



REPORT

On

The Implementation of Patient Summary Guidelines in Member States¹

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¹ Including Norway

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1. Foreword

The objective of this document is to report on the feedback from the Member State (MS) representatives responsible for the implementation of Patient Summary guidelines and to identify the barriers to and facilitators of the implementation of these guidelines in Member States, obtained from the questionnaire on the Patient Summary guidelines' implementation created within the framework of the JAseHN project. We believe that the results presented in this report will provide a better understanding of the conditions and barriers faced by Member States in the implementation of the guidelines; it will also form a basis for updating guidelines and establish a clear set of methodological standards for the assessment and monitoring of guideline implementation for future re-use.

2. Executive summary

This report is based on the answers to questions asked in the questionnaire that was distributed to associated and collaborating partners of the JAseHN. 27 Member State representatives (excluding Slovakia) and one non-EU Member State representative (Norway) were contacted. The questionnaire was based and focused on the Patient Summary guidelines' implementation in Member States. It was assumed that each country representative was in the best position to evaluate the most suitable response for his/her country.

The aim of the questionnaire was to collect data on the progress and impact of the Patient Summary guidelines' implementation in Member States and to outline some of the barriers for implementation. Conclusions are based exclusively on the questionnaire results and include the feedback received from JAseHN partners.

3. Introduction

The eHealth guidelines' implementation was assessed with regard to four interoperability aspects (i.e. levels²) in accordance with the European Interoperability Framework (EIF):

1. Legal (Questions 1-5: Information on legal interoperability)
2. Organisational (Questions 6-15: Information on organisational interoperability)
3. Semantic (Questions 16-25: Information on semantic interoperability)
4. Technical (Questions 26-35: Information on technical interoperability)

Member States were asked to answer questions both on the practical aspects of the Patient Summary guidelines' implementation (such as barriers to implementation) and on the factual information regarding the state of implementation.

Out of 28 countries contacted (Austria, Belgium, Bulgaria, Croatia, Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Sweden, Slovenia, Spain and the United Kingdom), 25 countries provided answers to the questionnaire. The countries that have answered the questionnaire are Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Portugal, Romania, Spain, Sweden and the United

² The European Interoperability Framework uses the term 'Interoperability layer' when discussing the different aspects of interoperability; see more here: http://ec.europa.eu/isa/documents/isa_annex_ii_eif_en.pdf

Kingdom. The Netherlands responded too late to be included in this report and Poland and Slovenia did not respond to the call.³

The main constraint of this report is its reliance on the questionnaire data gathered from Member States. The conclusions were based on responses gathered from national contact points, consisting of their opinion on matters pertaining to the national and cross-border implementation of Patient Summary guidelines, and are only a part of the complete picture. That being said, the answers might have been focused on the national capacity for legal, organisational, semantical and technical interoperability, which may or may not have an impact on the cross-border data sharing capability, and thus represent a Member State's subjective opinion. It should also be noted that some Member States opted for answering most of the questions with 'No' or 'I don't know'. The reason for this could be that the questions were unclear or that there was unwillingness to answer on particular aspects of the national ability to share data. It could also be that some of the respondents weren't able to answer the question due to its lack of alignment with the current situation within the respective Member State's internal organisation. From the Member States' answers, it seems this is particularly true for the technical interoperability section of the questionnaire. Other Member States showed willingness for cross-border healthcare data exchange. However, the fact that the prioritisation of eHealth and other healthcare-related projects is still underway is slowing this process down. Another constraint of this report is the close delivery deadlines and the fact that the questionnaire was conducted during the holiday season.

4. Notes on methodology

As a mechanism for obtaining information and opinion, questionnaires offer a number of advantages and disadvantages when compared to other evaluation tools. In general, questionnaires are effective mechanisms for the efficient collection of certain kinds of information. Although there are also some issues that need to be addressed when using questionnaires for data collection, in that the quality of respondent data is probably not as high as with alternative methods of data collection, such as interviews, there are significant benefits to using questionnaires. One key advantage of using questionnaires to collect data is that they permit respondents time to consider their responses carefully without any interference from the interviewer. They are also low-cost, as they can easily be electronically mailed to respondents. Even though the questions need to be both specific and broad, as they need to cover different aspects of a problem and at the same time provide an unambiguous answer, it is possible to provide questionnaires to large numbers of people simultaneously. Questionnaires provide uniformity because each respondent receives an identical set of questions and they are able to address a large number of issues and cover areas of interest in a relatively efficient way, with the possibility of a high response rate. With closed-form questions, responses are standardised, which

³ National organisations that participated in answering the questionnaire are the following: ELGA GmbH (Austria), Federal Ministry of Health (Austria), PFS Public Health (Belgium), BEAT (Bulgaria), Department Information and Communication Policy in Health in the Bulgarian Health Ministry (Bulgaria), IHIS (Czech Republic), Croatian Health Insurance Fund (Croatia), Ministry of Health (Cyprus), Danish eHealth Agency (Denmark), Estonian eHealth Foundation (Estonia), National Institute for Health and Welfare (Finland), French Ministry of Social Affairs and Health (France), Bundesministerium für Gesundheit (Germany), 3rd Regional Health Authority (Greece), AEEK (Hungary), Semmelweis University (Hungary), Department of Health (Ireland), Ministry of Health (Italy), National Health Service (Latvia), National Health Insurance Fund under the Ministry of Health (Lithuania), Vilnius University Hospital Santariskiu Klinikos (Lithuania), Agence eSanté (Luxembourg), Government of Malta (Malta), Norwegian Directorate of Health (Norway), Ministry of Health and Shared Services (Portugal), National Health Insurance House (Romania), Ministry of Health, Social Services and Equality (Spain), Swedish eHealth Agency (Sweden), HSCIC (UK).

can assist in interpreting answers from large numbers of respondents. In this way, the answers are mutually comparable, although they may lack depth and the root cause of the problem may remain hidden. We have opted for using the questionnaire as the data collection method due to its high distribution rate, standardisation of answers and ease of analysis.

5. Report

The following section outlines the results from the Patient Summary guidelines' implementation questionnaire. As previously stated, the questionnaire was structured in accordance with the European Interoperability Framework.

5.1. LEVEL 1: Assessing legal preparedness and interoperability

Q1. Does your country have a clear legal basis (a national law or other regulatory document) governing the privacy, security and safety issues regarding the use of patient data?

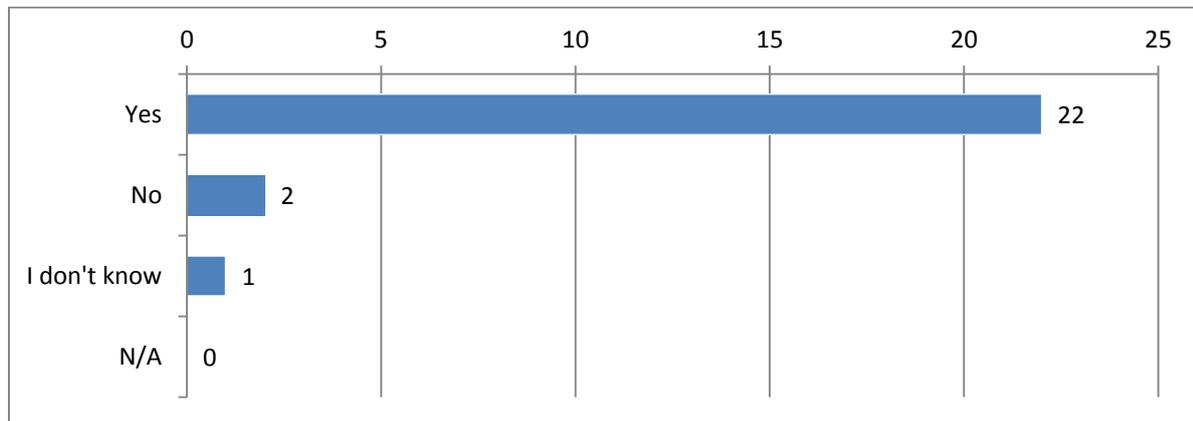


Figure 1. Question 1 on the legal basis for the use of patient data

Q2. Does your country have national laws in place that provide a legal basis for the interoperability of the cross-border exchange of personal healthcare data?

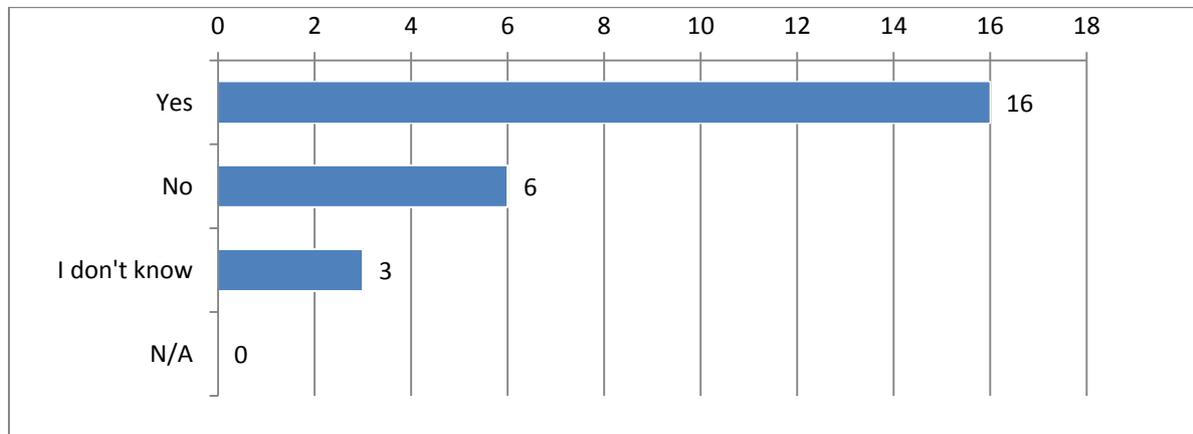


Figure 2. Question 2 on the legal basis for the use of patient data in a cross-border setting, i.e. the exchange of patient data across borders

Q3. Has your country established cross-border data controllers?

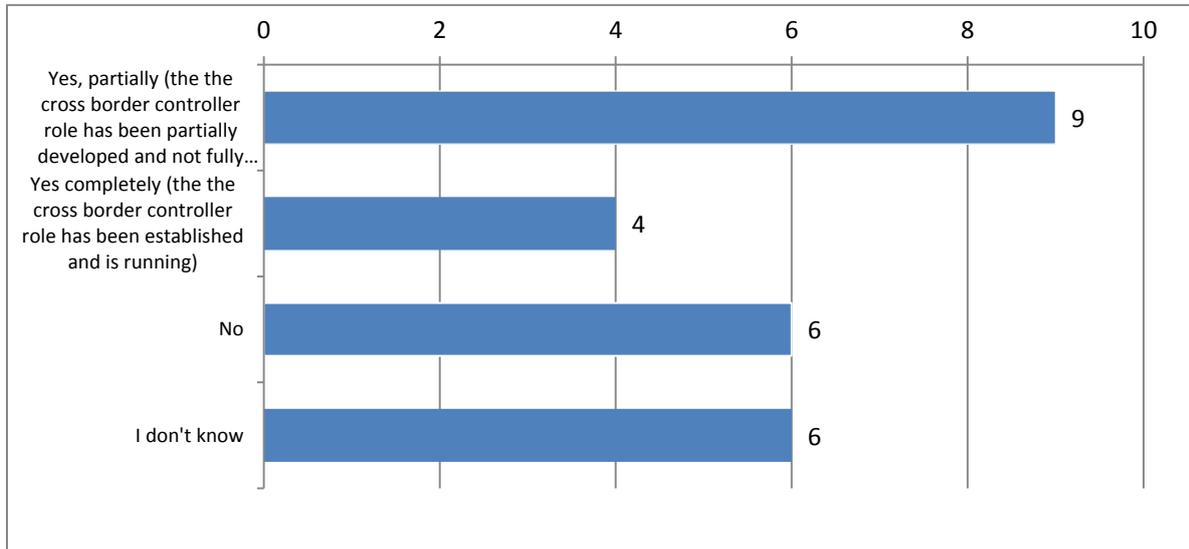


Figure 3. Question 3 on the establishment of the data controller role in Member States

Q4. Does your country implement consent management for the processing and storing of personal and/or patient data and subsequent authorised access?

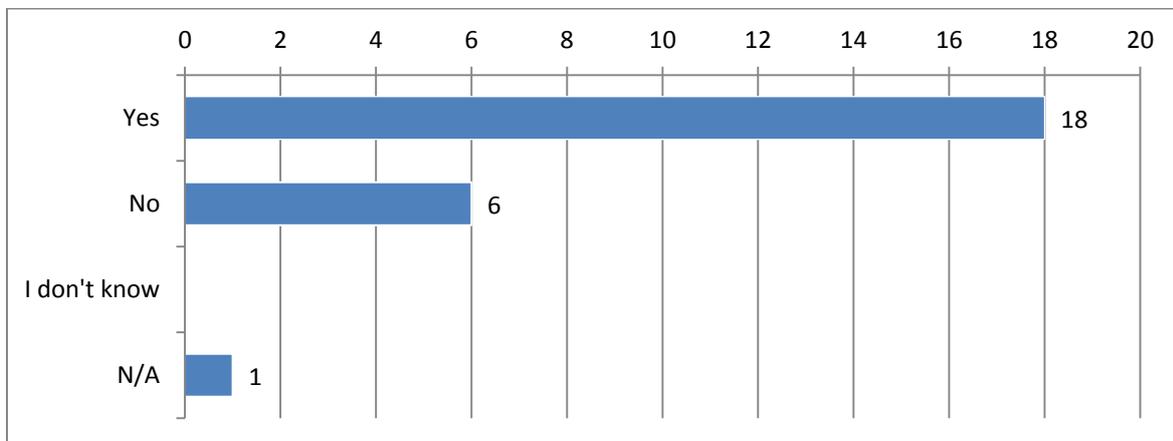


Figure 4. Question 4 on national consent management regarding the processing and storage of, and authorised access to, personal healthcare data

Q5. For how long are the patient data log files stored for litigation purposes in your country?

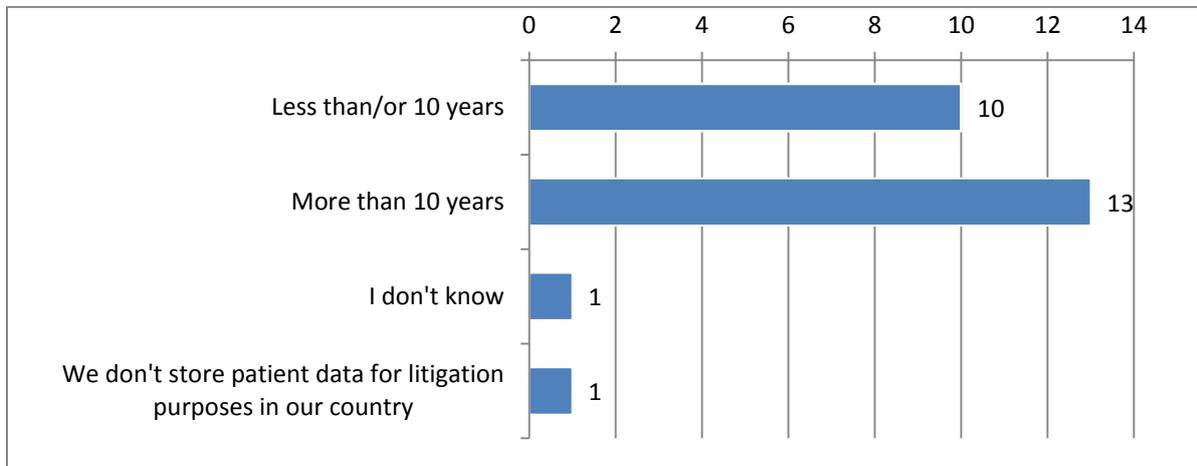


Figure 5. Question 5 on the duration of keeping personal patient data log files

Q6. Does the data subject (i.e. a person to whom the personal data relates) know to whom to address questions about access to any of his/her data in the cross-border exchange of information?

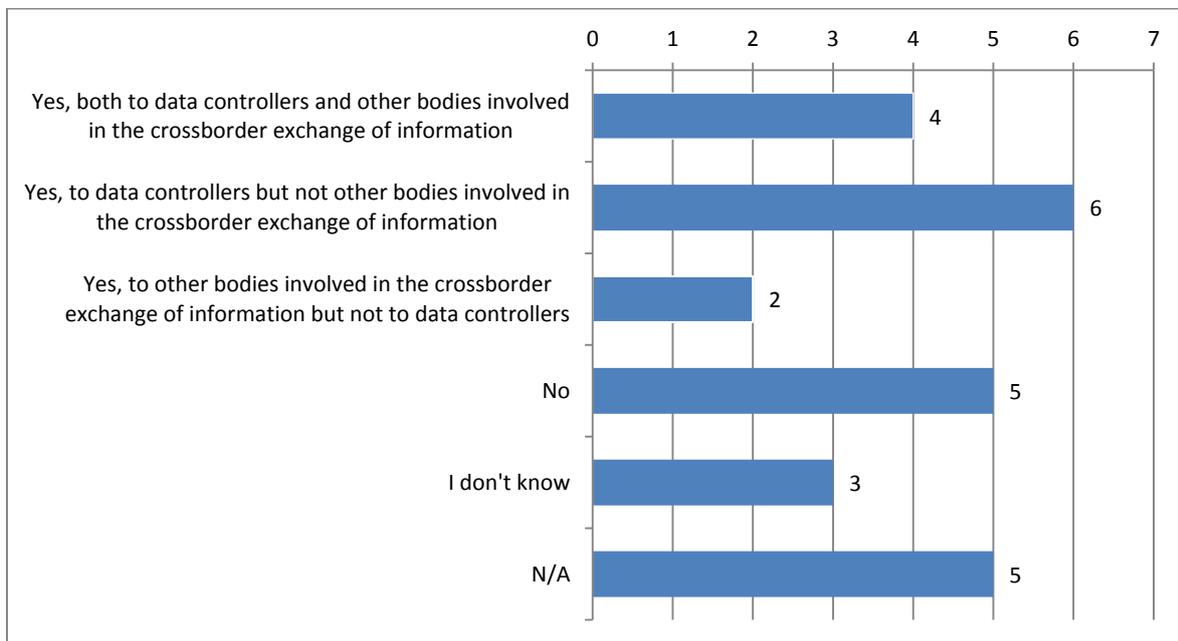


Figure 6. Question 6 on data subject awareness regarding personal data usage in a cross-border setting

5.2. LEVEL 2: Assessing organisational preparedness and interoperability

Q7. Has your country set up any of the following supervisory bodies for cross-border services monitoring the progress on technical and semantic interoperability and their successful implementation?⁴

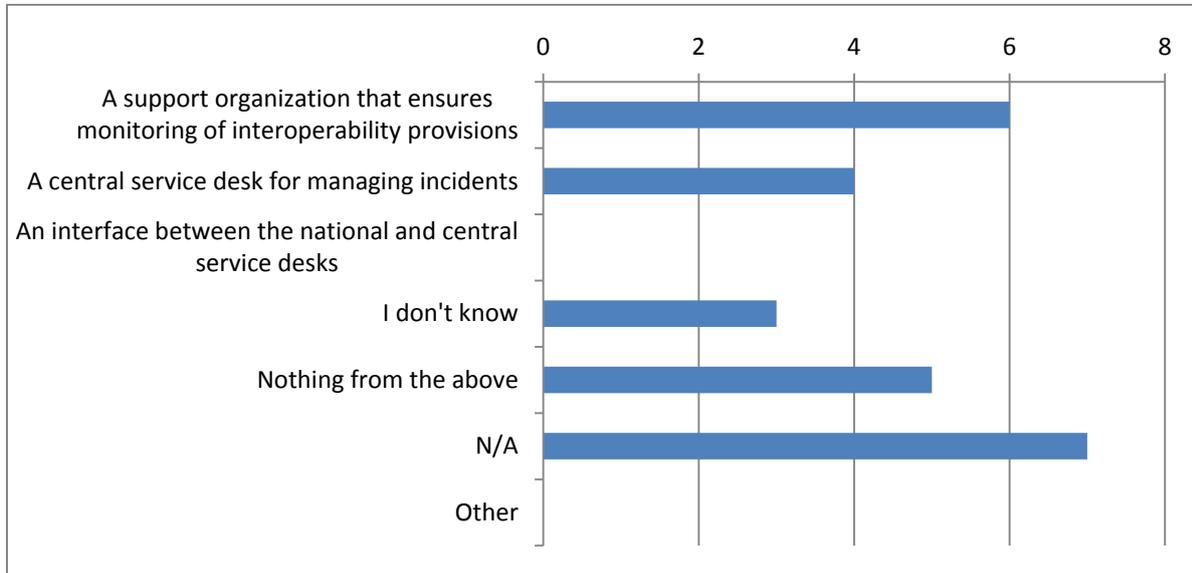


Figure 7. Question 7 on the set-up of supervisory bodies charged with implementing cross-border services monitoring the progress on technical and semantic interoperability

Q8. If so, are the respective contact details made available to all users by the supervisory body?

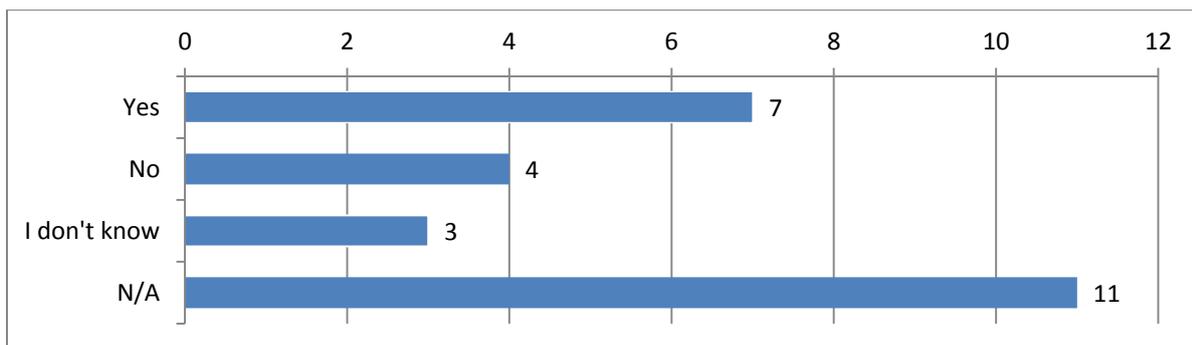


Figure 8. Question 8 on whether respective contact details are made available to all users by the supervisory body

⁴ Multiple-choice question

Q9. Has your country put in place assessment tools that allow it to measure the potential quantitative and qualitative benefits and risks (including economic benefits and cost effectiveness) of services?

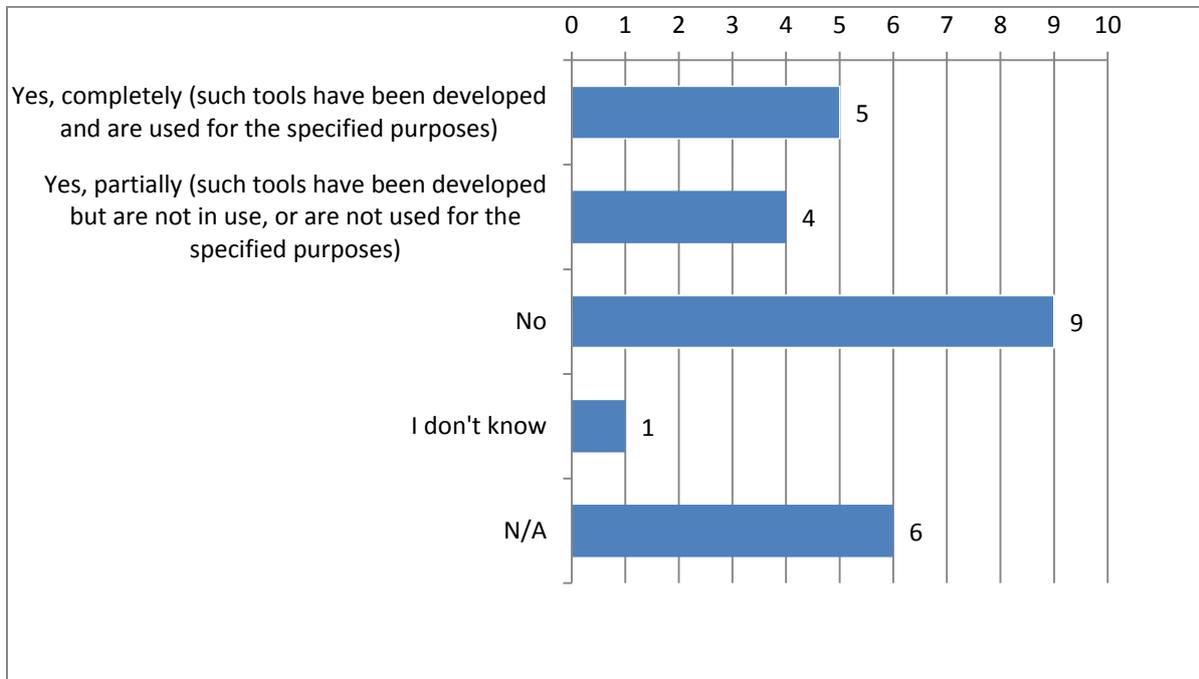


Figure 9. Question 9 on the assessment tools put in place by the Member State authorities to evaluate the potential quantitative and qualitative benefits and risks (including economic benefits and cost effectiveness) of cross-border personal healthcare data services

Q10. Does your country have a competent body in place that is responsible for maintaining and/or providing a healthcare provider registry for identification information purposes?

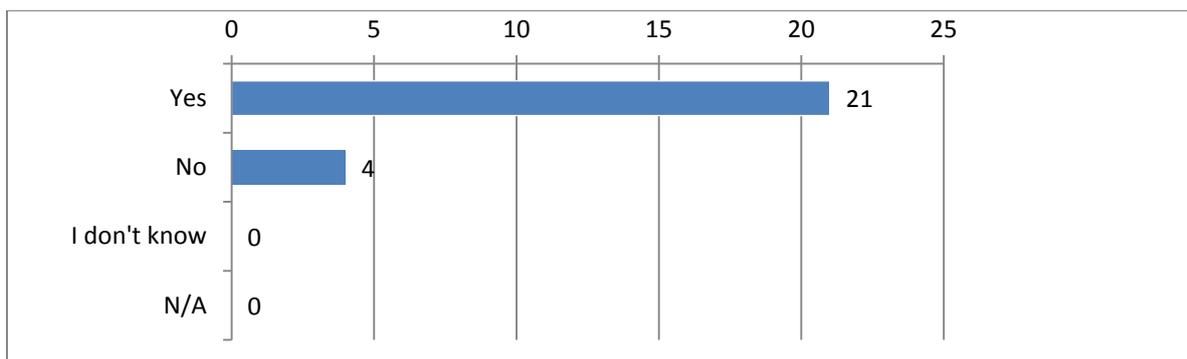


Figure 10. Question 10 on the maintenance and/or provision of a healthcare provider registry for identification information purposes

Q11. Does your country have an eHealth National Contact Point (NCP) for the purpose of ensuring interoperability across national borders with other Member States?

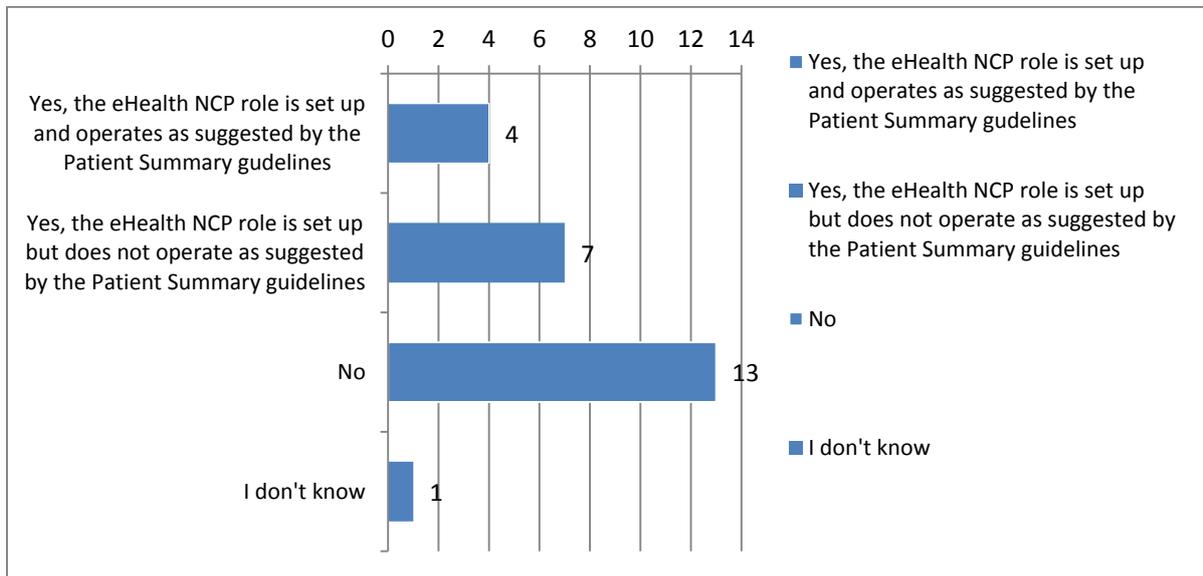


Figure 11. Question 11 regarding the NCP role and its supported functions

Q12. Does your country have a website providing relevant information on the specific rights of data subjects according to the different legislations of all the participating Member States?

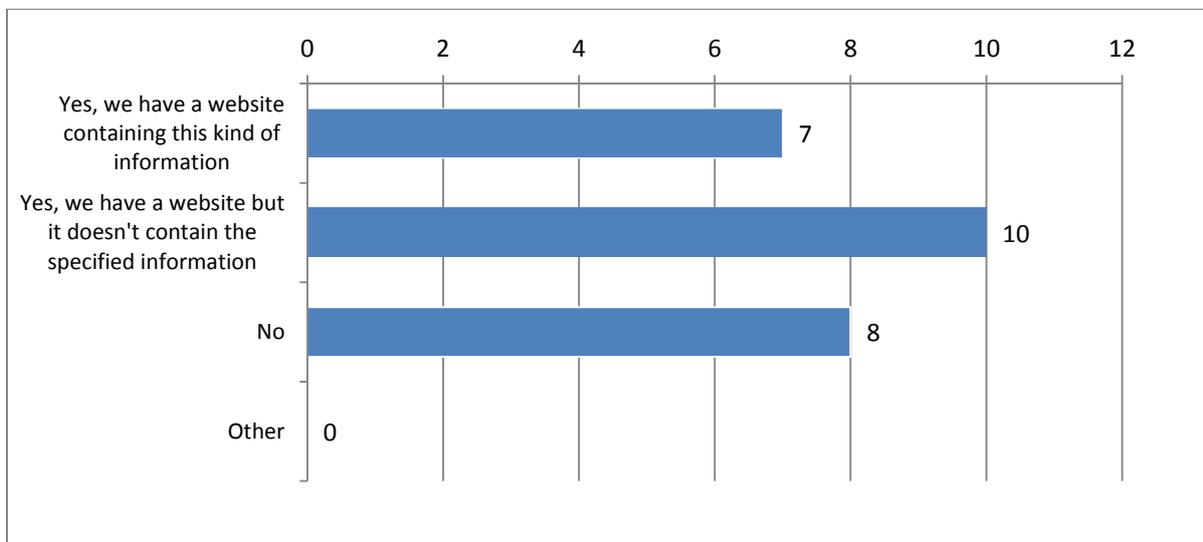


Figure 12. Question 12 concerning the existence of a national website containing relevant information on the specific rights of data subjects according to the different legislations of all the participating Member States, as described in the Patient Summary guidelines

Q13. Does your country use any of the following (answers provided)?⁵

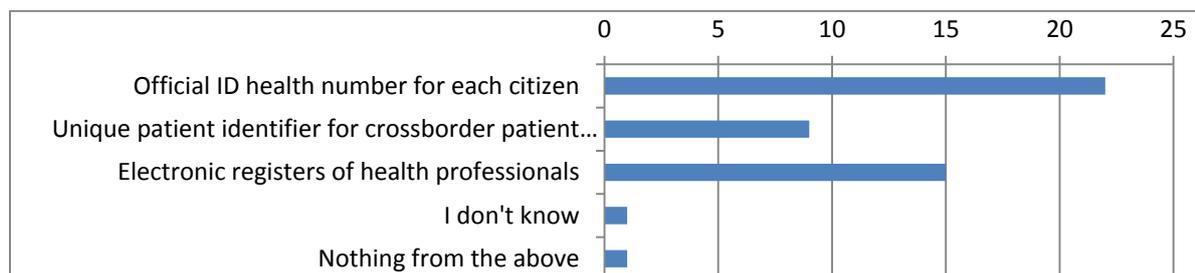


Figure 13. Question 13 on the Member State identifiers used for healthcare data management

Q14. Has your country implemented a digital signing system for health professionals and healthcare provider organisations?

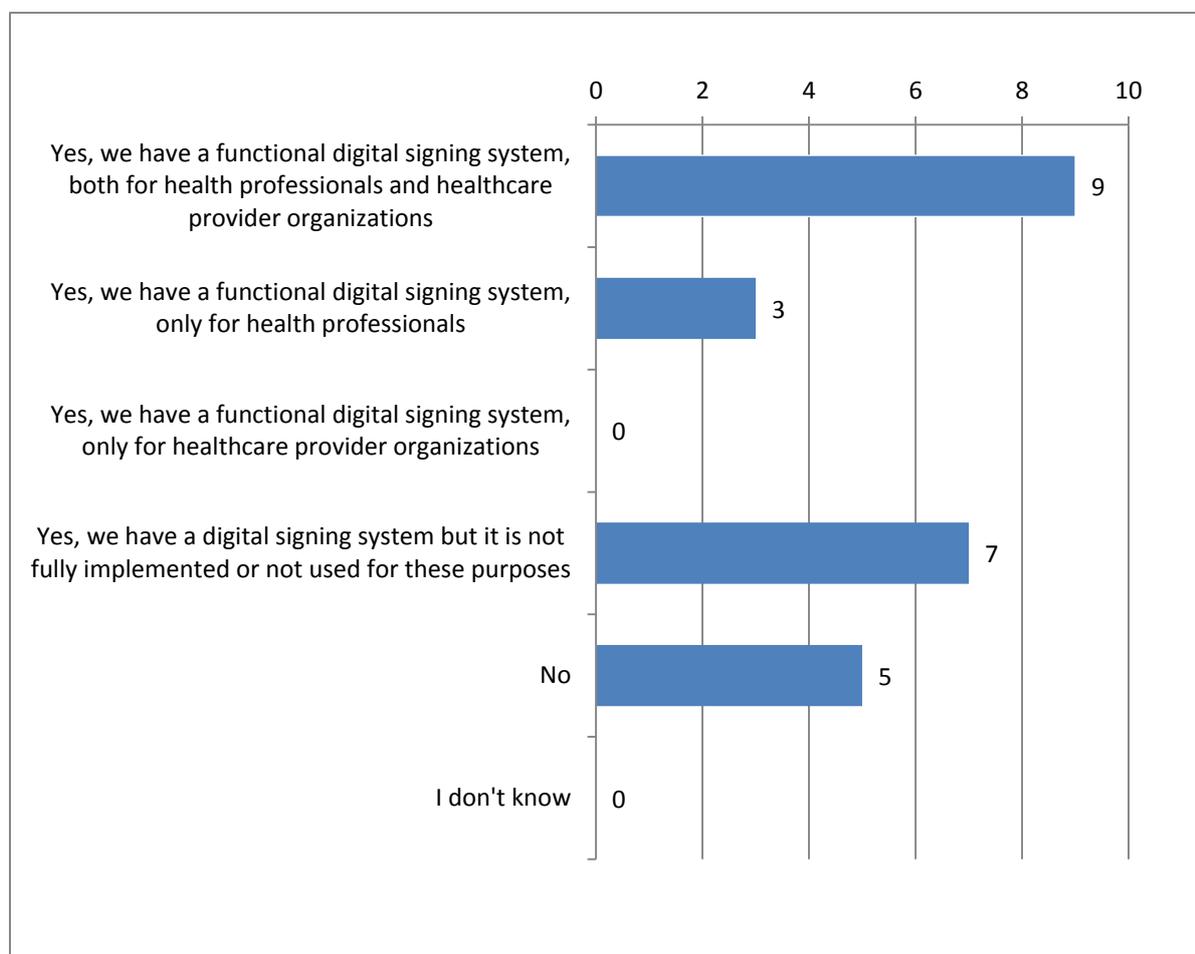


Figure 14. Question 14 on the implementation of a digital signing system for health professionals and healthcare provider organisations

⁵ Multiple-choice question

Q15. In terms of education, training and raising citizen awareness, which of the following applies to your country (answers provided)?⁶

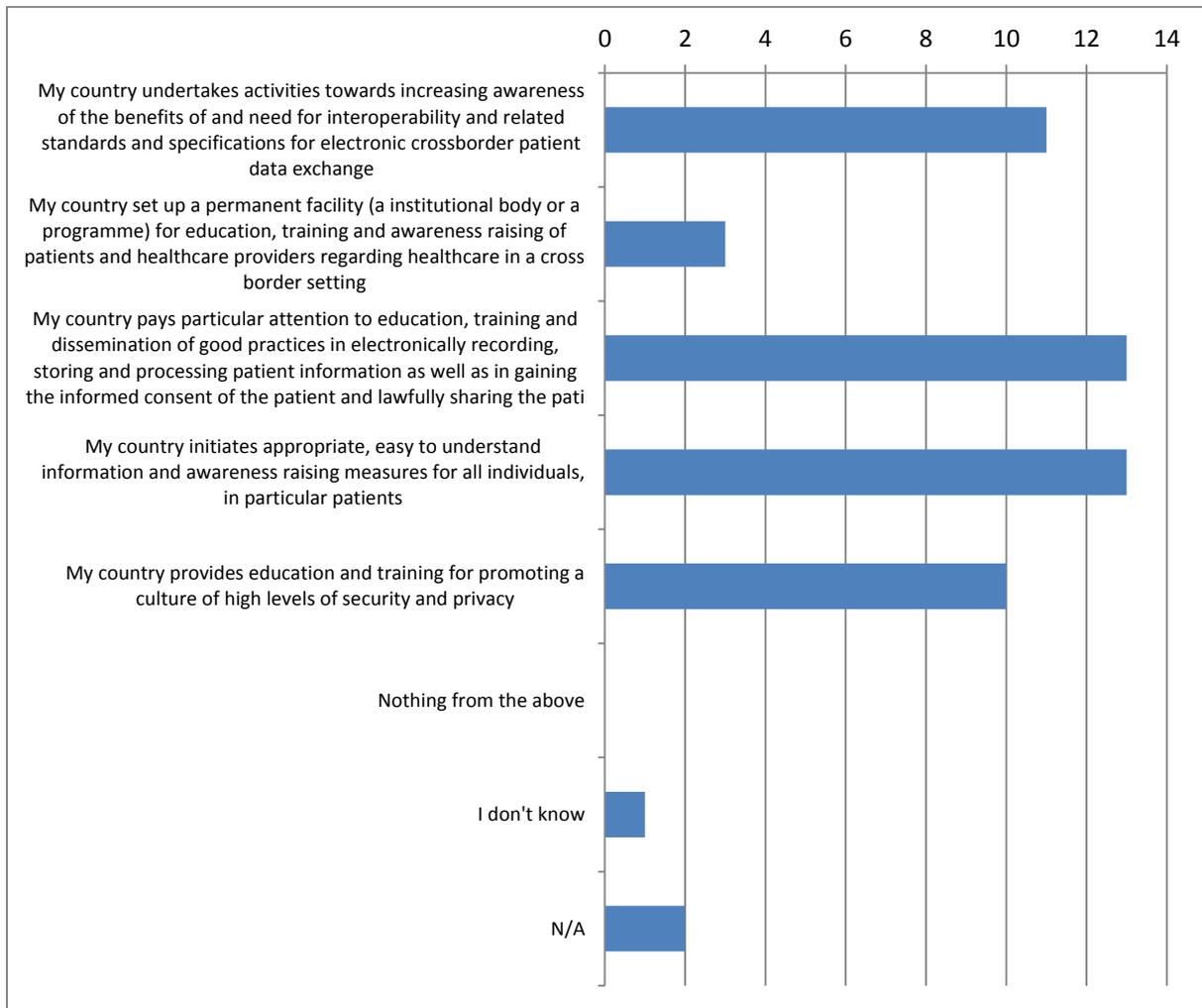


Figure 15. Question 15 regarding education, training and raising citizen awareness in cross-border healthcare data exchange

⁶ Multiple-choice question

5.3. LEVEL 3: Assessing semantic preparedness and interoperability

Q16. Does your country make use of the coding schemes (e.g. Emergency Dataset (EDS), ISO 215493, Patient Health Card Data – Limited Clinical Data, Hospital Data Project dataset, HL7 Terminology, IHE Recommendations) described in the Patient Summary guidelines?

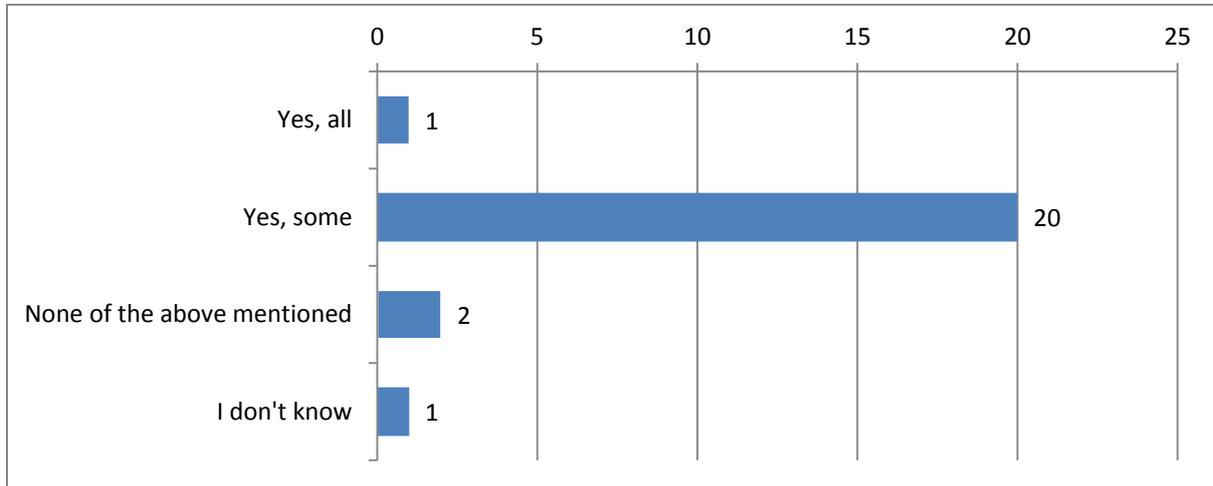


Figure 16. Question 16 on the usage of standardised coding schemes

Q17. Does your country apply commonly agreed upon quality and safety standards in the process of coding the information into patient records, as recommended by the Patient Summary guidelines?

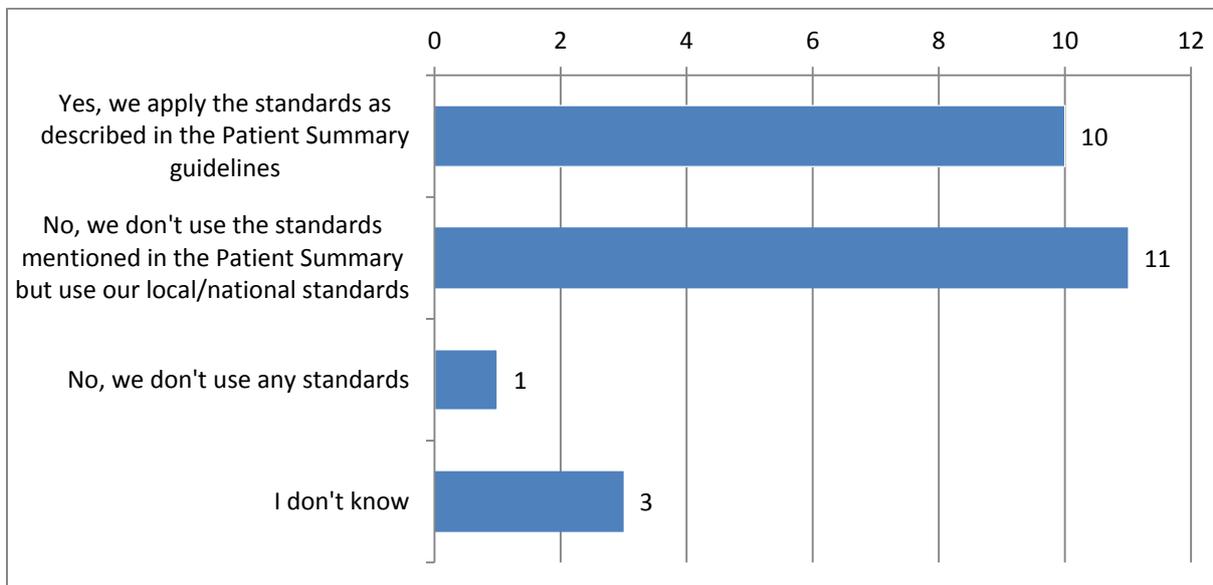


Figure 17. Question 17 on the application of commonly agreed quality and safety standards in the process of coding the information into patient records

Q18. Has your country established a testing environment that demonstrates compliance with agreed standards for the purposes of cross-border patient information exchange?

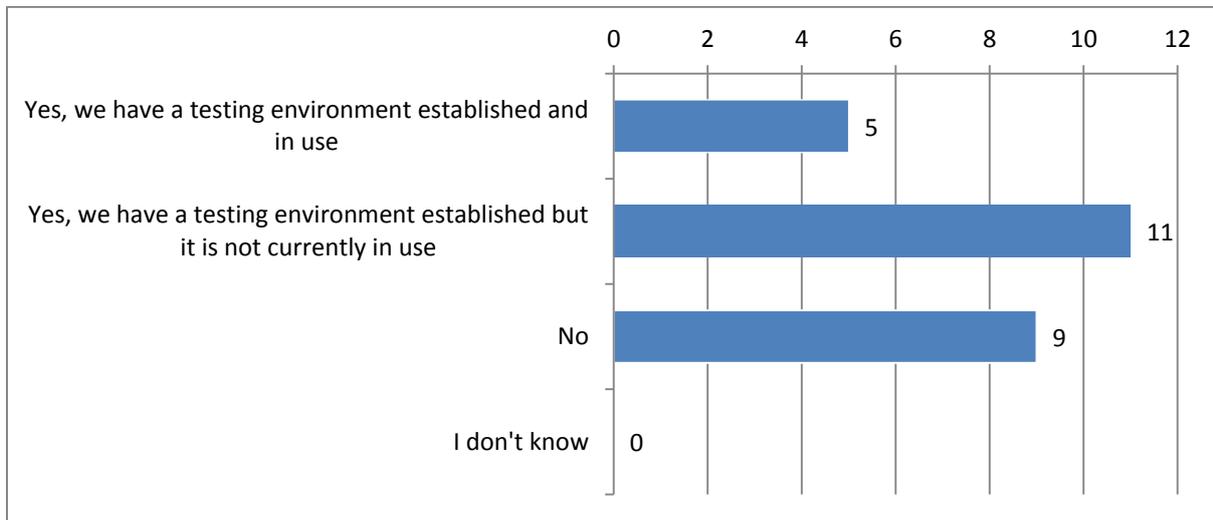


Figure 18. Question 18 on the usage of a testing environment that demonstrates compliance with agreed standards for the purposes of cross-border patient information exchange

Q19. Which of the following most accurately applies to your country's terminologies in use for cross-border healthcare data exchange (answers provided)?⁷

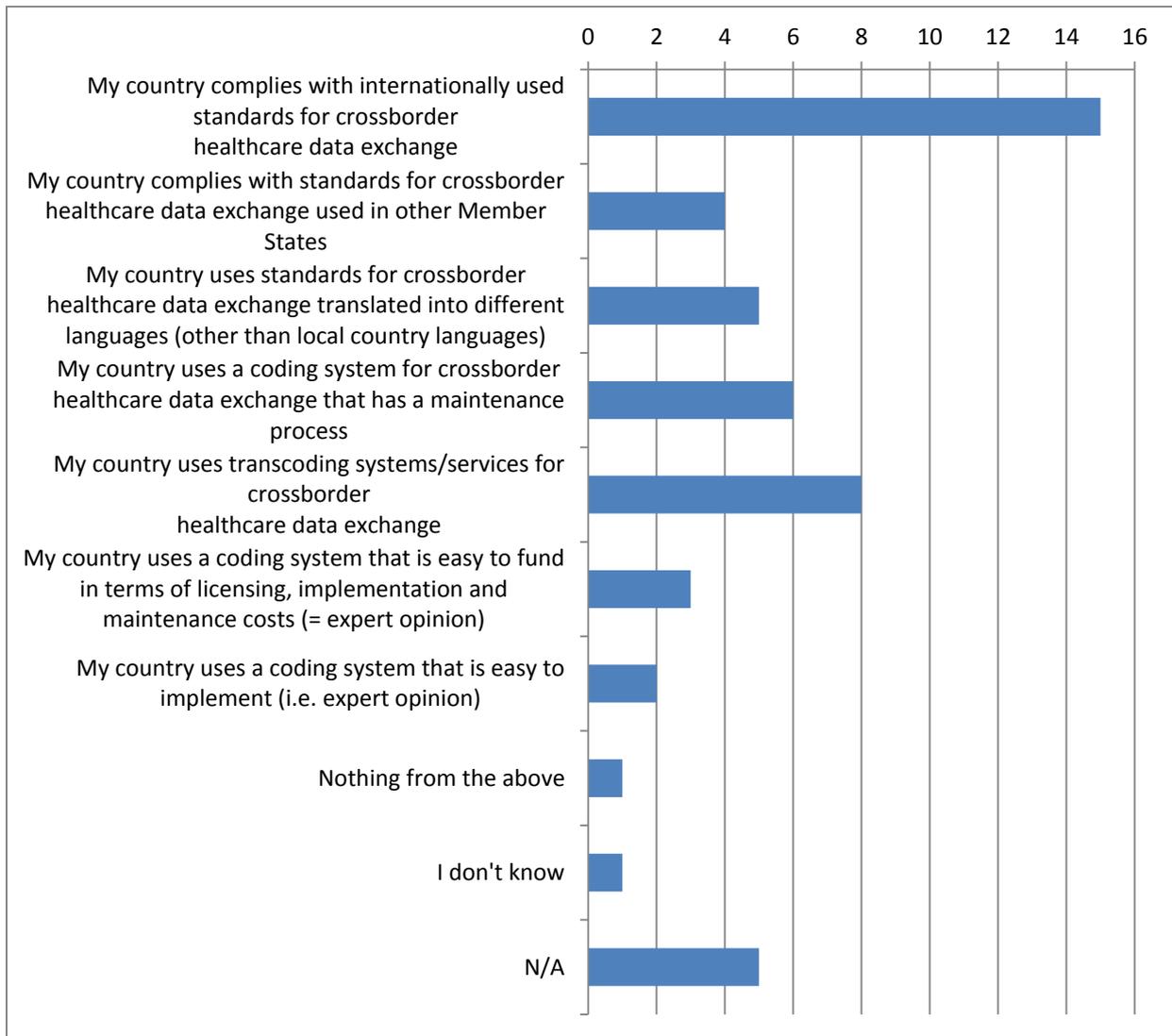


Figure 19. Question 19 regarding the Member State terminologies in use for cross-border healthcare data exchange

⁷ Multiple-choice question

Q20. Does your country have a translated version of the Master Valuesets Catalogue (MVC) in your country's local language(s)?

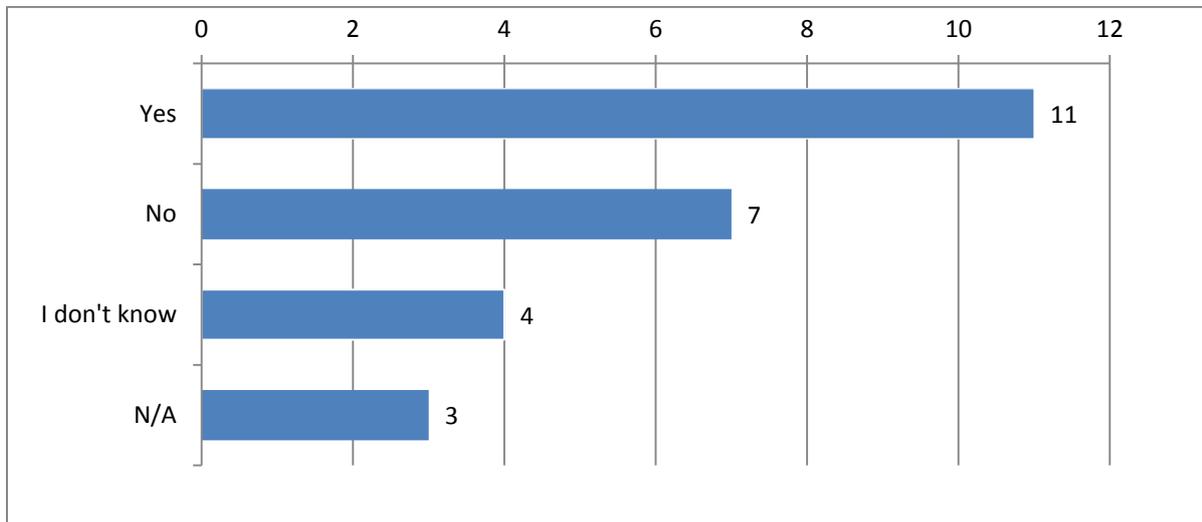


Figure 20. Question 20 on the existence of a translated version of the Master Valuesets Catalogue (MVC) in the national/ local language(s)

Q21. Does your country apply commonly agreed upon rules for quality and safety when creating catalogue entries with regard to the MVC?

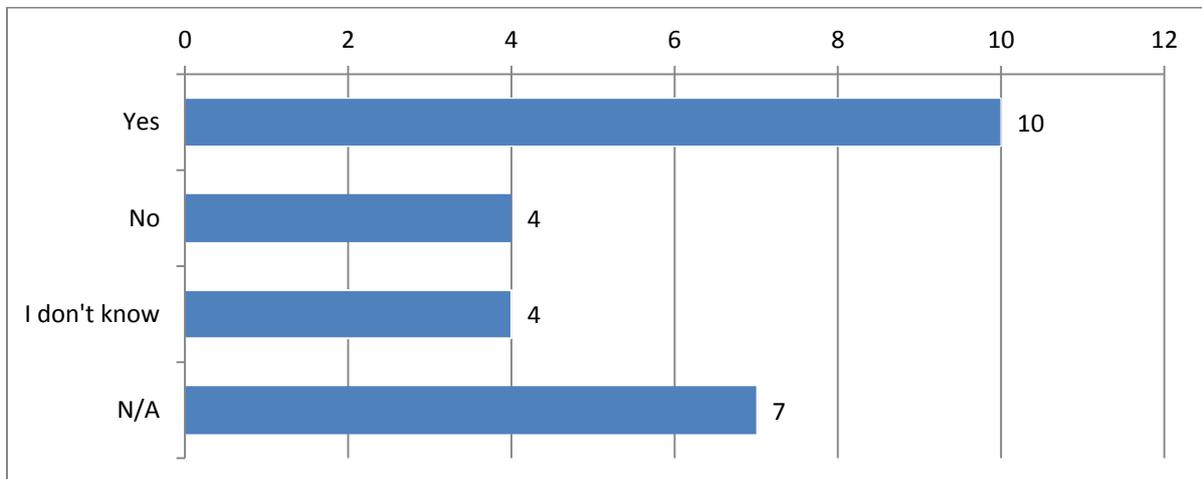


Figure 21. Question 21 on the application of commonly agreed upon rules for quality and safety when creating catalogue entries with regard to the MVC

Q22. Has your country set up a competent body that is responsible for the accuracy and integrity of the semantic translation, mapping and transcoding process of cross-border healthcare data?

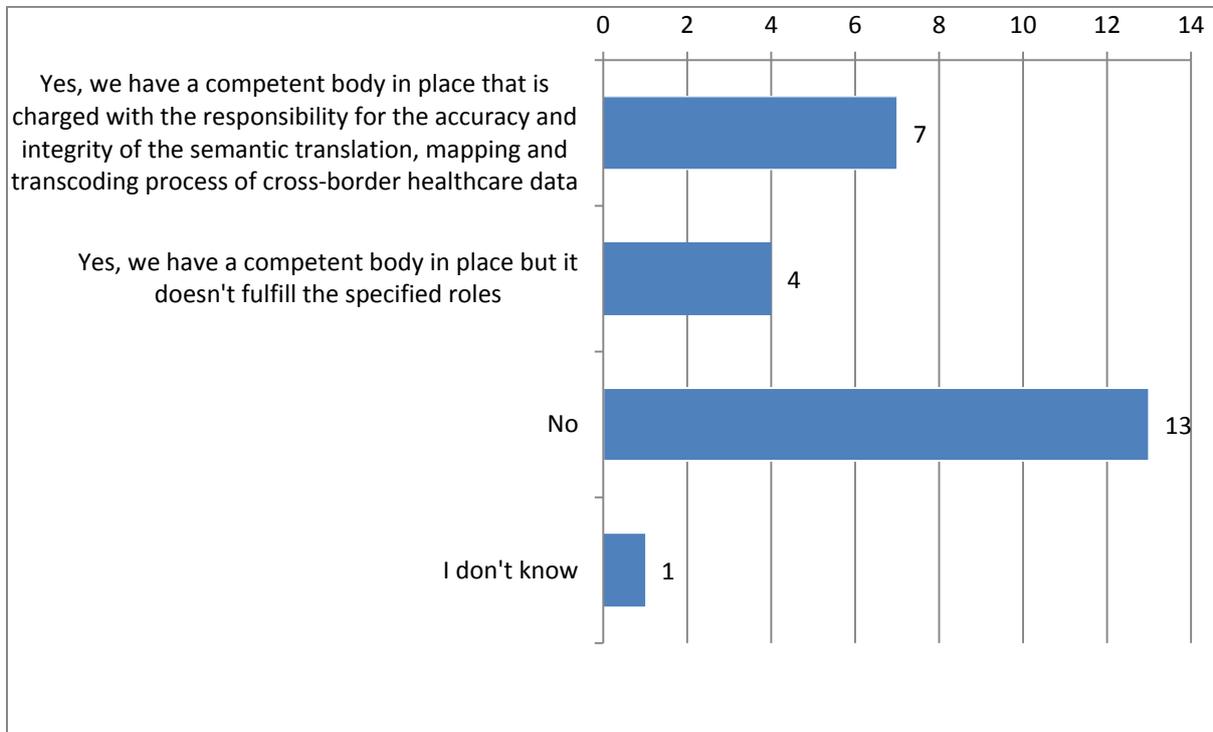


Figure 22. Question 22 regarding the set-up of a competent body that is responsible for the accuracy and integrity of the semantic translation, mapping and transcoding process of cross-border healthcare data

Q23. Does your country use testing mechanisms that demonstrate compliance with agreed standards for the purposes of cross-border patient information exchange?

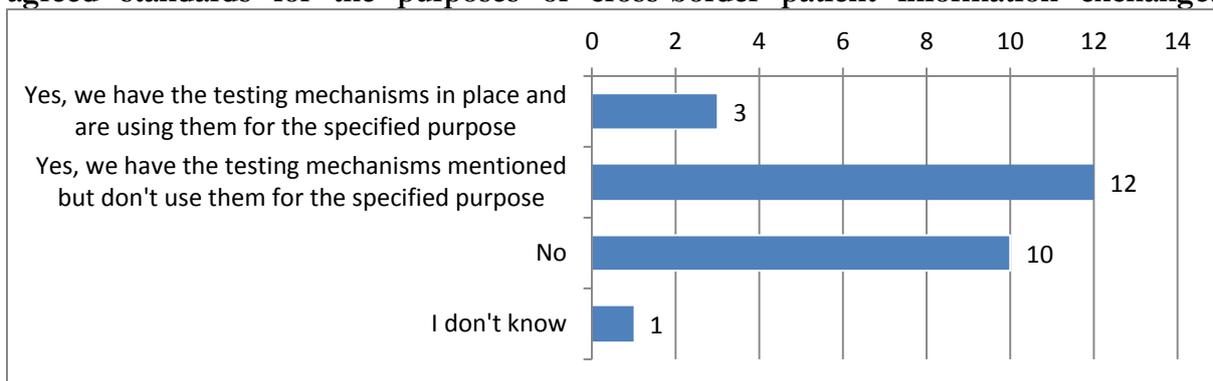


Figure 23. Question 23 on the use of testing mechanisms that demonstrate compliance with agreed standards for the purposes of cross-border patient information exchange

Q24. Is your country's software solution supporting cross-border healthcare data in compliance with the HL7 Clinical Document Architecture (CDA) Version 2, Level 3, with the additional constraints of the HL7 Continuity of Care Document (CCD) and IHE Patient Care Coordination (IHE PCC)? Tick the appropriate boxes.⁸

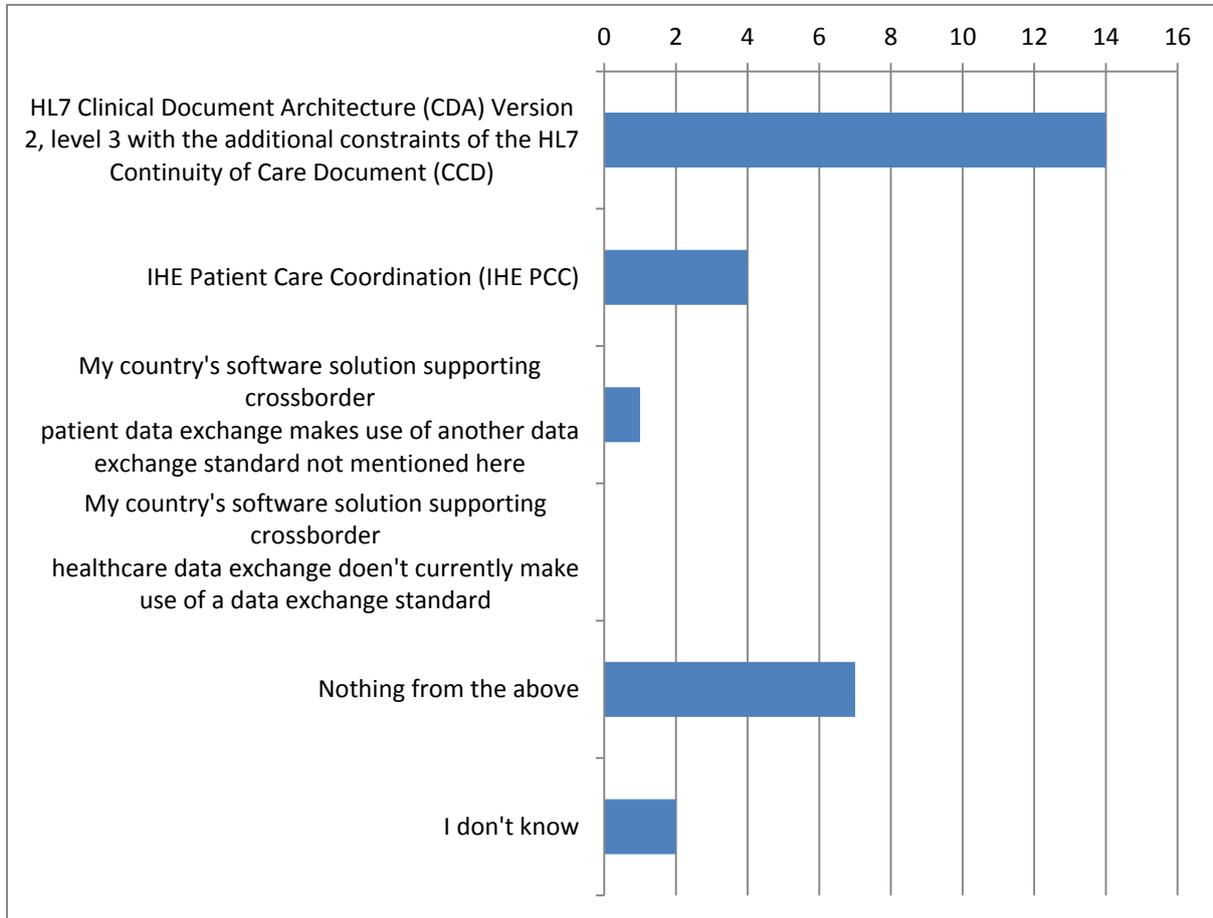


Figure 24. Question 24 regarding the use of the software solution supporting cross-border healthcare data in compliance with the HL7 Clinical Document Architecture (CDA) Version 2, Level 3 with the additional constraints of the HL7 Continuity of Care Document (CCD) and IHE Patient Care Coordination (IHE PCC)

⁸ Multiple-choice question

Q25. Is your country's software solution supporting cross-border exchange of personal healthcare data exchange regularly tested for compliance with the adopted normative standards set up by epSOS, i.e. IHE and HL7 data exchange standards?

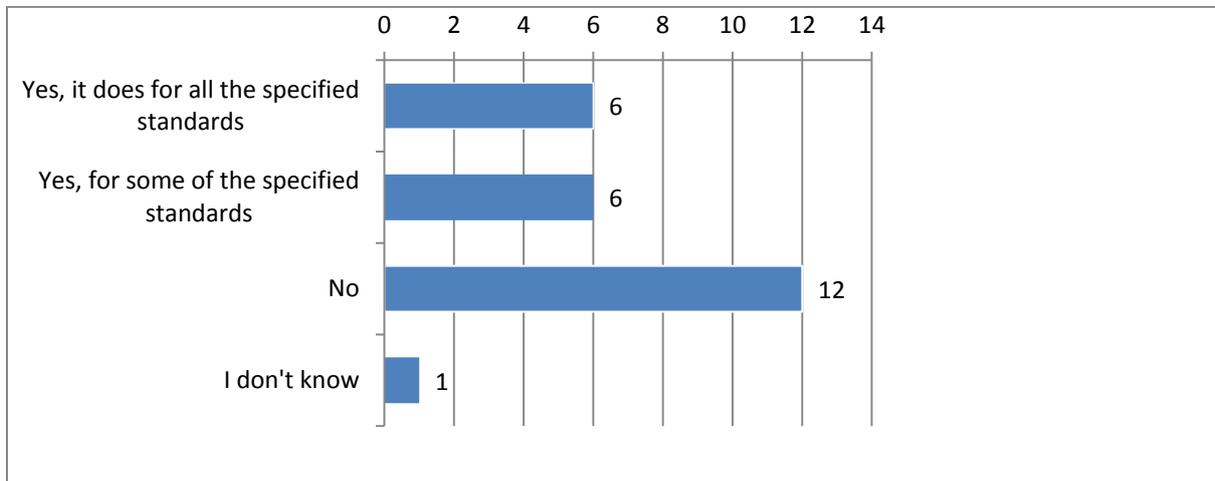


Figure 25. Question 25 regarding the software solution supporting cross-border exchange of personal healthcare data exchange being regularly tested for compliance with the adopted normative standards set up by epSOS, i.e. IHE and HL7 data exchange standards

5.4. LEVEL 4: Assessing technical preparedness and interoperability

Q26. Is your country able to incorporate (i.e. send and receive) information on cross-border healthcare data exchange from external sources?

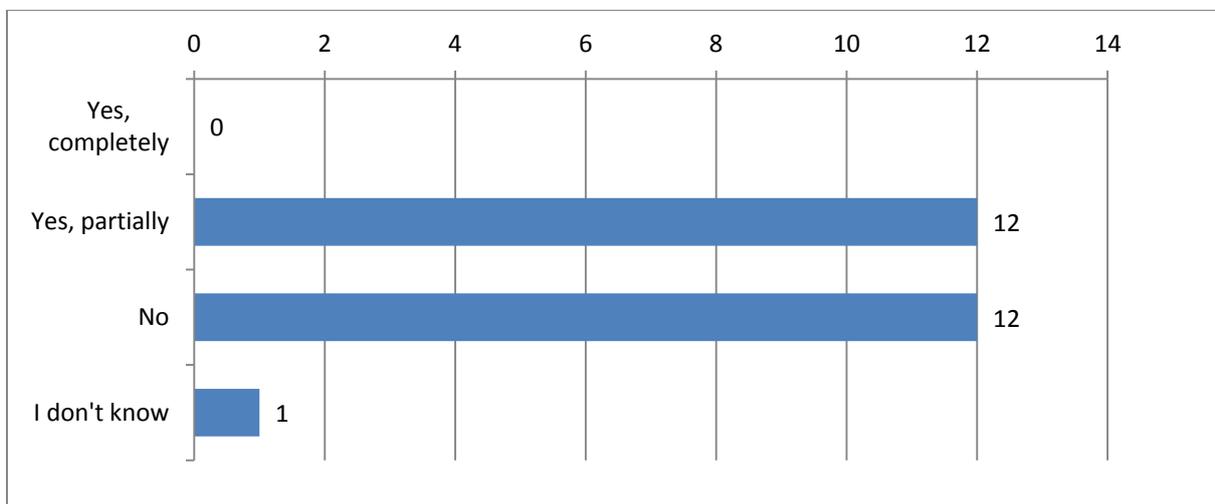


Figure 26. Question 26 regarding the Member State's ability to incorporate (i.e. send and receive) information on cross-border healthcare data exchange from external sources

Q27. Does your country have in place a standardised software solution supporting cross-border exchange of personal healthcare data, with specifications of protocols, procedures and exchanged documents?⁹

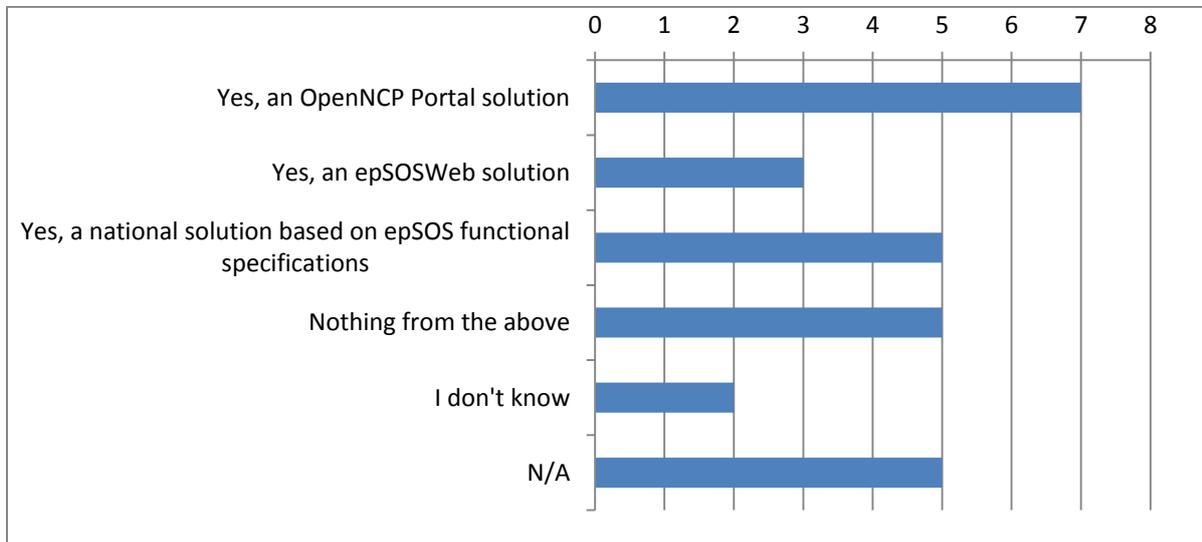


Figure 27. Question 27 on the standardised software solution supporting cross-border exchange of personal healthcare data

Q28. Does your country make use of the open-source components developed in epSOS and made available to all in the “JoinUp” EC-supported Open Source Community?

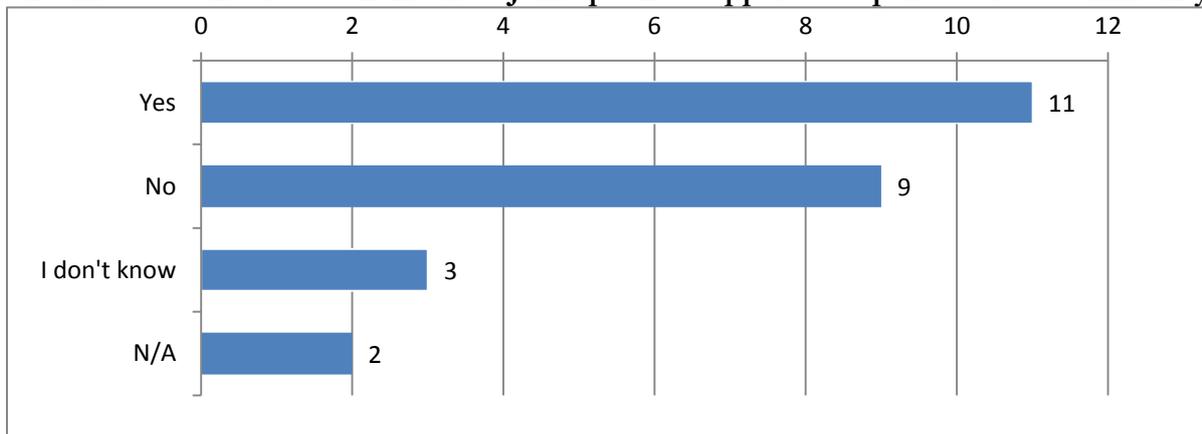


Figure 28. Question 28 on the use of the open-source components developed in epSOS and made available to all in the “JoinUp” EC-supported Open Source Community

⁹ Multiple-choice question

Q29. Which of the following functionalities apply to your software solution supporting cross-border exchange of personal healthcare data exchange (answers provided)?¹⁰

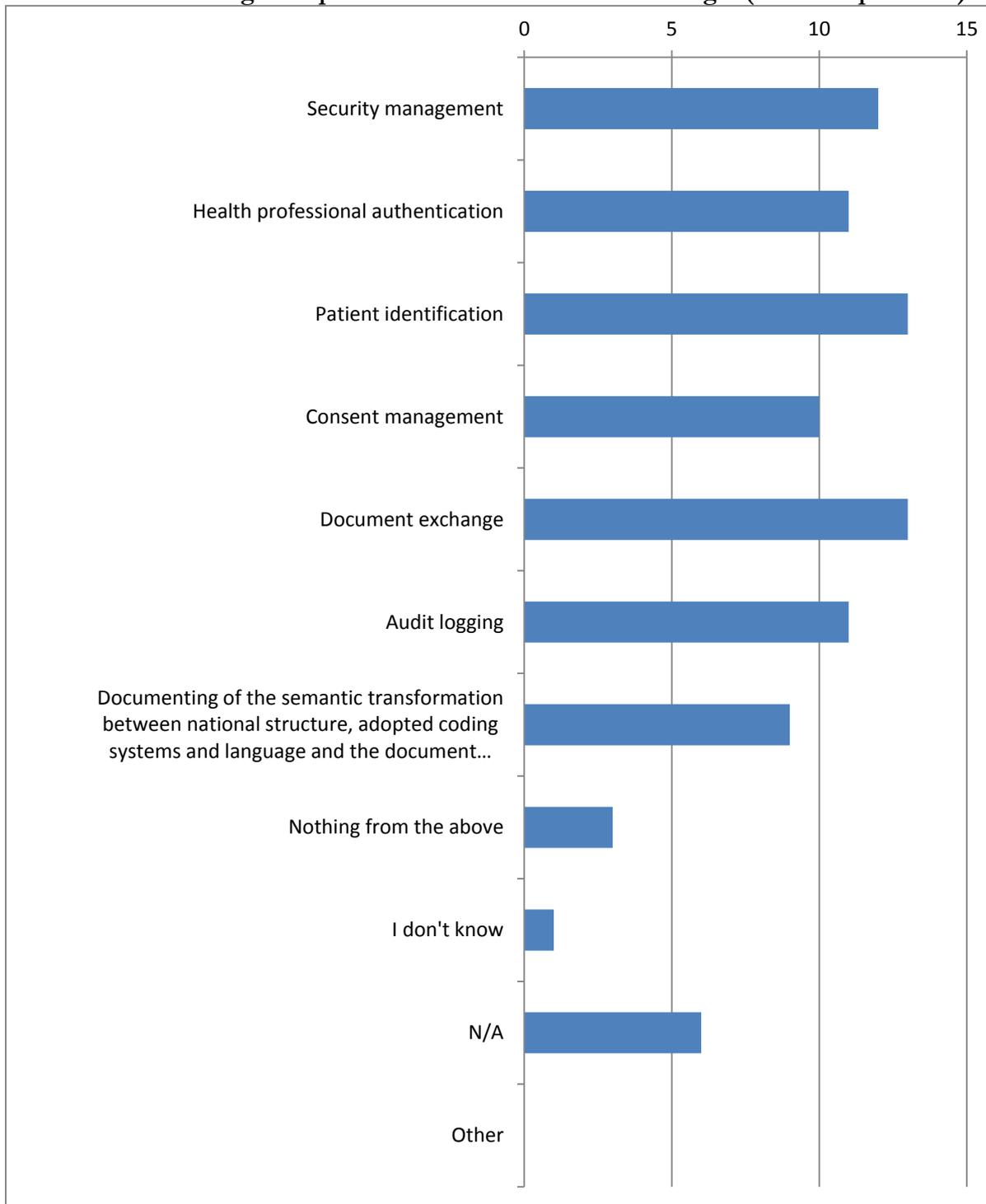


Figure 29. Question 29 regarding the software solution supporting cross-border exchange of personal healthcare data

¹⁰ Multiple-choice question

Q30. Has your country established a software solution supporting cross-border exchange of personal healthcare data in a way that supports the environments for interoperability testing, clinical end validation, data quality improvement and the operation environment for patient data exchange (answers provided)?¹¹

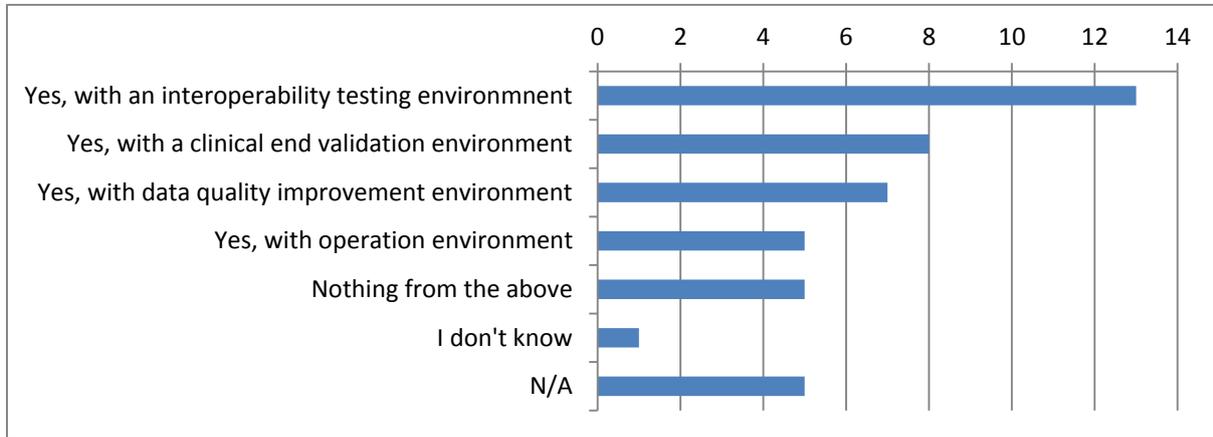


Figure 30. Question 30 regarding the establishment of a software solution supporting cross-border exchange of personal healthcare data in a way that supports the environments for interoperability testing, clinical end validation, data quality improvement and the operation environment for patient data exchange, as proposed by the Patient Summary guidelines

Q31. Does your country use secure communication and perform end-to-end security measures with regard to identifiable personal health data?

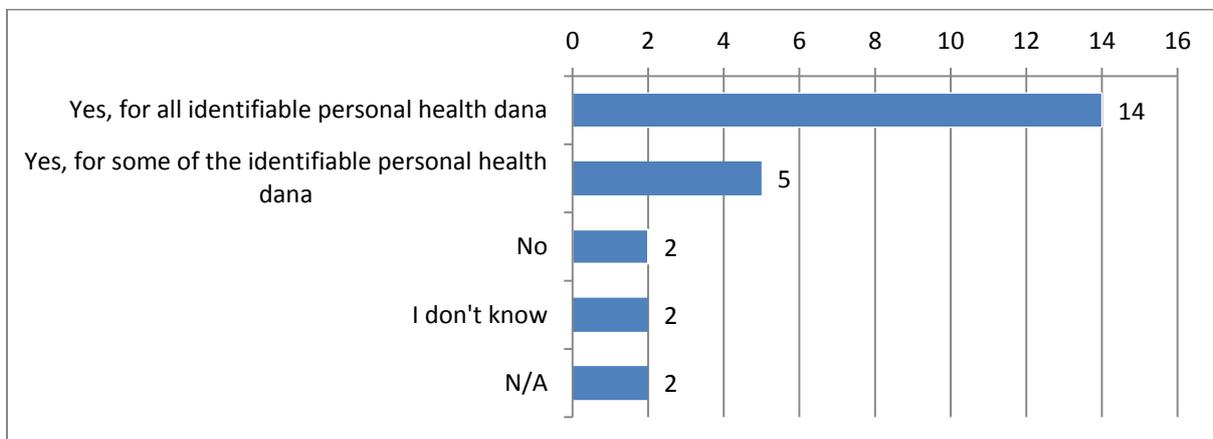


Figure 31. Question 31 on the use of secure communication and end-to-end security measures with regard to identifiable personal health data

¹¹ Multiple-choice question

Q32. Does your country use system logs with regard to handling identifiable personal health data (answers provided)?

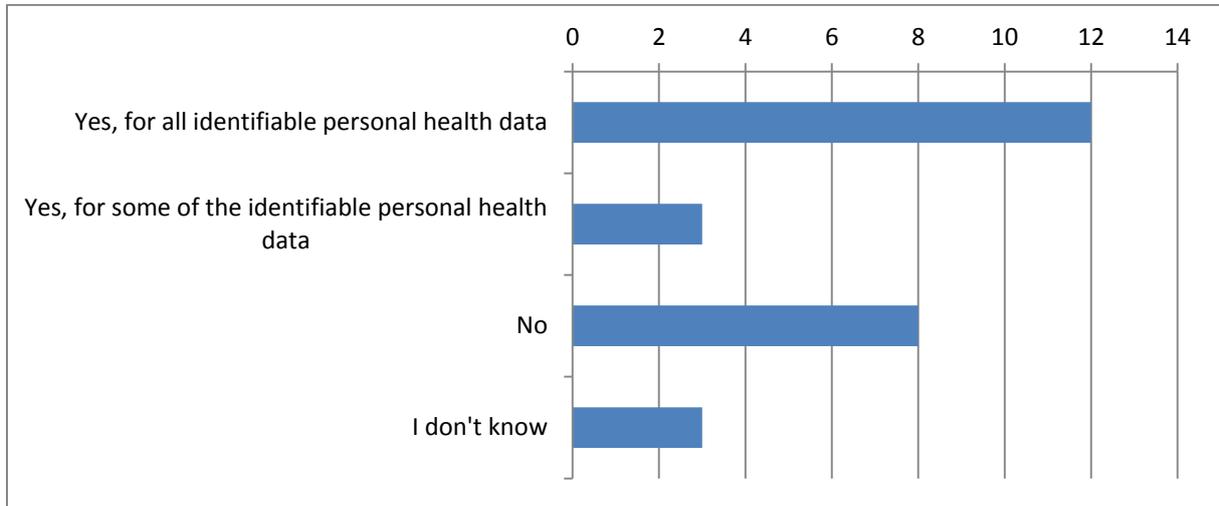


Figure 32. Question 32 on the use of system logs with regard to handling identifiable personal health data

Q33. Which of the following most accurately applies to your country's software solution supporting cross-border exchange of personal healthcare data (answers provided)?¹²

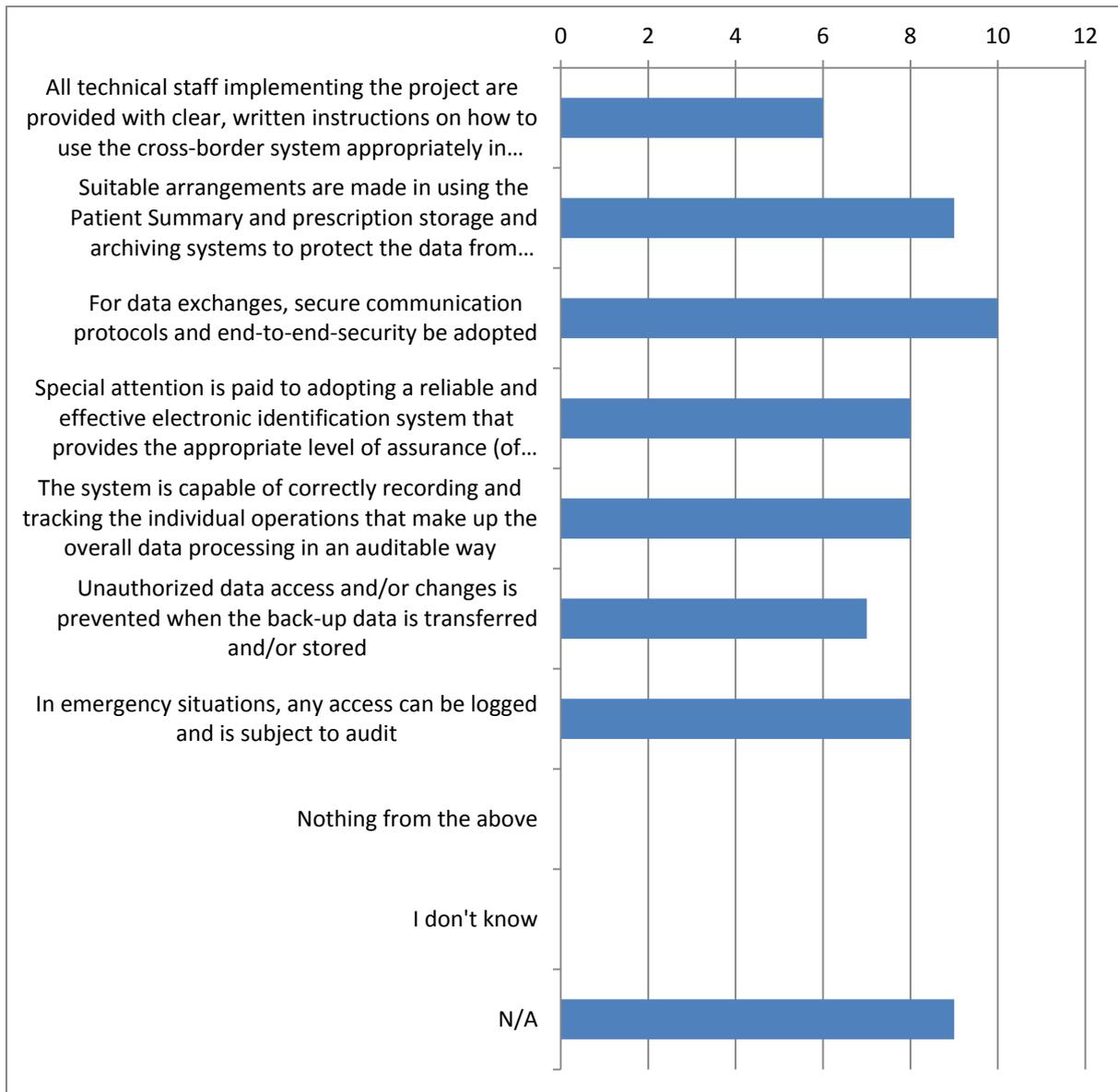


Figure 33. Question 33 regarding the software solution supporting cross-border exchange of personal healthcare data

¹² Multiple-choice question

Q34. Does your country maintain a full audit trail for personal and sensitive data within your patient data management systems?

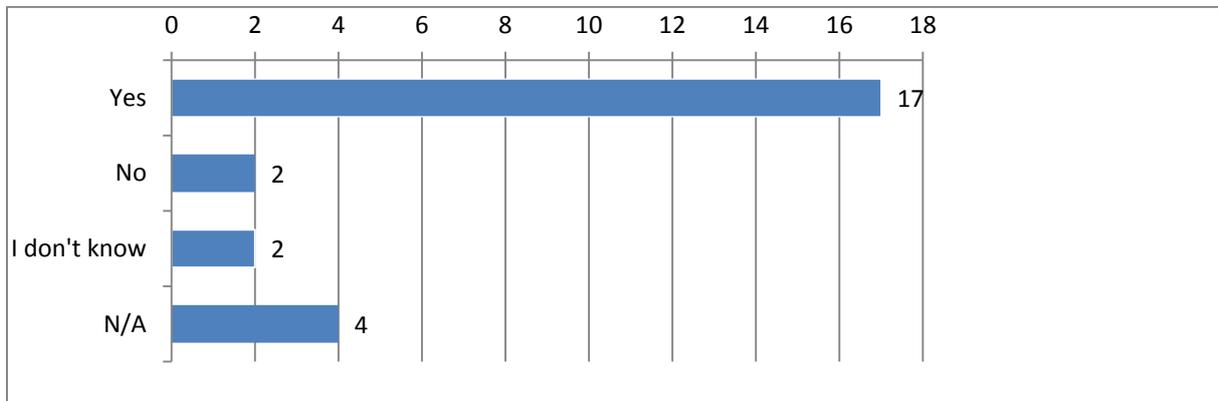


Figure 34. Question 34 regarding the software solution supporting cross-border exchange of personal healthcare data

Q35. Does your country's software solution supporting cross-border exchange of personal healthcare data maintain a log functionality that discerns who has accessed patient information, when was it accessed and what information was requested?

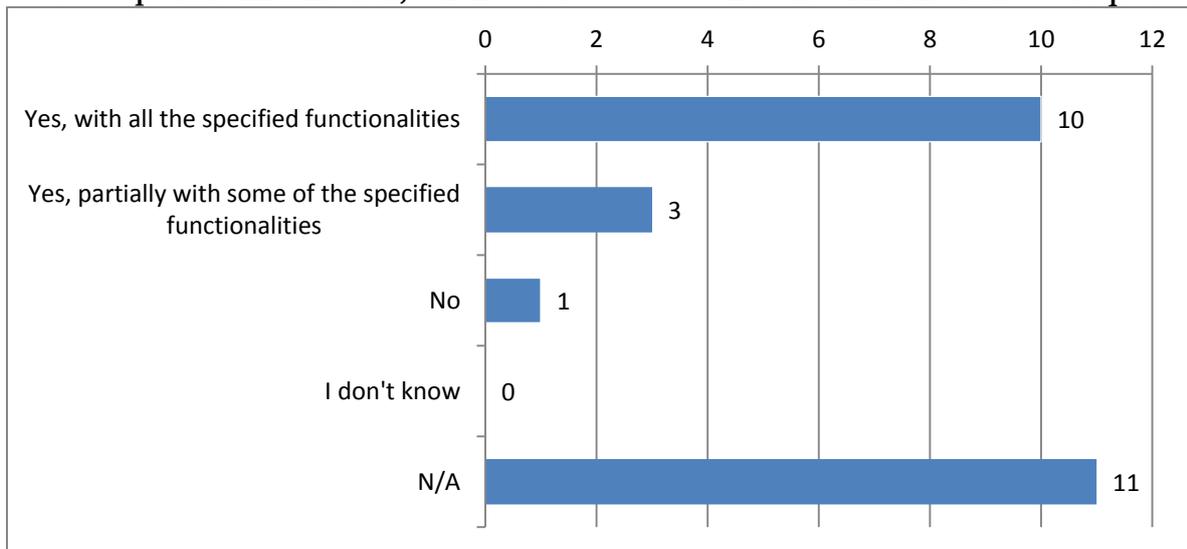


Figure 35. Question 35 on log functionality that discerns who has accessed patient information, when was it accessed and what information was requested

Q36. Which of the following most accurately applies to your country's experiences in the use of cross-border healthcare data exchange in terms of barriers to the implementation of the Patient Summary guidelines (answers provided)?¹³

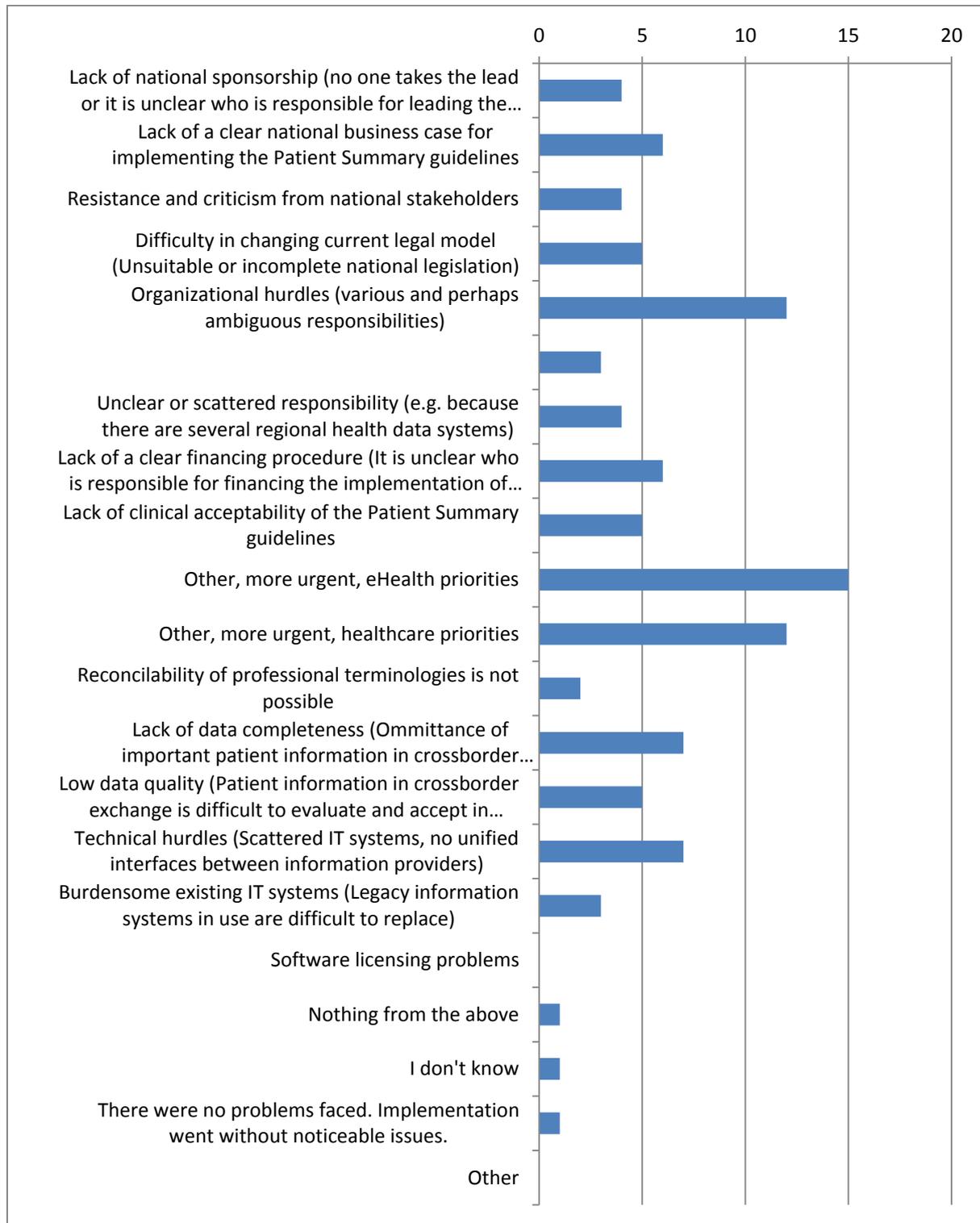


Figure 36. Question 36 on cross-border healthcare data exchange and barriers to the implementation of the Patient Summary guidelines

¹³ Multiple-choice question

5.5. Barriers to the implementation of the Patient Summary guidelines

Q37. In your opinion, are the Patient Summary guidelines in conflict with national professional bodies?

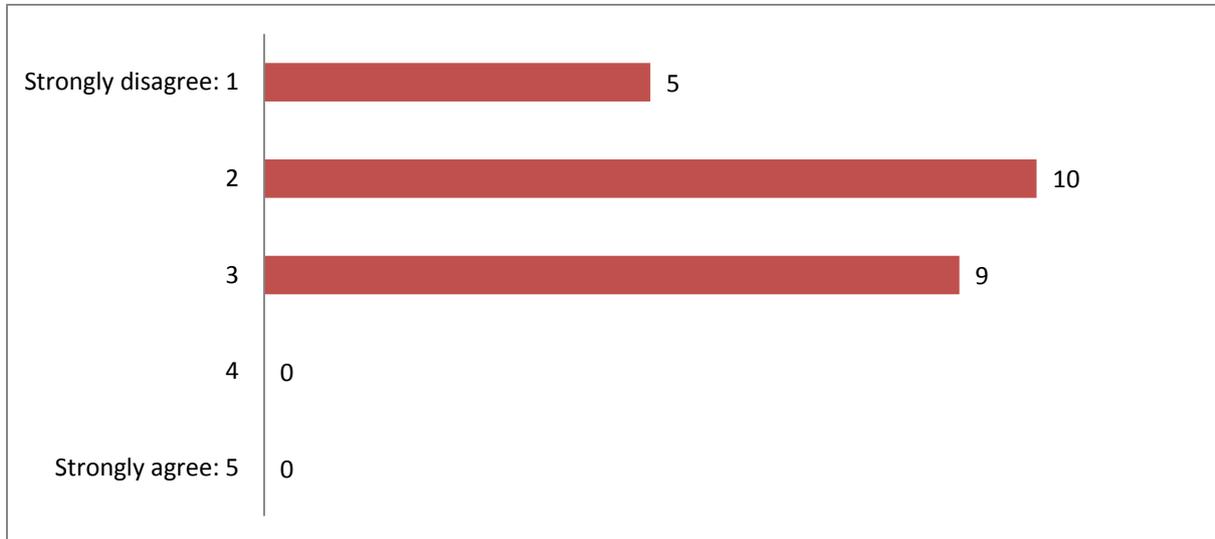


Figure 37. Question 37 on the possibility that the Patient Summary guidelines' are in conflict with other national stakeholders

Q38. Do you believe the Patient Summary guidelines are robust and evidence-based?

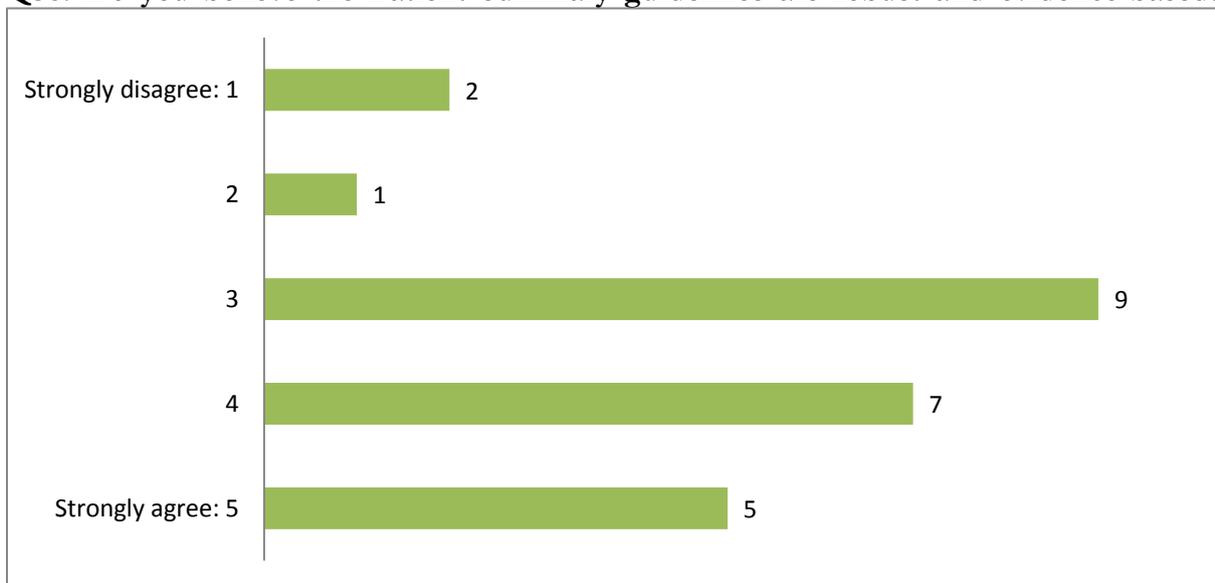


Figure 38. Question 38 on the Patient Summary guidelines' being robust and evidence-based

Q39. Do you believe that the Patient Summary guidelines' implementation will achieve better patient outcomes?

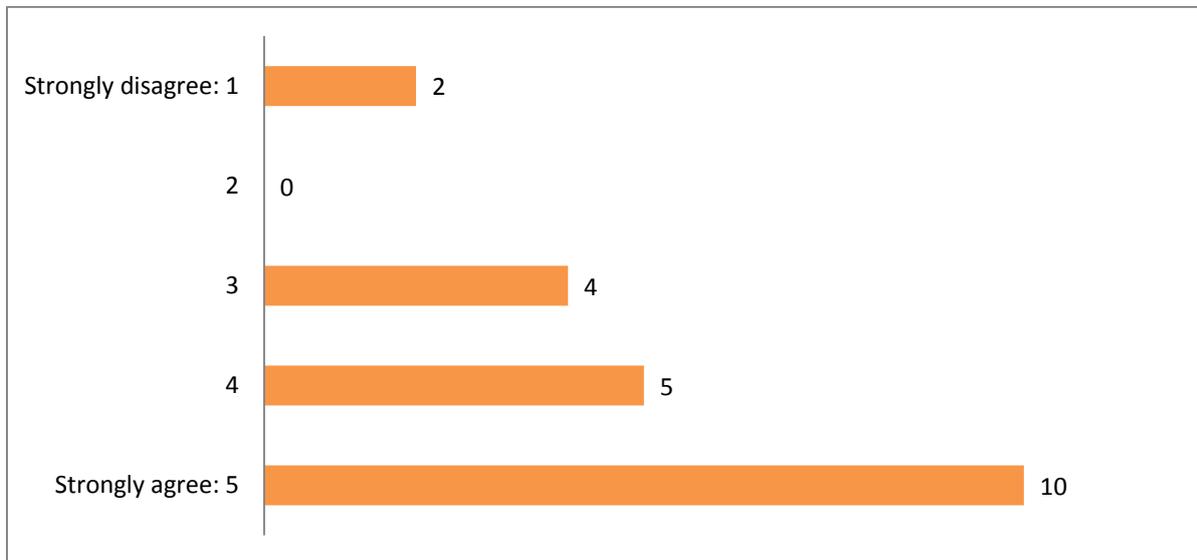


Figure 39. Question 39 regarding the opinions on whether the Patient Summary guidelines' implementation will achieve better patient outcomes

Q40. In your opinion, are the methods and steps needed for implementing the Patient Summary guidelines clear from the document itself?

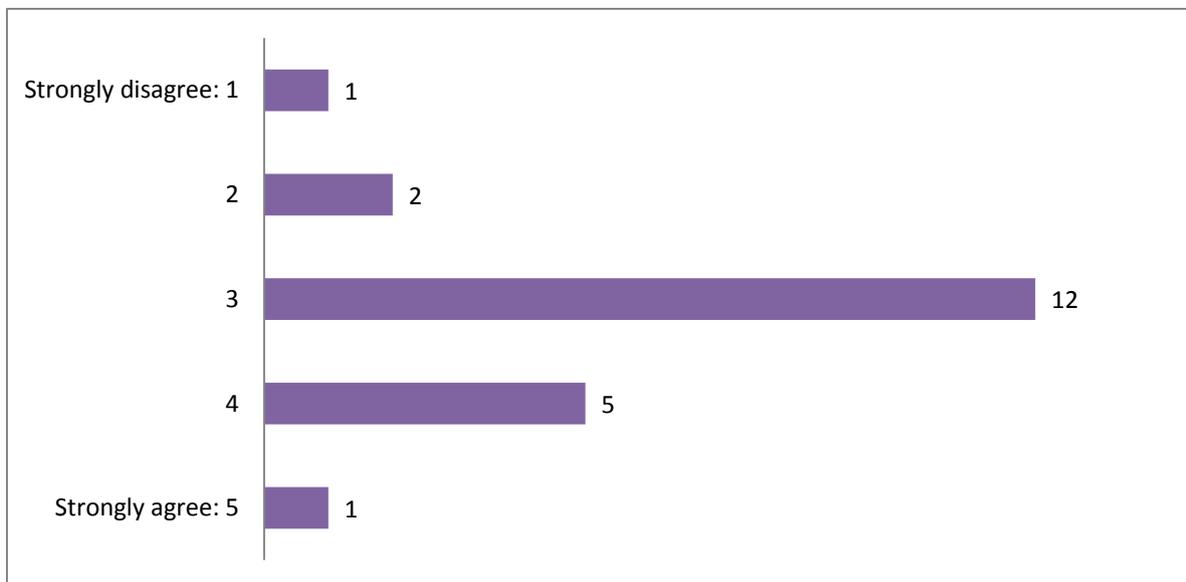


Figure 40. Question 40 regarding the clarity of methods and steps needed for implementing the Patient Summary guidelines

Q41. Do you have the right infrastructure to implement the Patient Summary guidelines?

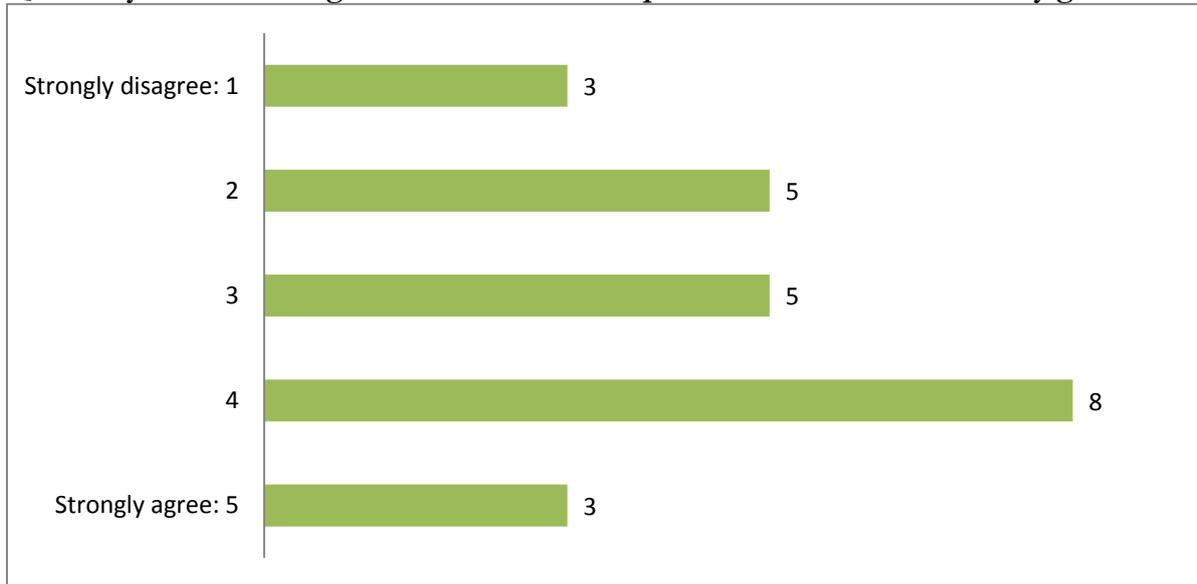


Figure 41. Question 41 regarding the infrastructure needed for implementing the Patient Summary guidelines

Q42. Do you find it difficult to prioritise particular elements of the Patient Summary guidelines in order to implement them in an efficient manner?

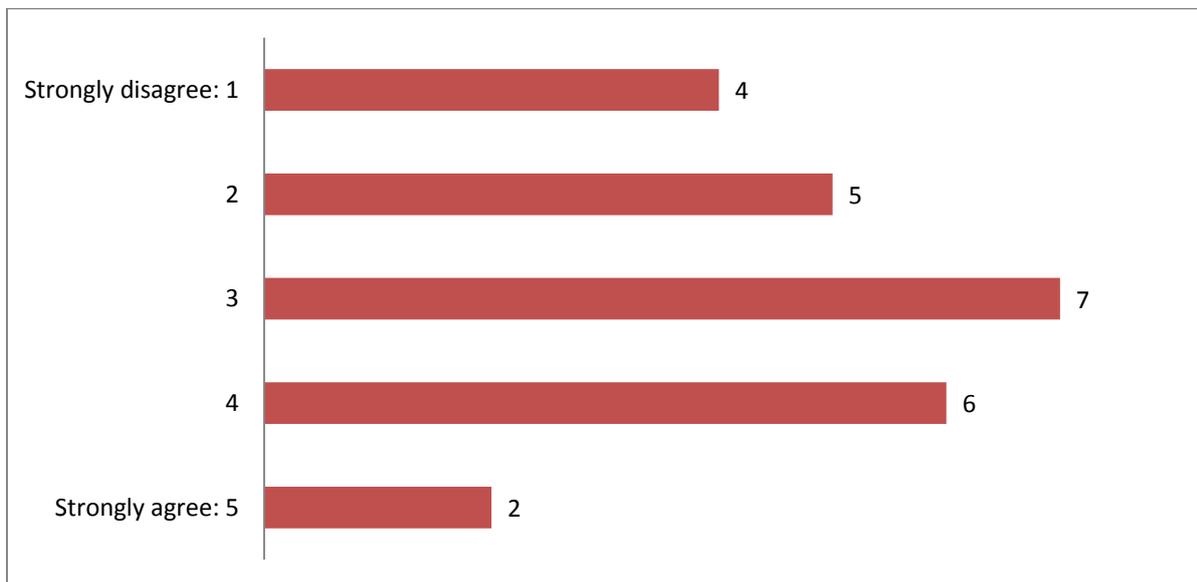


Figure 42. Question 42 regarding the prioritisation and efficient implementation of the Patient Summary guidelines

Q43. Do you think that the Patient Summary guidelines' implementation can be sustained in the long term?

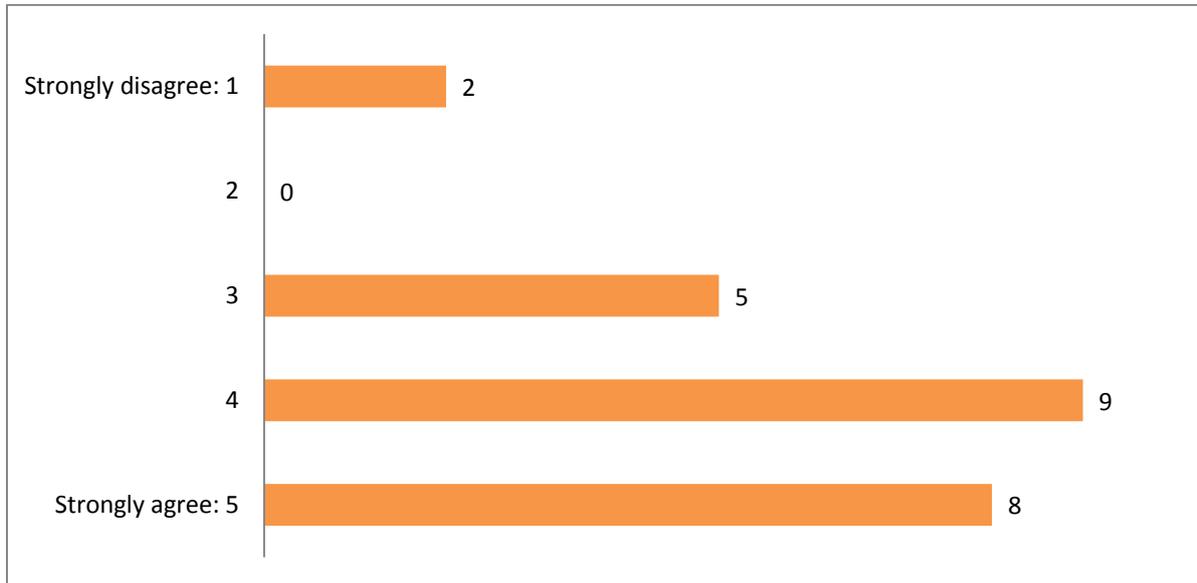


Figure 43. Question 43 regarding the sustainability of the Patient Summary guidelines' implementation

6. Findings

The questionnaire results indicate that in most EU countries the Patient Summary guidelines' implementation is at an early stage. Although some countries already have in place many of the components necessary for supporting the Patient Summary guidelines' implementation, in most Member States the implementation of the recommended interoperable public services has not yet been finished. Although most Member States actively participate in cross-border interoperability projects such as epSOS, PARENT, EXPAND, eSENSE and others, testing the national infrastructure and preparing the interoperability framework for cross-border data exchange, there remains the problem of the full deployment of all services envisioned by the Patient Summary guidelines. Member State feedback suggests that the prioritisation of other national projects in healthcare is one of the main obstacles to the full deployment of eHealth services recommended by the Patient Summary guidelines. At this point, the cross-border data exchange is perceived as a secondary issue for most Member States. Furthermore, due to healthcare system decentralisation in some Member States, both institutionally and geographically, historically there has not been a consolidated approach to technical and organisational aspects of cross-border interoperability. Other issues include ongoing project activities with deliverables still waiting to be fully implemented in real-world scenarios. Barriers to the implementation of the Patient Summary guidelines were identified by all Member State representatives; these are related to legal issues, implementation mechanisms (organisational and technical), tracking and coordination, possible internalisation problems and stakeholder engagement. Member States' responses show some level of indirect investment in cross-border interoperability, mainly in terms of education and raising awareness. The responses to the questions from the questionnaire show that most Member States have an established legal basis for personal data exchange, especially in terms of privacy, safety and security. What seems necessary, but is not yet fully established, is a cross-border data exchange regulation that would take into account the secondary usage of data by other Member States. Questionnaire responses also show that most Member States have established institutional data controllers to provide information to interested parties (e.g. patients). As a final note, the findings from this report were not based on a root-cause analysis and should not be taken as objective recommendations for further action towards the improvement of the Patient Summary guidelines' implementation in Member States. However, the questionnaire analysis shows some patterns that should be taken into account for the purpose of the Patient Summary guidelines update and further implementation.

7. Conclusions¹⁴

Although Member States expressed interest in implementing the eHealth guidelines that would lead to the creation of the Cross-Border eHealth Information Services (CBeHIS), there is still the need for some additional steps towards achieving the European Union's Single Market goals for healthcare. Most Member States have the majority of preconditions necessary to start cross-border data exchange in terms of semantic standards, technical solutions and infrastructure support with regard to the eHealth guidelines. However, they still do not have the necessary legal and organisational mechanisms to do so. There are still certain legal and organisational burdens to be tackled before the guidelines can be fully implemented. The technical and semantic uptake of the guidelines has been progressing steadily after the epSOS project, but there are some non-technical burdens to be negotiated before their full implementation. The updated guidelines should probably more seriously take into account the legal and organisational aspects of cross-border data exchange and should focus on recommendations on how to set up legal measures and coordinate the organisational goals of those national institutions that will support the cross-border data exchange. Flexible but permanent legal arrangements and organisational changes aimed at interoperability should ensure the long-term sustainability of these efforts. After epSOS, Member States reported that no mechanism for regional Patient Summary consolidation has been implemented beyond proof-of-concept essays. There has been neither enough harmonisation of contradictory contents among healthcare providers nor a shared encoding of values. Moreover, the progress of the conciliation of values has been rather slow. As these are prerequisites for a cross-border healthcare data exchange environment, which should guarantee integrity of information and avoid or document redundant registers, the recommendations on how to achieve this on the organisational level should be explained in more detail in the future.

However, Member States showed a high degree of awareness regarding the benefits of enabling cross-border data exchange, and they expressed their motivation to provide public information via eHealth NCP (NCPeH) websites. However, the provision of information can only go so far if the organisational support of the Member States' governing authorities does not recognise the need for organisational continuity and legal uptake, which are both lacking.

The crucially important next step in the eHealth guidelines' implementation is to find the best way to involve a wider community of experts and official authorities that would provide information dissemination and continuity. The updated guidelines could include recommendations on how to include other interest groups that already have access to information on cross-border healthcare. They would then participate in organisational and legal changes towards an improved EU-wide cooperation on raising healthcare standards or improving access to cross-border data. Empowering stakeholders after gaining their trust could be a bottom-up approach to organisational and legal changes. As the improved legislation could bolster the patients' ability to receive both healthcare in other Member States and the reimbursement thereof, thus providing a higher level of treatment, such a change could be of interest to stakeholders outside the healthcare system, so the new legislation should take this fact into account as well.

The next step in building a more robust environment providing cross-border healthcare data is the adoption of the more complete eHealth guidelines which would advance from the technical and semantic aspects of interoperability towards legal and organisational ones. What is also needed is the strengthening of the eHealth NCP role in Member States, which should provide continuity and sustainability to all future eHealth implementations.

¹⁴ Final conclusions and recommendations were based on the questionnaire data analysis, comments from stakeholders and feedback from project partners.

8. References

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9. Annex: Glossary of terms

CONCEPT	DEFINITION
CBeHIS	Cross-Border eHealth Information Services in the scope of the current document, namely Patient Summary and ePrescription (may include eDispensation)
CEF eHealth	EU financial (7.5M€) mechanism (based on call for proposals) that will be launched by November 2015, and may be used by MS to support CBeHIS provision (preparation, deployment and operation)
EIF	European Interoperability Framework
European public service	A cross-border public sector service provided by public administrations, either to one another or to European businesses and citizens
Guideline	A suggestion on how to perform a certain task. It is visible to those using or supporting the use of a particular service but there are no sanctions if not followed.
Interoperability framework	An agreed approach to interoperability for organisations that wish to work together towards the joint delivery of public services. Within its scope of applicability, it specifies a set of common elements such as vocabulary, concepts, principles, policies, guidelines, recommendations, standards, specifications and practices.
National Infrastructure	The healthcare IT infrastructure, which manages patient and HP identification and health care records in MS
NCP	National Contact Point as referenced in Article 4 of the 2011/24/EU Directive
NCPeH	National Contact Point for eHealth that may act as an organisation and technical gateway for the provision of eHealth Cross-Border Information Services