Patient perspective on the use and reuse of real-world data in Belgium

Conclusions from the patient round table on the use and reuse of routine care health data

Addendum on the report on the use of real-world data for personalized medicine, June 2022

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Colophon

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List of abbreviations

Abbreviation	Definition
AI	Artificial intelligence
ATHENA	Augmenting Therapeutic Effectiveness through Novel Analytics
BVZD/ABDH	Belgische Vereniging van Ziekenhuisdirecteuren/Association Belge des Directeurs d'Hôpitaux
EHR	Electronic Health Record
FAIR	Findable, Accessible, Interoperable and Reusable
GDPR	General Data Protection Regulation
HCP	Healthcare Professional
MELLODDY	Machine Learning Ledger Orchestration for Drug Discovery
PODS	Personal Online Data Stores
RUZB/CHAB	Raad van Universitaire Ziekenhuizen in België/Conférence des Hôpitaux Académiques de Belgique
RWD	Real-World Data
VOP	Vlaams Oncologisch Platform (Flemish oncological platform)

Patient perspective on the use and reuse of real-world data in Belgium

To be successful in the (re)use of patient healthcare data to improve quality of care and treatment outcomes, patients and patient organizations should be very actively involved in the decision-making and also a high degree of transparency on what has been (will be) done with their healthcare data is necessary. A patient round table on the patient's perspective on the (re)use of patient real-world data (RWD) delivered many useful insights to further support the successful implementation of a RWD framework in Belgium by increasing the number of patients willing to share their healthcare data for (re)use.

Full and clear transparency on what will happen to patients' data through patient communication adapted to patient profile and disease

General implementation of opt-out consent mechanism where patients actively have to opt out if they want to avoid that their data be (re)used

Involvement of patients and patient organizations in decision-making at local, federal and European level

Implementation of the best suited data management approach guaranteeing the highest data protection level resulting in a maximum trust from patients and patient organizations involved

Patients generally agree on sharing their healthcare data, irrespective the partner to share it with, to improve quality of care and treatment outcomes. Their willingness to share their healthcare data can be further improved by four key measures:

1. Develop **tailored communication to patients and patient organizations** to obtain **full transparency** on data (re)use initiatives, both public and industrial

2. Systematically **include patients and patient organizations in decision-making** processes on (re)use of data to optimize patient consent motivation

3. Initiate the **opt-out patient consent model on all healthcare levels** to include the highest number of patients in data (re)use initiatives and obtain the best possible results in care quality and treatment outcome improvement

4. Develop a **robust, well protected and carefully managed data (re)use approach,** ideally based on the **federated network** approach in which data is not exchanged fully, preserving patient privacy and security

1. Executive summary

The ATHENA (Augmenting THerapeutic Effectiveness through Novel Analytics) project aims to develop a platform that can access large datasets on the evolution of disease in individual cancer patients. The aim is to search for valuable correlations between data (data mining), while still complying with the highest standards of patient data privacy and security by using a federated model. This approach makes it possible to discover disease mechanisms that can be treated through new personalized therapies. The ATHENA project has developed a clear vision on the use of real-world data (RWD) for personalised medicine and, in a next step, the ' of an RWD framework for Belgium.[1]

It became very clear that, to be successful in the (re)use of patient healthcare data to improve quality of care and treatment outcomes, patients and patient organisations should be very actively involved in the decision-making and a high degree of transparency on what has been (will be) done with their healthcare data is necessary. That is the reason why a patient round table has been organized on the patient's perspective on the (re)use of patient RWD in Belgium. This round table delivered many useful insights to further support the successful implementation of a RWD framework in Belgium by increasing the number of patients willing to share their healthcare data for (re)use.

A first key element is patient communication, adapted to patient profile and disease. This communication should provide full and clear transparency to the patient on what will happen with their data, what purpose the data will be used for and how the data will be handled. The best channels for patient communication should still be determined.

A second key element is the general implementation of the opt-out consent mechanism where patients actively have to opt out if they want to avoid that their data be (re)used. The implementation of the opt-out consent mechanism should be supported by an informational campaign at national level.

A third key element is the active involvement of patients and patient organizations in decision making processes at local, federal, and European level to obtain broadly patient-supported decisions. The involvement process should be adapted to the level of professionalization of the different patient organizations.

The final key element is the implementation of the best suited data management approach guaranteeing the highest data protection level resulting in a maximum trust from patients and patient organisations involved. All stakeholders agree that, to reach this objective, a federated network approach is the preferred solution with the least exchange of patient information possible and fully in line with GDPR (General Data Protection Regulation) as it implements the "privacy by design strategies" to "minimize" and "separate" the processing of personal data as much as possible. This federated network approach is fully compatible with the preferred opt-out patient consent approach mentioned as second key element.

Patients generally agree on sharing their healthcare data, irrespective the partner to share it with, to improve quality of care and treatment outcomes. Their willingness to share their healthcare data can be further improved by the four key measures which have been identified in the patient round table organised by Janssen and Inovigate:

- Develop tailored communication to patients and patient organisations to obtain full transparency on data (re)use initiatives, both public and industrial
- Systematically include patients and patient organisations in decision-making processes on (re)use of data to optimise patient consent motivation
- Initiate the opt-out patient consent model on all healthcare levels in order to be able to include the highest number of patients in data (re)use initiatives to obtain the best possible results in care quality and treatment outcome improvement
- Develop a robust, well protected and carefully managed data (re)use approach ideally based on the federated network approach in which data is not exchanged fully, preserving patient privacy and security

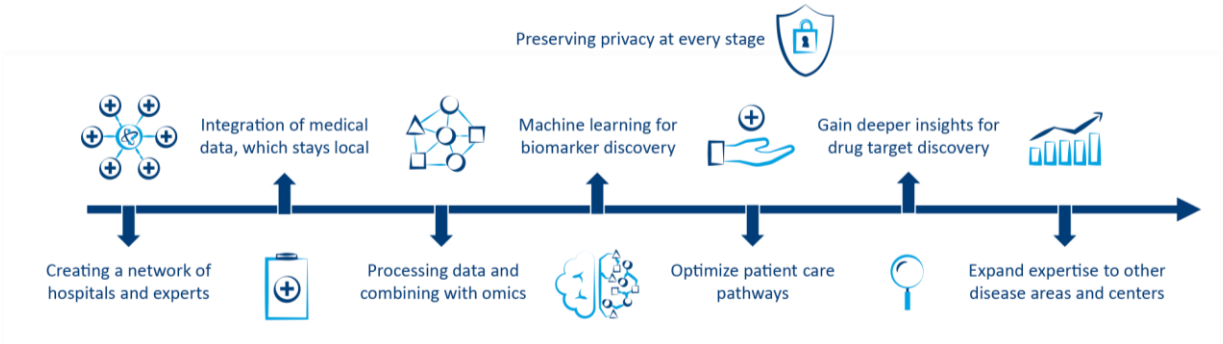
[1] https://portal-uat.athenafederation.org/web/athena

2. Context and objective

2.1 The ATHENA project and objectives

ATHENA is a collaborative network which brings together a unique, multidisciplinary and complementary partnership of academia, hospitals and industry which explore and use the concept of machine learning for the realisation of predictive analytics in oncology in order to optimise care quality and outcomes. By creating a federated and standardised analytics platform, it will be possible to combine different data types in one predictive model. It will allow access for partner hospitals and industries to detect and validate new therapies, while fully preserving the privacy of patients.

Clinical studies, as currently designed and implemented, only cover a selection of the population, leading to biased care recommendations that do not apply to everyone. A promising novel strategy to overcome this obstacle is to include virtually all data from patients suffering from a certain condition. This so-called RWD (data obtained from patients in a standard clinical setting of care) allows for the discovery of different patterns of disease progression and drug response through machine learning (Shah et al., 2019). Early identification of these patterns in patients, will lead to an optimal diagnosis and treatment strategy, adapted to the patient's needs and aiming at optimisation of treatment outcomes and maximisation of survival rates.



ATHENA is a public-private partnership supported by VLAIO. ATHENA was created based on, the one hand, the request of Professor De Ridder (urology UZ Leuven) to co-analyse clinical and genome data and, on the other hand, the excellent experience with MELLODDY (Machine Learning Ledger Orchestration for Drug DiscoverY), a project of 10 pharmaceutical companies working together in a federated manner around highly confidential structured databases. The current ATHENA consortium consists of 2 university partners (Universiteit Gent and KU Leuven), 3 hospital partners (OLV Aalst, AZ Groeninge and CHU Liège), and 5 industrial partners (Robovision, Illumina, Janssen, Imec and Inovigate).

The objectives of the novel approach as outlined by ATHENA are 4-fold:

- Optimised care for every patient: optimised, data-driven precision medicine will be accelerated through data (of any kind data, e.g., records, images, omics) mobilisation, to generate insights to inform research, support care and improve survival
- Novel markers that allow early diagnosis and optimisation of treatment strategy: patient stratification depending on potential therapy response based on new markers and/or algorithms
- Better treatment options, delivered to patients faster: targeted treatments delivered more efficiently (care pathway automation) and proactively to patients
- Novel disease insights and accelerated treatment development: integrating research and care, leading to better patient outcomes

The final overall objective is to develop and bring more adapted, personalised treatments faster and more efficiently to the patients to obtain better outcomes and increase survival rate, creating building blocks that can be exploited in future research and development projects, in other disease areas, and participating medical centers.

The ATHENA partners aim to reach these objectives through a three step approach, focusing on a few disease cases in first instance:

1. Collection of different types of patient data (patients records, genomics and imaging data etc.), focusing in first instance on bladder cancer and multiple myeloma as pilot cases
2. Development of a flexible, cohesive, manageable, modulatory and federated platform to integrate and process the different types of data
3. Transform data into information and knowledge to generate care recommendations and predictive care advice benefitting both healthcare professionals (HCPs) and patients

Data in the ATHENA project is analysed using a federated data network, based on multiple (often geographically) separated datasets. During this analysis, the data is not exchanged and can stay, for example, behind a given institution's firewall to increase the (impression of) security.

The ATHENA partners have, in line with the project objectives and the work performed until now, published a first report on 'The use of Real-World Data for Personalized Medicine' and, in a second phase, a report on an 'RWD framework for Belgium'. During these two RWD projects, it became very clear that patients should be very actively involved in the decision-making and degree of transparency on what has been (will be) done with their healthcare data. That is the reason why Janssen and Inovigate took the lead in organising a patient round table on the patient's perspective on the (re)use of patient RWD in Belgium.

Other vital aspects of patient healthcare data sharing, such as governance, legal and ethical requirements, data ownership and consent are also addressed.

2.2 The use and management of healthcare data

2.2.1 Access to patient data

It is often assumed that patient personal data processing is only possible if the individual patient has expressed his/her informed consent: the patient receives detailed information with the opportunity to discuss and/or ask questions and the patient clearly confirms that he/she allows his/her personal data to be collected for (re)use. However, informed consent is only one lawful base for processing personal data. For many purposes, consent will not be a necessary requirement for data (re)use under the data protection law. Two alternative systems to individual informed consent are currently being explored: opt-in and opt-out.

An opt-in still relies on a person actively indicating that his/her data can be (re)used, but is generally "lighter touch" than an informed consent approach. There are however many scientific and practical arguments against an opt-in consent model for (re)use of patient healthcare data. Population health research results can only be accurate, unbiased, and representative if all population segments are covered. With an opt-in model however, only the most engaged patients who actively take steps to opt-in will be included in the data pool. Everyone else will not be represented in the analysis results. The global picture about any health condition risks to be missed, because the data reflect only a small, selective portion of the population. In some cases, there are statistical ways to adjust for missing data, but it is much harder to assure accurate research for different population groups if the data is not fully representative.

In an opt-out system, data will be collected and used automatically unless the patients actively opts out. Opt-out will probably lead to higher coverage across the population than opt-in as, in general, patients are happy or at least not reluctant to share their data for (re)use. It is likely that only a few patients will actively take steps to opt out. An opt-out allows people to actively express a choice, so that if they object to their confidential patient information being used to improve treatment prediction and outcomes, they can do so. But it also ensures that if people don't express a preference, the data can be used, subject to safeguards and controls on its use. An opt-out system is therefore the best approach for population health provision and research. This does not mean that an opt-out system implemented on its own is a guarantee for patient confidence. Trust in (re)use of patient data can only be obtained if transparency, accountability, and a strong case for the public and social benefits of (re)using the data can be demonstrated.

Many patients are supportive of (re)using patient data to improve research and healthcare results but still feel they should be asked for permission first: they would prefer an opt-in or an informed consent-based system. However, an opt-out system seems the best approach when considering the (re)use of health data for research and healthcare.[2] To assess the view of the Belgian patients and patient associations on this topic, an in-depth discussion is needed.

2.2.2 Storage of patient data

Data should be stored according to article 5.1c of the GDPR where the data minimisation principle states that the collection of personal data should be restricted to "adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed". Ideally, data are stored at their place of origin using either a federated network (e.g. ATHENA) or personal online data stores (PODS) for data (re)use purposes.

Federated networks
Networks allowing analysis on data stored on different physical locations. The data is not exchanged and can stay, for example, behind a given institution's firewall. It allows for full preservation of patient privacy and security.

Data vaults or data PODS
Data vaults or also called data PODS for patient health data where all data stays with the patient and the patient has full decision power on potential (re)use.[3]

A federated approach receives general acceptance by hospitals, industry and government under the condition that data is FAIR: findable, accessible, interoperable and reusable. A federated approach is key for meaningful implementation of AI (artificial intelligence) algorithms. Their AI power increases with the amount and quality of data available to train the algorithms.

A federated approach for data (re)use between hospitals delivers only meaningful results if data is of high quality. Implementing the framework published by the RUZB/CHAB (Raad van Universitaire Ziekenhuizen en België/Conférence des Hôpitaux Académiques de Belgique) should contribute to this quality improvement.[4] Once high-quality data are available, doors open to (re)use the data for many applications benefitting patients, HCPs, research institutions, industry and government.

2.3 The importance of the patient perspective in data reuse

During the course of the ATHENA project, it became clear that access to patient health record data and the approvals to use the data for data analysis were very difficult to obtain. Many obstacles, justified or not, have to be overcome. One of the major obstacles is, from a patient perspective, a lack of information and knowledge about what would/could happen to the data, leading to distrust in some cases. A second important obstacle was the innovative federated approach which was not fully understood by the decision makers resulting in important delays. ATHENA had to tackle these obstacles, involving all stakeholders, to develop an efficient RWD framework for Belgium, corresponding to the objectives as described above.

As patient data (re)use is crucial to optimise patient care and obtain better treatment outcomes, patients, and the associations supporting them, are very important stakeholders in the RWD use and reuse process. Without active patient support, the outcome of the ATHENA project will never be successfully implemented into R&D and routine clinical practice. Patients want to be involved in the decision-making around (re)use of their data and see themselves as experts, nobody knowing the disease better than the patients themselves.

[2] https://understandingpatientdata.org.uk/news/why-an-opt-out
[3] https://assets.vlaanderen.be/image/upload/v1671522849/EN_DNB_magazine_19_12_2022_jgjbug.pdf
[4] Common position establishing a framework for secondary use of real-world data (routinely) collected in hospitals, RUZB/CHAB, 2022

A patient round table was organised on February 16th 2023 in Brussels to get a clear view on the patient perspective on the use and reuse of RWD in Belgium, and the level of involvement and information sharing they expect. **The outcome of this round table, together with additional research on certain topics, is summarised in this report.**

2.4 The hospital perspective

All stakeholders involved have high expectations and ambitions with regard to the (re)use of health-related data collected in the real world, including routinely collected data. With clock-like regularity and increasing variability in purpose, scope and nature, hospitals receive internal and external requests for the (re)use of health-related data. Examples include the support of evidence-based medicine and value-driven healthcare strategies, the development of medical devices, including those relying on machine learning and AI, the conduct of projects that ensure safe and high-quality care etc.

Responding to these requests, the hospitals have an essential role as a guardian of electronic patient health records (EHR). The pressure to guarantee the protection of patient data and to increase the attention for the rights of the patient as a data subject is high. The lack of a clear framework that allows the evaluation of the correct governance of data sharing for (re)use is experienced as a bottleneck.

The RUZB/CHAB recently published a joint position paper on this topic: 'Common position establishing a framework for secondary use of RWD (routinely) collected in hospitals'. In this position paper a governance framework for the secondary use of collected hospital patient RWD is proposed[5]. The position paper is not meant to be a code of conduct but rather represents a common position of university hospitals, which can, in a later stage, also be applied for peripheral hospitals. In a next step the hospitals plan to develop joint initiatives e.g. the creation of a central registration point for new requests for data (re)use, avoiding that all individual hospitals would receive and have to handle the same request from the same party.

In the position paper, the university hospitals have formulated six rules of thumb for the consideration and evaluation of requests for the (re)use of RWD. These rules of thumb are considered essential to achieve a balanced approach taking into account legal and ethical principles, patient expectations as well as interests of all stakeholders, including the general interest of the public. It concerns:

1. Registration
2. Privacy and compatibility assessment
3. Right to information
4. Legal basis and exemption to process health-related data
5. Right to opt-out
6. Security

The conditions for secondary use of RWD are built on three important assumptions that are discussed in the RUZB/CHAB position paper:

- Anonymisation vs. pseudonymisation: different treatment of data depending whether they are used for a retrospective or a prospective approach. Anonymised data is data that has been changed so that reidentification of the individual is impossible, making this type of data very suited to do retrospective studies, necessary for research into certain diseases. The amount of data needed to draw conclusions from the data usually requires the participation of many hospitals using the same data treatment standards. Pseudonymised data is data that has been de-identified from the patient but can be re-identified if needed. This type of data is mainly used in prospective studies where a long-term patient data follow-up is needed.
- The concept of public interest in GDPR: secondary use of data at academic level for research is obviously considered of public interest. Secondary use of data for research and development at private companies can equally be considered of public interest under the condition of an equal return to society.

[5] https://www.univ-hospitals.be/common-position-establishing-a-framework-for-secondary-use-of-real-world-data-routinely-collected-in-hospitals/

- The concept of the compatibility test in GDPR: further guidance from authorities is needed especially on the interpretation of some articles in the GDPR legislation.

The aim of the RUZB/CHAB framework is not to hamper the secondary use of RWD. RWD should be available to support both public and industrial initiatives. However, efficient and sufficient safeguards should apply when processing health-related data for secondary purposes. The developed framework clarifies the conditions for the (re)use of patient data, taking into account the call for patient empowerment and ensuring GDPR compliance.

Many hospitals are starting initiatives in (re)use and inter-hospital exchange and comparison of patient data according to the RUZB/CHAB position paper guidelines. The Flemish Oncological Platform (VOP, Vlaams Oncologisch Platform) started an initiative on lung cancer, in first instance, in collaboration with AZ Delta in Roeselare and ZOL in Genk. Their current dataset already contains 90% of what is needed for retrospective research. Several other hospitals are considering joining this platform. The implementation of such projects is hampered by obstacles in (re)using and exchanging data on technical and governmental level but an extra hurdle is the lack of funding, especially in the early stage.

This funding hurdle is often a problem: a concrete proposal by the Colorectal Cancer Patients' association to collect data was not broadly supported by hospitals, institutions and HCPs. The main reasons were a lack of resources and/or funding. Since the HCP is the gateway to the patient, many of these projects are difficult to kick off successfully if this HCP shows low interest in participating for resource or funding reasons, both being often linked to each other.

2.5 The patient and patient association perspective

The mission of patient associations is to help patients and their relatives improve their respective quality of life by helping them to overcome barriers and problems in terms of healthcare costs, access to the best possible health, patient rights, reimbursement possibilities etc.

An interesting case in the (re)use of data has been realised by the Digestive Cancers Europe patient organization, which developed the patient roadmap for colon cancer. For each stage of the care pathway, from prevention to diagnosis and follow-up, best practices in Europe were identified based on patient data (re)use. This case clearly showed that, at hospital level, many recent patient data needed for the development of a rational health policy (e.g. diagnostic, survival, treatment costs and treatment outcomes) are not accessible and/or available neither at the Belgian, nor at the European level. The Digestive Cancers Europe patient organisation highlighted that improving quality of care and patient treatment outcomes would only be possible if more high-quality data become available for (re)use. This supports the need of a Belgian and European policy on the use of RWD for higher quality personalised medicine and the implementation of a national and international RWD framework across hospitals, in the interest of all patients.

Patients should not be the hurdle for the implementation of such a policy and framework as many publications and surveys show that most of the patients have no objections in sharing their personal health-related data. The European Patients Forum for instance mentions that 80% of the patients is willing to share data if there is a benefit for population health and healthcare[6].

[6] https://digital-strategy.ec.europa.eu/en/library/infographic-digital-health-and-care-eu

3. Approach and objective of the round table

In order to get better insights on the patient point of view on the (re)use of his/her data and the governance aspects needed for that, a round table was organised in Brussels on February 16th 2023. The following patient representatives and experts participated in the round table:

Patient representative/Expert	Association
Stefan Gijssels	Patient expert Center, chair
Stefan Joris	MUCO association, managing director
Joke Soetaert	MS-liga, patient expert
Annelies Verbiest	UZ Antwerp, oncologist
Griet Verhenneman	UZ Leuven, DPO

The objective of the round table was to map the patient perspective and his/her expectations on four key topics:

- The willingness of patients to share data, in general, and, more specifically, which type of data
- The expectations of the patients on the kind of information they want to receive regarding the (re)use of their data and the level of transparency on what is done with their data
- The way patients want to be involved in the decision making about (re)use of their data
    - As an individual patient in the decision on his/her health data (re)use: opt-in vs. opt-out mechanisms
    - As patient representatives in governance bodies (participative and adaptive governance)
    - On a European level within the European Health Data Space (citizen control)
- The preferred tools and mechanisms to increase trust and reassurance that patient data is well protected and carefully handled, e.g. principle of federated data networks as a method

4. Outcome of the debate

The outcome of the discussion during the round table can be summarised in four topics.

4.1 Willingness to share data

Patients and patient organisations, in general, are convinced that sharing all patient data is necessary to improve research results, quality of care and patient outcomes. It will however never be possible to convince 100% of the individual patients.

All patients experience their specific disease differently. They can be divided, according to their attitude towards their disease, in four subgroups which should all four be approached in an adapted way to convince them to share their patient date for (re)use:

- The hero/extravert: cancer won't get me small
- The victim/extravert: the fatalist, there is nothing more to be done
- Out of control/introvert: totally dependent on others
- Under control/introvert: lone wolves

The willingness to share data may vary according to the patient typology but also to the type of disease, some diseases even inducing a certain reluctancy. Many Multiple Sclerosis patients for example suffer from cognitive problems and fatigue. Even at a young age, this can induce a lack of interest in their disease, in the therapy they receive and in the (re)use of their data, reducing significantly their willingness to share their patient data.

The willingness to share data does not depend on the profile of the research partner the data will be shared with. If transparency is respected and the standards for (re)use are correct, patients do not want to restrict their consent to public research partners.

Finally, it is clearly mentioned that, if data is (re)used to develop AI applications, complete data anonymisation must be guaranteed.

In an optimal communication to patients and patients organisations to increase the patient's willingness to share his/her healthcare data for (re)use, several aspects should be taken into account:

- The type of patient
- The pathology and its impact on the patient's willingness to share data
- The purpose the data will be used for
- A guarantee on transparency and respect of standards

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4.2 Expectations on information about the (re)use of data and level of transparency

Independent of the type of patient and his/her pathology, and the purpose of the data usage, transparency is the key to success to increase the patient's willingness to share data for (re)use. This is in line with the findings of the European Patients Forum on the sharing of patient data. The Forum states that, if trust is established in what happens with their data, patients have no problem making them available for research (public or industrial).

Patients realise the benefits of patient data (re)use and do not object if the principles of patient data (re)use are explained in a transparent way and the data handling happens in a correct manner. Transparency does not have to be very complicated and detailed, but a clear explanation on what will happen with the data is key. The need for transparency is valid for both the (re)use of individual, personal as well as the (re)use of aggregated patient data.

Communication is the only way to establish and increase transparency towards patients. It should be clarified, in multi-stakeholder consultation, which channel(s) should ensure, with one voice and message, the communication on the (re)use of data towards the patients to obtain and increased patient willingness to share data for (re)use:

- A single app for all patients? But what about patients with a low or inexistant digital profile?
- Patient associations?
- HCP: specialist, nurse, psychologist, general practitioner, pharmacist…?

In order to further increase motivation to share patient data, patients can be included in the selection of some of the data points to be registered. That will make it easier to capture high quality data sets especially outside the hospital, e.g. in home care which is recently gaining interest in the patient care pathway.

A good example is the data capturing about nutrition of cancer patients because many patients suffer from malnutrition due to a lack of information about specific dietary needs during treatment. A correct data registration will improve both patient nutrition status and data capture for (re)use to impact future patients.

4.3 Involvement in decision making about data (re)use

4.3.1 Opt-in vs. opt-out

The round table participants agreed that the opt-out mechanism would be the most adapted to convince the highest number of patients to consent with the (re)use of their data: data will be collected and used automatically unless the patients actively opts out.
This mechanism of consent on the (re)use of patient data should be very clearly explained in the consent forms to be signed by the patient at admission to the hospital. Patients should clearly understand the process, the intentions of (re)using data, the type of projects in which data can be (re)used, the requirements on correct data handling and the positive impact on future quality of care and treatment outcomes.

A concerted informational campaign at the Flemish or federal level would be very useful for a successful introduction of such an opt-out mechanism, as was demonstrated in the United Kingdom. A recent campaign by the Federal Public Service Health (FOD Gezondheid) unfortunately stayed completely under the radar[7]. Conclusions and lessons learned from this campaign should support the launch of a next, more successful initiative.

4.3.2 Involvement in governmental decision-making

Patients have to be involved in the governmental decision making process on patient data (re)use. "No decision about us without us" and "Our healthcare system is still too much a business run by suppliers without involving customers" were clear statements during the round table.

Patients should be involved both on local e.g. in a hospital ethic committee, and federal levels e.g. in discussions with the Health Data Agency.

In this involvement effort, the different levels of organisation and professionalisation of patient organisations should be taken into account. Some large patient organisations (MS League 15 FTEs, Radi-org 17 FTEs and Diabetes-Ligue 10 FTEs) are very active in collecting data from their patients to better understand the disease and the improvement of its management. Some other, smaller patient organisations function with volunteers only (patients or patient relatives) and have to limit their focus to assisting patients with reimbursement issues and concrete help.

[7] https://www.theguardian.com/society/2021/aug/22/nhs-data-grab-on-hold-as-millions-opt-out, https://digital.nhs.uk/services/national-data-opt-out

4.4 Tools for data protection to ensure patient trust

The round table participants consider a federated network approach as the preferred solution with the least exchange of patient information possible and fully in line with GDPR as it implements the "privacy by design strategies" to "minimise" and "separate" the processing of personal data as much as possible. This federated network approach is fully compatible with the preferred opt-out patient consent approach.

PODS can be developed as an alternative to federated networks. The Flemish government has recently decided to partner with Microsoft to develop these data vaults for its citizens. In the PODS approach, all patient data stay with the patient and he/she decides what can be done with it. This system presents several disadvantages:

- PODS revive the discussion on data ownership: can the patient be the data owner if collectivity pays for care?
- Patient data vaults managed by the patient correspond to the implementation of an opt-in or dynamic consent model, where the patient has to give consent for each data (re)use research question. This can significantly reduce the number of patients giving consent for data (re)use, hampering the increase of care quality and patient outcomes based on the (re)use of data of a high number of patients presenting the same disease
- Scaling of data (re)use will become more difficult
- Data vaults do not allow a federated approach. Data first needs to be centralised before it can be (re)used

5. Conclusion and recommendations for action

Patients generally agree on the (re)use of their healthcare data to improve quality of care and treatment outcomes. It is very important that the principles of patient data (re)use are explained in a transparent way to the patients.

Patient motivation to give consent can be further increased if patients and patient organisations are included in both local, federal and even European decision making processes on data (re)use and the organisation of data (re)use initiatives.

Patients agree that the most efficient way to organise patient consent to include the highest number of patients possible in data (re)use initiatives is the opt-out approach: data will be collected and used automatically unless the patient actively opts out.

The final step is that patients should trust that their healthcare data is well protected and carefully handled.

Based on the outcome of this patient round table, following recommendations can be formulated:

- Develop tailored communication to patients and patient organisations to obtain full transparency on data (re)use initiatives, both public and industrial
- Include systematically patients and patient organisations in decision making processes on (re)use of data to optimise patient consent motivation
- Initiate on all healthcare levels the opt-out patient consent model in order to be able to include the highest amount of patients in data (re)use initiatives to obtain the best possible results in care quality and treatment outcome improvement
- Develop a robust, well protected and carefully managed data (re)use approach ideally based on the federated network approach in which data is not exchanged fully, preserving patient privacy and security

Consolidating these recommendations in an integrated local, federal and European patient data (re)use approach will ensure the highest possible support of both patients and patient organisations for data (re)use initiatives both by public and industrial research partners.

Once full patient support is obtained, hospital and healthcare system data infrastructure should be further optimized to ensure a flawless implementation of high impact, high volume, high quality data (re)use initiatives.

About Inovigate

5.1 Inovigate

Inovigate is an independent strategy and management consulting company operating in the European Life Science and Healthcare industry, specialized in helping clients to innovate and navigate through an increasingly complex health ecosystem. We strive to achieve better outcomes for our clients by utilizing our deep sector knowledge and experience.

At Inovigate we value the diversity and talents of individuals and how they contribute to the capabilities of our team. We bring our passion and enthusiasm to reap the benefits of every project for our clients, our company, and our team.

We believe that our approach of working closely with our clients' creates value for both our clients and us.

Our experience gained through our many strategy and transformation projects allows us to consolidate multiple methodologies and tools into a unique Inovigate approach that is tailored to the specific client need. Our focus is on actionable outcomes and results that can be implemented immediately.

In our client engagements we also utilize a network of experts and partners with complementary skills. This helps us to mobilize the right team for every single engagement. Our network includes thought leaders, key opinion leaders and other experts from different fields within the health ecosystem.

For more information, please visit our website at https://www.inovigate.com.

5.2 The authors

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