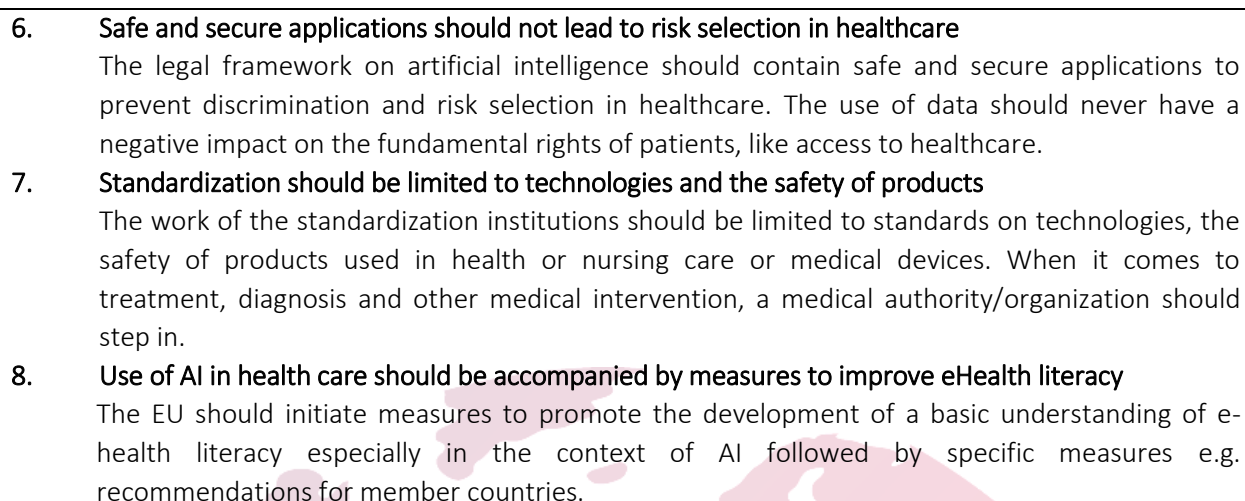AIM Healthcare and social benefits for all

ARTIFICIAL INTELLIGENCE: GREAT POTENTIALS AND SOME CHALLENGES FOR HEALTHCARE

I. At a Glance

The international umbrella organization of mutual benefit societies (AIM) welcomes the priority focus of the European Commission on artificial intelligence. Health insurance funds and health mutuals see an enormous potential of artificial intelligence in healthcare. A "(…) coordinated European approach to the human and ethical implications of AI (…)" is highly welcomed. AIM proposes taking the following criteria into account when working on a possible legal framework for artificial intelligence in healthcare in order to deploy its full potential:

Recommendations

1. **An adequate legal framework built on binding ethical guidelines is necessary**
   An adequate legal framework built on ethical guidelines is necessary to regulate the use of sensitive health data. Industry and public authorities should guarantee transparency about the algorithm used for automatic decision-making processes and the objective and data behind it.

2. **Specific guidelines for healthcare systems have to be developed**
   Ethical guidelines must focus on human agency and human oversight when artificial intelligence systems are involved. In specific sectors such as healthcare, where human control over algorithms is paramount, ethical rules specific to the healthcare ecosystem should be formulated. It's essential to create an "ecosystem of trust".

3. **Trust in the use of AI has to be established**
   AI is not only about technological and social innovation, but must be a trustworthy tool while complying with applicable laws and ensuring adherence to ethical principles and values. Performance transparency is key to building this trust. Therefore, a health technology assessment is needed to analyze the efficiency of AI, especially if it concerns medical care reimbursed by compulsory health insurance. Controlling bodies, monitoring the safety and efficacy of an AI algorithm, would be an additional fundament to build that trust on.

4. **Transparency on the algorithms is of utmost importance**
   Algorithms should be transparent. Data sets and processes that are used in building AI systems must be documented and traceable. Explanations on an AI system need to be available. It should contain how AI systems influence and shape the decision-making process, how they are designed and what is the rationale for deploying them. Where decisions made by self-learning AI systems that are not fully traceable to human presets, additional legal questions (e.g. concerning liability) must be tackled. The algorithm should be approved by an official authority, if the social security has a cost (reimbursement or benefit).

5. **Data of good quality is indispensable**
   To guarantee the use of objective, accurate and good quality data in respect of a certain purpose, specific quality criteria for data collection must be developed (for example when AI makes diagnoses on severe diseases like cancer). The collection and processing of data must comply with the General Data Protection Regulation (GDPR).

6. **Safe and secure applications should not lead to risk selection in healthcare**
   The legal framework on artificial intelligence should contain safe and secure applications to prevent discrimination and risk selection in healthcare. The use of data should never have a negative impact on the fundamental rights of patients, like access to healthcare.

7. **Standardization should be limited to technologies and the safety of products**
   The work of the standardization institutions should be limited to standards on technologies, the safety of products used in health or nursing care or medical devices. When it comes to treatment, diagnosis and other medical intervention, a medical authority/organization should step in.

8. **Use of AI in health care should be accompanied by measures to improve eHealth literacy**
   The EU should initiate measures to promote the development of a basic understanding of e-health literacy especially in the context of AI followed by specific measures e.g. recommendations for member countries.

Moreover, AIM emphasizes that

1. **Artificial intelligence should help to solve specific social problems**

   AI allows development of better policies based on AI predictions (for example target the right group of persons for a prevention or health promotion campaign). It can be used to better foresee the impact a particular policy would have if implemented, to obtain a clearer picture of the best policies to implement to solve specific social problems. Like this, AI can be used to tackle the problem of inequalities and to identify vulnerable groups. AI could also assist in deploying resources in a more accurate, strategic, and affordable way.

2. **Include all stakeholders**

   The further development of machine learning systems and artificial intelligence should include not only computer scientists and industry but not-for-profit healthcare insurances, doctors, hospitals, lawyers and economists.

1. Health insurance funds and health mutual: key players in adapting to current challenges

Members of AIM are embracing innovation and are willing to contribute to the development of a proper use of artificial intelligence in healthcare.

Health insurance funds and health mutuals are organizations that are keeping pace with a changing society and evolutions in healthcare. They are committed to foster and promote health services by developing health structures themselves or by influencing public authorities in the national decision making process. Having direct contact to citizens, who are their members, the use of artificial intelligence and machine learning offers many opportunities for health insurance funds and health mutuals to develop safe and patient-centered alternatives. [1] Health insurance funds and health mutuals are prepared to play a greater role in adapting to current challenges. AI is one of the possibilities to support them in doing so. So health insurance funds and health mutuals have a voice in this debate.

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[1] https://govinsider.asia/inclusive-gov/ai-changing-healthcare-insurers-taking-notice/ (accessed on 26/02/2020).

Large tech companies have long discovered the field of digital health and artificial intelligence in healthcare. Naturally, they are profit-oriented, and often customers pay for free apps with providing their personal data. Health data is a person's most sensitive information. It is therefore important that patients receive alternatives from providers not focusing on profit – like statutory health insurance funds or health mutuals.

Health systems face many other challenges too: For example, people are living longer but having fewer children. Many countries are not well enough equipped to support and care for a growing number of elderly citizens. The prevalence of chronic diseases is an additional task that needs to be solved. The needs of the patients are changing and so have to do the health insurance funds and health mutuals. The shift from curative to preventive care is only one of the key components.

2. AI as a tool to fight pandemics

AI might curb the next pandemic predicting them, speeding up diagnoses and developing a vaccine faster.[2]

Algorithms and machine learning can be used to fight pandemics such as the coronavirus epidemic:

AI can help to predict pandemics

In a time of a pandemic such as the coronavirus outbreak, the biggest challenges for researchers, governments and public health officials are to gather information quickly and to coordinate the response. In such a situation, AI can be used to predict an outbreak and also to minimize its spread. With AI algorithms mining through news reports and online content from around the world, including unexpected resources such as airplane ticketing data, experts are able to recognize anomalies even before it reaches epidemic proportions by finding patterns remembering of previous outbreaks.[3]

Moreover, AI is used for the so-called "*Coronavirus apps".* Beginning of April 2020, a code for an app was released that analyses Bluetooth signals between mobile phones to detect users who are too close and therefore risk infections. The data will be temporarily stored on the phones. If people will test positive, the app will warn anyone, who has been around this person. This can help health authorities to reduce the spread of a virus, while allowing slowly public life again. The new European software is supposed to anonymize personal information and to prevent abuse be third parties. It also complies with data protection standards, according to researchers. Germans, one of the countries which is very sensitive about privacy, is likely to introduce this app soon, without having parliament passing legislation for it. However, the app will be voluntary. The biggest challenge will be to get the population to download and use it.[4]

AI can speed up diagnoses of diseases

AI-based diagnostics that are being applied in related areas might be as well used for diagnosing infections such as COVID-19. Companies and start-ups in China and the U.S. claim to have an algorithm for automatically detecting both lung cancer and collapsed lungs from X-rays. This algorithm can

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[2] Newsletter POLITICO AI: Decoded: Ethics at IBM — How AI could help fight the coronavirus — Workforce surveillance from 11 March 2020.

[3] Ibid.

[4] Newsletter POLITICO AI: Decoded: How AI is helping fight a pandemic — Europe's coronavirus app — Insights from Valencia, 8 April 2020.

quickly identify chest X-rays from COVID-19 patients as 'abnormal' and therefore has the potential to speed up diagnosis and to ensure resources are allocated properly.[5]

AI can help in developing a vaccine or treatment

As mentioned above, AI has the capacity to quickly search enormous databases for an existing drug that can fight a new disease or develop a new one. AI-based systems are able to identify thousands of new molecules that could serve as potential medications for e.g. the coronavirus. The speed and scalability of AI is essential to fast-tracking drug trials and the development of vaccines.

There are no doubts that AI has great potential, notably in the healthcare sector. But many claims made by the industry still need to have scientific prove. Moreover, when it comes to the development of a treatment or vaccine, AI technology can help to accelerate the development of drugs. However, it cannot speed up clinical trials. They are necessary to prove their efficiency and safety before they can be used on the market.[6]

3. Artificial Intelligence as a powerful ally in healthcare

There is no doubt that the use of Artificial Intelligence (AI) in the field of healthcare can help to improve patient's lives and contribute to the sustainability of healthcare systems. AI can shape everything from prevention to early diagnostics and treatment, but can also help in the administration of health care systems. Often it becomes a "second opinion" of a diagnosis or any other kind of decision in healthcare. It's because AI can adapt without human intervention and can "learn" to target human health needs on its own. [7]

AI to support health and care

In the field of prevention, it has the potential to realize early detection of diseases and to identify and to support groups at high risk. Machines can provide mental health assistance via chatbot, monitor patient health, and even predict cardiac arrest, seizures, or sepsis.[8] Moreover, AI can be used to identify people at risk of certain chronic diseases, e.g. diabetes. Early intervention will lead to earlier disease management and reduce strain on healthcare resources further down the line.[9] Freeing up human capacity, AI may help care givers to focus on more meaningful, valuable work.

AI as a tool to reduce the costs of development of new drugs

AI can reduce the costs of the development of innovative medicines by rapidly assessing a huge amount of health data, which facilitates faster drug discovery and new insights. Faster than humans, AI is able to analyze health data coming from clinical trials, health records, genetic profiles, preclinical studies and research papers, allowing it to correlate and connect new information with existing data. Machine learning enables the AI to be trained so that it is able to work out the solution to a problem instead of relying on the answers being given to it by programmers. Thus, AI is able to foster

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[5] Ibid.

[6] Ibid.

[7] https://www.datamation.com/artificial-intelligence/artificial-intelligence-in-healthcare.html (accessed on 26/02/2020).

[8] https://www.thomasnet.com/insights/the-challenges-and-dangers-of-ai-in-the-health-care-industry-report/ (accessed on 26/02/2020).

[9] https://govinsider.asia/inclusive-gov/ai-changing-healthcare-insurers-taking-notice/.

personalized and evidence-based care and can speed up processes to 18 months, which usually take 3 – 6 years.[10]

AI to streamline and facilitate administration

AI can improve the way health insurance works. For instance, as the population is ageing and demands for more long-term disease treatments, health insurance funds and health mutuals will need to develop ways to approve claims more efficiently. Currently, the largely manual process can take anywhere from weeks to months. The application of AI could effectively automate claim approvals or other processes. The algorithm will be able to assess the validity of claims and recommend decisions and payment amounts in a matter of seconds. AI as part of digitalization can contribute to free up human capacity to focus in more meaningful valuable work. Health insurance funds and health mutual can serve people better, when getting rid of time-consuming routine work.

The same holds true detecting fraud in healthcare and abusively claiming of benefits. It requires looking through big amounts of information to detect conspicuities, mismatches or events that don't fit larger patterns. For example, AI can help to detect billing for services patients never received or "upcoding" for more expensive treatments, meaning that a simple procedure might be billed as much more costly and complex by providers to pad the bill. AI can sift through data to see, whether there is any documentation to prove that the patient has actually received the service or AI can use anomaly detection to understand, what the typical treatment is for a specific condition and detect any deviations by a provider from a peer group.[11]

II.   Next steps: AIM's calls to the European Commission

As useful as artificial intelligence can be in the healthcare sector, one should not forget about the challenges that come with it. To use the full potential of AI as a tool to contribute to sustainable healthcare systems and to guarantee access of patients to affordable and quality healthcare, AIM demands the following criteria to be met at EU level:

1.   An adequate legal framework built on ethical guidelines

AIM recommendation: An **adequate legal framework built on ethical guidelines** is necessary to regulate the use of sensitive health data. Industry and public authorities should guarantee transparency about the algorithm used for automatic decision-making processes and the objective and data behind it.

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[10] E.g. in the case of customized cancer treatment: Insurers of several German mutuals already profit from algorithm-based cancer diagnostics and therapy planning: https://www.molecularhealth.com/de/patienten/.
Another example is **Wilson's disease**: A rare disorder that prevent sufferers from metabolizing trace amounts of copper found in food (which can lead to liver disease and a host of neurological and other problems) a company's AI found such a connection with a very high speed. AI has deciphered precisely how a mutation leads to a crucial defect in an essential coppermetabolizing protein. Another AI sorted through billions of molecules and rapidly identified nontoxic compounds that could correct the error. The algorithms came up with fewer than 12 drug candidates. The entire process took 18 months instead of 3 – 6 years. https://fortune.com/longform/ai-artificial-intelligence-medicine-healthcare-pharmaceutical-industry/ (accessed on 26/02/2020).
[11] https://www.forbes.com/sites/insights-intelai/2019/02/11/how-ai-can-battle-a-beastmedical-insurance-fraud/#3abb766363e0 (accessed on 26/02/2020).

Health data are collected and processed in large quantities and used for AI-driven analysis and decisions. Patients hardly understand how this is done, but unconsciously, they are influenced in their daily lives. Art. 9 of the EU General Data Protection Regulation (GDPR) regulates when and where personal data of European citizens, including health data, may be used[12]. However, the regulation does not take into account all human rights issues that are raised by algorithmic decision-making systems and that go far beyond the right to privacy and personal data. Algorithmic systems can also discriminate, endanger security and raise liability questions. The General Data Protection Regulation alone, that only refers to individual rights, is therefore not sufficient. In June 2019, the High-level Expert Group for Artificial Intelligence, established by the Juncker Commission, published ethical guidelines and recommendations for measures and investments in the field of AI. However, ethics are not a substitute for binding regulations. Therefore, an adequate legal framework built on developed ethical guidelines addressing all AI stakeholders is necessary. AIM is convinced that voluntary guidelines or the methodology of "autoregulation" are not enough.

2. *Specific guidelines for the healthcare systems have to be developed*

AIM recommendation: Ethical guidelines must focus on **human agency and human oversight** when artificial intelligence systems are involved. In specific sectors such as healthcare, where human control over algorithms is paramount, **ethical rules specific to the healthcare ecosystem** should be formulated. It's essential to create an **"ecosystem of trust"**.

Ethical guidelines including human agency and human oversight, are indispensable to ensure human values. If needed, physicians and health professionals should always be able to take decisions by using their own judgement against automated decisions. Healthcare professionals shall be responsible for the decisions they take and hence legally liable for them. It is hence crucial that physicians and healthcare professionals are properly trained on the functioning of algorithms and their potential limits. In specific sectors, such as healthcare, where human control over algorithms and decision making is paramount, ethic rules specific to that area should be formulated.[13] Patients should not be subject to an unfavourable decision based exclusively on AI. In addition, humans should be able to override a decision made by the system.[14] This can be different for cases, where no medical decision is involved, for example reimbursement or costs refund decisions made by the health insurance fund or health mutual. Decisions on medical treatment can be supported by AI (e.g. suggesting a specific pharmaceutical), but should never be reached without human agency and responsibility. The ethical value base associated with artificial intelligence should be defined individually for each application area.

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[12] Art 9 of the GDPR: Processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation shall be prohibited

[13] Work in the age of artificial intelligence, Finish national AI strategy from 2018. http://julkaisut.valtioneuvosto.fi/bitstream/handle/10024/160980/TEMjul_21_2018_Work_in_the_age.pdf.

[14] Ethics guidelines for trustworthy AIM, High-Level expert group on Artificial Intelligence from June 2019.

3. Trust in AI has to be established

> *AIM recommendation:* AI is not only about technological and social innovation, but **must be a trustworthy tool** while complying with applicable laws and ensuring adherence to ethical principles and values. Performance transparency is key to building this trust. Therefore, a health technology assessment is needed to analyze the efficiency of AI, especially if it concerns medical care reimbursed by compulsory health insurance. **Controlling bodies**, monitoring the safety and efficacy of an AI algorithm, would be an additional fundament to build that trust on.

AI is an important tool for innovation. Regulation should not hinder technological and social innovation nor should it prevent the development of a dynamic market.[15] At the same time, the new legal framework and ethical guidelines should promote a trustworthy AI system that complies with all applicable laws and regulations and ensures adherence to ethical principles and values in order to avoid causing unintentional harm.[16] Just because someone builds an AI application does not mean it can or should be used in healthcare. Trust is built over time, not achieved in a single battle. Doctors and patients must be able to trust in the efficacy of the AI software. They need to know they can count on the AI application to deliver accurate results substantially equivalent to or better than the current standard of care. Performance transparency is key to building this trust. Therefore, health technology assessment is needed to analyse the efficiency of AI, especially if it concerns medical care that is reimbursed by the compulsory health insurance. The European eHealth Network of Member States, established by the directive 2011/24/EU, can be used to exchange best practices. The EU has to issue regulations based on their proposals. Controlling bodies, monitoring the safety and efficacy of an AI algorithm, could help to establish trust in AI. Possibly an amendment to the Medical Device Regulation may entrust notified bodies with this task.

4. Transparency on the algorithms is needed

> *AIM recommendation:* Algorithms should be transparent. Data sets and processes that are used in building AI systems must be **documented and traceable. Explanations** on an AI system need to be **available**. It should contain how AI systems influence and shape the decision-making process, how they are designed and what is the rationale for deploying them. Where decisions made by self-learning AI systems that are not fully traceable to human presets, additional legal questions (e.g. concerning liability) must be tackled. The algorithm should be approved by an official authority, if the social security has a cost (reimbursement or benefit).

There can be no trust without transparency on the algorithms. Data sets and processes that are used in building AI systems should be documented and traceable. An AI system should be identifiable; humans need to be aware that they are interacting with such a system. An AI system needs to be explainable. The explanations on an AI decision- making system need to be available. Challenging will be the so-called **black box effect,** when it is impossible to understand how a system has come to a conclusion that will be a basis for a decision in health care or even for patient treatment. That's why an explanation needs to be available on how AI systems influence and shape the decision-making process, on how they are designed and what is the rationale for deploying them. Where decisions are

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[15] Gutachten der Datenethikkommission, https://www.bmi.bund.de/DE/themen/it-und-digitalpolitik/datenethikkommission/arbeitsergebnisse-der-dek/arbeitsergebnisse-der-dek-node.html (accessed on 24 March 2020).

[16] Briefing EU guidelines on ethics in artificial intelligence, 2019, https://www.europarl.europa.eu/RegData/etudes/BRIE/2019/640163/EPRS_BRI(2019)640163_EN.pdf (accessed on 24 March 2020.

not fully traceable to human presets, additional legal questions (e.g. to solve liability questions) must be faced. The algorithm should be approved by an official authority, such as if the social security has a cost (reimbursement or benefit).

5. Data of good quality is indispensable

AIM recommendation: To guarantee the use of objective, accurate and good quality data in respect of a certain purpose, **specific quality criteria for data collection** must be developed (for example when AI makes diagnoses on severe diseases like cancer). The collection and processing of data must comply with the General Data Protection Regulation (GDPR).

One of the biggest challenges of AI adoption in healthcare is the quality and relevancy of data that is used to train AI systems. Healthcare data can be subjective, inaccurate, and often siloed, which makes it difficult to make informed data-driven decisions. A large amount of data is not essential. It rather depends on the structured collection of biological and clinical data as well as the intelligent cross-linking of information.[17] Data collected for a specific purpose do not need to be significant in other contexts. For example doctors sometimes use a code for a specific disease to obtain the best treatment for the patient, although the patient does not have this disease. The information that more and more patients have this exact disease would be wrong. Therefore, quality criteria for the data used must be developed.

6. Safe and secure applications should not lead to risk selection in healthcare

AIM recommendation: The legal framework on artificial intelligence should contain safe and secure applications to prevent discrimination and risk selection in healthcare. The use of data should never have a negative impact on the fundamental rights of patients, like access to healthcare.

AI should be used to empower patients and to support access to and sustainability of solidarity-based healthcare systems. Personal data should not be used to discriminate patients. AIM members are organisations based on solidarity. They stand for no risk selection and make healthcare accessible for everybody. AI should not lead to excluding vulnerable groups or people with serious diseases from social security or make access more expensive. AI should not have a negative impact on the social rights guaranteed by the Pillar of Social Rights.

7. Standardisation should be limited to technologies and the safety of products

AIM recommendation: The work of the standardization institutions should be limited to standards on technologies, the safety of products used in health or nursing care or medical devices. When it comes to treatment, diagnosis and other medical intervention, a medical authority/organization should step in.

The work of the privately organised standardisation institutions can be genuine and valuable resources for technologies, such as the safety of products used in health or nursing care or medical devices. However, there is no added value in developing standards by private-sector standardisation bodies for

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[17] https://www.molecularhealth.com/wp-content/uploads/2019/11/20191112_Molecular-Health-1.pdf (accessed on 02/03/2020 in German)

the quality of health and social services provided by human beings. When it comes to treatment, diagnosis and other medical intervention, medical authorities/organisations should step in. It should be carefully evaluated, where the technical standard ends and where the medical treatments start.

8. Use of AI in health care should be accompanied by measures to improve eHealth literacy

AIM recommendation: The EU should initiate measures to promote the development of a basic understanding of e-health literacy especially in the context of AI followed by specific measures e.g. recommendations for member countries.

Since AI is an invisible but far reaching technological innovation that may influence everyday day life it should be accompanied by social innovation focussed on technology users. As a consequence the citizens of the EU – patients, physicians, scientists - should be able to make use of future AI solutions and offers in a competent and sensible manner and realise the full potential of the technology.

However, the need for e-health literacy contrasts with the knowledge that there is no shared basic understanding of health literacy in general and e-health literacy in particular among experts, and therefore no basic understanding of responsibilities and accountabilities. The EU should initiate measures to promote the development of a basic understanding of e-health literacy especially in the context of AI followed by specific measures e.g. recommendations for member countries.

Furthermore, in order that AI is accepted as a key technology by a broad majority of the population it is crucial to transparently and openly talk about the strengths, limits and consequences of this technology and its possible impact on diagnosis, therapies and behaviour. It should clearly be talked about the potential und specific personal benefits of the technology and the prerequisites to benefit personally from it.

Only the acceptance of the users, their trust in the AI algorithms and ultimately the adequate use will help this new technology to make a breakthrough.

Moreover, AIM emphasizes that:

1. Artificial intelligence should help to solve specific social and health problems

*AIM recommendation: AI allows **development of better policies based on AI predictions** (for example target the right group of persons for a prevention or health promotion campaign). It can be used to better foresee the impact a particular policy would have if implemented, to obtain a clearer picture of the best policies to implement to solve specific social problems. Like this, AI can be used to tackle the problem of inequalities and to identify vulnerable groups. AI could also assist in deploying resources in a more accurate, strategic, and affordable way.*

As we move forward, AI could be even used for social policy purposes. AI can make predictions based on large amounts of information. Governments and social and health organisations could greatly benefit from systems that allow development of better policies based on AI predictions. Governments and social and health organisations could better foresee the impact a particular policy would have, if implemented, or run tests to obtain a clearer picture of the best policies and to solve specific social problems. It could also assist in deploying resources in a more accurate, strategic, and affordable way.

For example, AI could be used to tackle the problem of inequalities. With algorithms, it might be possible to identify vulnerable groups or people that do not use all the rights they have. AIM is open to enter in the discussions and embrace innovation in this respect.

2. *Include all stakeholders*

AIM recommendation: The further development of machine learning systems and artificial intelligence should not only include computer scientists and industry but also not-for-profit healthcare insurances, doctors, hospitals, lawyers and economists.

AI is already impacting healthcare challenges today — both in spositive and negative ways. Therefore, further development of machine learning systems and artificial intelligence should not only include computer scientists and industry, but also not-for-profit healthcare insurances, doctors, hospitals, lawyers and economists. This will allow to use AI in a best possible way in the healthcare sector. Balanced decisions representing all different perspectives from all stakeholders involved are highly important, especially in the healthcare sector.

The International Association of Mutual Benefit Societies (AIM) is an international umbrella organisation of federations of health mutuals and other not-for-profit healthcare payers. It has 57 members from 30 countries in Europe, Latin America and Africa and the Middle East. 33 of its members, from 20 countries, are based in the European Union. AIM members provide compulsory and/or supplementary health coverage to around 240 million people around the world, including close to 200 million people in Europe, on a not-for-profit basis. Some AIM members also manage health and social services. Collectively, they have a turnover of almost €300 billion. AIM members are either mutual or health insurance fund.

They are: private or public legal entities; solidarity based; not-for-profit oriented organisations: surpluses are used to benefit the members; democratically-elected members play a role in the governance of the organisation. Info: www.aim-mutual.org – Contact: corinna.hartrampf@aim-mutual.org