Draft standard for public consultation -

information requirements for a national patient summary -

IPPOSI Response

The draft text below has been created by IPPOSI in response to the public consultation on the Information requirements for a national patient summary - draft standard, opened by HIQA[1] . Questions 1-6 ask for information about the specific information requirements of different aspects of a patient summary whereas Question 7 asks for more general comments.

QUESTION 1 - Have you any alterations or additional items to include in the subject of care information requirements?

The information requirements for the subject of care section of the national patient summary standard should mirror the Joint Initiative Council *Patient Summary Standards Set* guidance[2] and the European Patients Smart Open Services (epSOS) work package 3.9 – Appendix B1/B2 epSOS Semantic Implementation Guidelines[3]. To this end we suggest changing items 1.2, 1.3, 1.5 and 1.6 from recommended to mandatory status i.e. from SHOULD to SHALL.

As a minor point, we do not see the need for the mandatory inclusion of item 1.1 as it is not in many international or European information standards and its inclusion can have an impact on marital and sexual orientation equality considerations. Similarly, for item 1.6 we suggest that patients are able to choose their administrative gender.

QUESTION 2 - Have you any alterations or additional items to include in the health condition information requirements?

The information requirements for the health condition section of the national patient summary standard should mirror the Joint Initiative Council *Patient Summary Standards Set* guidance[4] and the Guidelines on Minimum/Nonexhaustive Patient Summary Dataset for Electronic Exchange in accordance with the Cross-Border Directive 2011/24/EU[5]. To this end we suggest changing items 2.2, 2.3 and 2.5 from recommended to mandatory status i.e. from SHOULD to SHALL.

To facilitate the proper identification of patients, we propose that this section also recommend that GPs use the most accurate disease classification code (e.g. ICD, SNOMED, Orphacodes), according to approved guidelines to complete item 2.1 (current health status). These codes should be considered central as a core demographic variable so that they are visible to every health professional.

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[1] https://www.hiqa.ie/reports-and-publications/consultation/information-requirements-national-patient-summary-draft

[2] http://www.jointinitiativecouncil.org/registry/Patient_Summary_Standards_JIC_Jan_2018.pdf

[3] https://ec.europa.eu/cefdigital/wiki/download/attachments/55878732/D3.9.1_Appendix_B1_B2_Implementation_v1.4_20110725.pdf?version=1&modificationDate=1512129672783&api=v2

[4] http://www.jointinitiativecouncil.org/registry/Patient_Summary_Standards_JIC_Jan_2018.pdf

[5] https://ec.europa.eu/health/sites/health/files/ehealth/docs/guidelines_patient_summary_en.pdf

QUESTION 3 - Have you any alterations or additional items to include in the current medications information requirements?

The information requirements for the current medications section of the national patient summary standard may be among the most important to get right. A study of how doctors in Norway have used patient summaries indicates that this is the most widely used and most generally trusted section of the record; although this may be due to the fact that (in Norway) this section is automatically populated from the national prescribing system and therefore deemed more 'reliable'[6]. Given that Ireland also intends to introduce an e-prescribing system, albeit initially only at the community level, IPPOSI recommends that HIQA consider changing items 3.2-3.7 from recommended to mandatory status i.e. from SHOULD to SHALL. Even while this continues to be populated manually by individual doctors, an information requirement standard of SHALL is in line with the Joint Initiative Council *Patient Summary Standards Set* guidance[7] and the Guidelines on Minimum/Nonexhaustive Patient Summary Dataset for Electronic Exchange in accordance with the Cross-Border Directive 2011/24/EU[8].

In addition, it may be worth considering the inclusion of details to support medicines reconciliation, particularly at the point of transitions in care. Inclusion of the status for each item on the medication list allows for a clinician to include a detail regarding the status of a medication (i.e. started, stopped, modified, discontinued) as well as a reason for that status.

QUESTION 4 - Have you any alterations or additional items to include in the allergies information requirements?

The information requirements for the allergy section of the national patient summary standard should mirror the Joint Initiative Council *Patient Summary Standards Set* guidance[9]. 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.

QUESTION 5 - Have you any alterations or additional items to include in the procedures information requirements?

The information requirements for the procedures section of the national patient summary standard should mirror the Joint Initiative Council *Patient Summary Standards Set* guidance[10] and the Guidelines on Minimum/Non-exhaustive Patient Summary Dataset for Electronic Exchange in accordance with the Cross-Border Directive 2011/24/EU[11]. To this end we suggest introducing a six month timeframe and changing item 5.2 from recommended to mandatory status i.e. from SHOULD to SHALL. We also think it should be clearly stated the range of diagnostic tests which should or should not be included in this section.

QUESTION 6 - Have you any alterations or additional items to include in the vaccinations information requirements?

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[6] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5889579/
[7] http://www.jointinitiativecouncil.org/registry/Patient_Summary_Standards_JIC_Jan_2018.pdf
[8] https://ec.europa.eu/health/sites/health/files/ehealth/docs/guidelines_patient_summary_en.pdf
[9] http://www.jointinitiativecouncil.org/registry/Patient_Summary_Standards_JIC_Jan_2018.pdf
[10] http://www.jointinitiativecouncil.org/registry/Patient_Summary_Standards_JIC_Jan_2018.pdf
[11] https://ec.europa.eu/health/sites/health/files/ehealth/docs/guidelines_patient_summary_en.pdf

No comment.

QUESTION 7 - Have you any general comments you would like to make about this document?

7.1 **IPPOSI calls for a broader societal discussion on the topic of national patient summaries and the active education of the public and patient communities.** While we recognise that this consultation is limited to the topic of information requirements, we urge HIQA, in association with the Dept. of Health and e-Health Ireland to initiate a broader societal discussion on the related topics of national patient summaries / shared care records / patient summary records.

At present, neither the wider patient or clinical communities appear to be sufficiently informed of the utility and benefits of introducing a patient summary record. Given the limited resources available within the health sector, we believe that the huge investment needed to bring the summary care record to life must be matched by an enthusiasm among patients (and clinicians) for the potential and perceived benefit of having a record. Experience from the UK and other jurisdictions suggests that key stakeholder buy-in is essential to the success of a national patient record project, and we believe that this buy-in should be secured in the early planning phase to allow for greater patient and public involvement.

We believe a well-funded public information campaign, designed and delivered in partnership with patients and other key stakeholders, is urgently required to bridge the gap between national health policy and public expectation. As a society we need to understand the benefits derived from sharing health data; the different initiatives in progress to make this happen (patient summary records, electronic health records, individual health identifiers); the personal/professional responsibilities and protections in place to ensure that health data is appropriately collected, stored and used.

It would be disappointing to develop a national patient summary record only to find out that the majority of Irish patients choose to opt-out or that the majority of clinicians continue to repeatedly collect basic information directly from patients. We feel that a broader societal discussion is also needed to ensure that public and patient attitudes from vulnerable and hard-to-reach communities are captured, as witnessed in the UK by Prof Greenhalgh in her 2008 qualitative study of 'Patients' attitudes to the summary care record and HealthSpace[12]".

7.2 **IPPOSI asks that capturing patient (and clinician) perspectives be at the heart of HIQA's focus groups and one-to-one interviews, as well as any national patient summary record solution emerging from this consultation.**

IPPOSI welcomes the decision by HIQA to complement the formal written consultation process with more inter-active consultation approaches, namely focus groups and one-to-one interviews to identify information requirements for a national patient summary.

IPPOSI recommends that HIQA run at least one focus group and several one-to-one interviews with patients, and would be happy to offer our expertise in patient engagement to help HIQA to organise and facilitate these activities. We also believe it might be beneficial to organise a focus group with both patients and clinicians, so that complex or sensitive issues can be explored together.

[12] https://www.bmj.com/content/336/7656/1290

IPPOSI was concerned to see that a patient representative has not been actively involved in HIQA's eHealth Standards Advisory Group to date. We understand that this oversight has now been acknowledged and that plans are in place to rectify this lack of representation. We recommend that at least one patient representative (and one alternate) be appointed immediately. IPPOSI remains available to liaise with the chosen representative(s) to explore ways to ensure that their input into the Advisory Group reflects the wishes of the broader patient community.

IPPOSI firmly maintains that the final decision about the information requirements for the national patient summary record must remain independent of the requirements of any specific or preferred or in-use IT architecture. We recommend that the proposed national patient summary for Ireland be passed through a series of use cases including several clinician and patient use cases of the patient summary.

IPPOSI recommends that an important part of the outcomes from any consultations, focus groups, interviews with patients, is that they should be in a format that can be useable in an IT systems design. The OpenEHR[13] consortium is an international, standards based IT platform and community to facilitate consensus on data items and their aggregation for clinical use. A system/process could be used in Ireland for both patients and clinicians to express their ideas concerning information for Irish IT systems.

7.3 IPPOSI supports the introduction of standardised information requirements for a national patient summary and calls for a high-quality standard to be set.

We believe that the summary should provide as much quality information as possible, while still remaining true to its original function which is to deliver an accurate but concise summary for attending clinicians and healthcare professionals in unplanned and emergency settings. To this end, and in line with international standards, we recommend changing several of the record items from 'recommended' to 'mandatory' status i.e. from SHOULD to SHALL (see our responses to consultation questions 1-5). Ideally, the resulting summary record should also operate as an index and should contain links to more detailed/complete medical documents (such as in Finland[14]).

While we acknowledge that the summary cannot, or should not, capture all information about a patient, we question whether it might not be useful to recommend all or a selection of the following details:

- next of kin
- preferred health care provider
- minor guardian
- donor status
- do-not-resuscitate order
- blood type
- blood transfusion consent
- medical device or implant history
- vaccination history

[13] www.openehr.org

[14] https://www.eiseverywhere.com/file_uploads/75a400f8decc31928240b4ce66e9d793_Day2.Panel4.Speaker2.HeikkiVirkkunen.pdf

- preferred language

This information should be able to be added with the expressed consent of the patient.

We believe that the resulting summary record should include a document identification section where information such as when the record was created, when it was last updated, who authored the creation and updates, is captured and shared in a standardised way. We suggest that the document identification section of the record also indicate the level of consent a patient has provided and whether the record has been formally authenticated by the patient and the date of authentication.

We call for the national patient summary to be integrated and fully interoperable with the future national electronic health record. The experience from Norway shows that from both a patient safety and a clinical efficacy point of view, placing the summary patient record within the electronic health record allows health care professionals to access all information in one place. The summary record can be identified by a standardised icon. To alert professionals to critical information contained within the patient summary, the icon might be colour-coded, for example a blue icon signals no critical information registered while a red icon signals critical information like allergies, implants or chronic conditions[15].

7.4 IPPOSI supports the exchange of patient health data between European member states and believes that Ireland's national patient summary must be fit-for-purpose.

As Ireland moves towards meeting its commitment to share patient summaries with European Member States participating in the OPEN NCP initiative, IPPOSI asks that the best interests of patients (and specifically Irish patients) be placed at the heart of decision-making. Irish patients must be confident that the standards agreed nationally, are upheld (or exceeded) when information is shared across borders. Of priority, different models of consent need to be understood and respected by the European health care community.

7.5 IPPOSI believes that identifying the right model of consent will play an important role in the overall success of the national patient summary record.

To this end, we suggest that a dedicated working group be established within HIQA's eHealth Standards Advisory Group to explore the question of consent in detail. This group should link in with ongoing work by the Dept. of Health to establish a national policy framework and legal basis for processing personal health data. Patient representatives and individual patients with a particular interest or expertise in the area of consent might be invited to join the working group and work in partnership with HIQA to identify the most suitable consent model.

The Advisory Group, and any established working group, should develop a plan for engaging patients on this topic. The plan should ensure that the voices of vulnerable and hard-to-reach patients are captured and that their concerns inform any solution proposed. Engagement should not be limited to patient organisation representatives which advocate on behalf of patients. Consent needs to be understood by the 'naïve' patient – from those who hope that all their health information is already shared, to those who wish to limit access to their health information.

[15] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5889579/

All consent models should be up for discussion (opt-in, opt-out, consent to view, consent to edit, reconsent at the point of access, sealed envelope options) and the advantages and disadvantages to each should be impartially presented. The focus should be on finding solutions which work for all stakeholders. As an interesting example, Northern Ireland and Scotland have come up with a two-stage or double-lock consent model which involves 'implied consent' to collect initial personal health information, but requires 'explicit consent' to view at the point of accessing health services (obviously there may be challenges when a patient presents as unconscious or with mental health or substance abuse issues). We maintain that any solution put forward should seek to promote the model of dynamic consent, which allows patients to change their preferences over time.

Whatever the model of consent adopted, the result must be that patients know the health care professionals which are able to access their records. Therefore, traceability needs to be a key consideration. In Sweden, all health care professionals are listed on a national electronic catalogue which indicates what provider they work for and in what capacity. Professionals seeking to access a patient summary identify themselves using a special electronic ID card[16]. Guidance documents should be prepared to help health care professionals know what patient information can be accessed, used and shared. Ideally, in the future, all patients should be able to log onto an online service (or patient portal) to see what personal health information is being collected from them, who is able to access it, when it has been viewed and by whom, and what purpose it has been used for. The work to establish a patient portal in Ireland needs to be prioritised and fast-tracked.

Previously, the Irish government has asked individual GPs to 'opt-out' of various national schemes and initiatives. This should not be permitted in the case of national patient summary records. Every patient who wants and consents to have a record should be able to have one, regardless of the GP they attend.

7.6 IPPOSI proposes that the implementation of the information standard be carefully and regularly monitored and evaluated, with the involvement of patients.

We believe that the draft standard should outline the mechanism which HIQA will put in place to monitor the implementation of this standard nationally. We call on HIQA to involve patient representatives in designing this monitoring mechanism and in carrying out monitoring activities. Patient representatives should also be involved in evaluating the outcomes and in communicating results to the public and wider patient community. As part of the monitoring activity, a broad cross-section of the patient population should be approached – both in the immediate aftermath of the initial implementation and on an ongoing basis – to capture their confidence in the record.

7.7 IPPOSI cautions that the national patient summary record should not replace, but rather enhance, the traditional communication which takes place between patient and clinician.

Clinicians should be mindful that the record will only ever be a snapshot, and that additional information and clarifications must be sought from the patient where possible. The purpose of the summary should be to avoid patients having to repeatedly share basic information with their clinician, thereby releasing more time during the consultation for more important patient-clinician interactions. To foster this culture of practice, the national patient summary record may consider including a requirement which asks patients to verify the authenticity of

[16] http://www.telemedicine-momentum.eu/testimonial23/

the information provided on a regular basis, for example annually with their GP. Equally, the record may consider asking clinicians to again check at the point of access whether a patient wishes to contest, update or supplement a particular point of information provided which is relevant to his/her current care.