D5.4 EVALUATION TOOLBOX FOR EVIDENCE-BUILDING AND DATA MANAGEMENT

IN-4-AHA Project – Innovation Networks for Scaling Active and Healthy Ageing

Work Package: WP5 Innovation impact evaluation

Deliverable: D5.4 Evaluation Toolbox for Evidence Building and Data Management

Dissemination level: Public

Version: [V1.0 / 2022 10 25]

2022

Innovation Networks for Active and Healthy Ageing (IN-4-AHA) is a project funded by the European Commission under the Horizon 2020 programme Coordination and Support Action (CSA), Grant Agreement No. 101017603.

This document has been prepared within work package 5, Task 5.4 Evaluation Toolbox for Evidence Building and Data Management. This deliverable is to be reviewed and approved by the European Commission.

More information about the project can be found on the IN-4-AHA webpage and social media pages:

https://innovation4ageing.eu/

https://www.facebook.com/IN4AHA

https://twitter.com/EIP_AHA

https://www.linkedin.com/groups/8912125/

More information about the EIP on AHA community and FUTURIUM platform:

https://futurium.ec.europa.eu/en/active-and-healthy-living-digital-world

https://digital-strategy.ec.europa.eu/en/policies/eip-aha

DISCLAIMER OF RESPONSIBILITY:

The European Commission accepts no responsibility for the contents and results of any work carried out under the IN-4-AHA project.

Authors

Anni Kurmiste, Mariliis Öeren, Kelly Toim, Hille Hinsberg

Revised and contributed by

Organisation	Name
Praxis Centre for Policy Studies	Maali Käbin

History of changes

Version	Date	Modifications
1.0	28.09.2022	Initial version
2.0	25.10.2022	Consortium-reviewed version

Contents

Abbreviations

AHA	Active and Healthy Ageing
DPIA	Data protection impact assessment
EIP on AHA	European Innovation Partnership on Active and Healthy Ageing
EU	European Union
GDPR	General Data Protection Regulation (EU)
IN-4-AHA	Innovation Networks for Active and Healthy Ageing
MAFEIP	Monitoring and assessment framework for the European Innovation Partnership on Active and Healthy Ageing
MAPS toolkit	mHealth Assessment and Planning for Scale toolkit
MAST	Model for Assessment of Telemedicine
MOST	Multiphase optimization strategy
NASSS framework	Non-adoption, abandonment, scale-up, spread, sustainability framework
SCALS	Studies in CO-Creating Assisted Living Solutions
TEHDAS	Towards the European Health Data Space joint action
UK ICO	UK Information Commissioner's Office
UNF IWG	United Nations Fund Innovation Working Group
VOCAL	Virtual Online Consultations – Advantages and Limitations
WHO	World Health Organization

Introduction

It is necessary to find ways to meet people's demands to ensure them a happy, active, and healthy lifestyle while ageing. Ageing populations will lead to the urgent need to expand access to health and care services and innovative solutions. Innovative solutions are necessary to ensure sustainable health and care systems and to create services and products that meet people's needs to create a more person-centred and cohesive community.

Active and Healthy Ageing (AHA) is a field that is a priority for the European Commission and promoting scaling of innovative digital solutions is one of the actions taken. The Commission provides funding and supports the research in the AHA field, i.e., the partnership EIP on AHA. One of the main challenges in AHA is how to facilitate contributions from all stakeholders to scale their innovative solutions. The main aim is to create person-centred solutions in the field of health and care, which are tested, evaluated, and can be scaled across borders. We emphasise here the word "evaluated", as rigorous evaluation provides valuable insights on the impact of the solution, and gives justification to stop, adjust or scale the solution.

Like for other services and solutions, it is important to evaluate the impact of health and care innovations. Decision to adopt, use, or reimburse new health and care solutions are ideally based on evidence regarding their performance in the light of individual and systemic goals. Health technologies have changed exponentially since the early stages of medicine – knowledge has increased, intervention possibilities have expanded, health and care systems have evolved to be more complex. Health technologies have had great impact on our health and care systems already and the further effect is only expected to increase and evidence also supports this. Systematic evaluation of impact of innovative health and care solutions is therefore needed. (1)

This toolbox aims to support the aforementioned objective by providing an easy-to-understand collection of tools used for impact evaluation in the field of AHA. The toolbox gives a brief overview of impact evaluation principles, introduces the reader to designing impact evaluations and reviews different impact evaluation tools and toolkits suitable for the AHA field. Furthermore, practical instructions on how to collect, manage, analyse, and monitor data, including for the purpose of impact evaluation are given. Lastly, some case studies are provided to illustrate good examples of impact evaluation activities in the field of AHA.

This toolbox aims to fill the gap and provide an easy overview compiled of different tools for impact evaluation for the service provider to choose from. The toolbox aims to be the first document that refers to when an AHA field service provider or developer refers to, to expand their knowledge on impact evaluation and wishes to find suitable tips and tools to conduct impact evaluation.

Impact evaluation

Impact evaluation process focuses on gathering data to gain insight on what kind of impact is produced by an intervention. Impact is defined as "positive and negative, primary and secondary long-term effects produced by a development intervention, directly or indirectly, intended or unintended" (2). Impact evaluation can be done to support multiple purposes, i.e., to reorient a programme or to decide whether to continue, discontinue or scale up a programme. Impact evaluation can be done at the global, regional, or country level to make informed decisions (3).

Impact evaluations of health and care innovations, and guidance on how to perform such evaluations, are complex and hampered by several fundamental issues, i.e., health and care innovations take different forms (e.g., physical, digital) and take place in different levels (individual, systemic, etc.). Therefore, it is difficult to describe tasks related to impact evaluation in a one-size-fits-all and still detailed way. Rather, given the complexity, the processes will be described generally while giving concrete illustrating examples. (1)

If possible and appropriate for the specific digital innovation, the following tips should be considered before any evaluation activities are carried out (4):

- Develop the solution with evaluation in mind – make sure objectives are clear (what kind of impact is feasible and desirable) and data are available to collect, manage, analyse, and monitor.

- Consider evaluation when getting approved for ethics – make sure work and impact evaluation is conducted in an ethical way with consent and ethical data management practices.

- Ensure that the solution supports randomisation, including between users and events for single user.

Impact evaluation consists of different stages, which may sometimes vary in order and may be revisited, if needed (3,5,6):

1. Deciding on whether to conduct impact evaluation – impact evaluation should be considered when there is an actual need to understand the impact of the solution, there are resources to carry it out, and the results will be used to guide further actions;

2. Establishing management arrangements – ideally a group of neutral people, who will plan, prepare, conduct and follow-up the impact evaluation;

3. Preparing for the impact evaluation – creating or reviewing and revising the theory of change (comprehensive description and illustration of how and why a desired change is expected to happen in a particular context) as it provides input for the evaluation, identifying resources that are needed to carry out the evaluation and deciding (if not done by an external body) on the evaluation methodology;

4. Conducting the impact evaluation – collecting, managing, analysing, and monitoring data;

5. Following up the evaluation – draw lessons from the evaluation process, make the results publicly available, and conduct a follow-up evaluation of the recommendations, which were developed on the basis of the results.

The first stage is crucial in the process – to assess if it is necessary to conduct the evaluation. (4)

Most common reasons for conducting evaluations (4):

- Desire to know the effectiveness of the solution;

- Desire to go through a regulatory process;

- Desire to understand users' needs;

- Desire to make informed decisions to develop the solution.

When the decision has been made to conduct impact evaluation, the design process should begin. Before evaluating the innovative solution, different aspects should be thoroughly thought about, such as which evaluation approach to use, data collection, management, analysis, and monitoring methods, also the resources available to conduct impact evaluation. (4)

The approach for the evaluation process often requires compromises – a more complicated study will require more resources, however it will more likely also give a more confident answer, while a cheaper and quicker evaluation may be less rigorous. Also, different types of evaluations answer different questions and may require different approaches. Furthermore, different evaluations can complement each other

and may be done in different times – it is suggested that over the life of an innovation, multiple evaluations should be conducted. (4)

Evaluation approaches can be divided into four broader categories (4) – descriptive, comparative, qualitative, or economic studies.

Descriptive studies describe the characteristics of the solution. These studies will provide descriptive statistics, i.e., what proportion, how many, how much, or describe relationships between variables. Descriptive studies are usually weak at providing evidence of cause and effect – it is not possible to assess, whether the effect of one decision could have been different in case of another decision. Descriptive studies are usually also cheaper and quicker since data are readily available. (7–10)

When to use (7):

- To check if an in-use solution works and has no unintended consequences (ex-post evaluation);

- To check if a soon-to-be-used solution works in practice via testing with a pilot group.

Questions usually answered (7,9):

- How many people are using the solution?

- How many people stay engaged with the solution?

- How often do people use the solution?

- Do people like the solution?

Descriptive study methods (7,10):

- Analysis of routinely collected data (i.e., observational study, survey)

- Behaviour change techniques review

- Clinical audit

- User feedback study

Comparative studies help check whether the solution works and is effective. Comparative studies usually involve quanti-

tative data of people who are not given your product (control group) – this is more complex and expensive than a descriptive study. It is important to find a balance between robust evaluations and what is practical and affordable. (7,9)

When to use (7):

- To check how effective the in-use solution is (i.e., in comparison to using another solution or to not using any solution at all);

- To check if a soon-to-be-used solution works effectively.

Questions usually answered (7):

- What is the difference in health outcomes between people using the solution and people using a rival solution?

- What is the difference in health outcomes between people using different versions of the solution?

- What is the difference in health outcomes between people using the solution now and before the solution was available?

Comparative study methods (7,9):

- A/B testing

- Before-and-after study

- Case-control study

- Crossover randomised controlled trial

- Factorial randomised controlled trial

- N-of-1 study

- Quasi-experimental study

- Randomised controlled trial

Qualitative studies provide a deeper understanding on how users feel about the solution. These studies explain the thoughts and experiences of users or other relevant stakeholders. Qualitative studies are usually more subjective than quantitative studies, however, act weaker in describing quan-

titative parameters (i.e., how many users hold specific views) and its results are difficult to generalise to other subjects. (7,9,11)

When to use (7,11):

- To understand users' thoughts and experiences more in-depth;

- To find out how to improve the solution still in development;

- To make use of open-ended questions.

Questions usually answered (7):

- What was users' overall experience of the solution?

- How did users feel during their journey through the solution?

- What do users want to see in a new version of the solution?

Qualitative study methods (7,11):

- Contextual inquiry

- Ethnographic study

- Focus group study

- Interview study

- Observations

- Document study

- Think aloud study

- Usability testing

Economic studies help assess the costs and relative effectiveness and cost-effectiveness of the solution. Commonly, economic studies involve two types of economic analyses: economic evaluation and budget implication analysis. Economic evaluation enables to make efficient use of available resources. (7,9)

When to use (7):

- To help guide decisions on whether a tested or soon-to-be-launched solution should be adopted;

- To find out how the solution compares with competing alternatives in terms of benefits and costs;

- To find out if the solution offers most benefits given the available budget;

- To find out the broader economic implications of the solution.

- Questions usually answered (7):

- How much benefit is gained for each additional monetary unit invested in your solution?

- How cost-effective is the solution compared to alternative options when competing for local or national resources?

- Is the adoption and spread of the solution feasible within the decision-maker's available budget?

Qualitative study methods (7,9):

- Budget impact analysis

- Economic evaluation:

- Cost consequence analysis

- Cost effectiveness analysis

- Cost utility analysis

- Cost benefit analysis

There are also approaches that cross this type of categorisation, and different methods can be mixed and matched, depending on the objectives of the evaluation. Some mixed methods include Ecological momentary assessment, Feasibility study, Interrupted time series study, Micro-randomised trial, Multiphase optimization strategy (MOST), Mixed methods study and Patient-reported outcomes and experiences study. In case the most suitable method is unclear or designing the evaluation is difficult, make use of different available materials and contact a researcher/research consultant or a research group who could be of assistance. (7)

Tools

All around the world, multiple tools and toolkits have been developed to help conduct impact assessment. The aim differs from tool to tool and all of them take into consideration distinct domains – every tool and toolkit is unique and serves its own purpose. Studies show that around one to three domains are mainly used in the evaluation process and no toolkit addresses all domains (1).

In this chapter, brief overviews of different tools and toolkits in the AHA field are given. The aim is to introduce these options to the reader, so it is possible to find overlapping interests and explore further.

MAST

MAST (Model for Assessment of Telemedicine) is a framework used to measure the effectiveness and quality of care provided by telemedicine applications. The development of MAST began in 2009 in an effort to assess telemedicine applications, since, it was concluded, that there was little to no tools or guides for consistent assessment of the outcomes of telemedicine - a new growing field in 2009 (12). MAST represents a multidisciplinary process of evaluating the medical, social, economic, and ethical aspects of telemedicine in a systematic, unbiased, and robust manner (13).

MAST includes 7 topics including identification of the health problem and characteristics of the application, safety, clinical effectiveness, patient perspectives, economic aspects, organizational aspects, and socio-cultural, ethical, and legal aspects (13). MAST has been mostly used to, for example, assess preceding considerations, transferability, or whether services were based on scientific standards and guidelines. The tool can be used to support the decision-making process of different stakeholders involved with new, although technologically ready (TLR) telemedicine solutions.

The tool is to be applied in three steps. First, the purpose of the application and the maturity of the technology and organization is assessed (12). If any barriers are detected, they are to be addressed before the next stage. Second, a multidisciplinary assessment is carried out (6). This involves the evaluation of outcomes within each domain, i.e., the effectiveness of the technology. Third step is the assessment of transferability, during which it is evaluated, whether the application is able to be used in another setting (12).

Domains assessed:

Clinical effectiveness, technological efficiency, regulatory context, economic aspects, and ethical aspects.

NASSS

The NASSS (non-adoption, abandonment, scale-up, spread, sustainability) framework was developed to study unfolding technological programmes in real time and to identify and manage their uncertainties and interdependencies, as well as the challenges of extending and disseminating solutions and the sustainability of such solutions in healthcare organizations and systems (14). The main purpose of NASSS is to study the non-adoption and abandonment of technologies by individuals and the challenges to scale-up, spread and sustainability of such technologies in health and care organizations (14). It can be used to generate a rich and situated narrative of the multiple influences on a complex project; to identify parts of the project where complexity might be reduced; and to consider how individuals and organisations might be supported to handle the remaining complexities better.

The framework consists of 7 topics: the illness or condition, the technology, the value proposition, the individuals intended to adopt the technology, the organisation(s) and the wider system – along with a seventh topic that considers how all these evolve over time (14). Each of the topics are divided into the following complexity levels – simple (few components, predictable), complicated (many components, largely predictable), or complex (many components interacting in a dynamic and unpredictable way). According to the framework, the more domains fall into the "simple" category, the bigger chance of success the solution has.

The tool was made with the intention for it to be used in social and health care fields to study technology-supported change efforts. Studies (14–17) have shown NASSS being helpful with constructing a rich narrative of a technology programme and identifying various uncertainties and interdependencies that need to be contained and managed for success. The framework has proven to be useful in understanding how and why the implementation of a technology-based intervention had resulted in mixed outcomes. The framework is essential for explaining why programmes succeeded or failed, potentially allowing learning, and improving design of the future programmes.

Domains assessed:

Clinical effectiveness, technological efficiency, need for care, impact of the intervention, staff change, organizational change, adaptation, political context, regulatory context, socio-cultural context, patient perspective, age aspects.

MAFEIP

MAFEIP (Monitoring and assessment framework for the European Innovation Partnership on Active and Healthy Ageing) is a web-based toolkit aimed to assess the health and economic outcomes of different ICT-enabled social and health innovations, like care pathways, devices, new techniques and so on. The Markov model, which MAFEIP is based on, is a commonly used model in health and economic evaluations to assess the impact of innovations in terms of health outcomes and resource use. The toolkit measures the likelihood of interventions achieving expected impacts. It also allows to simulate changes in the interventions to improve impacts and guide further development and evaluation. In the case of MAFEIP, the large variation of interventions to be analysed across multiple settings and populations requires a high level of flexibility of the model. (18)

Domains assessed:

Cost-effectiveness, clinical aspects, technological efficiency, quality of life, societal change, impact of the intervention, staff change, regulatory context, socio-cultural context, time aspects, economic aspects, age aspects.

Rainbow Framework

The Rainbow Framework is a multi-perspective, interactive and more general (not specifically aimed at health and care technologies) evaluation model, which was designed by BetterEvaluation agency – an organisation with a global community aimed at creating, sharing, and supporting the use of knowledge about how to better plan, manage, conduct, and use evaluation. The framework organizes and mixes more than 300 methods and processes used in monitoring and evaluating into seven clusters of tasks: Manage, Define, Frame, Describe, Understand Causes, Synthesize, and Report & Support Use. BetterEvaluation provides an interactive website, which displays various methods or processes to be used in each task of the evaluation (19). Three tips were supplied to navigate in the Rainbow Framework. First, the type of question asked will determine which part of the frame-

work to access. Second, it is recommended to compare the pros and cons for each method presented and to make the decision based on the information provided on the website. Third, creating a two-dimensional evaluation matrix where the key evaluation questions are on one side of the matrix and the methods on the other as the toolkit can be developed to match questions with the methods that will be used to answer those questions. (20)

Domains assessed:

No specific domains emphasized; the user of the framework will define the domains to be assessed.

MAPS toolkit

The MAPS (mHealth Assessment and Planning for Scale) toolkit aims to provide actionable information for project teams to critically evaluate the progress of scaling up their innovation and helps to define their priorities and plan their next steps. It is based on an iterative cyclical process which aims to facilitate the successful scaling up of mHealth products and aid in establishing a foundation for sustainability. The toolkit brings forward three strategies for scaling up: government adoption, commercial adoption, and hybrid, which entails a combination between the two previous strategies. The key determinants or the "axes of scale" of the toolkit are groundwork, partnerships, financial health, technology and architecture, operations and monitoring and evaluation. Further, each axis consists of several domains. (21)

The MAPS toolkit was designed by the WHO and UNF-led Innovation Working Group (IWG) between 2011 and 2015. The toolkit was developed for managers or project teams of an existing digital health innovation, or a successfully tested mHealth product, meaning that it is not directed towards innovations in their early stages. The innovations for which the MAPS toolkit is useful for, should also use software or hardware for the purpose of improving health. (21)

Domains assessed:

Parameters of scale, contextual environment, scientific basis, strategic engagement, partnership sustainability, financial management, financial model, data, interoperability, adaptability, personnel, training and support, outreach and sensitization, contingency planning, process monitoring, evaluation research.

IN-4-AHA person-centredness tool

As no tools with a specific focus on person-centredness have been established before, a tool for evaluating service's person-centredness was developed within this project, IN4AHA. The person-centredness concept and approach addresses the needs of the person, identifies different stakeholders and contexts of use, and empathizes, communicates, interacts, and stimulates all the people involved. This kind of approach of human-centred design is very different from many traditional design practices because the focus lies on the people for whom the solution is intended, rather than in the designer's creative process or the technology or material solution itself. The domains of the tool were decided upon previous research, project reports and deliverables, and discussion with project consortium partners. Questionnaires were developed for three groups: service providers, service users and facilitators. The target groups were developed based on the usual care pathways and the persons with various roles in a pathway. (1)

While it is important to focus on person-centredness, from the service provider's point of view, other aspects of evaluation (economic, cost-effectiveness, efficiency, etc.) cannot be overlooked, and this evaluation framework and questionnaire would only be an additional method of assessing and improving one's service. (1)

Domains assessed:

Autonomy, coordination and cooperation, empowerment, personalization.

Data management

The principles, guidelines and tools as described below aim to support innovators who need to utilise data sets or processing methods for designing and deploying the service or application. Selected tools can be used as such or taken as examples to apply the principles in practice.

Principles to guide data management

The following principles are explained in more detail in the helpful guide by the UK Department of Health and Social Care (22).

1. Abide by ethical standards

People need to know that their data is being used for their benefit and that their privacy and rights are safeguarded. Innovators are responsible for ensuring people are properly informed about how and when data about them is shared so that they may feel reassured that their data is being used for legally, fairly and equitably (22).

Collecting and using patient generated data, beyond simply making an individual clinical decision, is ethically sound only if there is (or could reasonably arise) a question to be answered; the methodology (design, data collected, etc) will answer the question; and the costs, including both communal healthcare resources and any risks and burden imposed on the participants, justify the benefits to society. Asking the questions below will help to identify the nature and extent of any ethical concern. (23)

2. Demonstrate that the product collects, stores, and processes users' information in a safe, fair, and lawful way

Product owners should use data in line with the law and relevant guidelines. There are multiple layers of legislation concerning data use on regional, national or EU-level. Please see the IN-4-AHA Data Governance Guidebook for an overview of regulation on data and privacy protection in the EU.

Innovators must comply with the law, but they should also be able to explain why the data that was used was needed and how it is meeting the user need.

It is also expected to justify the necessity and proportionality of the data that is collected - either for product development, research or testing period or when the digital health product goes live and is provided for real-life users. It is preferable to use anonymised data in testing rather than identifiable patient data.

Questions to ask of any systematic data collection process in health care

The following checklist can be helpful in determining if data processing is necessary and proportionate:

- is it necessary to collect/use personal information?

- is it necessary to process it in this particular way?

- could you use anonymised data instead?

- are you collecting/processing more data than you really need?

- do the advantages of processing this data outweigh any disadvantages?

- does processing this data allow you to achieve the envisaged objective?

- could you use other less intrusive means to achieve the same objective? (22)

3. Be fair, transparent, and accountable about what data is being used

A good data flow map identifies the data assets (data at rest) and data flows (exchanges of data) that enable to achieve the value created by data to be delivered. Data flows enable anyone who handles data to understand how data moves through a product (or service process). The map may be included within a Data Protection Impact Assessment. Where data flow mapping identifies instances where data is processed by a data processor on behalf of a data controller, a legally binding written data processing contract is required. This should include clauses appropriate to the processing risks identified (highlighted in the DPIA), as well as mandatory clauses for all data processing contracts. Please see a template for data processing agreement as part of evidence for GDPR compliance.

If the data needs to move between several data processors, including across different jurisdictions, it is advisable to create a customer journey to make the case for data exchange.

TEHDAS initiative has created a sample service process for secondary use of health and social data ("User Journey"). The process consists of consecutive steps and is designed to help the innovator to benefit from the secondary use of data. Each step is explained in further detail in the publication. (24)

- Data discovery and pre-study

- Application for data access.

- Consents collection (optional)

- Data preparation for use

- Data access provision

- Data use

- Results output

In the case of building data-sharing projects, existing data flows need to be reviewed to identify new opportunities for value creation through data. SITRA has collected a set of principles to guide the building of data-sharing projects. These are based on the concept of Fair data economy and can be translated into technical and functional requirements to guide the software development. (25)

4. Ensure data protection compliance

Managing sensitive data, such as health data, in compliance with GDPR requires special attention to administrative and technical measures. The product owner must be able to provide and store consent forms for users, carry out impact assessments, employ specific staff such as a Data Protection Officer, and ensure staff training. Technical infrastructure requirements include authentication and access control procedures, secure data transfer between the solution and cloud infrastructure, data encryption, and audit logs. (See also IN-4-AHA Living Lab testing and innovation scale-up playbook, 2022).

In case of data-driven products, it may be necessary for the innovator to build data protection into the product by de-

fault. The ICO (UK Information Commissioner´s Office) has listed top 10 tips for innovators regarding data protection compliance. Each tip is linked to more detailed guidance. (ICO Innovation Hub project report)

Checklist for data protection compliance

1. Data protection is good for business. Building the data protection principles and information rights into your product is an advantage in the marketplace, encouraging customer confidence and lowering your risk of enforcement action.

2. Data protection will remain relevant, even as technology advances. Placing individual rights at the centre of your product development makes upholding them easier.

3. If you intend to process personal data, you must be aware of your obligations under the legislation. Search for information and guidance materials, including the Data Governance Guidebook. You could also seek mentors or external guidance to ensure your understanding of the legislation.

4. Take a 'data protection by design and default' approach. To save yourself headaches further down the line, data protection compliance should be built into your product from the start. Data protection by design and default is a legal requirement of the GDPR – putting in place the appropriate technical and organisational measures to implement the data protection principles and safeguarding individual rights.

5. Carry out a DPIA (please see an example annexed). If you are looking to process personal data in innovative ways or use a new technology, a Data Protection Impact Assessment might be obligatory. If you identify a high risk that you cannot mitigate, you will need to consult with a Data Protection Authority prior to starting your intended processing. And even if it is not legally required, a thorough DPIA can be a great way to identify and address risks associated with your product.

6. Decide what you are doing with data. Clearly frame the problem you are trying to solve, work out your lawful

basis, and only then decide what personal data – if any – you need to collect. Never hold data 'just in case'.

7. Open it up – and lock it down. New technologies open up fantastic opportunities for consumers through data sharing and data portability. But you must tell them where their data is going and why – and use appropriate security measures to stop it going anywhere else.

8. If your product uses AI, know your obligations. These include explaining to individuals how their personal data will be processed and complying with requirements on automated decision-making and profiling (see an example of Privacy Notice, annexed).

9. Consider using synthetic data. If you are testing a product, there are anonymisation and pseudonymisation techniques available to protect individuals in large datasets. Synthetic data may help to lower risk if it suitably reflects real-world data. If you really cannot do either and need to use live data, document your decision-making so that you can demonstrate that you are taking people's privacy seriously. Limit what you use and put measures in place to minimise the impact of things going wrong.

DPIA / data protection impact assessment

DPIA is an instrument by which the flows of personal identifiable data are governed, and the controls in place to ensure lawful processing. The vast majority of data processing in a health and social care contexts involve special categories of data and it is therefore a full DPIA need to be conducted. A DPIA is intended to be a 'living document' and should be regularly reviewed and updated. (22)

This sample DPIA checklist (See Annex 1) is based on the guidance by UK ICO.

Individuals have the right to be informed about the collection and use of their personal data. Innovators should assure that end-users are treated fairly and transparently, they are told what their data will be used for, they are reminded that they can withdraw their consent (and how), they are told who will process their data and how it will be stored, and they are given access to data protection and privacy policies. ((26), see also IN-4-AHA Living Lab testing and innovation scale-up playbook).

A privacy notice, which should be made readily available to individuals, must provide details about who the data controller is and disclose contact details for its data protection officer. It should also explain the purposes for which personal data is collected and used, how the data is used and disclosed, how long it is kept and the controller's legal basis for processing.

Please see an example, Privacy notice template (see Annex 2) which is included also in the Data Governance Guidebook.

5. Ensure that the product aligns with standards to ensure data quality and interoperability

To provide a seamless care journey, it is important that relevant technologies in the health and social care system are interoperable, in terms of hardware, software and the data contained within. For example, data from a patient's ambulatory blood glucose monitor can be downloaded onto appropriate clinical systems without being restricted to one type of information system. Those technologies that need to interface with clinical record systems must also be interoperable. It is necessary to demonstrate that a health technology and its back-end systems share data with other clinical systems within the appropriate rules regarding the capture, presentation, sharing and storage of data (22).

If a technology needs to communicate with clinical systems to share data, it must comply with the relevant clinical, professional, and technical standards. There are standards that create a common 'language' in the recording of healthcare data and digital health technologies must use these.

It is important that data is recorded in a particular standardised way at the time of its collection, as this allows useful information to be gathered from multiple sources, showing the provenance, and helping to ensure its quality. This can be achieved by following open standards.

An example of open standards used in healthcare technologies is OpenEHR, which is open platform for patient-centred health data, based on a standard architecture.

6. Generate evidence that the product achieves clinical, social, economic, or behavioural benefits

As described in the impact evaluation section above, generation of evidence happens in parallel with the development of the product and builds throughout the product's life. This means that data collection on the impact is a continuous process.

Technologies must meet core eligibility criteria and demonstrate substantial benefit to patients or the health and care system. They must also be able to evidence those benefits. In the UK, NICE has developed an Evidence Standards Framework for digital health technologies. In Germany, The BfArM assesses DiGA treatments in terms of patient benefit, data

protection and information security, and quality. These assessment frameworks and guidelines for data collection can be used by innovators who wish to access these markets and scale up their product or service.

Data analysis

Depending on whether you chose a qualitative or quantitative data approach in the design stage of your impact evaluation process, analysing data may differ.

Qualitative data analysis

Analysing qualitative data usually involves coding – associating themes and ideas with the data through a process of understanding and finding meaning. Most common method to analyse qualitative data is thematic analysis. (27)

Thematic analysis involves developing most common themes – topics or repeated patterns – in the collected data. The themes can be categorized by choice, divided into subthemes as well. To develop the themes, the topics should first be created and secondly data should be coded in line with the themes. Thematic analysis involves making connections between related words, topics, and concepts. (27)

When to use (27):

- To help make sense of qualitative data;

- To analyse data while it is still being collected, to adapt data collection methods;

- To analyse data after it has been collected via qualitative methods.

Quantitative data analysis

Quantitative data may need some preparation before analysing it, especially if this data is collected routinely rather than for one specific occasion. If needed, the data should be anonymised – any personally identifiable information should be deleted – and data protection regulations should be followed. Anomalies should be checked for also – is the data expected, are the numbers correct and is there any repeated data? (27)

Also check for any missing data, and the reasons why it is missing, and outliers, also known as data, that is not within the ranges you expect. The outliers and anomalies should be removed. (27)

To make sense of your quantitative data, the easiest descriptive way to do that, is to visualise data through graphs, maps, or something else. To find out more advanced statistical parameters, like correlation and causation between different information, the help of statistical methods and software (i.e., Excel, STATA, R, etc.) is needed. (27)

After analysing your data, it is also important to make good use of it by improving your intervention and reporting the impact evaluation results. Communicating results can be very helpful to gain trust, promote your solution, and disseminate evidence-based work. (28)

Monitoring

WHO (2016) has provided an important practical guide for the monitoring and evaluation of digital health interventions (29). The WHO report distinguishes between monitoring and evaluating, which is an important distinction, although the two can be strongly related. Monitoring is defined as "the continuous process of collecting and analysing data to compare how well an intervention is being implemented against expected results" (29,30). Monitoring the impacts of an intervention can provide input into the evaluation of an intervention. Hence, this entails routine collection, review, and analysis of data which are collected or generated by digital systems, and which measure progress towards achieving intervention's objectives (31).

Case studies

To illustrate how different health and care solution providers have used impact evaluation tools, some case studies are described.

Using MAFEIP

The i-PROGNOSIS app aims to detect early signs of Parkinson's disease with the tool used by most people daily – the smartphone (32). For the app, a research project conducted a systematic study of interventions for patients with Parkinson's disease in Greece, United Kingdom and Germany with the gathered intervention data analysed with MAFEIP. MAFEIP helped analyse the impact of the interventions and found that the differences between the parameters entered for the three countries are relatively small: costs are a bit higher in Germany and UK and mortality rates are also similar. However, the total Parkinson's disease patient population estimate for each country differs significantly and the cumulative incremental cost gains in the next 20 years also varied significantly. Therefore, with the intervention data and using MAFEIP, i-Prognosis gained useful information on what kind of impact their app might have. This research helped make evidence-based decisions. (33)

Using NASSS

Through two United Kingdom research programmes **VOCAL** (Virtual Online Consultations – Advantages and Limitations) and SCALS (Studies in CO-Creating Assisted Living Solutions) **six different technological programmes** were analysed through the NASSS framework. The six programmes were not publicly announced; however, it is known that their work included 1) video outpatient consultations, 2) GPS tracking of people with cognitive impairment, 3) pendant alarms, 4) telehealth for heart failure, 5) care organising software and 6) shared data warehouse for integrated case management of patients at risk of hospital admission. NASSS was used to analyse all of the programmes individually and the results showed how complexity is a prevalent characteristic in multiple dimensions of many technological programmes. In all six cases, there was a mismatch between how the work was imagined and how work was actually done. Using NASSS helped make sense of the complex interventions and improve them according to the results. (17)
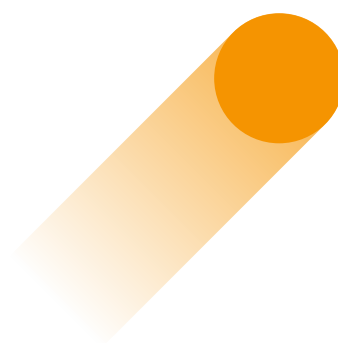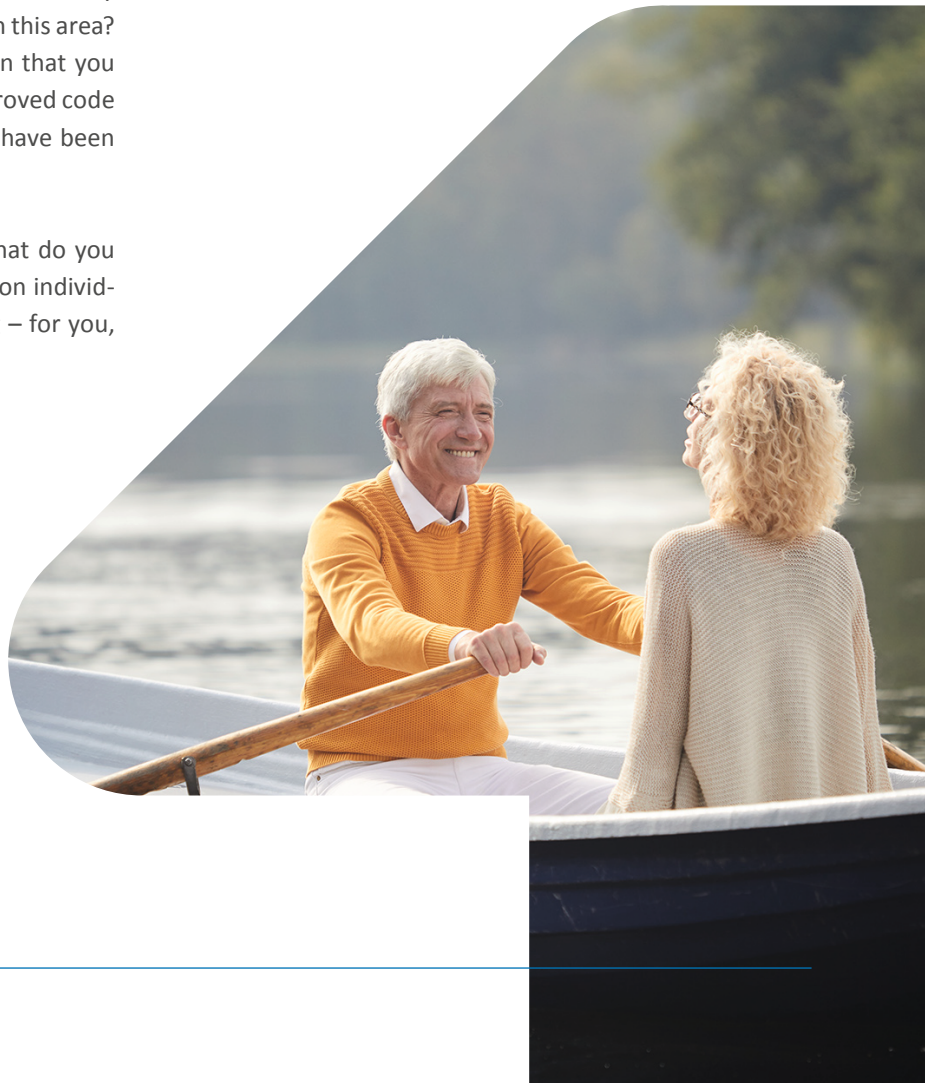
Sources

1.   Paat-Ahi G, Kurmiste A, Purge P, Hinsberg H. AHA innovation assessment framework. Praxis Centre for Policy Studies; 2022.

2.   OECD-DAC. Glossary Key Terms in Evaluation and Results Based Management. Paris: OECD; 2010.

3.   Rogers P. Overview of Impact Evaluation, Methodological Briefs: Impact Evaluation 1. Florence: UNICEF Office of Research; 2014.

4.   UK Health Security Agency. Design your evaluation: evaluating digital health products [Internet]. 2020. Available from: https://www.gov.uk/guidance/design-your-evaluation-evaluating-digital-health-products

5.   TolaData. Designing an impact evaluation work plan: a step-by-step guide [Internet]. TolaData. 2021. Available from: https://www.toladata.com/blog/designing-an-impact-evaluation-work-plan-a-step-by-step-guide/

6.   Peersman G. Impact evaluation [Internet]. BetterEvaluation. 2015. Available from: https://www.betterevaluation.org/en/themes/impact_evaluation

7.   UK Health Security Agency. Choose evaluation methods: evaluating digital health products [Internet]. 2021. Available from: https://www.gov.uk/guidance/choose-evaluation-methods-evaluating-digital-health-products#descriptive-studies

8.   San Diego State University. Basic Research Concepts. Descriptive Studies [Internet]. Basic Research Concepts. Available from: https://ori.hhs.gov/education/products/sdsu/res_des1.htm

9.   Lau F, Kuziemsky C. Handbook of eHealth Evaluation: An Evidence-based Approach. Victoria: University of Victoria; 2017.

10. Aggarwal R, Ranganathan P. Study designs: Part 2 - Descriptive studies. Perspect Clin Res. 2019;10(1):34–6.

11. Busetto L, Wick W, Gumbinger C. How to use and assess qualitative research methods. Neurological Research and Practice [Internet]. 2(14). Available from: https://neurolrespract.biomedcentral.com/articles/10.1186/s42466-020-00059-z

12. Kidholm K, Ekeland AG, Jensen LK, Rasmussen J, Pedersen CD, Bowes A, et al. A MODEL FOR ASSESSMENT OF TELEMEDICINE APPLICATIONS: MAST. Int J Technol Assess Health Care. 2012 Jan;28(1):44–51.

13. Kidholm K, Clemensen J, Caffery LJ, Smith AC. The Model for Assessment of Telemedicine (MAST): A scoping review of empirical studies. J Telemed Telecare. 2017 Oct;23(9):803–13.

14. Greenhalgh T, Wherton J, Papoutsi C, Lynch J, Hughes G, A'Court C, et al. Beyond Adoption: A New Framework for Theorizing and Evaluating Nonadoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies. J Med Internet Res. 2017 Nov 1;19(11):e367.

15. Benson T. Digital innovation evaluation: user perceptions of innovation readiness, digital confidence, innovation adoption, user experience and behaviour change. BMJ Health Care Inform. 2019 Apr;26(1):e000018.

16. Dijkstra A, Heida A, van Rheenen PF. Exploring the Challenges of Implementing a Web-Based Telemonitoring Strategy for Teenagers With Inflammatory Bowel Disease: Empirical Case Study. J Med Internet Res. 2019 Mar 29;21(3):e11761.

17. Greenhalgh T, Wherton J, Papoutsi C, Lynch J, Hughes G, A'Court C, et al. Analysing the role of complexity in explaining the fortunes of technology programmes: empirical application of the NASSS framework. BMC Med. 2018 Dec;16(1):66.

18. Paat-Ahi G, Kurmiste A, Purge P, Randväli A, Hinsberg H. Overview of innovation toolkits: Innovation Networks for Scaling Active and Healthy Ageing IN-4-AHA. Tallinn: PRAXIS Centre for Policy Studies; 2021.

19. BetterEvaluation. Rainbow Framework [Internet].
Available from: https://www.betterevaluation.org/rainbow_framework

20. Board of Global Health, Institute of Medicine. Evaluation Design for Complex Global Initiatives: Workshop Summary [Internet]. Washington, DC: National Academies Press; 2014.
Available from: https://nap.nationalacademies.org/catalog/18739/evaluation-design-for-complex-global-initiatives-workshop-summary

21. World Health Organization. The MAPS Toolkit: mHealth Assessment and Planning for Scale. Geneva; 2015.

22. NHS. A guide to good practice for digital and data-driven health technologies [Internet]. 2021.
Available from: https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology/initial-code-of-conduct-for-data-driven-health-and-care-technology

23. Wade D. Ethics of collecting and using healthcare data. BMJ [Internet]. 2007;
Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1906611/

24. TEHDAS. Report on EHDS service users' expectations [Internet]. 2021.
Available from: https://tehdas.eu/results/tehdas-identifies-user-journey-for-cross-border-health-data-sharing

25. Wong D. Twelve principles for value creation at ecosystem level through data sharing [Internet]. SITRA. 2022.
Available from: https://www.sitra.fi/en/articles/twelve-principles-for-value-creation-at-ecosystem-level-through-data-sharing/

26. Moore K, Poitras S. GDPR and Clinical Investigations: Five Pointers for Medical Device Companies. [Internet].
Available from: https://www.sptsa.com/news/50-gdpr-and-clinical-investigations-five-pointers-for-medical-device-companies.html

27. UK Health Security Agency. Analyse your data: evaluating digital health products [Internet]. 2020.
Available from: https://www.gov.uk/guidance/analyse-your-data-evaluating-digital-health-products

28. UK Health Security Agency. Use your results: evaluating digital health products [Internet]. 2020.
Available from: https://www.gov.uk/guidance/use-your-results-evaluating-digital-health-products

29. WHO. Monitoring and evaluating digital health interventions [Internet]. WHO. World Health Organization; 2016 [cited 2021 May 6]. Available from: https://apps.who.int/iris/handle/10665/252183

30. WHO. Transforming and scaling up health professionals' education and training: World Health Organization guidelines [Internet]. 2013. Available from: http://apps.who.int/iris/bitstream/10665/93635/1/9789241506502_eng.pdf

31. WHO. Monitoring and evaluation   of health systems strengthening: An operational framework [Internet]. 2009.
Available from: https://apps.who.int/iris/bitstream/handle/10665/258734/9789241564052-eng.pdf

32. NARPO. i-PROGNOSIS, Early Parkinsons Detection Research Project [Internet].
Available from: https://www.narpo.org/i-prognosis-early-parkinsons-detection-research-project/

33. Grammalidis N, Hadjileontiadis, L, Lupiáñez-Villanueva F, Folkvord F, Febrer, N, Esmail L. Support Services for the Management and Utilization of Monitoring and Assessment of the EIP - MAFEIP Tool [Internet]. 2015 [cited 2021 May 14]. Available from: http://mafeip.eu/sites/default/files/MAFEIP_UC19_iPrognosis_v2_compressed.pdf

Annex 1. Checklist for data protection impact assessment

Source: Information Commissioner's Office, UK

1. **Describe the nature of the processing:** how will you collect, use, store and delete data? What is the source of the data? Will you be sharing data with anyone? You might find it useful to refer to a flow diagram or other way of describing data flows. What types of processing identified as likely high risk are involved?

2. **Describe the scope of the processing:** what is the nature of the data, and does it include special category data? How much data will you be collecting and using? How often? How long will you keep it? How many individuals are affected? What geographical area does it cover?

3. **Describe the context of the processing**: what is the nature of your relationship with the individuals? How much control will they have? Would they expect you to use their data in this way? Do they include children or other vulnerable groups? Are there prior concerns over this type of processing or security flaws? Is it novel in any way? What is the current state of technology in this area? Are there any current issues of public concern that you should factor in? Are you signed up to any approved code of conduct or certification scheme (once any have been approved)?

4. **Describe the purposes of the processing:** what do you want to achieve? What is the intended effect on individuals? What are the benefits of the processing – for you, and more broadly?

5. **Describe compliance and proportionality measures**, in particular: what is your lawful basis for processing? Does the processing actually achieve your purpose? Is there another way to achieve the same outcome? How will you prevent function creep? How will you ensure data quality and data minimisation? What information will you give individuals? How will you help to support their rights? What measures do you take to ensure processors comply? How do you safeguard any international transfers?

6. **Identify and assess the risks:** describe source of risk and nature of potential impact on individuals. Include associated compliance and corporate risks as necessary.

7. **Identify measures to reduce risks.**

8. **Record the outcomes of assessment.**

Annex 2. Privacy notice (example) Our Company Privacy Policy

Source: https://gdpr-info.eu/issues/consent/

Our Company is part of the Our Company Group which includes Our Company International and Our Company Direct. This privacy policy will explain how our organisation uses the personal data we collect from you when you use our website.

Topics:

- What data do we collect?
- How do we collect your data?
- How will we use your data?
- How do we store your data?
- How will we use your personal data for marketing purposes?
- What are your data protection rights?
- What are cookies?
- How do we use cookies?
- What types of cookies do we use?
- How to manage your cookies
- Privacy policies of other websites
- Changes to our privacy policy
- How to contact us
- How to contact the appropriate authorities

What data do we collect?

Our Company collects the following data:

- Personal identification information (Name, email address, phone number, etc.)
- [Add any other data your company collects]

How do we collect your data?

You directly provide Our Company with most of the data we collect. We collect data and process data when you:

- Register online or place an order for any of our products or services.
- Voluntarily complete a customer survey or provide feedback on any of our message boards or via email.
- Use or view our website via your browser's cookies.
- [Add any other ways your company collects data]
- Our Company may also receive your data indirectly from the following sources:
- [Add any indirect source of data your company has]

How will we use your data?

Our Company collects your data so that we can:

- Process your order and manage your account.
- Email you with special offers on other products and services we think you might like.
- [Add how else your company uses data]

If you agree, Our Company will share your data with our partner companies so that they may offer you their products and services.

- [List organisations that will receive data]

When Our Company processes your order, it may send your data to, and also use the resulting information from, credit reference agencies to prevent fraudulent purchases.

How do we store your data?

Our Company securely stores your data at [enter the location and describe security precautions taken].

Our Company will keep your [enter type of data] for [enter time period]. Once this time period has expired, we will delete your data by [enter how you delete users' data].

Marketing

Our Company would like to send you information about products and services of ours that we think you might like, as well as those of our partner companies.

- [List organisations that will receive data]

If you have agreed to receive marketing, you may always opt out at a later date.

You have the right at any time to stop Our Company from contacting you for marketing purposes or giving your data to other members of the Our Company Group.

If you no longer wish to be contacted for marketing purposes, please click here.

What are your data protection rights?

Our Company would like to make sure you are fully aware of all of your data protection rights. Every user is entitled to the following:

- The right to access – You have the right to request Our Company for copies of your personal data. We may charge you a small fee for this service.

- The right to rectification – You have the right to request that Our Company correct any information you believe is inaccurate. You also have the right to request Our Company to complete the information you believe is incomplete.

- The right to erasure – You have the right to request that Our Company erase your personal data, under certain conditions.

- The right to restrict processing – You have the right to request that Our Company restrict the processing of your personal data, under certain conditions.

- The right to object to processing – You have the right to object to Our Company's processing of your personal data, under certain conditions.

- The right to data portability – You have the right to request that Our Company transfer the data that we have collected to another organisation, or directly to you, under certain conditions.

If you make a request, we have one month to respond to you. If you would like to exercise any of these rights, please contact us at our email:

Call us at:

Or write to us:

Cookies

Cookies are text files placed on your computer to collect standard Internet log information and visitor behaviour information. When you visit our websites, we may collect information from you automatically through cookies or similar technology

For further information, visit allaboutcookies.org.

How do we use cookies?

Our Company uses cookies in a range of ways to improve your experience on our website, including:

- Keeping you signed in

- Understanding how you use our website

- [Add any uses your company has for cookies]

What types of cookies do we use?

There are a number of different types of cookies, however, our website uses:

- Functionality – Our Company uses these cookies so that we recognise you on our website and remember your previously selected preferences. These could include what language you prefer and location you are

in. A mix of first-party and third-party cookies are used.

- Advertising – Our Company uses these cookies to collect information about your visit to our website, the content you viewed, the links you followed and information about your browser, device, and your IP address. Our Company sometimes shares some limited aspects of this data with third parties for advertising purposes. We may also share online data collected through cookies with our advertising partners. This means that when you visit another website, you may be shown advertising based on your browsing patterns on our website.

- [Add any other types of cookies your company uses]

How to manage cookies?

You can set your browser not to accept cookies, and the above website tells you how to remove cookies from your browser. However, in a few cases, some of our website features may not function as a result.

Privacy policies of other websites

The Our Company website contains links to other websites. Our privacy policy applies only to our website, so if you click on a link to another website, you should read their privacy policy.

Changes to our privacy policy

Our Company keeps its privacy policy under regular review and places any updates on this web page. This privacy policy was last updated on 9 January 2019.

How to contact us?

If you have any questions about Our Company's privacy policy, the data we hold on you, or you would like to exercise one of your data protection rights, please do not hesitate to contact us.

Email us at:

Call us:

Or write to us at:

How to contact the appropriate authority?

Should you wish to report a complaint or if you feel that Our Company has not addressed your concern in a satisfactory manner, you may contact the Information Commissioner's Office.

Email/Address

in4aha

http://ec.europa.eu/digital-single-market/ehealth