Guideline quality AI in health care

This document is a summary of the Guideline for qualitative diagnostic, prognostic, monitoring and screening applications of AI in healthcare (doi10.17605/OSF.IO/TNRJZ). The AI quality guideline in healthcare (hereinafter referred to as 'guideline AI') is an expression of what is considered good professional conduct in the development, testing, implementation, and application of so-called *Artificial Intelligence Prediction Algorithm (AIPAs)* in the medical sector including the public health field and care. Such AIPAs are used to support diagnosis, prognosis, therapy response monitoring, disease monitoring, lifestyle monitoring, prevention, and e-health.

The full guideline AI can be viewed at doi10.17605/OSF.IO/TNRJZ

Table of content

Guideline quality AI in health care 1

1. Guideline AI, constructed by professionals in the field, for the development, validation, implementation, assessment and reimbursement of AI prediction algorithms (AIPAs) in health care and public health sector 2

2. Objective and design of guideline AI 2

3. Phases of development, validation, and implementation of AIPAs 3

4. Intended Use and Status of Guidance 4

5. Application of the guideline AI in health care practice 5

Appendices 6

Appendix 1. Background information guideline for high-quality diagnostic and prognostic applications of AI in healthcare 6

Appendix 2. Overview of requirements and recommendations guideline AI quality in health care 9

1. Guideline AI, constructed by professionals in the field, for the development, validation, implementation, assessment and reimbursement of AI prediction algorithms (AIPAs) in health care and public health sector

The creation of this guideline was one of the main actions of the program Valuable AI for Health from the Dutch ministry of Public Health, Wellbeing and Sports (VWS, see appendix 1 and website Kwaliteit AI in de zorg). The guideline AI has been developed by and for the health care field in many multidisciplinary teams of experts and representatives of AI, health care and other health policy organisations in the sector. This guideline is about the development, validation (testing), implementation, and application of so-called *AI prediction algorithms* (AIPAs) that could or could not be part of a medical device. It is meant to be used in and by the health(care) domain, including public healthcare and primary prevention, and health research and private organisations. The developers of the guideline defined transparent criteria to enable the development, validation, implementation, scaling, assessment, and reimbursement of medical AIPAs. More information on the background of the guideline can be found in appendix 1 and on the website Kwaliteit AI in de zorg.

AI prediction models or AIPAs are defined as “models/algorithms that yield an estimated probability of some health outcome or event in individuals”. This includes the prediction or classification of the presence of health outcomes (so-called diagnostic or screening AIPAs); or the prediction of developing any desired or undesired health outcome over time (so-called prognostic AIPAs). In addition to applications in medical diagnostics and prognostics, AIPAs are also used in therapy(response)-, disease- and lifestyle-monitoring, in screening, early detection, prevention, medical apps, e-Health, and in remote and home monitoring of patients and citizens in care institutions. The guideline AI describes how safe and (cost-)effective AIPAs can be developed, evaluated, used, and assessed in the health sector. The ambition is for this guideline to be accepted as a widely supported field standard, for AI developers (private and public), AI researchers, AI users and assessors in healthcare, and healthcare policy makers and insurers. Given the rapid developments in the field, this is a dynamic standard, and the latest updates are accessible via the OSF webpage doi10.17605/OSF.IO/TNRJZ

2. Objective and design of guideline AI

The guideline AI applies to the development, evaluation, testing and application of an AIPA that may or may not form part of a medical device intended for use in health care, including domains like home and self-care, primary prevention, e-health, and public health care. The guideline AI supports AI developers and researchers (private and public), healthcare providers, patients, healthcare policy makers, healthcare insurers, regulating and monitoring healthcare authorities, and purchasers of medical technology to assess the quality of AIPAs offered. The guideline AI helps public and private developers and researchers to design, evaluate and implement safe, high-quality, reliable and (cost-)effective AIPAs. The guideline AI specifies what healthcare providers, citizens, patients, insurers, policy makers and testing authorities can expect from quality requirements of an AIPA including associated software, if they purchase, use, apply or reimburse such tools.

The guideline AI is relevant for the following stakeholders:

- Users of AIPAs (e.g., healthcare professionals, healthcare providers, medical and scientific associations, education, IT suppliers, patients and citizens);
- Developers of AIPAs (e.g., data scientists, AI/machine learning engineers, statisticians and epidemiologists in the industry, and scientific researchers such as statisticians, epidemiologists, healthcare providers, data scientists, and machine learning engineers in the public and private sector);
- Health policy and regulating authorities (e.g., healthcare supervisors, notified bodies, privacy officers, testing authorities, health insurance organisations, medical ethical committees and reviewers);
- Societal parties (e.g., patient associations and representatives, and political parties).

3. Phases of development, validation, and implementation of AIPAs

The AI guideline distinguishes seven phases for the development, validation, implementation, and upscaling of AIPAs. In addition to preparations for the development process (phase 0), these are:

Phase 1	Collection and management of the data
Phase 2	Development of the AIPA
Phase 3	Validation of the AIPA
Phase 4	Development of the required software
Phase 5	Impact assessment of the AIPA in combination with the software
Phase 6	Implementation and use of the AIPA with software in daily practice

Phases 1 to 6 are detailed in the guideline AI. The supposed chronology of the phases is not intended to be coercive and is not always the most efficient or factual sequence of actions. An overview of the topics per phase can be found in Figure 1. The Innovation Funnel for Valuable AI in Healthcare offers a broader context for medical innovations.

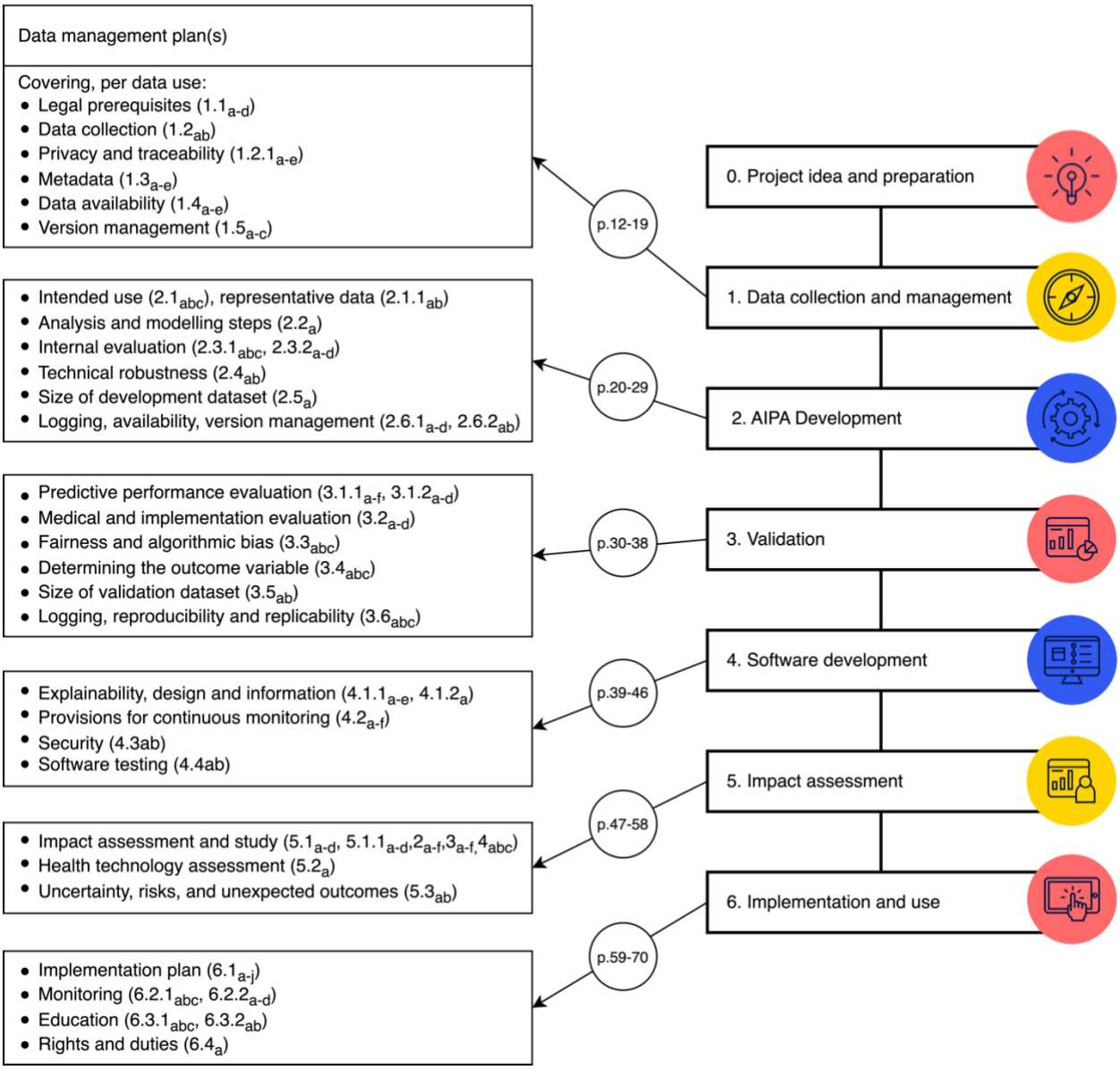

Figure 1. Overview diagram of the guideline AI, with the page numbers per phase (indicated on the arrows) and within each phase per topic (the bullets) the numbers of the recommendations drawn up (in brackets).

4. Intended use and status of guideline AI

The guideline AI is an expression of what is considered good, professional, safe, and high-quality conduct in the health(care) field, by all stakeholders involved somewhere in the development, validation (testing), applying, implementing, assessing, advocating and reimbursement of AIPAs in the health(care) sector, including public health, primary prevention, home- and self-care. The guideline AI is the result of good professional conduct, and

not necessarily about how an organization can shape and monitor safe and good professional conduct in the various contexts in which the guideline can be used.

5. Application of the guideline AI in health care practice

Impact of algorithm predictions on a patient, client or citizen is the most important consideration when assessing risks and consequences of developing, using, advocating, and reimbursing AIPAs in the health(care) sector. The guideline AI distinguishes between requirements and recommendations for good professional conduct in the development, evaluation, testing, implementation, and reimbursement chain of AIPAs (see Appendix 2 for an overview). The requirements are indicated by ‘mandatory’. Recommendations are indicated by ‘strongly recommended’ or ‘recommended’. Use of the guideline implies a *comply or explain* approach, in which the decision whether or not to implement the recommendations is based on a risk assessment that can only be made in line with a specific application of the AIPA. The guideline AI helps making this risk assessment explicit and explainable to third parties. Risks and medical-ethical considerations, which may differ per stakeholder, organisation and user of the guideline, determine which recommendations from the guideline AI are applied. In some instances, the guideline clarifies which risks or circumstances are related to specific recommendations. For a specific AIPA or targeted context, and with a good explanation or risk assessment, the guideline AI can be followed without exactly addressing all recommendations.

Appendices

Appendix 1. Background information guideline for high-quality diagnostic and prognostic applications of AI in healthcare

Programma Waardevolle AI voor gezondheid

The development of the guideline AI was one of the action lines of the program 'Waardevolle AI in de zorg' (Valuable AI for health) of the Dutch Ministry of Health, Welfare and Sport (VWS). The coordination of the entire action line was in the hands of Rosalie van Oostrom on behalf of VWS. With the delivery of this guideline, not only this line of action, but all lines of action and thus the program came to an end. The program has also produced the following tools, among others:

- Mindmap governance of valuable AI in healthcare
- Innovation Funnel
- Early HTA on the value of an AI-based decision support system in multiple sclerosis
- Handleiding aanpak begeleidingsethiek voor AI in gezondheid en zorg (in Dutch)
- Podcastserie 'Waardevolle AI voor gezondheid'

Creation of the guideline AI

An action team was started based on the results of a literature study conducted by the UMC Utrecht and the LUMC into scientific safety and quality criteria for AIPAs. Following the research, an overview was made of the available national and international guidelines and criteria for the development, validation, evaluation, and implementation of AI in the medical sector. This has been recorded in a published article in Nature Partners Journal Digital Medicine (de Hond AAH, Leeuwenberg AM, Hooft L, Kant IMJ, Nijman SWJ, van Os HJA, Aardoom JJ, Debray TPA, Schuit E, van Smeden M, Reitsma JB, Steyerberg EW, Chavannes NH, Moons KGM. Guidelines and quality criteria for artificial intelligence-based prediction models in healthcare: a scoping review. *NPJ Digit Med*. 2022;5(1):2. https://doi.org/10.1038/s41746-021-00549-7).

Multi-stakeholder working groups were then formed for each of the six phases. Care providers, standards experts, epidemiologists, data managers, ethicists, statisticians, policy officers, quality officers, data scientists, AI experts and developers from the public and private sector, working at many different organizations and companies in the healthcare field, have all contributed. The working groups met frequently for a year and developed minimum requirements and recommendations for each phase. The result: a first version of the guideline AI quality in health care.

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Appendix 2. Overview of requirements and recommendations guideline AI quality in health care

Phase 0	**Preparations for the development process**	**Mandatory**	**Strongly recommended**	**Recommended**
0.1	**Insight into the parties and people who have an interest in the AIPA that is to be developed**			Involving users, patients, clients or citizens (p. 9)
0.2	**Need for development of AIPA**			Conduct experiments or proof-of-concept (p. 9)
0.3	**Feasibility of idea for development of AIPA**			Conduct experiments or proof-of-concept (p. 9)
0.4	**Risk assessment**			▪ Informal risk assessment (p. 9) ▪ Action plan in a multidisciplinary context, including risk management measures and internal supervision (p. 9)
0.5	**Cost-effectiveness evaluation**			Estimating total costs and benefits of implementing an action plan (p. 9)
Phase 1	**Collection and management of the data**	**Mandatory**	**Strongly recommended**	**Recommended**
1.0	**Data management**	Drawing up a data management plan with legal preconditions, data collection, metadata and data availability as core domains (p. 13)		

1.1	**Legal prerequisites**	▪ Describing legal preconditions and context (p. 14) ▪ Describing applicable national and European legislation and regulations (p. 14) ▪ Describing (processing)agreements, agreements in agreements and agreements regarding intellectual property law (p. 14)	Recording the existence and operation of general information security measures (p. 14)	
1.2	**Data collection**	Recording properties of the data collection in the data management plan (p. 14)		
1.2.1	**Privacy and traceability**	▪ Respecting the privacy of persons from whom data has been obtained (p. 15) ▪ Preventing traceability to persons (p. 15) ▪ Following principle of data minimization (p. 15) ▪ Recording in a data management plan how possible incidental findings and the right to destroy data are dealt with (p. 15) ▪ Preliminary testing by METC or CCMO (WMO-required research) (p. 16)	Planning tests through data protection impact assessment (p. 15)	Investigating the possibility of identification by combining the data about the person and the metadata about the data (p. 15)
1.3	**Metadata**	▪ Describing in detail the metadata in data management plan (p. 16)	▪ Recording metadata at three levels: data provenance, medical	

		▪ Making a choice for metadata and the description of the metadata based on an inventory of the interests of the stakeholders (p. 17)	context and properties and descriptive statistics of the data (p. 16) ▪ Presenting and specifying each data source separately (p. 17)	
1.4	**Availability of data**	▪ Clear information about the availability of the data in the data management plan (p. 17) ▪ Recording agreements in a data management plan about the storage of the data used in the event that data is made available to partners or third parties (p. 17) ▪ Recording how the applicable national and international laws and regulations are complied with (p. 17)	Following FAIR principles for making data available (internally or externally).(p. 17)	Making data available in forms that comply with common information standards in digital information exchange in healthcare (p. 17)
1.5	**Version management and availability of the data management plan**	▪ Making a data management plan available to the parties involved (p. 18) ▪ Implementing version control for all parts of the data management plan (p. 18)		Making the data management plan publicly available or available upon request, for example by placing it on a publicly accessible website (p. 18)
Phase 2	**Development of the AIPA**	**Mandatory**	**Strongly recommended**	**Recommended**
2.0	**Step-by-step plan of the AIPA**		Using a standardized step-by-step plan according to the TRIPOD reporting guidelines (p. 21)	

2.1	**Explanation of intended use**	Defining and recording the target use of the AIPA (p. 21)	Involving stakeholders such as users and patients in the definition of the target use (p. 21)	
2.1.1	**Dataset(s) and intended use**	Documenting and substantiating the content if there is a suspicion that the data used is not (fully) representative (p. 22)	Carrying out a representative sample from the target population (p. 22)	
2.2	**Analysis and modellingsteps**	Recording all analysis and model development steps (p. 22)		
2.3	**Internal evaluation of the model**			
2.3.1	**Internal validation**	Taking adequate measures to minimize the predictive power of optimism (p. 23)	▪ Describing in context the predictive power of AI predictive model (p. 22) ▪ Applying statistically efficient internal validation methods (p. 23)	
2.3.2	**Analysis of potential (negative) impact of the model**		▪ Mapping as much heterogeneity as possible in estimated predictive power (p. 23) ▪ Recording expectations in the medical context of the AIPA (p. 24)	▪ Credible and transparent analysis of possible negative impact of the use or input of the AIPA (p. 23) ▪ Assessing fairness risks together with stakeholders from a medical context (p. 23)
2.4	**Technical robustness**	Investigating technical robustness of the model, at least for those models used in the external validation (p. 24)	Using technical robustness, in addition to predictive power, as a criterion for model selection (p. 24)	

2.5	**Size of the data set for development of the AIPA**		Using a priori or a posteriori methods to evaluate whether the data set size meets minimum criteria (p. 25)	
2.6	**Logging, availability and version management**			
2.6.1	**Logging, reproducibility and replicability**	Recording all analysis steps and internal validation steps and analysis of technical robustness (p. 25)		▪ Publishing the results found in a scientific journal (p. 25) ▪ Making AIPA available publicly or on request so that it can be used by third parties for independent validation (p. 25) ▪ Where possible, making data available on request to ensure replicability by third parties (p. 26)
2.6.2	**Version management and availability of the model**	Complete version history recording (p. 26)	Making the actual model and/or models publicly accessible, if available including (minimal) software (p. 26)	
Phase 3	**Validation of the AIPA**	**Mandatory**	**Strongly recommended**	**Recommended**
3.1	**Evaluation of predictive (statistical) characteristics of the AIPA**			
3.1.1	**Target population and context**	▪ Using a different dataset for external validation than that used	Refraining from using a research design in which only data from so-called healthy controls is used (p. 31)	▪ Avoiding exclusion of individuals who do belong to the target population or context (p. 32)

		for the development of the AIPA (p. 31) ▪ Recording in a data management plan the origin of the data, method of data collection, measurement and registration procedures, any selections and inclusion and exclusion criteria (p. 31) ▪ Recording the reason for the difference in target populations between phases 2 and 3 (p. 32)		▪ Comparing baseline characteristics and statistical testing between the data used for development and for external validation (p. 32)
3.1.2	**Model performance**	▪ When evaluating predictive power, when choosing estimators, take into account the scale on which the predictions are made (p. 32) ▪ When choosing estimators of predictive power, take into account the predicted output of the AIPA (p. 32)	▪ Placing the estimates of predictive power in the intended context as much as possible (p. 33) ▪ Comparing the estimates of predictive power from external validation with predictive power reported after internal validation (p. 32)	
3.2	**Evaluation of medical characteristics and expectations for implementation of the AIPA**	▪ Analysis of anticipated costs and benefits (p. 33) ▪ Estimating expected barriers to implementation of the AIPA (p. 33)	▪ Involving stakeholders from the medical setting intended for the target use (p. 33)	
3.3	**Fairness and algorithmic bias**	Investigating and documenting the presence of certain types of bias that	Involving stakeholders in the evaluation of fairness risks (p. 35)	

		may lead to adverse outcome disparities for certain groups		
3.4	**Determining the outcome variable (labelling)**	Labeling outcomes in a dataset for external validation as accurately and as transparently as possible (p. 35)	Quantifying the quality of labeling (p. 35)	Accurately tracking and reporting which experts were involved in labeling (p. 35)
3.5	**Size of the data set for external validation**	Arguing dataset size for external validation (p. 36)		Calculating minimum data set size (p. 36)
3.6	**Logging, reproducibility and replicability**	Complete and transparent recording of the process followed and the data used for external validation (p. 36)		▪ Making publicly available the computer codes used for external validation (p. 36) ▪ Making (publicly) available the data used for the external validation (p. 36)
Phase 4	**Development of the required software**	**Mandatory**	**Strongly recommended**	**Recommended**
4.1	**Explainability, transparency, design and information**			
4.1.1	**Explainability, transparency, design of the AIPA software**	▪ In the case of an inherently explainable model, making information about the interpretation of the model and model predictions available to the intended end users (p. 40) ▪ Informing intended end users in an end user-oriented presentation of model predictions by the software (p. 40)	▪ Designing customized model presentation and explanation per end user and developing and making educational material available about the interpretation of the AIPA ▪ Involving stakeholders in the design of the model presentation and explanation	

		▪ In the case of complex models, substantiating why an explainable model has not been chosen, and if a post-hoc explanation is chosen, why this is appropriate for the model and the intended end user (p. 41)		
4.1.2	**Information pertaining to the software**		▪ Drawing up a digital instruction for the end user containing information about the use of the AIPA in the software (p. 42)	
4.2	**Provisions for continuous monitoring**	Facilitating a feedback loop for end-user feedback and reporting of technical issues (p. 43)	▪ Drawing up a monitoring plan (p. 43) ▪ Facilitating the possibility in software to monitor used data, the model and the use of the AIPA after introduction into practice (p. 43) ▪ Automated validation of input data in the software (p. 43) ▪ Monitoring software for systematic shifts in the data (p. 43)	Building a possibility into the software to register whether the end user actually follows the prediction or not (p. 43)
4.3	**Security**	Version management for the software and saving training and test datasets together with the corresponding version of the AIPA (p. 44)	Ensure that end users are trained in the use of secure (cloud) systems, and the standards and regulations in the field of data sharing, security, and privacy (p. 44)	

4.4	**Software testing**		▪ Locally testing components of AIPA according to existing standards (p. 45) ▪ (Re)performing validation of the AIPA where the model itself can be classified as an off-the-shelf component (p. 45)	
Phase 5	**Impact assessment of the AIPA in combination with the software**	**Mandatory**	**Strongly recommended**	**Recommended**
5.1	**Impact assessment and setting up accompanying study**	▪ Conducting an impact assessment of the AIPA within the binge-targeted use case (p. 48) ▪ Involving end users and patients, etc., as early as possible in the development of software that includes the AI predictive model and the associated impact assessment (p. 48) ▪ Drawing up an implementation plan in the case of development within a healthcare organization (p. 49)	▪ Drawing up an implementation plan is not mandatory but strongly recommended if the impact assessment is (partly) implemented within the care process (p. 48)	
5.1.1	**Expected effects**	▪ Making clear how the AIPA operates: independently or advisory according to the *level of automation* (p. 49)	Estimating expected effects in a multidisciplinary context, in consultation with the end user(s) and patients and others (p. 52)	Taking into account the goals as defined in the *quadruple aim* model for improving the healthcare sector,

		▪ Determining in more detail what the expected effects of the AIPA are on potentially relevant (health and process) outcomes (p. 49)		which is applied in value-driven care (p. 50)
5.1.2	**Risk assessment**	▪ Carrying out a risk assessment to identify the possible risks of using the AIPA in daily practice (p. 52) ▪ Mapping the possible undesirable effects (risks) of implementing the AIPA per part of the care process (p. 52) ▪ Choosing and implementing risk mitigating measures (p. 52) ▪ Including sources of uncertainty in the results of the empirical study (p. 52) ▪ Including identified risks in the risk inventory in the results of the empirical study (p. 52)	Involving stakeholders such as users and patients in the risk assessment (p. 52)	
5.1.3	**Human-machine interaction**	▪ Connecting the software of the AIPA as closely as possible to current medical care processes (p. 53) ▪ Involving multiple end users in the local implementation team (p. 53) ▪ Mapping expected changes in the healthcare context by	▪ Demonstrating the desired presentation of the results of the AIPA in the software and the associated work process to the end users (p. 53) ▪ Checking that the layout of the software, the required input and any actions requested from the end user are appropriate for the current workflow (p. 53)	

		interacting with the software (p. 53)	▪ Mapping the so-called facilitating factors and barriers surrounding the implementation of the AIPA (p. 53)	
5.1.4	**Comparative study**	▪ Carrying out a comparative study in which the (desired and undesired) effects of using the AIPA are compared against the same context without using the AIPA (p. 54) ▪ Substantiating the choice of the population and context in which the software of the AIPA is studied (p. 54)	Choosing a reasonably comparable population with the target population for which the software was developed (p. 54)	
5.2	**Health technology assessment**		Carrying out a model-based impact study, or a model-based Health Technology Assessment (HTA)	
5.3	**Uncertainty, risks and unexpected outcomes**			
5.3.1	**Uncertainty in predictions**	Clarifying which sources of uncertainty exist after carrying out the impact assessment and which mitigating measures have been taken		
5.3.2	**Unexpected outcomes, viligance**	Recording unexpected outcomes during the impact assessment and also reporting in accordance with legislation and regulations		

Phase 6	Implementation and use of the AIPA with software in daily practice	Mandatory	Strongly recommended	Recommended
6.1	**Implementation plan**	▪ Drawing up an implementation plan by the healthcare organization (p. 61) ▪ Evaluating the reliability and applicability of the AIPA of implementation plan by the healthcare organization (p. 61) ▪ Introducing the AIPA into the healthcare process in a controlled manner (p. 61) ▪ Carrying out prospective risk assessment to identify risks of using the AIPA in daily medical practice (p. 62) ▪ Evaluation of the identified risks (p. 62) ▪ Including the intended implementation team in the implementation plan (p. 62) ▪ Supporting the implementation team through the ambition and conscious choice for AI by the managers involved in the healthcare organization (p. 62)	▪ Explicitly including the findings from the impact assessment in the prospective risk assessment (p. 62) ▪ Carrying out a data protection impact assessment (p. 62) ▪ Drawing up an implementation plan in collaboration with patients or clients (p. 62)	
6.2	**Monitoring**			

6.2.1	**Responsibilities of manufacturer or developing care organisation**	▪ Monitoring for technical errors in the AIPA and the associated software, etc (p. 63) ▪ Paying attention to monitoring and analysis of incorrect predictions, technical errors, fairness, uncertainties and risks and deployment bias (p. 63)		Automatically documenting in the software whether the user follows the algorithm's advice or not (why not) (p. 64)
6.2.2	**Responsibilities of the care organisation**	▪ Drawing up a local monitoring plan by the healthcare organization where the software containing the AIPA is implemented (p. 65) ▪ Describing at least certain elements in the monitoring plan (p. 65)	To determine local deployment bias, monitor, register and control five aspects (p. 65)	Requesting individual experiences from stakeholders (e.g., the patient and the healthcare provider) as part of the monitoring plan (p. 65)
6.3	**Education**			
6.3.1	**End user**	▪ End-user access to information and/or education on five topics (p. 66) ▪ If the end user is a healthcare provider, healthcare provider access to information and/or education on five topics (p. 66)	Repeating the teaching on a regular basis, depending on the application and the medical context (p. 66)	
6.3.2	**Care organisation**	▪ Access for healthcare organization to information and/or education on five topics (p. 67)		

	▪ Space and opportunity for end users for education on the AIPA (p. 67)		
6.4 Rights and duties		Using a list of rights and obligations of healthcare providers, healthcare organizations, patients/citizens and manufacturers to determine that these can be exercised effectively (p. 68; see p. 68 to 70 for an overview of rights and obligations)	