with regard to epidemiological research. Further if pharmaceutical care is to be advanced into the future or concepts such as adaptive pathways are used where initial drug utilisation is restricted until further evidence is available, access at pharmacy level to information on indication will be critical. We understand that it is a challenging area so it may well have been consciously excluded."

HIQA's Response

Following review of the submissions with the eHealth Standards Advisory Group, it was decided to add in the route of administration and to make strength and type, number of units per intake and duration of treatment mandatory for medications. It was identified that route of medication should be added to the information requirement and that field 3.8 should be altered to mean date medication prescribed. The additional requirements were considered to be outside the scope of medication information required for a national electronic patient summary but would be relevant to a medication record within a local clinical information system or national patient medication record.

4.5 Question 4: Have you any alterations or additional items to include in the allergies information requirements?

A total of 35 comments were received during the public consultation related to allergies details. A significant number of respondents thought the information requirements were complete and required no changes.

Suggestions for alterations to the allergies information requirement included the addition of outcome and duration of the reaction to the information requirements. There were a number of comments related to the need to make reaction and severity of reaction mandatory fields.

What respondents said:

"I think this will be populated from the GP record (as it is not a field on the transfer of prescriptions at present). Would be important to be able to populate this from secondary care/other settings and should allow users to record and amend patient allergy or ADR details at any time (subject to robust change control). The SCR should allow the user to record serious adverse drug reactions (other than allergies). This could be achieved by adjusting 4.1 to...patient has a susceptibility to an allergy/ adverse drug reaction upon exposure..."

"It may be beneficial to include the type of reaction as a compulsory field as from experience a lot of people say that they are allergic to certain things and only really have a sensitivity. Such sensitivities should not preclude the patient from receiving an urgent/emergency medication based on a simple sensitivity."

"Perhaps the severity of the allergy to be changed to SHALL for cases where patient has had a previous severe/life threatening reaction to a substance."

"Make 4.5 a subset/option of 4.1 - A patient either has an allergy or does not. Making 4.5 and option in 4.1 removes an optional input while providing greater clarity i.e. if a patient has no allergies, filling in a mandatory answer in 4.1 is not possible unless 'no known drug allergies' is an option."

"Change the name to Allergies and Intolerances."

"The information requirements for the allergy section of the national patient summary standard should mirror the Joint Initiative Council Patient Summary Standards Set guidance. To this end we suggest changing items 4.2-4.4 from recommended to mandatory status i.e. from SHOULD to SHALL. For example, this would enable a clinician to know that an allergy to penicillin in a 35 year old woman was first established by a rash at 10 years old."

"I think the information in allergy section is sufficient."

"It should precede the Current Medications section, as traditionally done on paper forms to alert readers in advance to reading the list of current medications."

"Is reaction onset data of relevance in a summary care record?"

"[We propose] addition of a column to the table to capture information on the outcome of the reaction."

"Reaction onset and date: [we propose] addition of a reference to the duration of the reaction."

"Item 4.2 Change 'should' to 'shall'."

"Item 4.5 Change 'should' to 'shall'."

HIQA's Response

Following review of the submissions with the eHealth Standards Advisory Group, it was decided the definition of an 'allergy' needed to change but to make no other alterations to the allergy information requirement at this time. The scope of a national electronic patient summary should contain the minimum dataset for a specific purpose, in this instance, emergency care and out-of-hours care. The additional requirements identified during our consultation were considered to be outside the scope of allergy information required for an national electronic patient summary, but would be relevant to the patient's allergy record within a local clinical information system.

4.6 Question 5: Have you any alterations or additional items to include in the procedures information requirements?

A total of 41 comments were received during the public consultation related to the procedure details. A significant number of respondents thought the information requirements were complete and required no changes.

The definition of 'procedures' used in the draft document was questioned and the need to clarify the scope of the definition was raised in responses. The relevance of including procedures which were carried out in the past into a current patient summary was questioned. Additional data items to include in the information requirements included planned and cancelled procedures, follow-up post procedures, the performing clinician and where the procedure took place. Finally, the inclusion of information on devices implanted during procedures was requested.

What respondents said:

"Planned procedures should be documented."

"Any complications experienced during or after a procedure to be included in the description of the 'procedure' data item e.g. if a patient has a history of a DVT or PE after a previous procedure it is vital that this information be known before any future procedures."

"We are satisfied with existing data items."

"Procedure needs to be further defined and explained. Is a venipuncture a procedure? Is an ECG a procedure? What constitutes a procedure?"

"The patient summary should contain cautions before and after procedure: For example, whether the individual should be fasting or not, drugs to be hold like metformin for angiogram, clopidogrel on biopsies etc."

"I would include the country where the procedure was carried out."

"It is also unclear what time frame applies to the procedures section. Is there scope for multiple procedures to be recorded? If restricted to one procedure it might miss significant procedures undertaken earlier in the admission, or previously. While the primary aim may be to use the summary for the purpose of emergency, unscheduled and out-of-hours care, there may be instances where the older/previous history needs to be known."

"Will implants be listed?"

"5.1 Which procedure - the most recent - all recent - all procedures ever - only those that the GP is aware of and has recorded?"

HIQA's Response

Following review of the submissions with the eHealth Standards Advisory Group, it was decided the definition of a 'procedure' needed to change but to make no alterations to the procedure information requirement at this time. The scope of a national electronic patient summary should contain the minimum dataset for a specific purpose, in this instance, emergency care and out-of-hours care. The additional information requirements for a procedure identified from the consultation process were carefully considered. The requirements for a local electronic patient record or national electronic health record are broader in scope and it would be more suitable to incorporate the additional requirements identified through submissions to the public consultation and through focus groups.

4.7 Question 6: Have you any alterations or additional items to include in the vaccinations information requirements?

A total of 35 comments were received during the public consultation related to the vaccinations details. A significant number of respondents thought the information requirements were complete and required no changes.

It was suggested that outstanding or refused vaccinations, batch number and possible reactions should be included in a patient summary. It was requested that a link to vaccine guidelines should be accessible from the patient summary.

What respondents said:

"Link to vaccine guidelines which could be interactive with the person's situation - e.g. pregnant women should be offered influenza and pertussis vaccination."

"Item 6.2 Change 'should' to 'shall'."

"Needs to be able to be populated by hospitals and community health settings including community pharmacies."

"The name of the vaccine should include the full name of each vaccine component (via barcode)."

"Record date when revaccination is due or when the immunity expires e.g. for travel vaccines."

"The date of a vaccination to be changed to SHALL for vaccinations that require boosters or have a limited life span."

"We are satisfied with existing data items."

"In the case of infants, what vaccinations due as well as what has been given to date."

"This information will be a very welcome inclusion and particularly important for information regarding children's vaccinations and for healthcare workers."

"Batch number should be available. This is always recorded and may be relevant at point of care."

"The requirement statement should change to 'shall'. The vaccination date may be relevant to the for future community care."

"If No vaccinations have been administered, has the patient refused vaccination or is there an allergy to same."

"I think the information in this section is sufficient."

HIQA's Response

Following review of the submissions with the eHealth Standards Advisory Group, it was decided that no alterations were needed for vaccinations. The scope of a national electronic patient summary should contain the minimum dataset for a specific purpose, in this instance, emergency care and out-of-hours care. The additional requirements were considered to be outside the scope of vaccinations information required for a national electronic patient summary but would be relevant to the patients vaccination record within a national immunisation clinical information system.

Question 7: Have you any general comments you would like to make about this document?

A total of 70 comments were received during the public consultation in response to the questions asking people to provide general comments. A significant number of respondents thought the information requirements were complete and required no changes.

Themes which arose from the general comments included governance requirements and the need to record the patient's consent status. People identified that a patient summary can be very beneficial in the medication reconciliation process. The need to record resuscitation status, infection control status and next of kin was reiterated.

What respondents said:

"Clarity on purpose - and form following function...As this appears to be mainly about medication safety and urgent care, special emphasis on history of medication issues including interactions, over-treatment, iatrogenic incidents etc, drug related incidents need to be included in conditions."

"Also, views in relation to resuscitation might be recorded - as a doctor myself, my current view is that I do not wish to be resuscitated and yet there is nowhere that I can have that recorded and acted upon. The procedure on keeping this information up to date must be taken very seriously as this information will be given a lot of weight so should be validated as much as possible. The patient should also have sight of it and agree with it if possible."

"Will the source of the data, and last revision date, be included in the summary? This information would potentially increase its 'trustworthiness'."

"The inclusion of a Next of Kin information to the min data set."

"Some information about how a patient can access their electronic patient summary and validate some of the information from same."

"Very comprehensive document."

"If operationalized will be fantastic for a safety and saving time and reducing doctor stress"

"The document appears to be comprehensive with multiple references to international research reported and advisory bodies consulted regarding the benefits of the implementation of a Patient Summary specifically in the acute care/out-of-hours setting. However, as mentioned in the answers given above I feel that the recommendations fall short in ensuring safer delivery of care to patients in the

absence on up-to-date clinical information and particular when patients have reduced communication/functional capacity to interact with carers in acute situations."

"The document is very informative and is easy to read and understand. It follows a logical process and the jargon is very limited. There is possibly too much detail in 2.3.1 (International review on patient summaries) for the lay person who is not interested in research evidence and literature reviews."

"We welcome the publication of this draft standard and we are in agreement with most of the content. The literature has pointed to the value of having a summary care record as a data source for medicines reconciliation on admission…An electronic patient care record will be invaluable to not only hospital pharmacist but all staff working in the hospital setting. The medicines record section is a critical section – studies on doctors attitudes to electronic patient care records have shown that this is the section most consulted, particularly in emergency situations."

"Would be nice to see formal input from hospital pharmacy sector in drafting these documents (Ideally hospital pharmacy informatics). IPU only represents Community pharmacists. Hospital pharmacists have a unique viewpoint in a patient's journey through the health system and their expertise would be valuable in this regard."

"Section 7.3 Patient Consent, Access and Audit. Should the National Patient Summary contain information on the patient consent status of the information?"

Chapter 5 Conclusion and next steps

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. A national electronic patient summary is required for Ireland 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.

HIQA has developed information requirements for a national electronic patient summary. 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 electronic patient summaries. Previous standards developed by HIQA — including clinical datasets for diagnosis, procedures and adverse reactions — informed these information requirements.

As part of the standards development process, HIQA also undertook 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. Appendix C documents the questions which were asked during focus groups and in interviews. All feedback was reviewed and, where necessary and appropriate, the draft standards will be revised.

The draft standards were developed in collaboration with the eHealth Standards Advisory Group, whose members are listed in Appendix A. The information requirements for a national electronic patient summary was available for a six-week public consultation, running from 13 August to 21 September 2018. Appendix D documents the consultation questions which were asked.

These standards have been approved by the Board of HIQA and submitted to the Minister for Health. HIQA looks forward to the introduction of a standards-based national electronic patient summary in Ireland.

Appendix A Membership of the eHealth Standards Advisory Group and HIQA project team

The eHealth Standards Advisory Group consists of the followed individuals:

Niall Sinnott	Department of Health
Loretta Grogan	HSE – Clinical Care Programmes
Iryna Pokhilo	CAIRDE – Patient Representative
Jack Shanahan	Irish Pharmaceutical Union
Gerry Kelliher	Royal College of Surgeons in Ireland – Surgical Affairs
Brian O'Mahony	Irish College of General Practitioners (General Practice IT Group)
Gerardine Sayers	HSE – Health Intelligence
Emer Kelly	Royal College of Physicians of Ireland
Eileen Bell	Enterprise Ireland
Roisin Doherty	Access to Information
Peter Connolly	HSE – Office of Chief Information Officer – EA
Yvonne Goff	HSE – Office of Chief Information Officer (CCIO)
Fran Thompson	HSE – Office of Chief Information Officer
Damon Berry	National Standards Authority of Ireland
Paul Gallagher	National Association of Directors of Nursing and Midwifery

The HIQA project team consisted of:

Kevin O'Carroll	Standards and Technology Manager
Louise Mc Quaid	Standards and Technology Lead
Deirdre Laffan	Standards and Technology Lead

Appendix B Contributing Organisations

National Cancer Control Programme

DMF Systems

Quality Improvement Division, Health Service Executive

Irish Pharmacy Union

General Practice Information Technology Group

Irish College of General Practitioners

Antimicrobial Resistance & Infection Control Team, Health Service Executive

Pre-Hospital Emergency Care Council

St Patrick's Mental Health Services

Irish Platform for Patient Organisations, Science & Industry

Data Protection Commission

Emergency Medicine Program

Enterprise Architecture Function of OoCIO, Health Service Executive

Irish Society of Chartered Physiotherapists

Allcare Pharmacy Group

Office of Chief Information Officer, Health Service Executive

eHealth and Information Policy Unit, Department of Health

Road Safety Authority

Health Products Regulation Authority

Irish Medical Organisation – IMO GP Committee

Healthcare Pricing Office

Appendix C Schedule of Questions for Focus Group Discussions

The following are the questions that were used during each of the focus group meetings and structured interviews.

1. If you were rushed to hospital or had to attend emergency care or out-of-hours care, what information do you think is given by your general practitioner to the nurses and doctors who treat you?
2. If your GP was to make information available in advance to hospitals and out-of-hours, what information do you think that should be?
3. Ask participants to consider each heading and data items and state whether they were in support of its inclusion and their reasons for their response.
4. Would you want to have an electronic patient summary (that could be used in OOH or emergency care)? Why/why not?
5. What do you think are the benefits of the electronic patient summary?
6. What would you see as the disadvantages of the electronic patient summary?
7. Any other concerns?

Appendix D Public Consultation Feedback Form

Draft Standard for Consultation: Information requirements for a national patient summary

Consultation Feedback Form - August 2018

Your views are very important to us. We would like to hear what you think about the draft Standard on the information requirements for a national patient summary.

Your comments will be carefully considered and will inform the final standard in conjunction with HIQA's eHealth Advisory Group.

The closing date for consultation is 5pm on Friday 21st September 2018

You can email or post a completed form to us. You can also complete and submit your feedback online at https://www.hiqa.ie.

About you

Name:	
Contact Details: (Email, Phone)	
Date:	

I am responding:	as an individual	
	on behalf of an organisation	

Organisation: (If you are responding on behalf of an organisation)	

Feedback questions

We would like to know your views on the draft Standard for Consultation: information requirements for a national patient summary. Please provide us with feedback on the draft Standard, or alternatively you can provide us with general comments.

Consultation Question 1

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

Consultation Question 2

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

Consultation Question 3

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

Consultation Question 4

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

Consultation Question 5

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

Consultation Question 6

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

Consultation Question 7

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

Thank you for taking the time to give us your views.

Please return your form to us either by email or post:

technicalstandards@hiqa.ie

Health Information and Quality Authority

Technical standards consultation,

George's Court

George's Lane

If you have any questions you can contact the consultation team by calling (01) 8147685.

Please return your form to us either by email or post before

5pm on Friday 21st September 2018.

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