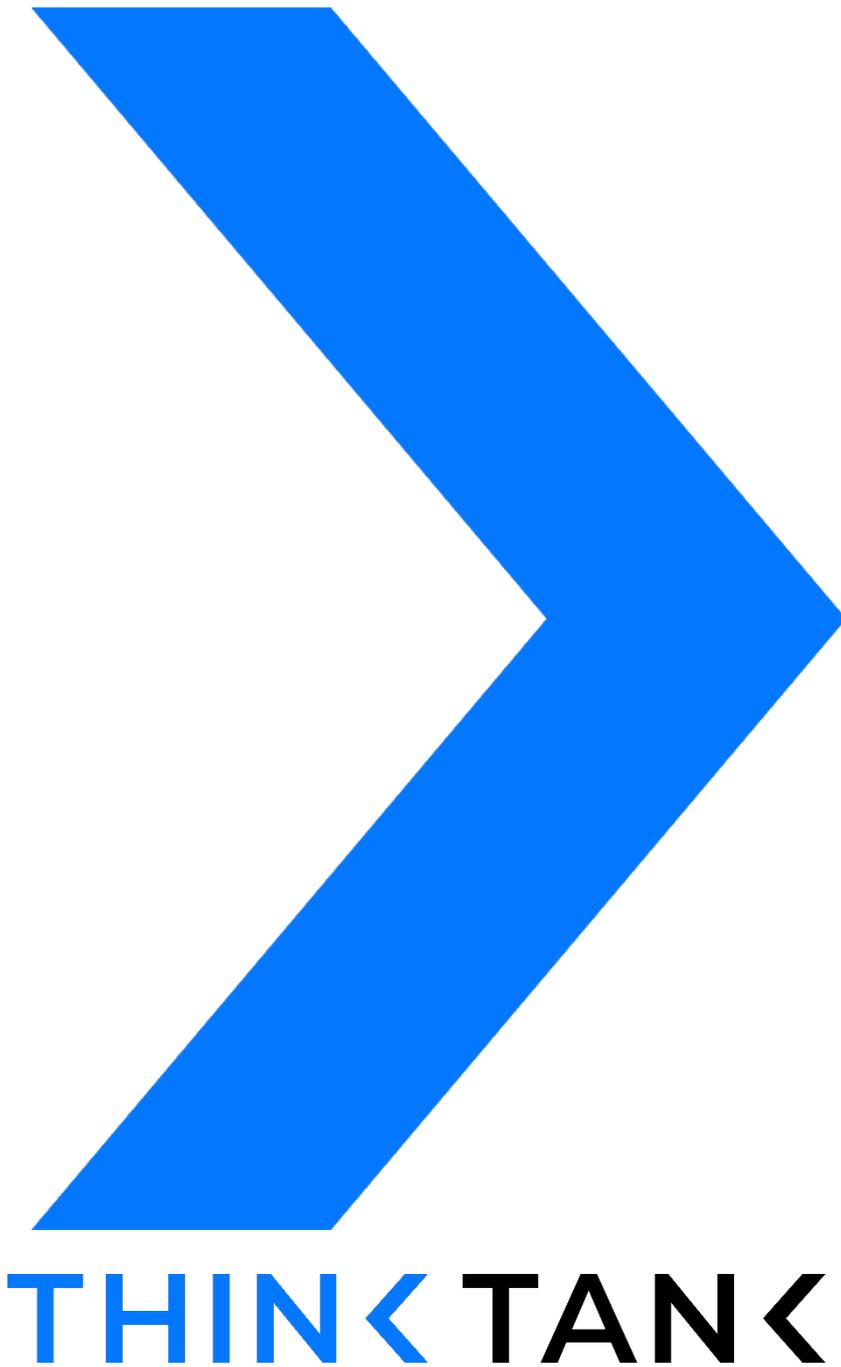


Healthcare
Workforce and
Organisational
Transformation with
AI – Enacting Change



Think Tank Round Table
Meeting Proceedings

Denmark
05.11.20



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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.

Objectives 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: Danish Round Table

Hosted by EIT Health Scandinavia.

Moderated by: Henrik Ullum, Professor and Chief Physician, Rigshospitalet, København.

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

Introduction

In March 2019 the Danish Ministry of Finance together with the Ministry of Industry, Business and Financial Affairs published the 'National Strategy for Artificial Intelligence' with the overall message: "Denmark is to be a front-runner in responsible development and use of AI".

Development and implementation of AI in Denmark should be straightforward in a society that is based on a very high degree of trust both amongst the population and towards the institutions and public sector, and a society that is generally positive towards digital and technological development. However, concerns about that rapid development of AI may cause the population to feel insecure about the future, and the government therefore considers it crucial that Danes will continue to feel secure and be confident that developments in society and in the use of AI will be centred around shared values of freedom, liberty, security and equality.

In addition to these concerns the National Strategy highlights other challenges for the use of AI in Denmark:

- > **The need for common guidelines and an ethical framework for AI** AI entails a new way of making decisions. It raises several ethical issues relating to the relationship between advantages from using new technologies on the one hand, and consideration of people's basic rights, due process, and Danish social values on the other.
- > **Need for more available data for the development and use of AI in Denmark** An example is that there is a demand for more data to train algorithms, and the Danish language is a small linguistic area. This constitutes a barrier to developing solutions that use language understanding or voice recognition in Danish.
- > **Lack of employees with the right skills** 60% of businesses report that they face challenges recruiting IT specialists. At European level, there is an estimated demand of 600,000 specialists within IT programming, and this is expected to increase in the years to come.
- > **Low level of investment** Denmark ranks lower than comparable countries regarding private investment in AI.

According to the National Strategy, the government has earmarked DKK 60 million (€9.2 million) for 2019–2027 in order to escalate the development of AI. This supplements the DKK 295 million (€45.4 million) allocated in the Finance Act 2019 from the research reserve for research into new technological possibilities and digital technologies and for a national centre for research into digital technologies. In addition, the government has proposed a new investment fund to expedite the dissemination of digital welfare solutions. Together with initiatives already launched, the investment fund will have a total investment budget of DKK 410 million (€63.1 million) for 2018–2022. Investments should fall into several priority areas: healthcare, energy and utilities, agriculture and transport. Investments in AI in healthcare should lead to quicker diagnosis of diseases, improved prioritisation of patients with the most acute needs, and contribute to better capacity utilisation in hospitals.

There are already good examples of existing implementation of AI in Denmark:

- > The emergency medical services in the Capital Region of Denmark together with [Corti](#), have developed a solution that, by listening in when a citizen calls the emergency number, can help healthcare staff identify symptoms of heart failure which would not otherwise be detected over the phone.
- > [Vital Beats](#) are working on heart failure prediction in patients who have a pacemaker.
- > [Hedia](#) has developed an app to help predict blood sugar levels in diabetic patients.
- > [Radiobotics](#) have developed validated algorithms for the routine analysis of bone fractures.

This report summarises the Think Tank Round Table meeting in Denmark which included participants from various sectors with an interest in implementation of AI in the healthcare system. The discussion took place, online, on November 5th, 2020 and addressed the challenges in introducing AI into the Danish healthcare system and increasing the speed and efficiency of its adoption.

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.

The importance of the six domains in a Danish national context

The Round Table participants agreed that AI has large potential for creating positive change in all sectors of society, particularly within the health sector. To unlock that potential however, a range of challenges must be addressed. Each of the six domains was given a similar level of importance in survey responses, most likely because the participants themselves were chosen based on their different focus areas and work affiliations. Having this wide diversity of participants at the Round Table ensured that all six areas received more or less the same level of attention, and that each individual area was discussed with the aim of identifying barriers and solutions. This report gives an insight into the status of the use of AI in Denmark, the challenges stand in the way of further implementation, and suggestions for how these might be overcome.

Round Table participants identified some overall challenges and themes which they considered were particularly important:

The Danish healthcare system

Denmark has a healthcare system which, from an international perspective, is potentially one of those that is most ready to implement AI solutions. There is a large degree of data security, very detailed and thorough data registers and blood banks, and Denmark is generally professionally strong and already has a thoroughly digitised healthcare system.

In general, there is a lack of leadership and driving forces all the way through the system which prevent quicker and more effective implementation of artificial intelligence in the healthcare system.

Summary of overall considerations

- > In Denmark, many companies are in the process of or have already implemented solutions based on AI, as an integrated part of their business, and there are also several exciting and innovative one-off projects underway from start-ups. But at the overall society level and within the healthcare system, there overarching and unifying initiatives are still lacking.
- > In countries like the USA and China, AI is being embraced and is spreading to a far greater extent than in Europe. These countries could be considered 'best practice' in the sense that they have managed to overcome many of the challenges seen in Denmark. But the use of AI in surveillance and control in these countries, for example, is extremely problematic and cannot be considered best practice. The same can be said for the American 'Big Tech' companies' use of AI to attempt to affect behavioural changes, which

is also seen by many as problematic. The use of data and data security are considered important parameters in Denmark when it comes to the implementation of AI-based solutions and therefore the brakes are firmly applied when it comes to concerns over data security. The guidelines for the use of and dissemination of data are therefore quite restrictive. But high data security is also a quality and a strength that can be of great value to companies that work with AI and to consumers. But it requires a strategic commitment to maintain these requirements for security, data use and data dissemination so as not to lose a relevant and flexible access to usable data. Round Table participants pointed out that we should actively decide where the level should be, so that the guidelines are clear, and so that we can get started on the development and implementation of AI solutions, thereby ensuring that Denmark is not left behind by countries like the USA and China.

- > COVID-19 has had, and continues to have, its own learning value with regards to the use of digital solution models in the future. The pandemic has resulted in several solutions being implemented and many good cases and initiatives have emerged. However, there is a lack of will and incentive to expand these projects and to roll them out on a larger scale.
- > Round Table participants recommended that concrete examples are gathered of successfully developed, validated and implemented AI-solutions in Denmark and that these are used as a starting point for discussions about the vision and strategy for this area.

Summary of overall challenges

- > There is a high degree of resistance to a mixing of public and private interests that could result in the industry having difficulty accessing the necessary data.
- > It is unclear where the responsibility for executing development, validation and the commissioning of new AI solutions lies.
- > It is unclear what data may be shared with whom and for what purpose.
- > It is generally difficult to achieve effective data sharing. The infrastructure is not completely in place and there is a lack of uniform standards for data storage, curation and sharing.
- > The distance between health professionals and IT professionals is too great.
- > Implementation should be the focus in all phases of the development of AI projects, so as to ensure that there is the necessary connection between research, project and operation.
- > There is a general lack of focus on innovation when new technology is bought and implemented.

Summary of overall solutions

- > The often-watertight barriers that exist in Denmark between the industry and clinics need to be broken down, and frameworks and practices for collaboration that benefit both parties must be created.
- > Collaboration between health professionals and the industry (public–private partnerships) should be encouraged and not treated with suspicion.

- > Legislative changes should be clearly defined, as there are currently too many procedural and potentially legislative obstacles around the use and re-use of data.
- > There is too much legal red tape within AI and health. There is a need for simple and unambiguous frameworks.
- > Improved interdisciplinarity in AI projects must be developed through education. Collaboration across study areas such as medicine, technology, computer science, mathematics, psychology and anthropology must be promoted.
- > It should be recognised that it is not possible to solve all the problems that require innovation, but focus more specifically on what we can do to create value for patients and citizens.

Discussion of outcomes

There is no doubt that AI will continue to be implemented at an increasing rate in Denmark, but it will not occur at the same speed and with the same effectiveness across the whole healthcare system. Round Table participants considered that it should be a priority amongst decision makers to accelerate the implementation of sensible AI use in the healthcare system.

EU-level versus national-level

Round Table participants discussed the role of the EU versus Member States and highlighted that because global companies work across nations, this should be taken into consideration in the advice the participants propose. It should also be taken into account that countries like China and the USA are able to bypass Member States and win market share and positioning. The value of solutions built on a solid data-protection groundwork should be clearly championed and presented as a unique selling point and therefore put high on the common European agenda.

A lack of communal action in the EU

With regards to the Danish context within the EU, it was discussed whether the many AI pilot initiatives in Denmark and lack of unifying initiative reflect that, as a nation, Denmark suffers from a kind of self-sufficiency that limits how much we offer our data or projects to international actors.

Round Table participants suggest that 5-6 initiatives or actions should be chosen within the health service, that as a country we can set out to solve with the help of AI. With a communal and therefore strengthened effort, Denmark could demonstrate in the European arena that it is a country that is able to act as a spearhead in the implementation of AI in the healthcare system. In order for this to happen, coordinated national decisions in the area of AI are needed. This would make it possible to consider all the smaller pilot projects that are ongoing around the country, that could provide inspiration and show the way for even bigger projects. A coordinated effort such as this could accelerate implementation and lead to decisions that better meet the needs of patients.

In Denmark there is a lack of concrete strategies for health innovation. We should realise that we can't solve all problems, but should instead focus on solving some problems as fully as possible.

Denmark lacks a consensus on which needs we should address first and foremost, and so the Round Table participants proposed focusing on 5-6 initiatives to start.

After implementation of these initiatives, Denmark must obviously determine its national strategy and enter into a dialogue with the EU to ensure these are placed on the common European agenda.

GDPR and data sharing

In connection with the General Data Protection Regulation (GDPR) and data sharing, it is necessary to adhere to both the local requirements and those of the EU. The Danish Regions (Dansk Regioner) are attempting to collate initiatives, to gain an overview of regulatory and legal guidelines, as well as attempting to break down the barriers for further implementation of AI within the healthcare sector. This is happening at the same time as addressing both GDPR requirements and CE marking under the remit of the EU. The goal is a common labelling scheme that will strengthen both the national and the common European initiatives, and which will lead to an improvement in the possibilities for implementing AI-based solutions.

At a political level, there is a general concern when it comes to the sharing of health data. Discussions on data sharing often come up, for example, in the Health Committee (Sundhedsudvalget) but are put off time and time again because of a lack of consensus. The discussions often become skewed when financial factors are considered above improved future patient care as an argument for strategic investment in AI. It quickly becomes too much talk and not enough action around the innovative use of health data. Add to that the fact that GDPR is interpreted differently in the individual regions, then path from talk to action is further hindered. The Danish Regions will therefore collate all the challenges and barriers along the way in order to suggest a solution. From a political perspective, it has been made clear that we need to supply specific examples of issues that are making the implementation of AI more difficult, for example, the health service. A focused effort that involves a wide range of stakeholders, industry organisations, hospitals and regions, and which highlights these specific problems and suggestions for solutions for politicians, will increase the likelihood of effective, concrete decisions being made, assuming there can be political consensus across parties.

One suggestion to support faster processing and decision-making processes could be the establishment of a hotline to escalate the removal of barriers that are identified between project initiation and implementation. A new radiology AI test centre is under construction in the Capital Region (Region Hovedstaden). One of the projects at the new centre will be the automation of lung diagnostics. As part of this, discussions have taken place around whether or not it would be possible to introduce this kind of hotline to the Regions and politicians, as a fast track system that would make it possible to quickly remove barriers for the implementation of AI. Such a solution could apply across all strategic initiatives and should of course take place within the context of a broad and informed discussion about the development and use of AI.

Denmark as a laboratory for the world

As an EU Member State, Denmark has a good basis and potential for becoming a laboratory for the world. As a starting point, Denmark and the Nordic region as a whole, has the potential to create an international laboratory for the development of AI solutions based on high-quality data, a high level of technological understanding, a world-class healthcare system and high educational competence. This is related to an ethical foundation and a basic trust across all sectors and

institutions which give a unique opportunity to create and implement functional AI solutions with high global relevancy.

If we can get away from silo-thinking and build concrete, operational solutions communally and across sectors and regions, Denmark could attract international attention and be ready to roll out initiatives and solutions on the global stage. It is important that there is a move away from solo initiatives and, to a higher degree, an attempt to gather stakeholders around the table, to put into action coordinated initiatives on a larger scale for the good of patients, the economy and the health service.

We should also look closer at models in countries like the UK and Finland, which are good at developing concrete solutions across sectors. These countries have developed their initiatives as a part of a coordinated national strategic effort in health innovation, with both public and private partners. Good solutions can potentially assure that a country attains a spearhead position with regards to development and implementation of AI and thereby secure the country's future economy, by lowering cost margins in healthcare delivery and creating a source of income that can be compared to GreenTech technologies, for example.

As a response to this, a concrete effort in the form of a Danish–Finish cross-national partnership could be proposed. It has been suggested that Danish health companies could play a role in this effort. Clinics should be involved much earlier in the process, preferably in the development phase. In this way we can ensure that interdisciplinary teams of health professionals, IT and data experts are established in the development phase and that the solutions address real patient needs and health system workflows.

Round Table participants considered that Denmark has one of the best possible starting points for putting itself at the forefront of development and implementation of AI in the health service. It has a healthcare system that is driven less by capital and more by what is best for the patient. This starting point is the best for ensuring that we develop the most relevant and value-generating solutions.

Sessions II–IV: How to improve ‘on the ground’ impact of AI

For each of the six areas below, Round Table participants discussed and developed a list of actionable recommendations. They identified the people who need to be involved and proposed the actions that need to be taken, in order for these to be realised.

1. Clinical leadership

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

Clinical leaders are not measured by innovation

Consideration of the performance of health service leaders should include measures of how good they are at innovation, both clinically and administratively. Digital leadership should be incorporated into leadership roles and become a defining part of modern leadership. We should actively go in and influence the regional management level, just as professional companies should evolve to be equipped in this regard. Clinical leadership should emerge from the hospital director and clinical department management-level, and all management levels should be involved in implementation of AI in the health service, in the same way that we should launch more interdisciplinary initiatives. There is a need to better articulate and support clinical management’s responsibility for the implementation of AI in the health service, and specific challenges must be solved so that patients are provided with the best solutions possible.

We should therefore involve clinics and other relevant parties in the health service early in the development phase, where they can be a part of developing the solution that will most benefit patients. This can happen with a good framework for how development and implementation projects should progress with interdisciplinary teams and with space for mutual learning through iterative design, implementation and evaluation processes. It can also be achieved by creating a solid framework for how clinicians can take active co-ownership of projects in companies working with AI solutions, but this requires a breakdown of the often-watertight barriers existing between clinics and the industry in Denmark.

Establishment of clinical innovation units could become important organisational features and create platforms for development, clinical validation and implementation of value-generating solutions and changes in clinical practice.

Capacity to act

The barriers between clinics and the industry in Denmark are often very strong. Many clinicians don’t want to take part in projects and initiatives that grow out of referrals from the industry. One of the reasons for these barriers is that clinicians are often mistrusted if they are fulfilling too many different roles, and in particular if they work in projects that are entirely or partly funded by the industry. It doesn’t help a doctor’s reputation to work in a commercial context, as this calls into question their moral credibility. With that in mind, it is not possible to expect that doctors would participate in interdisciplinary collaborations with the industry on a regular basis. A process of evolution is needed, which requires the support of political parties in the long run, because we

should recognise that in order to create innovation, cooperation is vital. Therefore, significant work must be done in order to break down those barriers for the benefit of patients, clinicians and the clinics.

Round Table participants pointed out that the current legal requirements for healthcare professionals to register, make public and seek official approval for all collaborations with private industry in itself encourages this suspicion, and is therefore a further barrier to coordinated development efforts.

A common vision and a monetary dimension

Maybe we should have a new vision: 'If you help to implement this innovative solution, then you also help solve a global health problem in the long term.' This would shift the current, accepted narrative of private initiatives focused exclusively on commercial objectives to projects focusing on generating clinical and health value.

There is a need to come together across disciplines to solve patients' problems, and there needs to be an economic dimension early in the development process. Otherwise it will be difficult to roll out local solutions at a global level. Money will inevitably influence the implementation of AI. Innovation Fund Denmark (Innovationsfonden) has until now supported many AI projects and with its AI: Denmark project, The Danish Industry Foundation (Industriens Fond) has supported increased coordination and collaboration between the industry and the Computer Science Department at Copenhagen University, The Institute for Mathematics and Computer Science (DTU Compute), Aalborg University, the Alexandra Institute and the Danish Technological Institute. These brilliant financial injections are important and more funds should be set aside by the government's finance bill to finance AI-based solutions.

What is working well and best practices identified in this area

Successful existing projects and positive experiences

- > [Vital Beats](#) is an example of a collaboration between a start-up and clinics, that has resulted in the development of an AI-driven platform for the remote treatment of patients who have a pacemaker.
- > [Radiobotics](#), in collaboration with clinics, has developed an AI-based diagnostics tool for the quick and effective analysis of X-ray images.
- > [BoneXpert](#) (Visiana) is a Danish company that has developed an AI-based system for determining bone age, to assist medical decisions relating to the treatment of children with growth disorders. The solution is web-based and standardises an important measurement in the clinical decision-making process using an algorithm.

Best practice examples

- > The [CT Innovation Unit](#) at the Department of X-Ray and Scanning, Herlev and Gentofte Hospital, is an example of a clinical research unit at the heart of a clinical practice. The Innovation Unit (established in 2012) deals with need- and user-driven innovation across a range of initiatives and projects, where the results and solutions are implemented in clinical practice across organisational silos. The strategic focus areas are AI, advanced CT scanning and acute patient diagnostics. One of the unit's goals is to develop a self-service CT scanner.

- > [Radiological Artificial Intelligence Testcenter \(RAIT\)](#), a collaboration between the Departments of Radiology at Herlev, Gentofte, Frederiksberg and Bispebjerg Hospital. The collaboration combines the experience of the CT Innovation Unit at Herlev Hospital with an active research section at Frederiksberg and Bispebjerg Hospitals. The departments involved want to establish a common foundation for the development, clinical validation and implementation of AI in radiological departments across the capital region of Denmark.

Key Points

- > In Denmark there are several excellent examples of public–private initiatives that have resulted in AI-based solutions that greatly influence the precision of decision-making and lead to better outcomes for patients. We need to make it easier for such initiatives to be implemented.

Proposed actions and recommendations

Clinical leadership	
Action	Target Stakeholder(s)
Clinical leaders need to take responsibility for driving AI	Hospital management; regional leaders
Break down of barriers between private industry and clinics	Politicians; the Danish Regions; hospital management at individual hospitals
All clinical departments should have innovation integrated in their daily clinical routines	Hospital management; regional leaders

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 area?

Integrating AI and digital transformation into healthcare education

The seven medical roles (medical expert/doctor, communicator, collaborator, manager/administrator/organiser, health promoter, academic/researcher/teacher and healthcare professional) do not cover competencies that are needed for digital readiness. There should be an eighth medical role, which ensures that future doctors are ready to make the most of new technology for the good of patients. And a ninth role, which ensures that innovation and a targeted focus on value-generating improvements are brought into the competency profiles of future doctors. At the same time, it should be made clear that those who sit on the sidelines will become redundant in the future health service.

Digital readiness, however, is not included in the curriculum of health science education, nor in undergraduate or postgraduate medical education. This is the huge challenge that faces Denmark in the years ahead; so, how should the country prepare its health education to embrace and implement digital transformation and AI?

In order to futureproof medical education, there should be less focus on rote learning and instead more time spent on subjects that prepare the doctors of the future for AI, digital transformation and innovation. This will require developing a new thinking amongst students. There needs to be a bigger focus on innovative processes and it should be made clear that it will be necessary for the doctors of the future to have AI knowledge readily available. At the same time, technology and computer science studies should contain a greater focus on health issues, so that the distance between the three forms of education are reduced. Studies within psychology, anthropology and the humanities should also be considered.

New targets should be set for what clinicians should be competent at in 10–15 years time. These targets can then help alter the curriculum of the medical faculties. Many trainee doctors have an interest in digital transformation and AI, but development goes too slowly, and there is no job waiting for those who have written their PhD on subjects within data science and AI. They are put on hold and we leave them to travel the beaten path through the system, instead of paving the way for them by supporting their interests and abilities in AI and digital transformation, for the benefits of both patients and society.

What is working well and best practices identified in this area

- > A good example of a project that focuses on interdisciplinary competencies which also include knowledge of AI and AI-based solutions is [Inno X](#), established at Aarhus University. Inno X has an interesting approach to education and research based on a curriculum that creates value for the health sector, for the benefit of patients and society as a whole. It is an ambitious project that strives to make companies better at developing and commercialising products, whilst at the same time preparing health professionals for the integration of needs-driven innovation in their daily lives.

Key Points

- > Traditional rote learning must be confronted head-on and education must be transformed so it has a sharper focus on innovation, digital transformation and problem solving, together with a further integration of different health and technology disciplines.
- > Needs- and user-driven innovation in clinical practice are both critical for the development, validation and implementation of value-generating digital solutions within AI.
- > Innovation is an important (clinical) leadership task, and should be a core clinical benefit.
- > We must ensure career and educational opportunities for talented future professionals (e.g. doctors) with the desire and ability to pave the way for AI in the health service.
- > Future doctors are being educated now. There is a need for an 8th and 9th medical role in technology and innovation, respectively.

Proposed actions and recommendations

Establish clinical innovation units throughout Denmark, where both the organisation and the staff, across disciplines and organisational silos, can co-create important and value-generating digital solutions in interdisciplinary teams and public-private partnerships. These innovation units should be thought into undergraduate and postgraduate studies.

Education and skills	
Action	Target Stakeholder(s)
Think out of the box and think interdisciplinary. Frequent meetings for planning what future clinicians should be able to do.	Deans; hospital managers; regional leaders; clinical managers; medical companies; study leaders; educators; data experts
Attempt to get medical faculties to implement an annual sprint for students, where they collaborate with students from data science faculties (as an example) on innovative solutions. Introduce a new 'cultural understanding' at the universities. Introduce interdisciplinary sprints at the Technical University of Denmark (DTU) and the medical and data science faculties at Copenhagen University, embedded in clinical innovation units.	Deans, The National Board of Health (Sundhedsstyrelsen), and medical companies should be able to put the pressure on
Bring clinicians into play at the faculties. Together with university management, allow them to decide what should be achieved from a curriculum and what needs to be done with regards to the future that we will one day need to navigate.	Deans; medical societies; visionary pioneers
Statistics should be weighted higher on the curriculum of all medical science studies, as AI is in reality applied and automated statistics.	Deans

3. Regulation and policy making

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

An environment of facilitation

There is a general concern in the Danish Parliament about giving access to data from patient registries, blood banks etc. It is of course good to protect the privacy of citizens and have a clear understanding that data must not be misused. But there is wide agreement amongst patient- and medical associations that there is a great deal of data that could be shared and used for the benefit of patients. In order for these data to make a serious difference to patients, a lot of awareness-raising efforts are required, and patient- and medical associations, along with the

newly-established Treatment Council (Behandlingsrådet), should be involved in the work on a new vision for this. These groups could work together to produce comprehensive information on the pros and cons, as well as potential solutions, to present to decision makers.

Part of the problem is that data in Denmark is maybe too well protected, perhaps even to the extent that we risk being overtaken by countries that are more lenient on the use of data. On top of this, there is such great uncertainty in Denmark around the secondary use of data, such that Round Table participants considered that legislative changes are required to overcome this. There is simply too much legislative red tape around the use and re-use of data.

The regulatory landscape in Denmark needs to evolve but currently operates within an environment comprising many subcontractors for many different solutions, without being able to control the processes around them and ensure quality. There are some positive changes developing however, in terms of the relaxing of regulations and with getting politicians to support the introduction of AI into the healthcare system, but it is a process that seems to stretch far into the future. This process must be accelerated if Denmark is to be a serious player in digital health in the future.

EU Medical Device Regulations

AI as a medical device is subjected to requirements from the regulatory authorities. These requirements are well described in the regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices. Besides the requirements described in these medical device regulations (MDR), some additional points should be considered when developing AI-based solutions: Inspectability and reproducibility of AI solutions, and representability and version-control of AI and the data used. The need for this is exemplified by self-learning algorithms which are constantly updated with new data thus inducing an inherent risk of being trained by data of unknown, or even of poor, quality. This could create a bias that, in the worst case scenario, leads to unintentional mistakes. As such it is generally recognised that to develop good quality AI-based solutions one needs good quality data. From a regulatory perspective, AI as a medical device needs to comply with the MDR requirements as a minimum and apply solid AI principles to secure inspectability, reproducibility and data representability to avoid mistakes and unintentional bias.

Rules for health data access

There is a need to quickly establish clarity at a national level around who in society should be allowed access to health data and to which end. It must be clarified whether the same thinking on data sharing should apply to Danish start-ups and small and medium-sized enterprises as to large multinational companies. It should also be clarified whether it is acceptable to pay for data. This could be payment in the form of access to technology for Danish citizens over a particular period, or direct monetary compensation to the public bodies taking part.

Possible scenarios include a model where senior doctors, at one end of the spectrum, allow access for Danish start-ups and small/medium-sized companies to anonymous data 'for a good cause'. At the other end of the spectrum, regional public bodies could give access to data to large multinational companies.

There is an urgent need to resolve the different forms of legal red tape that exist within the regulatory landscape. An important first step could be to focus on which powers in relation to

health data can reasonably be exercised as part of the multifaceted management responsibilities of senior physicians, which include quality assurance of core services, patient safety, professional development (research and innovation), efficient operation, education, working environment and more.

The question remains as to how an environment of facilitation for development processes and approval of solutions can be established at a national level. Round Table participants considered that key competency clusters should be formed within the EU, as no Member State can carry out this task alone.

What is working well and best practices identified in this domain

Existing successful projects and positive experiences

- > [Data for Good](#) works to break down the silos of traditional behaviours within registered professional areas and to create a common consent structure that can actually enable citizens to use data. This includes working to utilise the potential within GDPR legislation positively by breaking down existing barriers.

Best practice examples

- > [The Regions' Clinical Quality Programme](#) (Regionernes Kliniske Kvalitetsudviklings Program) works to drive development of around 85 of Denmark's clinical quality databases with the aim of improving opportunities for data use, which in turn will improve treatment offers, as well as general efforts and results within the health service.

Key Points

- > There is no clear and definite user guide within the law that sets guidelines for how data can be accessed and used.

Proposed actions and recommendations

Regulation and policy making	
Action	Target Stakeholder(s)
Introduce an ethical label for the use of data, a kind of 'Nordic Ecolabel', in an attempt to introduce a competitive element for partners. Work to a greater extent with corporate social responsibility as a motivator.	Politicians; patient associations; medical companies
'Invest in Denmark': We must continue to tell the story that Denmark can offer the right framework for growth in AI solutions. We must 'infect' the world with 'trust' and stick to the Danish view of the world, not compete on other countries' terms or on the basis of other national parameters. The vision should be that Denmark is a laboratory for the world.	Business community
Introduce fines and penalties for companies and hospitals that use data to create unethical solutions, rather than focus on which data they have access to. Data should be used for the greater good with responsibility and penalties be given if data is mis-used or shared with third parties.	Politicians
Pass legislation that allows 'fast track' implementation of AI solutions and introduce national strategies for implementation. Introduce laws around secondary use of data. Give some of the responsibility for managing data to those professional leaders who already have responsibility for meaningful and value-generating use of data on a daily basis.	Politicians
Collaborate with Danish Patients (Danske Patienter) – if they become the spokespeople for relaxing the laws with regards to data sharing, there may be a greater chance of people listening and making it happen. If the request comes from academics, or from the private business community, there will be suspicion that it is about furthering careers or earning money, not about best serving the patient.	Danish Patients (Danske Patienter); patient associations in general
Learn from countries that are further along the process than Denmark. Specifically, Finland, where they have introduced a clause in legislation that states data may be used to the benefit of society in a secondary purpose.	Political level

4. Funding and reimbursement

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

The USA and China have accounted for more than 90% of global investment and patents in AI over the last 10 years. In the USA, this is mainly driven by technology giants and multiple start-ups, while in China it is largely promoted by the central government. However, Denmark lags behind comparable countries such as Israel, Finland and Sweden when it comes to private investment and the number of patents created within AI.

In many of these competing countries, especially the USA and China but also Finland, ambitious development plans for the use of AI have been created which will boost investment in this technology. In Denmark there are only a few businesses and public authorities that have a strategic focus on AI.

The existing environment for investment in Denmark works on the one hand with WellTech, developing apps which will provide commercial returns after 18 months, and on the other hand with BioTech, which is only expected to give returns after 10-15 years. In HealthTech, where the average time for return on investment lies somewhere between the two, there is a need for an investment environment that understands this and will still invest in AI solutions. A HealthTech network should be established which is more commercially funded, because it will then be able to support ideas and initiatives in a way that is not happening today. In the long run, Copenhagen could be developed into a centre of investment within HealthTech. Health Tech Hub Copenhagen could then be considered a valid starting point for such a centre.

Appropriate and mutually-acceptable business models for AI solutions in healthcare should be developed, that can accommodate all phases from co-creation to prototype testing, clinical validation, pilot implementation and normal operation. Key Performance Indicators (KPIs) should also be established for AI innovation that are more operational than academic. The focus should be on (a) realised value generation and (b) implementing practical improvements.

Round Table participants considered that a potential solution could be MedTech Denmark, patient- and medical associations establishing a joint effort to put extra focus on regulation, funding and reimbursement. As part of this, it will be vital to find a voice that can bring together the start-ups that already operate within HealthTech, but which do not currently have a unified communication in relation to opportunities, needs and solutions.

What is working well and best practices identified in this domain

Existing successful projects and positive experiences

- > The Danish Regions have a common digital transformation strategy (2020). This common commitment and direction is already created and could potentially be revived with AI brought more into play.

Key Points

- > Appropriate and mutually-acceptable business models for AI solutions in healthcare should be developed.

- > An investment environment that is willing to invest in establishing and scaling AI solutions within the health service is also needed.

Proposed actions and recommendations

Funding and reimbursement	
Action	Target Stakeholder(s)
Denmark should be more of a laboratory for AI and health technology than a market.	Politicians
The Danish Regions have a common digital transformation strategy (2020). This common commitment and direction is already created and could potentially be revived with a greater focus on AI.	The Danish Regions
The Treatment Council should be brought into play. It should be made clear to the council that AI creates value for patients and that they are the obvious choice for giving the stamp of approval to different AI solutions. They should be made ready for the task and have an understanding of what it entails. This council could also include members from the start-up community and the medical industry.	The Treatment Council; the Danish Regions
Produce a common vision document which can be used to prepare actors in the process. Medical organisations and Danish Patients could as an example take ownership of this vision document.	Medical organisations; Danish patients
Give responsibility for regulatory changes to the Medico Industry in Denmark. This could happen in collaboration with the Danish Association of the Pharmaceutical Industry (LIF), as an example.	Medico Industry; LIF

5. Strengthening data quality, governance, security and interoperability

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

We should lean on international standards

Denmark has a unique reputation for generation, quality and storage of data. How can the country become better at using it and move to the forefront internationally in the use of such data? How can we go from something that is good, to something that is excellent?

The advances being made in ensuring data can be extracted from various systems are coming from the USA. Development of data standards are storming ahead. In Denmark we need to lean on these developments happening internationally to a greater extent if we are to be able to use data more widely. Currently, Denmark is only doing sandbox tests, so it is therefore not necessary to invent new Danish standards. We should instead use international standards for data development, for example the [Fast Healthcare Interoperability Resources](#) (FHIR) or HL7. In

addition, data curation in one project should be able to benefit another. A low-hanging fruit to be picked is the sharing of data-cleaning algorithms. We should be able to share these but many do not. Initiatives are underway, however, at a regional and national level. For example, the Radiological AI Test Centre, that has a data infrastructure and an anonymisation robot for the sharing of curated data in a non-competitive development zone, is being established in the Capital Region.

How do we gather and store data and get ourselves ready to exchange data with other systems? We do this by purchasing more solid, futureproof systems.

Denmark has many data banks, but lacks the infrastructure (IT structure) to improve the quality. It is analogous to building a skyscraper without first having the foundations in place.

What is working well and best practices identified in this area

Existing successful projects and positive experiences

- > [DataFair](#) is supported by Innovation Fund Denmark (Innovationsfonden) and works to collect data and make it commercially available in an ethically responsible way. DataFair has collated projects worth almost 100 million Danish kroner, with the purpose of being able to create secure and anonymous access to Danish health data. The projects are carried out in collaboration with both public and private actors.

Best practice examples

- > [Radiological Artificial Intelligence Testcenter](#) (RAIT), a collaboration between the Departments of Radiology at Herlev, Gentofte, Frederiksberg and Bispebjerg Hospital, is a good example.
- > [Tværspor](#) is a research project that gathers data across a wide range of actors to gain insight into inappropriate hospital admissions and readmissions, and which has developed a security model with Region Midtjylland's lawyers, which describes how the project solves the legal requirements under data protection legislation, regulation and health law.

Key Points

- > Objective rules need to be introduced to define how to secure equal access to data for all, and a National Board should be established that can drive and oversee implementation.

Proposed actions and recommendations

Strengthening data quality, governance, security and interoperability	
Action	Target Stakeholder(s)
After a waiting period, data from one project should be moved to a general non-competitive zone, where other projects can benefit from the same data. This could become a requirement from grantmakers.	Government; private non-profit foundations
Establish non-competitive zones for the re-use of data.	Existing innovation structures
Progress the central interdisciplinary extraction of clinical data from electronic patient records, for use across research, quality assurance and innovation.	The Danish Regions; RKKP, The Danish Board of Health Data (Sundhedsdatastyrelsen)
Create a kind of 'Dogme Manifesto' for the sharing and curation of data, alongside the creation of non-competitive zones for the secondary use of data.	Round Table Participants
Gather political support for a common data model, that allows the use of existing international data forms, such as the FHIR or HL7.	Politicians

6. Liability and managing risk

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

Building trust in AI algorithms

Algorithms today are able to show a cancerous mass on a heatmap, something which the human eye cannot always see. But how much can we and should we actually trust the technology?

Round Table participants considered that it would be beneficial to build up trust in algorithms over time. Today, for example, we use two sets of professional eyes on diagnostic images for some clinical tasks (like breast cancer screening and X-ray examination in emergency rooms/joint emergency departments). In the future, it will be possible to use one algorithm and one set of human eyes, and in some cases it will be possible to let the algorithm perform the full diagnosis, thus completely phasing out the human reading of certain types of diagnostic imaging. The feeling of being able to trust data is an evolving process.

Common EU recommendations or even international recommendations could be developed, but here we should be careful about the demographic and genetic differences in data. As a general rule, good data is clean (curated), fresh (new) and as local as possible.

It is recommended that a governing body should be established, a certification council, that can take responsibility for making sure AI solutions are being used, especially when they create more quality, value and security than the medical/human alternatives.

What is working well and best practices identified in this area?

Existing successful projects and positive experiences

- > Some paediatric departments today are implementing tools for the measurement of children’s bone age based on a solution delivered by the company Visiana. [BoneXpert](#) and it is based on mathematical modelling. It is the first example of a commercial AI system which has completely replaced a radiologist’s interpretation. Both the parents and clinicians are accepting of the results, which creates calm in the paediatric department.
- > Other companies are well on the way: as mentioned previously, [Corti](#), [Radiobotics](#) and [Vital Beats](#) are all companies delivering solutions which completely or partially deliver inputs into the clinical decision-making process.

Key Points

- > Further implementation of AI-based solutions will increase the credibility of these solutions as being critical to the diagnostic and clinical decision-making processes.

Proposed actions and recommendations

Liability and managing risk	
Action	Target Stakeholder(s)
Those testing algorithms should be able to vouch for the algorithm’s effectiveness, sensitivity and precision and to recommend its use.	Medical companies
Risk assessment is a part of the core services provided in the health service. It would be advantageous to have The Danish Council on Ethics (Etisk Råd), the Ethical Data Council (Dataetisk Råd) and Danish Patients ready and able to talk about risk assessment and when and to what extent we should be able to bring in and rely on AI.	The Treatment Council; The Danish Council on Ethics; the Ethical Data Council; Danish patients

Session V: Driving acceptance and use of AI in healthcare

Clinical leadership

Clinical leadership needs to be implemented from the very top of the Danish health service and down through the ranks.

All clinical departments should have innovation integrated in their daily clinical lives and the barriers that limit the facilitation of interdisciplinary projects must be broken down.

A unified voice and a core narrative about AI as an inevitable part of the future health service are needed, and this should be integrated into education for the good of patients.

The large value-generating potential with AI in the health service typically lies across established professional and organisational silos.

Education

A marked and necessary confrontation with rote learning needs to happen in order to make room for AI in higher health education, both undergraduate and postgraduate studies (including medicine and other professional health studies). There is a need for people to spearhead AI in healthcare and who can help create career opportunities for the talent coming through education (for example in combined areas like Radiology/Technology or Acute Medicine/Technology).

A practice of interdisciplinarity should become the norm with regards to AI projects throughout education, and collaborations across studies, for example medicine and computer science. Bridges should be built from both sides – those in technical studies should also build professional health knowledge.

Changes are needed to the health professional education curriculum; this should be articulated politically, so that it becomes crystal clear that some insight into AI is necessary in order to be able to work within the healthcare system of the future.

COVID-19 has been a 'disruptor' that has led many people to become interested in healthcare and to want to work with it in the future. This is especially evident in the Northern parts of Europe and Denmark should attempt to turn this to its advantage with regards to attracting new students in the areas of AI and health education. A few hundred skilled AI health professionals could have a major impact on the implementation of AI in healthcare.

Regulation and policy making

It is becoming increasingly important to talk about AI at both the national and regional level.

A voice that is particularly important to listen to is that of the patient. Denmark has very well organised patients' associations which can make a difference, just as the innovators within the public system can, who also should be listened to.

The industry should speak with a united voice rather than individual voices.

The Medico Industry is an obvious choice as an organisation which could deliver a regulatory framework. The Medico Industry should embrace smaller start-ups to a greater extent and not just the large industry players. Otherwise it needs to be made clear to them that they are missing

an obvious opportunity to support the implementation of new technology in the Danish healthcare system.

Funding and reimbursement

Denmark should cultivate a basic understanding that it needs an attractive investment environment. It should be attractive to invest in Denmark. This means that clear models are needed for how data can be used to achieve successful solutions.

There should be a clear platform from which the possibilities in Denmark can be clearly stated.

Models are needed for how public employees like doctors can get actively involved in the development of AI without coming under suspicion for being in the pocket of private industry.

It will be necessary to talk to both politicians and The Danish Regions about how to make it clear that being involved in the development of innovative solutions is a positive thing. We should see Denmark as a laboratory, not as individual regions. The market is not just Denmark, but the whole world, both commercial market and the market where these solutions will ultimately be used.

Strengthening data quality, governance, security and interoperability

Clearer and more comprehensive data models are needed, and for data curation to be shared. It should also be clearly articulated that clean data may be used for secondary purposes.

There should be a greater understanding of the fact that Denmark is a small player in a big market. We should therefore not develop our own standards, but make use of the good, professional international standards already available, such as FHIR or HL7.

Round Table participants will attempt to put together a digital manifesto - a 'Dogme Manifesto' - which all or many of the parties working with data can be part of. There will be a kind of non-competitive zone, where algorithms and data can be stored and used by others, so they do not end up developing parallel solutions but build on the work already done by others.

Liability and managing risk

It should be clearly articulated that of course there are risks in implementing new AI, but there are definitely also risks if we do not implement new AI.

There is no tradition in Denmark for measuring the precision of individual doctors, but with AI algorithms this quantitative quality measure will become part of all development, validation and clinical delivery of decision-making support.

As a system and a society, we have a big responsibility to implement the algorithms that work, because it will not take long before the work of health professionals themselves will be checked by AI algorithms, if and when they overlook critical signs of illness.

Appendix 1: Round Table Meeting participants

EIT Health would like to thank the following participants for their input into the Round Table Meeting:

Name	Organisation
Advisers	
Henrik Ullum, Moderator	Professor, Chief Physician, Formand for LVS, Overlæge, Rigshospitalet
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Finn Kensing	Professor, Computer Science, Kbh's Universitet
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Mette Lindstrøm	Centerchef, Danske Regioner
Michel Nemery	Chairman, Radiologisk Afdeling, Herlev og Gentofte Hospital, RH
Stinus Lindgreen	Medlem af Folketinget for Radikale Venstre
Organisers and other attendees	
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Jørgen Schøller	Head of Operations & and Head of Division at DTU, Member of EIT Health Scandinavian Board
Stine Kruse	Head of Innovation, DTU Health Tech
Trine Winterø	Vice Dean for Innovation and External Relations at Faculty of Health and Medical Sciences, UCPH Deputy Chairman of EIT Health Scandinavian Board

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