Disclaimer: We kindly ask to acknowledge that due to the diverse and heterogeneous nature of the questions and dynamic situations they pertain to, some of the information might be incomplete or only correct for the time being. Thus, please consider the date and date of last update with the below information. All available information was provided by a country representative from the PHIRI network during or in connection to the respective meeting.

Date: 08.04.2024

Table 1: Country responses: Regulatory frameworks for artificial intelligence (AI) in health

Country	**Topic: Regulatory frameworks for artificial intelligence (AI) in health** • Are there any regulations, directives, or other forms of legislation available in your country that specifically relate to artificial intelligence in health care settings and population health? For instance, AI-specific legislation, regulations on the use of certain (commercial) algorithms, emerging or innovative technologies, etc. • How does this regulatory framework benefit or limit the use of AI in population health (research and management)? Equally, how does this regulatory framework safeguard the health and safety of consumers, citizens, and/or patients? • Is AI being used in your institute for population health purposes?
Austria	• In Austria, there are no specific laws besides the supranational AI-Act defined by the EU that apply solely to the use of artificial intelligence (AI) in healthcare. However, AI applications in healthcare are subject to various existing laws and regulations. Key legal issues in digital health include compliance with data protection laws, the requirement that only a licensed physician may give medical advice, and the determination of whether a product qualifies as a medical device (ICLG, 2024). Digital applications are playing an increasingly important role in the Austrian healthcare system, especially in hospital management and care. A GÖG report commissioned by the Ministry of Health provides an overview of telemedicine solutions and AI applications in the intramural sector in Austria. A total of 116 applications were identified, revealing the geographical and functional breadth of the field. The aim of the report is to test the possibilities of systematic monitoring of digitalisation developments and to support decision-makers in the relevant exchange and transfer of knowledge. This report is currently being updated. Similar to other EU countries, the states that most original research in Austria in this area focuses on image diagnostics and systems that aim to support diagnosis and treatment decisions by analysing medical records. In the area of research and development on AI in the healthcare sector, the scientific output at MedUni Vienna, MedUni Innsbruck, the Austrian Institute of Technology (AIT) and St. Anna Children's Hospital is highlighted with studies in the areas of neural networks, neuro-oncology, machine learning for cancer detection, predictive and preventive approaches to medicine and automated diagnostics. In addition, research into the technological aspects of AI in healthcare is being conducted at the AIT, the Vienna University of Technology, and the University of Applied Sciences Upper Austria (European Commission 2021b, 8). Furthermore, in Austria, an assessment framework for artificial intelligence is being considered as part of a reimbursement process for DiGAs and is being developed as a concept by Gesundheit Österreich GmbH. As part of this process, functions that make use of artificial intelligence, e.g. certain recommendations for health behaviour, etc., are to be tested and evaluated for their function and safety. As already mentioned, there are already various pilot projects in different health sectors in the federal states in Austria. Processes are still being developed that will also be useful for the regulatory framework. One example is the City of Vienna, which has also published its own strategy for the use of artificial intelligence as part of its Digital Agenda. This is intended to further develop the use of new technologies based on initial, concrete use cases. In addition, the strategy defines the necessary rules for the use of artificial intelligence and establishes framework conditions and guidelines for the ethical, transparent, and trustworthy use of AI. Of the 116 applications, 54 (46.6%) are in regular operation, 33 (28.4%) are in the pilot stage and 29 applications are in the status of a study, an application or temporarily in use. The ratio of pilot projects to regular operation is balanced in the field of AI. In the area of telemedicine, a larger proportion of applications are already in regular operation. In a comparison of the federal states (see Figure 1), the proportion of pilot projects is higher in Salzburg, Styria and Upper Austria than in Tyrol or Vienna. However, a larger number of projects are in the application stage in Tyrol and a number of research projects have been registered in Vienna and Styria. This leads to the use of AI varies greatly between the federal states, which makes standardised regulation and the exchange of knowledge more challenging.

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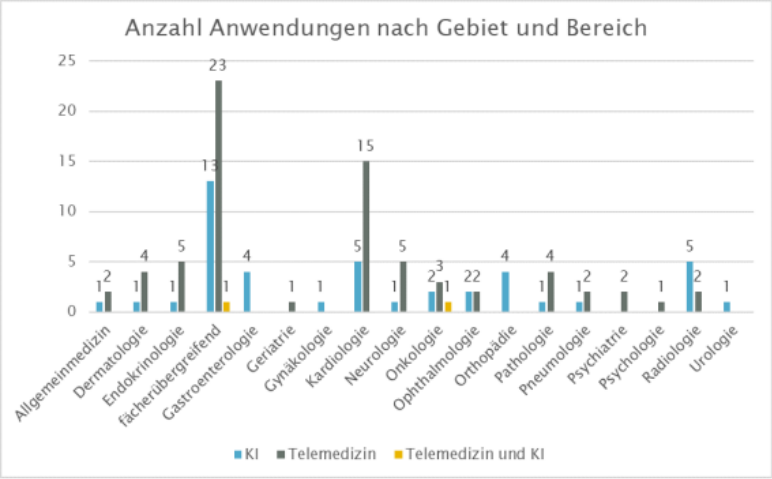

Figure 1: Number of applications by area and sector (source: Telemedizin und Künstliche Intelligenz im intramuralen Bereich Österreichs 2022).

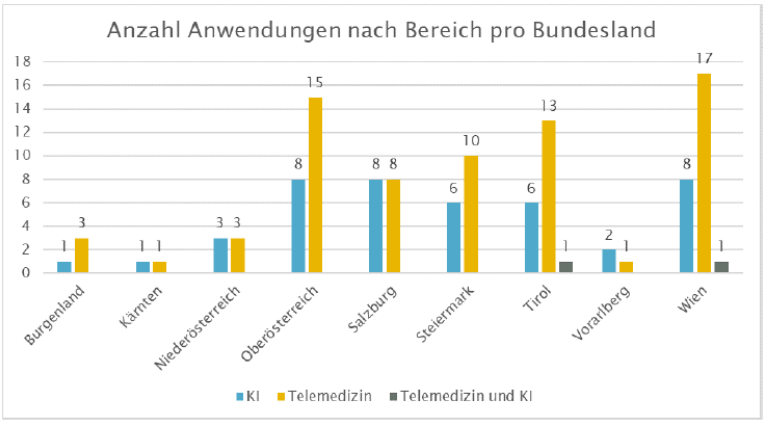

Figure 2: Number of applicants by implementation status 2023

- Such frameworks promote the responsible use of AI in healthcare. They help to ensure that AI applications are developed and used in a manner that respects data protection for example, while also giving a sense of security to developers of AI applications by ensuring them that their product can actually be brought to market.
- The Austrian National Public Health Institute is currently developing a set of guidelines for the responsible and ethical use of generative artificial intelligence (AI). These guidelines include principles such as data protection, transparency, validation, and responsibility. The benefits of the usage of AI tools within these guidelines lies in the described use cases above. As much of the work within the institute is related to interacting with documents in various ways, generative AI holds an inherent benefit here.
  However, there are also challenges associated with the use of AI. Since these systems can generate content that is not based on reality, and the generated content can be misleading, inaccurate, or discriminatory, one of the biggest challenges lies within creating awareness for these issues and training all colleagues accordingly. This also extends to the need for high data protection, as leaking confidential information from within the institute to an external AI application might be damaging.

Belgium	AI is not used much in Sciensano. What we would like to do is strengthen it, because health units could benefit greatly from it. There are some applications in use in the economic department, but not many. As far as legislation in Belgium is concerned, the AI act applies, as do all other data acts. In terms of data policy, there is a national interpretation of JDPA, which makes it a bit stricter. But even though the Health Data Agency is being set up, there is no binding national policy on specific issues.
Bosnia and Herzegovina	AI is used in daily work, but the legal regulation and a strategy are still under development.
Bulgaria	In Bulgaria many applications are used in medical care processes. It is not used as frequently in the public sector. Further information will be provided in written.

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Hungary	There is no specific regulation for AI in Hungary. A couple of months ago, the health government stated that affords were being made to create a national regulation and emphasized that AI will be used in the assessment of medical diagnoses. There are couples of studies and research projects that have been carried out by health universities. During a 2-year project involving researchers from the University of Debrecen and specialists from GE HealthCare, a modern artificial intelligence-based solution was created that enables the research of diagnostic image and text findings with the help of newly developed natural language processing (NLP) algorithms in Hungarian. The application of the innovative IT solution provides the opportunity for the targeted identification of patients who meet the specified criteria and, as a result, the inclusion of more patients in health research, which contributes to the effectiveness of clinical trials related to domestic and international pharmaceutical research. The State Secretary of Health emphasized that artificial intelligence would be used in the evaluation of imagers, supporting medical diagnostics. (2023. November, Digital Helath Conference, Hungary)
Malta	Malta has tried to mainstream AI as a sort of government policy direction. There is the so-called Malta Enterprise, which aims to promote direct investment and is working on an AI plan. The latest approach in this regard came from the UK, where a number of health trusts have been trying to add an AI layer on top of their data repositories. Malta was attractive for this initiative from Swansea University to try to implement and pilot this approach. Since 2019, there is a secondary processing legislation in place that also refers to AI. The need to revise this law is recognize in regard to both the upcoming EHDS and the AI act but is still in process. The Public Service in Malta has also introduced Microsoft Co-pilot for all employees, and many are using this generative AI platform (which includes the otherwise premium service ChatGPT 4.0) to support document preparation primarily. Malta's AI Strategy, published in 2019: https://www.mdia.gov.mt/malta-ai-strategy/ What could also be interesting is this discussion around an ethical framework in AI (please note that these two documents are not limited to health applications): https://www.mdia.gov.mt/wp-content/uploads/2023/04/Malta_Towards_Ethical_and_Trustworthy_AI.pdf
Netherlands	• The Netherlands counts on European legislation. Apart from the current discussions at EU level, no further national legislation is in preparation. • Nivel is working on national language processing tools to analyse electronical health records data that can be regarded as AI applications. The difficulty with AI is that it encompasses so many different aspects. There is no institutional policy in that respect.
Portugal	Legislation started in 2019. In 2020, a national call for research projects in the field of AI was launched and in 2021, Portugal's EU presidency, legislation in the field of artificial intelligence was pushed forward so that it would be adopted by most EU countries. Since then, legislation has been in place to support this topic. In terms of research and developing applications in population health, work is being carried out in 3 main areas: working with Chatbots to support patients after surgery (https://www.sciencedirect.com/science/article/pii/S1386505624000480). The role of AI in education is also currently being discussed. This is quite a challenge. Students should be motivated to use AI in a transparent way and always indicate how the AI has been used.
Serbia	Serbian AI governmental platform: https://www.ai.gov.rs Serbian ongoing AI strategy 2019-2025 (first review is expected): http://demo.paragraf.rs/demo/combined/Old/t/t2020_01/t01_0005.htm
Slovenia	In Slovenia, there is no specific regulation, or other form of legislation available at the moment, regarding artificial intelligence use in health care settings. There is currently some research and testing of the possibility of using AI to automate coding according to the NANDA classification and also some resarch in the field of diagnosis and treatment of borderline personality disorder with the help of artificial intelligence. But as said, nothing officialy implemented so AI is not used on any routine basis in healthcare in Slovenia.
Sweden	• In the institution of health sciences in Skövde, the discussion has been mostly focused on how to prevent students from cheating on their assignments with AI. I'm not aware of any special use in our teaching or research activities • In the Swedish healthcare, AI starts being used and there is a thesis that describes this that was published in 2022 https://www.diva-portal.org/smash/get/diva2:1679460/FULLTEXT02 and a summary document by • As for regulations, there are guidelines for the use of AI in the healthcare system published by the Swedish Drug authority: https://www.lakemedelsverket.se/4a5f16/globalassets/dokument/medicinteknik/artificiell-intelligens-ai/vagledning-anvandning-av-artificiell-intelligens-i-svensk-sjukvard.pdf and what I assume was a proposal from the Swedish Parliament to the EU during the discussion of the

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	new EU regulation on AI: https://data.riksdagen.se/fil/B9E2F955-31EA-4E9E-91EB-9AE0A3A8FFA7 • Finally, an organization called “AI Sweden” was founded a few years ago and is supposed to help private and public organizations implement AI in their work: https://www.ai.se/en

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