

Healthcare
Workforce and
Organisational
Transformation with
AI – Enacting Change



Think Tank Round Table
Meeting Proceedings

Germany
22.09.20



THINK < TANK <

CONTENTS

- Context for the selection of the 2020 Round Table Series Topic 3**
- Objective of the National Round Table Meetings 4**
- Agenda and participants: German Round Table..... 5**
 - Discussion topics 5**
- Session I: Validate the relevant barriers and enablers for the successful adoption of AI at the Member State level 6**
 - Synopsis of participant survey results 6**
- Sessions II–IV: How to improve the 'on-the-ground' impact of AI 7**
 - 1. Clinical leadership 7**
 - 2. Rethinking education and skills and investment in new roles and talent 10**
 - 3. Regulation and policy making 14**
 - 4. Funding and reimbursement 17**
 - 5. Strengthening data quality, governance, security and interoperability 19**
 - 6. Liability and managing risk 21**
- Session V: Driving acceptance and utility of AI in healthcare22**
- Appendix 1: Round Table Meeting participants25**

Context for the selection of the 2020 Round Table Series Topic

In March 2020, a joint report between EIT Health and McKinsey & Company 'Transforming healthcare with AI: the impact on the workforce and organisations' was launched which aims to contribute to the debate surrounding Artificial Intelligence (AI) in healthcare but going a step further in helping to define the impact of AI on healthcare practitioners, and the implications of introducing and scaling AI for healthcare organisations and healthcare systems across Europe.

With AI in healthcare being a fast-moving field, the report provides a unique vantage point from the frontline of healthcare delivery and innovation today, and the latest view from a wide array of stakeholders on AI's potential, the real state of play today, and what is holding us back from widespread uptake and adoption.

As the report takes a broad pan-European perspective, identifying levers for change at the personnel, infrastructural and environmental levels, further exploration of how these findings and recommendations could be translated at a national level is warranted.

Through this Round Table Series, national-level decision makers representing key stakeholders that play a role in developing and implementing AI approaches at scale within existing national healthcare systems were identified to provide opinion and potential solutions that could be applied to support practitioners and providers to fully embrace the potential of AI.

Objective of the National Round Table Meetings

In each of our seven locations, by reviewing the national infrastructural context, educational and health systemic structure, we aim to:

- > Validate the relevant barriers and enablers, as indicated within the report, for the successful adoption of AI at the Member State (MS) level, whilst also identifying similarities and differences between countries.
- > Identify how to improve 'on the ground' impact of AI by specifying obstacles to overcome and opportunities to maximise within the defined domains.
- > Outline a national (MS level) 'plan-of-action', indicating individuals, organisations, bodies or other relevant vehicles to accelerate and expedite integration of AI to drive workforce capability and organisational receptivity.

In addition, it will be useful to look at the role the EU could play in encouraging greater adoption of AI in healthcare.

Agenda and participants: German Round Table

Hosted by EIT Health Germany.

Moderated by: Dr Anke Diehl, Physician, Digital Change Manager, University Hospital Essen.

Other participants: A full list of meeting participants can be found in Appendix 1.

2020 Round Table Series Co-Chairs:

- > Charlotte Stix – former Coordinator for the European Commission’s High-Level Expert Group on Artificial Intelligence
- > Zineb Nouns – Physician, Medical Education Specialist and HR Manager
- > Farzana Rahman – CEO, London Imaging Network

Discussion topics

The agenda for the Round Tables was developed following a review of the EIT Health and McKinsey & Company report ‘Transforming healthcare with AI: the impact on the workforce and organisations’ and with the input and advice of the 2020 Think Tank Round Table Co-Chairs.

- > **Session I**

Validate the relevant barriers and enablers as indicated within the report for the successful adoption of AI at the Member State level, whilst also identifying similarities and differences between regions

- > **Session II–V:**

Identify how to improve ‘on the ground’ impact of AI by specifying obstacles to overcome and opportunities to maximise within these six domains:

- 1. Clinical leadership**
- 2. Rethinking education and skills and investment in new roles and talent**
- 3. Regulation and policy making**
- 4. Funding and reimbursement**
- 5. Strengthening data quality, governance, security and interoperability**
- 6. Liability and managing risk**

Outline a national (MS level) ‘plan of action’ to accelerate and expedite integration of AI to drive workforce capability and organisational receptivity

Session I: Validate the relevant barriers and enablers for the successful adoption of AI at the Member State level

Synopsis of participant survey results

A survey was sent to all participants prior to the Round Table meeting to gather feedback on the situation in their country regarding AI and healthcare in relation to the six domains identified in the joint EIT Health and McKinsey & Company report, namely:

- > Clinical leadership
- > Rethinking education and skills and investment in new roles and talent
- > Regulation and policy making
- > Funding and reimbursement
- > Strengthening data quality, governance, security and interoperability
- > Liability and managing risk

Participants considered that the **ethical aspects** of the use of AI in healthcare warranted a separate discussion due to the wide-ranging importance of these factors.

They agreed that the six domains identified in the report were those that were most influential for the introduction of AI into the healthcare sector.

Overall, it was considered that Germany is not sufficiently prepared for the comprehensive transformation of the healthcare system that will result from the implantation of AI.

Sessions II–IV: How to improve the 'on-the-ground' impact of AI

1. Clinical leadership

Challenges and barriers: What is not working/what needs to change in this domain?

The need for a cultural and technological transformation

Currently, when AI systems are introduced into the German healthcare system, the impetus for technical innovations comes primarily from research and industry, including small start-ups. To date, clinical leadership has not been well represented. What AI can do in this area and the goals that can be achieved using AI have not yet been defined, in part due to the diversity of AI applications.

In Germany, expansion of the digital infrastructure has been underway for a number of years – although without the broad involvement of patients. This omission, which is crucial in terms of data protection law – since patients must actively consent to their health data being passed on – needs to be remedied. The aim should be for patients to develop into digitally-competent administrators of their own data and be able to make individual decisions about its use, e.g. in the context of AI applications, in each individual case.

The Think Tank Round Table in Germany primarily discussed the use of AI data for research purposes, which is currently at the forefront of developments. In Germany, AI is initially implemented at the level of research institutions and university clinics, i.e. institutions that conduct research financed using public funds. There are also examples of AI applications in the pharmaceutical industry and in the economically-important sector of medical technology manufacturing.

Beyond the need for technical transformation, the entire process of AI implementation in healthcare represents a cultural transformation which has to be carried out on several levels. This development needs to be guided by the legislature and should be considered as a complex change-management process.

Clinical leadership in the development and implementation of AI solutions in the German healthcare system is largely absent, as drivers of AI developments can only be identified in university hospitals. Nevertheless, professional associations, such as the German Diabetes Association, among others, will define the framework conditions for the implementation and use of AI-supported solutions in chronic care.

Collaboration between innovators and clinicians to achieve user-centred design

Close cooperation between developers and practitioners from the clinical sector is crucial to producing AI solutions that have real practical benefits, but it is too rarely implemented. Currently developers, start-ups and innovative think tanks have limited involvement in establishing national digitisation concepts.

In order to develop user-centred AI applications, healthcare institutions need increased incentives to actively communicate their requirements for AI and to take part in the evaluation of AI-supported solutions. The development of isolated solutions is counterproductive and should be avoided as it circumvents the desired collaborative process.

Funding and investment

Relating to the billing system, which is primarily based on a per-case flat rate, hospital operators lack incentives to invest in digital infrastructure, interoperability and human resources related to AI. Participants in the Think Tank Round Table considered that the lack of willingness to innovate was higher in the healthcare system than in other industries.

The [Hospital Future Law](#), passed on 20th September 2020, and the establishment of a Hospital Future Fund both offer improved opportunities for AI. Funds for digitising clinic areas will be available from 1st January 2021. The federal government will provide €3 billion and the federal states are to contribute a further €1.3 billion.

Changing the perception of AI

Applications which limit the time-consuming documentation required for medical and social care could contribute to the improved acceptance of AI solutions. This aspect has been gaining in importance in recent years, also due to the continued high demand for healthcare personnel. On the one hand, AI can improve patient care and, on the other hand, by increasing efficiency or making processes easier, it can also result in significant improvements on the employee side and lead to greater job satisfaction. However, it can also be seen as problematic in some instances when staff who are already overworked are required to familiarise themselves with AI. In this respect, the objectives of AI in the healthcare sector are varied and require a broad developmental approach.

Effective integration into existing work processes

When used, AI systems must show that they – at least partially – offset the costs of digitisation by increasing the quality of healthcare services and using them more efficiently.

The possibility of uncomplicated integration into existing processes and the willingness of the clinic management to make human resources available are core requirements for AI systems and their developers.

Generating evidence of quality and effectiveness

The acquisition of clinical evidence should first be tested using manageable AI applications that are highly likely to provide a clear demonstration of the positive effects of AI.

Many AI applications are perceived as 'high risk, for example those that automate the delivery of drugs, such as closed-loop metabolic control systems that automate insulin delivery (essentially an 'artificial pancreas') in people with diabetes. AI solutions should therefore be validated in the context of secured test environments, in which the high ethical and regulatory standards of traditional clinical research should be applied.

Clinical Research Organisations CROs could play a role here in providing scientific, regulatory and implementation support to young start-ups, SMEs and academic initiatives. They can offer secure test environments for safe evaluation of AI-powered medical devices, along with a full array of

integrated data sciences services and operate with high ethical standards for data management, analysis, reporting and interpretation.

What is working well and best practices identified in this domain

Existing successful projects and positive experiences

- > Nationwide data evaluations already take place, some examples being oncology networks, the genomic medicine network, or the [Medical Informatics Initiative](#) (MII). The MII is funded by the German Federal Ministry of Education and Research (BMBF) and was created to close the gap between research and healthcare. All of Germany's university hospitals have joined forces with research institutions, businesses, health insurers, and patient advocacy groups to create a framework that harnesses research findings for the direct benefit of patients.
- > The [Integrated Diabetes Management Goes Europe](#) (iPDM-GO) EIT Health innovation project, led by Roche Diabetes Care, had used a collaborative machine learning approach to develop predictive algorithms that enable differential stratification of patients with Type 2 diabetes and a more accurate prediction of iPDM effectiveness. iPDM-GO aims to transform diabetes management towards another paradigm example for value-based healthcare
- > [ClampArt](#) is a metabolic algorithm-powered solution that enables a remote monitoring of clinical experiments for the assessment of insulin action and uses state-of-the-art sensor technology for the processing of metabolic data generated by the trial participant. This CE marked class IIb medical device was developed, manufactured and distributed by a transdisciplinary team integrating expertise in medicine, algorithm development, regulatory affairs, and manufacturing.

Best practice examples

- > Areas of application of AI technology can already be seen in outpatient and inpatient care settings, and in the assisted living/home care sector. Here, start-ups have been able to achieve improved (technologically supported) outpatient care which enable a longer period of autonomous life at home.

Key Points

- > In Germany, there is insufficient clarity regarding what research on AI is already taking place and what possibilities exist for the participation of smaller hospitals; more information is needed on this.
- > An agile, national strategy is necessary to implement AI technologies more quickly into the German healthcare system.

Proposed actions and recommendations

Clinical leadership	
Action	Target stakeholder(s)
Identify suitable incentive systems for hospitals and determine current involvement of clinical leadership in AI development and progression.	Clinic operators
Establish secure test environments for (high-risk) AI applications.	Clinical Research Organisations
Integrate the usage of AI-powered tools to make personalised medicine strategies, e.g. for diabetes management, ready for value-based healthcare.	Large research organisations with connections to tertiary care hospitals
Promote transdisciplinary collaboration within organisations for AI innovation development.	CROs; research physicians; pharmaceutical industry; clinical trial participants; natural scientists

2. Rethinking education and skills and investment in new roles and talent

Challenges and barriers: What is not working/what needs to change in this domain?

Building stakeholder trust, acceptance and access

Discussions about the ways that AI can improve healthcare, how it works, and what technology it is based on have been very limited to date in Germany. Information deficits can be seen across the entire medical sector (clinicians, nurses, other healthcare personnel) and also among patients and citizens. In terms of AI, there has been little interest so far in advancing digital health literacy in any of these groups. Specialists who express their support for AI are often overlooked.

Reservations about AI applications are primarily due to concerns about its possible disadvantages. The introduction of AI systems must therefore be prepared and be accompanied by a comprehensive programme of information for all stakeholders. Sustainable development of trust and acceptance is essential. To this end, there must be clear communication across the board that AI applications have the potential to improve healthcare in the long term. As has already been described, the main potential of AI lies in the fact that the research results can be converted into products and then used throughout the sector for the benefit of all. The ethical mandate for the use of AI, arising from its enormous potential to achieve a profound improvement in the treatment of serious diseases, should also be emphasised.

A lack of digital engagement by large population groups is a very real problem. It is estimated that 2.8 million people in Germany are affected by poverty. With this in mind, apps must be designed so that they can be used on basic smartphones, i.e. not only on the latest models in the upper

price range. A lack of education and old age can also make access to AI mobile phone applications more difficult.

Adapting healthcare professional education

The assumption is that younger age groups in the healthcare sector are more willing to integrate AI solutions into their everyday working lives due to an overall higher affinity for digital media. Older healthcare professionals who have been trained for a longer period of time and will therefore form the 'backbone of care' in the system for many years to come, may need a greater amount of information about AI. Engaging support for AI from these older groups is important as they can communicate the benefits of the introduction of AI when interacting with patients. However, the fear of possible job losses that might result from introducing AI may mean that this positive communication does not happen routinely. It is therefore important that all stakeholders have a clear understanding of how AI can support (not replace) existing medical staff by undertaking time-consuming, routine activities, thereby creating capacity for personal communication with patients. In view of the lack of availability of qualified medical personnel, this aspect also has a strong ethical dimension.

Updating medical school curricula

AI concepts should form part of the training and further education components of all health professions.

For broad development of digital competence, new job profiles must be initiated and funded. Data scientists and data engineers as well as specialists who convey AI content (e.g. app functions) directly to users are needed, among other roles. Digital Change Managers could moderate this process.

Digitisation and AI concepts, including the ethical, legal and social framework, should be taught as standard in medical studies and integrated into the curricula of nursing professions as well as into the training of Medical Technical Assistants (MTAs) and Medical Assistants (MFAs). This requirement should be proposed to the relevant professional institutions or supporting organisations, as well as to the medical faculties. Knowledge about AI and digitisation should also be built into specialist training, i.e. in the medical profession itself. The demand for integration into regulations for ongoing professional development should be made to medical associations.

Some universities are now offering part-time courses in such as 'Digitisation in Nursing'. These are important in order to build-up appropriate skills in employees whose training dates back a few years and who have a knowledge deficit in digitisation/AI; they also help to raise awareness of the topic. Some clinics promote practical implementation by offering employees defined modules from these courses as advanced training certificates free of charge. This can encourage uptake of further training opportunities, since they don't require a full degree, which may discourage older employees.

At the professional user level, the provision of AI can be accompanied by classic training concepts or certification programmes. This requires incentivisation through inclusion in the further training programme for doctors and nurses and the requirement for a minimum number of points in the AI area, which must be completed annually. Good experiences with hands-on seminars have been reported from other industries. Attendees learn how to prepare a simple AI tool over the course of a day in order to understand AI technology and the courses discuss fundamental questions about data management.

Training for new occupational categories and hybrid roles

In the hospital sector, it was considered important to make training available in the field of digital medicine with a low entry threshold, and to make it widely available across each institution. This should include the development of models in which employees are supported by releasing them from ongoing obligations in order to undertake training.

One possibility to help achieve this is cooperation between industrial companies and research institutes with academic partners. As an example, some tertiary care University hospitals are adapting their training courses as part of the trans-European development of an automated insulin administration system for home care-dependent persons with type 2 diabetes and also incorporating the development of control algorithms. It was commented that one possible way to implement AI is to link the innovation process – even on a small scale – directly to the training of young and enthusiastic people. This aligns with the EIT Health ‘knowledge triangle’, which describes the integration of technological innovation, education and training, and business creation.

Target group-specific education

The development of medical devices connected to the AI-powered exploitation of patient-generated data needs to be accompanied by target group-specific education and training as well knowledge of outcome predictors (defining patient groups and individuals who could benefit most from the application) and multi-dimensional performance measurement instruments assessing the impact of the AI-powered application in terms of patient reported health outcome measures, healthcare processes, and costs.

Educating patients on the benefits of AI in healthcare

It was noted that making AI applications as simple and user-friendly as possible is important for all stakeholders, however it is crucial for applications that are to be used by patients.

The introduction of AI systems, for example, must not result in patients being given large amounts of additional information. In addition, using up additional time to explain applications, results, and therapeutic consequences to the patient would completely contradict the objective of healthcare professionals acquiring more time to develop an empathic patient relationship due to the benefits of AI support. Patients also need to understand that AI will not reduce the care they receive from their doctor, but complement it in a meaningful way, leaving more time for a personal doctor–patient discussion.

The considerable improvements in care that AI could bring to patients who live in economically underdeveloped areas that have limited medical infrastructure should also be emphasised. Recent situations, such as the refusal of many patients to visit hospital clinics during the COVID-19 pandemic for fear of becoming infected, have demonstrated how useful AI applications can be in helping to deliver care.

Resource planning and training to meet future healthcare needs

According to Round Table participants, a particular problem relating to the use of AI in hospitals is the very hierarchical nature of the medical sector; the multidisciplinary collaboration and flat hierarchies that are crucial in the context of AI are largely uncommon. New structures for cross-professional, non-hierarchical cooperation are important, especially with the implementation of new roles and job profiles. Therefore, an appreciation of, and openness to, new perspectives

should be promoted in the context of new training courses, without overlooking older generations and the need for lifelong learning.

Since a high proportion of healthcare service is delivered within the private sector, improved digital competence is also considered important here too.

What is working well and best practices identified in this domain

Existing successful projects and positive experiences

- > Successful development and implementation of AI solutions, including the development of algorithms, are seen when the innovation process is directly linked to the training of young employees in the sense of *co-creation*.
- > [CLOSE](#) – Automated glucose control at home for people with chronic disease – is an EIT Health innovation project. The CLOSE consortium has established a ‘train-the-trainer’ programme as part of the Automated Insulin Delivery solution to be launched for people with Type 2 diabetes. The programme is designed to educate caregivers to be able to install and operate the system and help manage the diversity of possible outcomes. When designing train-the-trainer modules, CLOSE decided on a contextual approach, so not giving isolated information about the usage of the technology but rather providing a holistic understanding of what living with diabetes means, how it impacts a patient’s lifestyle, and how an informed usage of diabetes technologies can be embedded in daily routines. The prerequisites for program implementation in healthcare service provision were identified in an academia–industry collaboration between KU Leuven, Air Liquide Healthcare and Profil GmbH. The academic education of students, healthcare professionals and executives is another activity driven by the CLOSE consortium, with the goal of increasing both awareness and acceptance of Automated Insulin Delivery and to strengthen informed and compliant usage of the system.
- > The EIT Health innovation project [RealWorld4Clinic](#) is developing an implantable multi-sensor system that will collect real-world cardiorespiratory health data for AI-powered exploitation in outpatient cardiology. The system is being developed alongside outcome predictors (recommending the system to subpopulations of heart disease patients who might benefit most) and performance measurement tools as well as education and training. A clinical CRO is included in the RealWorld4Clinic consortium in order to support the eligibility of the system for usage in clinical research. This will require the training of clinical research staff and ensuring compliance of data collection and transmission and AI-based exploitation with the regulatory requirements and legal obligations of different countries and regions.

Best practice examples

- > Associations, such as the Deaconry of Protestant Churches in Germany, which has 40,000 employees across 900 companies, train digital coordinators for their institutions. These enable institutions to participate in ongoing digital projects or to implement their own concepts.

Key Points

- > The most important deficit (seen across all domains) in the lack of knowledge amongst both healthcare professionals and patients/citizens about the possibilities of AI, including basic information about how AI works and what it is based on. In summary: there is a significant a digital health literacy deficit in terms of AI.

Proposed actions and recommendations

Education and skills	
Action	Target stakeholder(s)
Integrate digitisation and AI concepts as essential components in curricula, e.g. for medical studies. Develop appropriate training concepts for all employees in the healthcare sector.	Medical associations; universities; advanced and further training institutions; federal states
Develop low-threshold educational opportunities for citizens about digitisation, data use and AI in medicine.	Patient organisations; clinics; researchers; health policy makers
Undertake target group-specific training including education on outcome predictors and multi-dimensional performance measurement instruments assessing the impact of AI-powered applications. Develop descriptions for professionals (standard operation procedures) and clinical trial participants (informed consent forms)	Medical professionals; students; health economists; quality assurance managers; statisticians; data scientists; CRO personnel; patients
Promote collaboration between privately-owned training institutes and tertiary care University hospitals to implement train-the-trainer programmes facilitating authorised and knowledgeable installation of AI solutions across EU countries and healthcare systems (geographical scalability).	University hospitals; healthcare service providers; business schools; CROs; doctors; nurses; students; operators of privately-owned training institutions; professional associations

3. Regulation and policy making

Challenges and barriers: What is not working/what needs to change in this domain?

Improving regulatory frameworks in Germany

Due to national data protection regulations, the use of health data, for example for research purposes, is more complicated in Germany than in neighbouring countries, which have long had national registers. Hospitals that wish to research AI applications in a network need the consent of their patients, or they have to ensure that the data records are anonymised so that they cannot be traced. They have to ensure data security themselves and are liable for the consequences associated with an AI application (e.g. clinical results).

In order to improve conditions for the future use of AI applications, Round Table participants proposed a regulatory framework for the use of patient and study data for the benefit of society. It was proposed that a national, tax-financed, public institution should be set up that would define the legal framework for data usage. This institution would collect and curate health data from healthcare providers and process them in such a way that they could be made available for use in high-quality research projects. Technologically, this could be supported by the implementation of a data lifecycle management platform which guarantees full compliance with European regulatory requirements and legal obligations.

It could also make neutral decisions on applications made by pharmaceutical companies for the use of health data records, for example for research into personalising therapies. Currently this is only possible after anonymising clinical study data with the express consent of the participants in the study and thus excludes the merging of several data sources and long-term observations.

Testing and monitoring AI applications in real-world settings

It was noted that Roberto Viola (Director General of DG Connect at the European Commission) had recently shared the idea of establishing 'world reference testing facilities for AI', starting at the European level, that can provide secure validation environments that apply high ethical and regulatory standards. Public-private partnerships, such as [EIT Health](#), which represents key stakeholders in healthcare and AI, might be able to facilitate this.

It was suggested that the introduction of AI applications, for example in the hospital sector, should be accompanied by regular monitoring. Post-approval studies, such as those that are undertaken in the pharmaceutical sector (Phase IV studies) could serve as a model. This would offer the possibility of testing the uses of AI under real-world conditions supported by high-quality research demonstrating their benefit.

Data storage

In terms of storing sensitive data, it was recommended that solutions from other (industrial) sectors or from other EU countries should be adopted. The convergence of regionally-proven solutions into a uniform EU-wide approach was considered as a sensible approach in the medium term, especially since it could potentially leverage cost savings.

The storage of health data in a cloud, for example the UK Government's 'G-Cloud' framework, was described by industry representatives at the Round Table as relatively safe and practicable. A representative from the hospital sector had reservations about such a solution due to concerns about data security.

European data space

Trust in the use of AI in the context of healthcare research and resource planning would benefit from setting up an independent body representing a wide array of societal stakeholders including the citizens themselves. This service should be financed by the EU and potential users but a public-private-partnership, such as [EIT Health](#), could facilitate qualified access to the data resources hosted in a national/European Health Data Space. This partnership could curate the data space and review research proposals aimed at making use of the data resources allocated to the Health Data Space. The partnership should be a trusted organisation representing a wide array of stakeholders and having the full backing through the EU.

Consent for data use

Health data belongs to the patients. In order to obtain their consent for further data usage, e.g. for research purposes, the potential benefits of AI applications for the system or the individual must be presented transparently. Participation and informed consent from patients and the public is key. Patients are fundamentally willing to pass on their data if it serves to support research and therefore to improve their own health and that of other people. However, misuse of this data through sale or commercial use would significantly reduce this willingness. Consent is, of course, also particularly relevant for the development of future AI products.

In clinics, questions about data use may not be discussed in connection with the admission contract. This poses problems for institutions because additional infrastructure has to be set up for these calls, and this is currently not being financed.

As part of the Medical Informatics Initiative funded by the Federal Ministry of Education and Research (BMBF), a [nationwide uniform sample text for patient consent](#) (termed 'broad consent') was submitted after two years of consultation. One criticism of this initiative is that the resulting 10-page form may be too long and complicated from the patient's perspective.

What is working well and best practices identified in this domain

Existing successful projects and positive experiences

- > The European research project [Hypo-RESOLVE](#) (Hypoglycaemia – Redefining SOLutions for better liVEs) aims to provide researchers and clinicians with validated data on hypoglycaemia. Hypo-RESOLVE brings together data from over 100 clinical trials in an (anonymised) European database, which can be accessed for research purposes.

Key Points

- > Germany needs a new, centralised, tax-financed organisation, to take responsibility for implementing common European standards for health data infrastructure, including regulations for access, anonymisation, and use of these health data sets for national patient-, technology- and health system-driven research as well as larger European projects.

Proposed actions and recommendations

Regulation and policy making	
Action	Target group
Establish a tax-financed, public, national institution/authority responsible for regulating data use in the health context	Health policy makers
Establish an independent body representing a wide array of societal stakeholders, financed by the EU and potential users, to curate a national/European Health Data space.	Multiple stakeholders in health organised in public-private partnerships; citizens, national and European parliamentarians and governmental bodies
Support EU initiatives to establish AI testing facilities that provide secure validation environments.	Public-private partnerships; medical device manufacturers integrating AI; clinical CROs, hospitals; patients; payers; EIT Health could facilitate

4. Funding and reimbursement

Challenges and barriers: What is not working/what needs to change in this domain?

Outdated IT infrastructure

As a result of relatively cautious investments in IT, the progress of innovation in the German healthcare system is hampered by a comparatively outdated infrastructure. Many clinics do not currently have the resources to evaluate projects using a variety of clinical data sources. This problem became apparent, in a publicly-funded Medical Informatics Initiative, which aimed to use data across various clinics. As mentioned previously, funds for digitising hospital clinics will be available from the Hospital Future Fund from 1st January 2021.

Incentive systems and financing models

In the hospital sector, the current billing and coding system, based on flat rates per case, favours patient care which is financially driven. Against this background, many hospitals do not consider it economically attractive to invest in technologies that are aimed at providing better-quality care. Incentives to optimise the quality of care could be created by policy, for example through remuneration which is more oriented towards the outcomes of treatment (value-based healthcare).

It is assumed that the costs of digitisation can be at least partially recouped through the increasing quality of health services and using them more efficiently. For example, algorithm-

based evaluations of biomarkers in chronically ill people could enable early statements to be made about the risk of developing serious disease-related sequelae. This suggests regular health economic modelling of the impact of AI-supported applications with regard to therapy costs and patient-reported outcomes is needed.

It was noted that some hospitals in the US are developing new revenue models in the context of AI systems. Large clinic operators are considering buying in AI applications in order to market them themselves.

In the case of public tenders for digital health services, digitally-organised procurement processes (demand utility models) could be used, which would enable optimised use of the funds.

Prescription of digital health applications

To date, the outpatient sector in Germany has had minimal involvement in the digitisation of healthcare. It was suggested that change is needed here, in particular due to the high proportion of doctors in this sector. One step in this direction is the recent opportunity for doctors to prescribe digital health applications. These prescriptions take the form of traditional printed prescriptions which patients then submit to their health insurance providers.

In this sector, there is still a high demand for information about AI from both service providers and patients. AI applications are seen as user-initiated processes. In order to win patients over to applications, incentive systems are required which are yet to be defined. In addition, refinancing is necessary in the statutory health insurance sector. To this end, the German Federal Institute for Drugs and Devices (BfArM) has recently published a guideline on "The Fast-Track Process for Digital Health Applications (DiGA) according to Section 139e SGB V" supporting medical device manufacturers, services providers and users in promoting the launch of clinically validated and refundable digital health applications on the Germany health market.

What is working well and best practices identified in this domain

Existing successful projects and positive experiences

- > Prognosis models for disease progression are currently being tested in pilot studies, e.g. for Type 2 diabetes in terms of the risk of kidney dysfunction. Such models will help determine whether AI-based therapy options that aim to minimise long-term damage on chronic diseases are financially viable.

Key Points

- > The German healthcare system is hampered by a comparatively outdated infrastructure but it is hoped that this may improve with the launch of the Hospital Future Fund which will be available from 1st January 2021 to support digitisation of clinics.
- > A move is needed towards value-based healthcare reimbursement to better support AI applications that improve overall care quality.

5. Strengthening data quality, governance, security and interoperability

Challenges and barriers: What is not working/what needs to change in this domain?

Collection and provision of health data: a task for the public sector

In Germany, health data is stored in different sectors (inpatient and outpatient) as well as in various systems and complementary formats. Examples are the hospital information system (HIS) as well as the laboratory (LIS), radiology (RIS) and image management system (PACS). These data are currently not accessible to start-ups or tech companies outside of specified partnerships. In addition, there is no nationwide uniform strategy. Different approaches are being pursued at the state level.

The objective is to make this national (health) data resource available for joint (research) use. The overarching goal was formulated at the EU level and involves creating an infrastructure in which patients can access and provide their own data at every care interface – general practitioner, specialist or clinic. This would create a new dynamic, as start-ups and research institutes would then be able to work with large datasets. An initial step could be the data in each patient's electronic health record in accordance with Section 291, which is managed by the patient themselves and, according to the current planning status of the Federal Government, should be made available in a more detailed, standardised and interoperable manner over the next few years, and will also be accessible in this form by the patient for research and development.

Round Table participants considered that the collection of health data, as well as its structured processing and provision for research across clinics and practices, was a task for a new institution, located in the public sector, financed by taxes, and which operates nationwide.

Promotion of interoperability and networking

Uniform standards for data acquisition and usage resulting from international nomenclatures that have been introduced, such as [LOINC](#) or [Snomed CT](#), are a prerequisite for interoperability and networking. A national Snomed CT license is to be made available in Germany from 2021 so that access, which was previously limited to research-based or university institutions, is significantly improved.

Roadmap to a European Data Space

From a technical point of view, participants proposed that central data stores in the sense of *data lakes* at the hospital level, for example, should be set up. In contrast to data warehouses, these are ideal for storing raw, unprocessed data. In *data lakes*, the data are highly malleable and it can be analysed for a wide variety of purposes in a short time. Both these qualities are good requirements for AI applications.

When undertaking further data analysis, one problem that is commonly encountered is that the providers of the clinical data information systems generally do not disclose the interfaces used by their systems. Therefore, external connections sometimes result in high costs. In order to significantly promote networking, it was proposed to make it law to disclose such interfaces.

Ideally, uniform technical standards should be defined for the transfer of health data. The suggestion was to rely on solutions which have already proven themselves effective in other EU

countries. Development platforms such as FHIR have been suggested as a possible future standard. Currently, the HL7 standard, which is no longer up to date, is essentially used for the transmission of communication and performance data in the medical sector.

Problems of standardisation, and therefore of interoperability, could be solved by appropriate legal standardisation. However, the focus here should not be on a national solo effort, but rather on a European solution. Progress has started in a small way, for example with the SNOMED CT licences available since 2020 with a national licence for Germany being available from 21st January 2021.

Data protection and security

It was suggested that the legal provisions for storing sensitive data in Germany are sufficient and therefore there is no reason to regulate the storage of health data beyond the general data protection provisions.

Future access management remains to be defined; however existing solutions could also be adopted. The standard open ID Connect (OIDC), an authentication layer based on the authorisation framework OAuth 2.0, was mentioned. In terms of User Managed Access (UMA), there would be the advantage that a data management system could be transferred to users if they were adequately prepared.

Introducing AI into healthcare

When introducing AI into the German healthcare system, participants recommended focusing initially on application systems that are 'manageable' and not too complex. It was suggested that lessons could be learned from previous disappointing experiences with projects such as the oncological diagnostic aid, WATSON. As an initial step, focus should be on solutions to problems where the use and functioning of AI applications can be reliably achieved and clearly demonstrated.

The quality of data from the hospital sector in Germany must be checked to determine that it accurately reflects clinical indication and actual use, and not just the specific reimbursement procedure. To avoid bias, it may be necessary to clean up data records.

What is working well and best practices identified in this domain

Best practice examples

- > The Smart Hospital Information Platform (SHIP) at the [Essen University Medical Centre](#) is an FHIR-based data lake which receives patient data from various internal hospital data sources in order to use it for further analyses. This was an ideal prerequisite for founding the 'Institute for Artificial Intelligence in Medicine' (IKIM), which started in 2020 at University Hospital Essen with four professorships. The embedding of the institute in a University clinic and the SHIP platform enable not only excellent research conditions, but also the development and testing of user-oriented applications.

Key Points

- > National health data should be made available for research use.
- > Data collection, structured processing and provision for research should be undertaken by a new a publicly-funded national institution.

- > European standards should be implemented for data collection, transfer and use to ensure interoperability.
- > The initial focus should be on on application systems that are not too complex to help support a managed introduction of AI into the healthcare system.

Proposed actions and recommendations

Strengthening data quality, governance, security and interoperability	
Action	Target group
For the initial introduction of AI into the German healthcare system focus on 'manageable', not too complex applications whose benefit can be clearly demonstrated.	AI developers and clinicians

6. Liability and managing risk

Challenges and barriers: What is not working/what needs to change in this domain?

Decision-making authority and liability lie with the doctor

The participants in the Think Tank Round Table considered that there were system-dependent differences in terms of application risks and liability issues. A distinction was made between AI systems which run fully automatically (autonomously) and those which, for example, support medical decision-making in the background. With the exception of a single ophthalmological application, autonomous AI systems have not yet been used in the German healthcare system. A widespread introduction of these systems is not expected in the near future.

There was broad agreement among participants in the Think Tank Round Table that suitably-used AI-based decision-making aids can reduce the risk of incorrect clinical decisions, for example in the hospital sector. The decision-making authority, and therefore also the liability, will continue to lie with the doctors.

It is currently unclear whether doctors would also be liable if they followed the recommendations for action from AI systems despite differing assessments, i.e. if the AI application contradicted their own clinical decision. However, since AI-based systems reduce the overall error rate, the potential benefits outweigh these issues. A need to protect doctors from liability claims was not seen as an issue.

Legal regulations

With a view to introducing autonomous systems, an overarching legal regulation is expected to regulate liability issues, which includes other areas of application of AI besides the medical sector, such as self-driving cars. In this area, initially the focus will be on collecting real application data in order to calculate the insurability of the application risks of AI. On this basis, conclusions about questions of liability can be determined.

Monitoring and tracking of errors

The introduction of AI applications requires their validation using sufficiently large samples. There is a not insignificant risk of the misinterpretation of the outcome data sets that are generated with the aid of AI applications. The recording and tracking of error states should be automated using logging and traceability concepts in order to gradually reduce possible application risks.

Key Points

- > Authority for clinical decisions that are supported by information from AI applications lies with the doctor, therefore liability is also the responsibility of the doctor.
- > Widespread introduction of autonomous AI applications is not expected to happen in the near future, but if and when that occurs a legal regulation is expected to apply to liability issues for such applications, as occurs in other sectors.

Session V: Driving acceptance and utility of AI in healthcare

Communicate positive examples of successful AI use

Implementation of AI into the German healthcare system should start with applications that are 'manageable' and not too complex. As a first step, solutions to problems should be identified where use and functioning of AI applications can be reliably achieved and clearly demonstrated so that the message can be communicated: AI systems can help to make healthcare better and safer. The presentation of positive examples can contribute to an overall improved social acceptance of AI applications. Only then should higher goals be pursued.

The introduction of more complex systems could be preceded by the collection of real-world data under controlled conditions. This approach will require significant investment.

Overall, the introduction of AI technology in Germany will require staying power from all stakeholders.

Expand centres of excellence

The establishment of AI lighthouse centres for research and innovation in healthcare is seen as the right step and one which deserves further support. These centres already exist at state level, for example in the form of the competence platform KI.NRW, an umbrella organisation for applied AI in North Rhine-Westphalia.

It could be a challenge to coordinate these competence centres to ensure that no isolated solutions are produced, however a nationwide or Europe-wide approach continues to be pursued.

Improve digital health and AI literacy

Germany is currently not sufficiently prepared for a comprehensive transformation of the healthcare system through AI. A lack of information was identified as the most important deficit, which affects the occupational groups in medicine and nursing and in particular the public (patients and citizens). The lack of information relates to both the possibilities of AI applications and also knowledge of how AI works. In summary: a general 'digital health literacy deficit related to AI'.

Encourage patient and citizen participation

A broad application of AI solutions therefore requires intensive preparation in terms of patient participation. Measures which increase confidence in AI technology will improve the chances of successful implementation.

Research on AI should be expanded significantly. Patients should be closely involved and health economic (health system) as well as technological (AI-specific) aspects must be taken into account. All three areas are equally important and their close cooperation is essential.

Develop a standardised health data structure

For Germany, the establishment of a new, tax-funded central organisation is suggested which will be responsible for a standardised (common EU standards) health data structure. This body should

define the options for access to health data (e.g. evaluation of project applications against predefined quality criteria) as well as rules for its anonymisation. Likewise, the possibilities for using the health data sets for patient-, technology- and health system-driven research can be determined. This includes the planning and implementation of larger national and pan-European projects. The possibility of using it for the development of new AI applications should also be taken into account.

Transforming healthcare with AI

The introduction of AI applications in health systems requires and implies cultural and professional changes. These should be not only supported, but also adequately financed. To support these processes, legislative changes will need to be implemented, for example the obligation of industry to provide open interfaces for the promotion of research.

Appendix 1: Round Table Meeting participants

EIT Health would like to thank the following participants for their expert contribution to the Think Tank Round Table:

Name	Organisation
Advisers	
Dr Anke Diehl	Digital Change Manager, Universitätsmedizin Essen
Prof Dr Jan Alexandersson	Principal Researcher and Research Fellow, Deutsches Forschungszentrum für Künstliche Intelligenz GmbH (DFKI),
Christine Dehn	Patient Representation & EU Affairs, Deutsche Herzstiftung e.V.
Dr Tobias Heimann	Head of Artificial Intelligence Germany, Siemens Healthineers
Dr Julia Hoxha	CEO, ZanaTechnologies GmbH , Head of Working Group Healthcare – Federal AI Organization
Dr Razvan Ionasec	Technical Leader for Healthcare EMEA, Amazon Web Services
PD Dr Dominik Pfüringer	Head of Digital, Unfallchirurgie, TU München
Dipl.Ind.Eng. Daniel Reiberg	CTO, medzapp GmbH, Focus Group on Connected Health, Bundesverband Digitale Wirtschaft (BVDW) eV
Prof Dr Freimut Schliess	Director, Science & Innovation, Profil Institut für Stoffwechselforschung GmbH
Prof Dr Wilhelm Stork	Director FZI, KIT Karlsruhe Institute of Technology
Dr Christoph Wagner	CEO, WBG Holding GmbH
Johannes Walter, MBA	Das Diakonische Werk der Evangelischen Landeskirche in Baden e.V.
Organisers and other attendees	
Dr Katharina Ladewig	Managing Director, EIT Health Germany
Dr Michael Lüttgen	Liaison Manager, EIT Health Germany
Sameena Conning	Director of External Affairs, EIT Health e.V.
Mayra Marin	Think Tank Manager, EIT Health e.V.