

# AI IN SWEDISH PATIENT CARE: THE EXISTING LEGAL BUILDING BLOCKS\*

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Artificial intelligence, as a field of technology, has advanced significantly over the last decade. Although it has not reached its peak, it has already found its place in Swedish healthcare, including in patient care. It is therefore highly desirable to clarify how the law addresses AI in healthcare in Sweden. However, comprehensive insights remain quite limited. This article aims to fill this gap and explore the existing legal building blocks for the use of AI in healthcare. It highlights the scope and limitations of applicable laws in ensuring patient protection, as well as the complex interplay between EU law on the quality and safety of AI in healthcare, on the one hand, and national healthcare regulation, on the other. It puts forward a four-tier model for integrating EU requirements surrounding AI in the Swedish standard of care, science and proven experience, and shows how informed consent elements can support disclosure of AI use in patient care. Finally, it illuminates the challenges that emerge when integrating AI into patient care in Sweden and indicates areas for further legal inquiry to enhance legal certainty in the field.

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## 1. Introduction

Artificial intelligence (AI) is broadly understood as a system's ability to interpret provided data, learn from it, and use this learning to achieve particular goals and tasks through adaptation.<sup>1</sup> It entails the use of various computational methods that use data in forms such as text, images, and sound to enable programs to perform specifically defined or requested tasks.<sup>2</sup> Within the broader

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<sup>1</sup> Andreas Kaplan and Michael Haenlein, *Siri, Siri, in My Hand: Who's the Fairest in the Land? On the Interpretations, Illustrations, and Implications of Artificial Intelligence*, *Business Horizons* vol. 62, 2019 p. 15.

<sup>2</sup> There are various attempts to define AI, however, none of the definitions is challenge-free. For insights into the scholarship, see, for example, Denis Steckelmacher, Bart Bogaerts, *Definition*

field of AI, machine learning refers to algorithms that automatically extract knowledge from provided input data.<sup>3</sup> Natural language processing enables computers to interpret, create, and utilize different human languages.<sup>4</sup> Large language models (LLMs), such as those at the core of well-known systems like ChatGPT and Claude, have experienced significant advances in performance, reliability, and safety.<sup>5</sup> Moreover, in addition to general LLMs, there are also LLMs emerging for particular tasks. Examples include Med-PaLM, a large language model from Google Research, developed for the health field,<sup>6</sup> and BioBERT, Bidirectional Encoder Representations from Transformers for Biomedical Text Mining, a domain-specific language representation model, which is pre-trained on large-scale biomedical literature.<sup>7</sup>

AI is widely regarded as one of the most transformative forces of our era.<sup>8</sup> In healthcare, it is already an everyday clinical reality, contributing to, for example, diagnostic automation, precision medicine, and operational workflows.<sup>9</sup> Significant developments have taken place over the last few years, partially due to the volume of data generated in healthcare,<sup>10</sup> but its full potential is yet to be realized.<sup>11</sup> While state-of-the-art large language models have been reported to challenge physicians on benchmarks, these gains have yet to trans-

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of AI. I: Vera Lucia Raposo (eds.) *The European Artificial Intelligence Act*, Springer 2025. For a regulatory definition, in so far as the AI Act applies, see Article 3(1) of the AI Act, Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (Text with EEA relevance) PE/24/2024/REV/1 OJ L, 2024/1689.

<sup>3</sup> Denis Steckelmacher, Bart Bogaerts, Definition of AI. I: Vera Lucia Raposo (ed.) *The European Artificial Intelligence Act*, Springer 2025.

<sup>4</sup> Chihung Lin, Chang-Fu Kuo, Roles and Potential of Large Language Models in Healthcare: A Comprehensive Review, *Biomedical Journal* vol. 48(5), 2025 p. 100868.

<sup>5</sup> Robert Korom et al., AI-based Clinical Decision Support for Primary Care: A Real-World Study, *arXiv:2507.16947*, 2025 p. 1.

<sup>6</sup> See Med-PaLM, <https://sites.research.google/gr/med-palm/>. See also Karan Singhal et al., Large Language Models Encode Clinical Knowledge, *Nature* vol. 620, 2023 p. 172 and Karan Singhal et al., Toward Expert-level Medical Question Answering with Large Language Models, *Nature Medicine* vol. 31, 2025 p. 943.

<sup>7</sup> Jinhyuk Lee et al., BioBERT: A Pre-trained Biomedical Language Representation Model for Biomedical Text Mining, *Bioinformatics* vol. 36(4), 2020 p. 1234.

<sup>8</sup> Christos Chatzichristos, Bridging the AI-Literacy Gap in Health Care: Qualitative Analysis of the Flanders Case Study, *Journal of Medical Internet Research*, 2025 p. 1.

<sup>9</sup> Zahir Babar et al., AI Applications in Emerging Tech Sectors: A Review of AI Use Cases Across Healthcare, Retail, and Cybersecurity, *American Scholarly Research Conference* vol. 1, 2025.

<sup>10</sup> Andre Esteve et al., A guide to deep learning in healthcare, *Nature Medicine* vol. 25, 2019 p. 24.

<sup>11</sup> For challenges with bringing AI into the medical education, see Trista M Benítez et al., Harnessing the Potential of Large Language Models in Medical Education: Promise and Pitfalls, *Journal of the American Medical Informatics Association* vol. 31(3), 2024 p. 776.

Förvaltningsrättslig tidskrift 2026, <https://doi.org/10.53292/b27d21fc.bbae46fa>

late into concrete benefits for patients and healthcare providers.<sup>12</sup> As noted by Korom et al., there is a bottleneck in the AI ecosystem, specifically the gap between model capabilities and their implementation in healthcare settings.<sup>13</sup> However, there are reasons that explain the bottleneck, at least for the EU, including those associated with AI opacity.<sup>14</sup>

This widespread integration is clearly reflected in Sweden as well. In 2025, there were 98 AI-related initiatives reported in healthcare, covering areas such as diagnostics and prediction-based diagnosis, clinical care, resource allocation and prioritization, and the role of patients in clinical care.<sup>15</sup> Although formal statistics on the use of AI in healthcare are lacking, the available insights offer a glimpse. In 2024, it was reported that one in four medical doctors has used AI in their work in some way.<sup>16</sup> Such uses include medical record writing, image and signal diagnostics, and translation.<sup>17</sup>

Despite AI now being part of Swedish healthcare, the legal discussion has lagged significantly behind. In 2026, the Swedish Medical Products Agency updated its guidance on the use of AI in Swedish healthcare, addressing questions such as product classification and liability, and highlighting ethical concerns.<sup>18</sup> The Swedish National Council on Medical Ethics (Statens medicinsk-etiska råd, SMER) has also examined the diverse uses of AI and its ethical considerations.<sup>19</sup> Although these are important guidance documents that consider the existing legal frameworks, a legal analysis of how AI use fits within the existing legal building blocks of Swedish healthcare

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<sup>12</sup> Robert Korom et al., AI-based Clinical Decision Support for Primary Care: A Real-World Study, arXiv:2507.16947, 2025.

<sup>13</sup> Robert Korom et al., AI-based Clinical Decision Support for Primary Care: A Real-World Study, arXiv:2507.16947, 2025.

<sup>14</sup> Alberto Fernández, Opacity, Machine Learning and Explainable AI in Lara, F., Deckers, J. (ed) *Ethics of Artificial Intelligence. The International Library of Ethics, Law and Technology*, vol. 41, Springer 2024.

<sup>15</sup> AI Sweden, Vårdkartan. En kartläggning av svenska regioners AI-initiativ inom vårdsektorn, 2025, <https://www.ai.se/sites/default/files/2025-04/vardkartan-rapport-april-2025-v2.pdf>.

<sup>16</sup> Anna-Cajsa Torkelsson, Många läkare använder AI i jobbet – men förbundet varnar för risker, Läkartidningen, 2024, <https://lakartidningen.se/nyheter/manga-lakare-anvander-ai-i-jobbet-men-forbundet-varnar-for-risker/>.

<sup>17</sup> Anna-Cajsa Torkelsson, Många läkare använder AI i jobbet – men förbundet varnar för risker, Läkartidningen, 2024, <https://lakartidningen.se/nyheter/manga-lakare-anvander-ai-i-jobbet-men-forbundet-varnar-for-risker/>.

<sup>18</sup> See Läkemedelsverket, Vägledning rörande användning av artificiell intelligens i svensk hälso- och sjukvård, 2026, [https://www.lakemedelsverket.se/globalassets/dokument/medicinteknik/artificiell-intelligens-ai/vagledning-anvandning-av-artificiell-intelligens-i-svensk-sjukvard\\_ver\\_2.pdf](https://www.lakemedelsverket.se/globalassets/dokument/medicinteknik/artificiell-intelligens-ai/vagledning-anvandning-av-artificiell-intelligens-i-svensk-sjukvard_ver_2.pdf).

<sup>19</sup> SMER, Kort om Artificiell intelligens i hälso- och sjukvården, 2025, [https://smer.se/wp-content/uploads/2025/05/kort-om-ai-i-halso-och-sjukvarden-smer-2025\\_1.pdf](https://smer.se/wp-content/uploads/2025/05/kort-om-ai-i-halso-och-sjukvarden-smer-2025_1.pdf).

remains uncharted.<sup>20</sup> As recently as 2025, calls were made emphasizing that national guidelines regarding how the law regulates AI in healthcare are necessary.<sup>21</sup> Clarity in the field is a starting point for further legal inquiries and for addressing key problems, such as liability for violations of patient rights and protections,<sup>22</sup> including cases where a patient has suffered harm due to AI involvement in healthcare.

Against this background, the article addresses this legal gap in understanding how the current legal framework responds to AI in healthcare. Through a doctrinal legal inquiry, it examines the legal preconditions for the use of AI in patient care shaped by EU law and national legal requirements. The inquiry is confined to the regulation of medical devices, *in vitro* diagnostic medical devices, AI, and the provision of healthcare.<sup>23</sup> Questions such as data protection in connection with the use of AI in patient care, as well as broader human rights implications, are considered as part of the overview of the legal framework and when contextualizing the specific legal questions. However, a deeper analysis falls outside the scope of this article due to space constraints. Likewise, specific questions related to the use of AI in patient care, such as liability, are highlighted but not examined in detail due to these same limitations.

The article begins by providing an overview of key legal acts shaping the legal preconditions for the use of AI in patient care in Sweden. It then explores the requirements pertaining to AI as software. Thereafter, it addresses the legal requirements placed on healthcare providers that shape patient protection. This mapping highlights the scope and limitations of applicable laws in ensuring patient protection, as well as the complex interplay between EU law on the quality and safety of AI in healthcare, on the one hand, and national healthcare regulation, on the other. The intersection of this mapping sets a foundation for a four-tier model for integrating EU requirements for AI in

<sup>20</sup> Some exploration, highlighting key challenges and current themes within AI in healthcare, has been made by Titti Mattsson and Petra Holmberg, see E-hälsa, I: Kavot Zillén, Titti Mattsson, Santa Slokenberga, (eds.), *Medicinsk rätt*, 3 vol. 2025 p. 139–154.

<sup>21</sup> *Vårdkartan: En kartläggning av svenska regioners AI-initiativ inom vårdsektorn*, rapport, April 2025, <https://www.ai.se/sites/default/files/2025-04/vardkartan-rapport-april-2025-v2.pdf>. This places an emphasis on national guidelines.

<sup>22</sup> In Swedish law, the protections afforded to patients are not called rights, despite their human rights foundations. Rather, as pointed out by Lind and Litins'ka, rights are realized through a number of foundational principles in Swedish healthcare, including the principle of human dignity, need and solidarity, as well as cost-effectiveness. Anna-Sara Lind, Yana Litins'ka, Rätten till hälsa och den medicinska rätten, I: Kavot Zillén, Titti Mattsson, Santa Slokenberga (eds.), *Medicinsk rätt*, 3 vol. 2025 p. 55.

<sup>23</sup> It does not, thus, address the use of AI in healthcare more broadly, excluding dimensions such as AI for healthcare administration and administrative tasks, such as medical record writing. Neither does it cover specific dimensions relating to the use, e.g., patient data processing.

the Swedish standard of care, science and proven experience. Moreover, it shows how informed consent requirements can support AI use disclosures in patient care. Finally, it illuminates challenges that emerge when bringing AI into patient care in Sweden and indicates areas for further legal inquiry to enhance legal certainty in the field.

## 2. An Overview of the Legal Framework

### 2.1 Multiple Layers of Regulation

Although there is no single specific law governing AI in Sweden, it is nonetheless subject to a considerable legal framework. The legal framework governing the use of AI in patient care is highly complex and consists of multiple co-existing and overlapping layers of regulation. The implementation of AI technologies in patient care must comply with not only relevant national Swedish laws, in particular, those regulating the provision of health and medical care, patient safety, patient integrity, and patient data protection, but also with a broad range of EU legal requirements, rooted in the internal market, public health, and data protection. Furthermore, the use of AI in patient care also raises human rights considerations, including those relating to privacy protection, autonomy, and equality. International human rights, however, have a rather complex relationship with Swedish national law, and that applies to health matters too.<sup>24</sup> While fundamental rights are set out in the constitution, the effects of international human rights instruments on the use of AI in patient care vary by instrument. In the following sections, therefore, emphasis is placed on the former two: EU and national law.

### 2.2 EU Law for AI in Patient Care

Key EU legal requirements are set out in four regulations: the AI Act,<sup>25</sup> the Medical Devices Regulation (MDR),<sup>26</sup> the *In Vitro* Diagnostic Medical Devices

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<sup>24</sup> See Yana Litins'ka, *Folkkrätten i svensk medicinsk rätt*, in Anna-Sara Lind, Rebecca Thorburn Stern, Inger Österdahl (eds.) *Folkkrätten i svensk rätt. Ett nytt decennium*, 2024 p. 271.

<sup>25</sup> Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828, OJ L, 2024/1689, 12.7.2024.

<sup>26</sup> Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 5.5.2017 pp. 1–175.

Regulation (IVDR),<sup>27</sup> as well as the General Data Protection Regulation (GDPR).<sup>28</sup> These create directly applicable obligations, and the latter three are also complemented by national laws implementing particular provisions of the respective regulations.<sup>29</sup>

Under EU law, medical devices and *in vitro* diagnostic devices, including software, have long been subject to regulation. Most recently, these are regulated under the MDR and IVDR, both adopted in 2017. The requirements set out in these regulations are primarily intended to ensure a high level of health and safety, whilst also supporting the functioning of the internal market. While these legal instruments provide for a harmonized EU-wide framework, they also leave some room for further national regulation, e.g., in the area of in-house medical devices or *in vitro* diagnostic medical devices.

AI use in patient care is also subject to the newest addition to the field, the EU AI Act,<sup>30</sup> adopted in 2024, which has already been amended in 2026 with the Digital Omnibus on AI.<sup>31</sup> The AI Act is a horizontal legal framework, focused specifically on AI. Pursuant to Article 3(1) of the AI Act, it captures the AI that falls within the scope of “AI systems”, and this Act co-exists with the sectoral frameworks, including those for medical devices and *in vitro* diagnostic medical devices.

Insofar as the use of AI in patient care entails the processing of patient data, the GDPR also applies. It not only defines legal preconditions for the processing of patient data but also sets out a range of data-related rights for patients and obligations on healthcare providers. Among those is the right not

<sup>27</sup> Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, OJ L 117, 5.5.2017 pp. 176–332.

<sup>28</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance) OJ L 119, 4.5.2016 pp. 1–88.

<sup>29</sup> See Act containing supplementary provisions to the EU General Data Protection Regulation (Lag med kompletterande bestämmelser till EU:s dataskyddsförordning) SFS 2018:218 and the Swedish Medical Products Agency's regulations on supplementary provisions to the EU Regulation on medical devices (Läkemedelsverkets föreskrifter om kompletterande bestämmelser till EU:s förordning om medicintekniska produkter) HSLF-FS 2021:32.

<sup>30</sup> Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (Text with EEA relevance) OJ L, 2024/1689, 12.7.2024.

<sup>31</sup> Regulation (EU) 2026/1744 of the European Parliament and of the Council of 8 July 2026 amending Regulations (EU) 2024/1689, (EU) 2018/1139 and (EU) 2023/1230 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI) (Text with EEA relevance) OJ L, 2026/1744, 24.7.2026.

to be subject to a decision based solely on automated processing, except for when allowed under the GDPR, with further constraints for the processing of health data,<sup>32</sup> as well as a right to object to data processing in some cases.<sup>33</sup>

The EU legal requirements set out in the MDR, IVDR, and AI Act, however, are predominantly focused on technology regulation rather than on its use. Nonetheless, the AI Act sets out two important use-related requirements: AI literacy and human oversight, examined in detail below. The organization and delivery of healthcare, pursuant to Article 168(7) of the Treaty on the Functioning of the European Union,<sup>34</sup> are reserved to the Member States and are commonly organized taking into account their relevant international human rights commitments.

### 2.3 National Law for the Use of AI in Patient Care

Key national legal requirements regarding the use of AI in patient care are set out in the Health and Medical Care Act.<sup>35</sup> Key requirements regarding patient safety are set out in the Patient Safety Act.<sup>36</sup> Central requirements relating to

<sup>32</sup> See Article 22 GDPR. This provision is subject to amendments as part of the Digital Omnibus package. This provision currently constrains when a patient may be subject to a decision based solely on automated processing. However, given that the norm applies to decisions “based solely on automated processing”, cases where AI is used to support human decision-making would currently not fall within the scope of this provision. As elaborated by Working Party 29 in guidelines endorsed by the EDPB, where a human being reviews the automated recommendation and considers other factors in arriving at the final decision, the decision in question would not meet the criterion “solely” mandated by Article 22(1). See Guidelines on Automated individual decision-making and Profiling for the purposes of Regulation 2016/679 (wp251rev.01), p. 20.

<sup>33</sup> See Article 21 GDPR. Whether a right to object to the processing is relevant will depend on the legal basis for the provision of care. Pursuant to Article 21(1) of the GDPR, this applies when data processing in healthcare is based on legitimate interests pursuant to Article 6(1)(f) of the GDPR, or when the processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller pursuant to Article 6(1)(e) of the GDPR. While the former is unlikely, the latter may be relevant in some cases. See Table A1.1, p. 29, [https://health.ec.europa.eu/system/files/2021-02/ms\\_rules\\_health-data\\_en\\_0.pdf](https://health.ec.europa.eu/system/files/2021-02/ms_rules_health-data_en_0.pdf). Consequently, the healthcare provider shall no longer process the personal data unless the controller demonstrates compelling overriding legitimate grounds for the processing in accordance with Article 21(1) GDPR. The Patient Data Act sets some constraints on data processing in connection with a patient medical record, but not in connection with healthcare per se. See Chapter 2 Section 2 of the Patient Data Act (Patientdatalag) SFS 2008:355.

<sup>34</sup> Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union Consolidated version of the Treaty on European Union Consolidated version of the Treaty on the Functioning of the European Union Protocols Annexes to the Treaty on the Functioning of the European Union Declarations annexed to the Final Act of the Intergovernmental Conference which adopted the Treaty of Lisbon, signed on 13 December 2007 Tables of equivalences, OJ C 202, 7.6.2016 pp. 1–388.

<sup>35</sup> Health and Medical Care Act (Hälsö- och sjukvårdslag) SFS 2017:30.

<sup>36</sup> Patient Safety Act (Patientsäkerhetslag) SFS 2010:659.

the protection of patients are set out in the Patient Act,<sup>37</sup> and patient data protections are addressed through a range of legal requirements in addition to the Patient Data Act and the more general law implementing the GDPR,<sup>38</sup> as well as the Public Access and Confidentiality Act for public healthcare providers and the Patient Safety Act for private healthcare providers.<sup>39</sup> While neither of these laws addresses AI specifically, each of them adds a fundamental dimension to the protection of core human rights related to the use of AI in patient care, such as the right to health and the protection of informational and bodily integrity. Moreover, other regulations can also be relevant in particular contexts, such as the Swedish Medical Products Agency's regulations on supplementary provisions to the EU Regulation on medical devices for the in-house development and use of AI in patient care.<sup>40</sup>

### 3. EU Legal Requirements for AI Software

#### 3.1 MDR, IVDR and the AI Act

The exact EU requirements differ depending on the AI in question and the modalities surrounding it. The MDR and IVDR are mutually exclusive. If a healthcare product is classified as a medical device, it will be subject to MDR requirements. Whereas, if it is an *in vitro* diagnostic medical device, it will fall under the IVDR requirements. The AI Act, however, as a horizontal legal framework covering AI more generally, will apply in many cases in addition to those requirements. This has generated a complex coexistence between these legal frameworks,<sup>41</sup> an issue that is being tackled by the EU legislator: firstly, through the mentioned Digital Omnibus on AI amendments;<sup>42</sup> sec-

<sup>37</sup> Patient Act (Patientlag) SFS 2014:821.

<sup>38</sup> Act containing supplementary provisions to the EU General Data Protection Regulation (Lag med kompletterande bestämmelser till EU:s dataskyddsförordning) SFS 2018:218.

<sup>39</sup> Public Access and Confidentiality Act (Offentlighets- och sekretesslag) SFS 2009:400 and Patient Safety Act (Patientsäkerhetslag) 2010:659.

<sup>40</sup> HSLF-FS 2021:32.

<sup>41</sup> E.g., Marinella Quaranta, *Obligation for AI Systems in Healthcare: Prepare for Trouble and Make it Double?*, *The Review of Socionetwork Strategies*, vol. 17, 2023 p. 275.

<sup>42</sup> See Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI), COM/2025/836 final. See also Regulation (EU) 2026/1744 of the European Parliament and of the Council of 8 July 2026 amending Regulations (EU) 2024/1689, (EU) 2018/1139 and (EU) 2023/1230 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI) (Text with EEA relevance) OJ L, 2026/1744, 24.7.2026.

only, through the revision of the MDR and IVDR.<sup>43</sup> Insofar as the AI system processes patient data, the GDPR will apply.

Thus far, in the AI medico-legal discussions, significant focus has been placed on software as a medical device (Sa MD) or AI as a medical device (AI MD). AI *in vitro* diagnostic medical devices (AI-in-IVD) have received significantly less attention in the legal debate.<sup>44</sup> This is despite the fact that the strategic pivot of the AI-in-IVD is paramount, given that about 60–70% of all critical clinical decisions, from diagnosis to treatment, are estimated to be influenced by information derived from laboratory tests.<sup>45</sup>

### 3.2 AI as a Medical Device or an *in vitro* Diagnostic Medical Device

#### 3.2.1 Definitions and Their Borders

MDR and IVDR regulate the placing on the market or putting into service of medical devices and *in vitro* diagnostic medical devices, as well as their accessories.<sup>46</sup> Both regulations are based on largely similar regulatory approaches. Designed in the last decade, neither of them envisages specific rules for AI. Instead, the general rules on the classification of software presented below apply.

Under the MDR, software will be classified as a ‘medical device’ and also regarded as an active medical device<sup>47</sup> if the manufacturer’s intention with the software corresponds to any of the uses specified in the MDR and it simultaneously does not achieve its principal intended action by pharmacological, immunological, or metabolic means, in or on the human body. The listed uses for when an AI can be regarded as a medical device are “diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,” “diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or

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<sup>43</sup> See Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and *in vitro* diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I, COM(2025) 1023 final.

<sup>44</sup> See e.g., Ugur Ilker Atmaca, Data-driven Medical Devices and the EU MDR: Mapping Gaps in Standards for Regulatory Compliance, *npj Health Systems* vol. 3, 2026 p. 1.

<sup>45</sup> Hieu Le Ngoc, Artificial Intelligence in *In Vitro* Diagnostics (IVD): A Comprehensive Review of the New Frontier, *IEEE Access* vol. 14, 2026 p. 19536. See also Jicui Dong et al., Artificial Intelligence Applied to Local Production of Diagnostic Tests, *Bull World Health Organ*, vol. 103(12), 2025 p. 826, emphasizing the potential of integration of AI technologies in local *in vitro* diagnostic production.

<sup>46</sup> Article 1.1. MDR and Article 1.1 of IVDR.

<sup>47</sup> See Article 2(4) MDR.

disability”, and “investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,” as well as “providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations”.<sup>48</sup> Other software, including that which may be used in a health context or even a healthcare setting, but does not deliver the specified information, will not be regarded as medical devices. Those include, for example, software for lifestyle and well-being purposes,<sup>49</sup> which may have links to health, such as a healthy lifestyle (e.g., pulse, weight monitoring). They are nonetheless subject to the general product safety requirements.<sup>50</sup> Examples of AI MD include Aidoc, released in 2019 and intended for identifying and triaging pulmonary embolism in computer tomography pulmonary angiograms,<sup>51</sup> and BoneXpert, which performs automatic determination of bone age and the bone health index.<sup>52</sup>

On the other hand, under the IVDR, a software will be regarded as an *in vitro* diagnostic medical device if the manufacturer intends it, among other things, to examine “specimens... solely or principally for the purpose of providing information” concerning a physiological or pathological process or state, congenital physical or mental impairments, concerning the predisposition to a medical condition or a disease, to determine the safety and compatibility with potential recipients, to predict treatment response or reactions, or to define or monitor therapeutic measures.<sup>53</sup> Examples of AI-in-IVD include SOPHiA DDM™ Platform, intended for analysing, standardizing, and interpreting complex healthcare data,<sup>54</sup> as well as QIAGEN Clinical Insight Interpret for oncology and hereditary applications.<sup>55</sup>

Both the MDR and IVDR focus on manufacturers’ responsibilities and set requirements that must be met to ensure a device is deemed safe before it is placed on the market. Generally, an AI-based device that is classified as

<sup>48</sup> Article 2(1) MDR.

<sup>49</sup> See Recital 19 MDR.

<sup>50</sup> Another question is if these can be deemed satisfactory. For example, Yu has been critical of the absence of a special legislation in the field. Yu H, Regulation of Digital Health Technologies in the European Union: Intended versus Actual Use, in I.G. Cohen et al. (eds.). *The Future of Medical Device Regulation: Innovation and Protection*, Cambridge University Press, 2022, p. 113.

<sup>51</sup> Aidoc, Announcing our CE Mark for the First AI-based Workflow Tool for Pulmonary Embolism, <https://www.aidoc.com/learn/blog/announcing-ce-mark-for-pulmonary-embolism/>.

<sup>52</sup> BoneXpert, <https://bonexpert.com>.

<sup>53</sup> Article 2(2) IVDR.

<sup>54</sup> SOPHiA Genetics, <https://www.sophiagenetics.com/sophia-ddm/>.

<sup>55</sup> QIAGEN, QIAGEN receives European IVDR certification for QIAGEN Clinical Insight Interpret, its medical device software for clinical decision support, 2024, <https://corporate.qiagen.com/English/newsroom/press-releases/press-release-details/2024/QIAGEN-receives-European-IVDR-certification-for-QIAGEN-Clinical-Insight-Interpret-its-medical-device-software-for-clinical-decision-support/default.aspx>.

a medical device or an *in vitro* diagnostic medical device may be placed on the market or put into service only if it complies with the requirements set out in the MDR or IVDR.<sup>56</sup> Key among those are the general safety and performance requirements set out in Annex I to each regulation.<sup>57</sup> Devices that meet the applicable requirements shall bear a Conformité Européenne (CE) mark, signifying conformity with the MDR or IVDR. Devices with a CE mark may freely circulate in the EU internal market. However, the considerable requirements placed on the manufacturer have some parallels with the manufacturer's role and the limitations that follow. Both legal instruments take the manufacturer's intention as a point of departure for then tailoring the content of the applicable requirements. That also means a manufacturer cannot, consequently, take responsibility for the off-label use of the devices that it has put on the market.

### 3.2.2 *Conformity with the Applicable Requirements*

The exact requirements applicable to AI as a medical device or as an *in vitro* diagnostic medical device will depend on the device's classification under these frameworks. One central dimension is the assessment of conformity with the applicable requirements. The MDR and the IVDR create two different classification systems, but within those they follow similar principles. Devices that fall within a lower-risk class have less stringent requirements than those in a higher-risk class. Software as a medical device or *in vitro* diagnostic medical device is commonly jointly addressed as medical device software,<sup>58</sup> whereas AI as a medical device is commonly regarded as Medical Device Artificial Intelligence (AI MD).<sup>59</sup>

Under the MDR, medical devices are classified as follows: Class I, IIa, IIb, and III.<sup>60</sup> Active devices, which include software as a starting point, are classified as Class IIa, IIb, or even Class III.<sup>61</sup> Pursuant to Rule 11, software used for diagnostic or therapeutic decisions is generally Class IIa, unless errors could cause death or irreversible harm, which would render it a Class III device, or serious harm/surgical intervention, which would render it a Class IIb device.

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<sup>56</sup> Article 5.1 IVDR and Article 5.1 MDR.

<sup>57</sup> See Articles 5.2 MDR and 5.2 I IVDR.

<sup>58</sup> Medical Device Coordination Group Document, Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR, October 2019, June 2025 rev.1, p. 7.

<sup>59</sup> Medical Device Coordination Group Document, Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR, October 2019, June 2025 rev.1, p. 4.

<sup>60</sup> Software is classified as classification rules are set out in Annex VIII MDR.

<sup>61</sup> Annex VIII, Chapter III.6.1 MDR.

Software for monitoring vital physiological parameters that could pose immediate danger is Class IIb, while all other software that falls under the definition of a medical device is Class I.<sup>62</sup> Before an AI MD is placed on the market, conformity assessment must be conducted.<sup>63</sup> For most Class I devices, conformity with applicable requirements is self-certified by the manufacturer,<sup>64</sup> whereas for Class IIa, IIb, and III devices, a notified body is involved. Only the successful completion of this process allows the CE mark to be affixed, indicating compliance with the applicable requirements.<sup>65</sup> The conformity assessment procedure varies depending on the device class.

Under the IVDR, *in vitro* diagnostic medical devices are divided into classes A, B, C, and D based on their intended purpose and inherent risks, with Class A being the lowest risk and Class D the highest risk.<sup>66</sup> Class D covers devices used for detecting transmissible agents in blood, tissue, organs, cells, or their derivatives to assess transfusion, transplantation suitability, or cell administration. Devices intended for blood grouping or tissue typing can be Class D or C, depending on which markers they detect.<sup>67</sup> Class C covers the detection of a range of serious diseases, including screening, diagnosis, or staging of cancer; the management of patients with life-threatening diseases or conditions; and screening for congenital disorders in the embryo or fetus. Self-testing devices are considered Class C devices, except for pregnancy detection, fertility testing, cholesterol determination, and devices for detecting glucose, erythrocytes, leucocytes, and bacteria in urine. In such a case, the devices are Class B.<sup>68</sup> Class A includes general laboratory products and their accessories without critical characteristics.<sup>69</sup> Finally, Class B also includes devices not covered by the detailed classification rules and devices that are controls without a quantitative or qualitative assigned value.<sup>70</sup> Unlike under the MDR, there is no specific software rule for diagnostic medical devices. For Class A devices, other than those for performance study, manufacturers shall declare the conformity of their products by issuing the EU declaration of con-

<sup>62</sup> Annex VIII, Chapter III.6.3 MDR.

<sup>63</sup> Article 52(1) MDR.

<sup>64</sup> Exceptions apply to medical devices that have a measuring function (known as Class Im), that are placed on the market as sterile devices (known as Class Is), or are reusable surgical instruments (known as Class Ir). See further Läkemedelsverket, Risk classification, 2021, <https://www.lakemedelsverket.se/en/medical-devices/manufacture/risk-classification#hmainbody1>.

<sup>65</sup> Article 20(1) MDR.

<sup>66</sup> Classification shall be carried out in accordance with Annex VIII (Article 47.1 IVDR). Section 1 of Chapter V of the IVDR addresses classification.

<sup>67</sup> See Annex VIII, Section 2.1 and 2.2 IVDR.

<sup>68</sup> See Annex VIII, Section 2.3 and 2.4 IVDR.

<sup>69</sup> See Annex VIII, Section 2.5 IVDR.

<sup>70</sup> See Annex VIII, Section 2.6 and 2.7 IVDR.

formity referred to in Article 17, after preparing the technical documentation set out in Annexes II and III. Devices for performance study that fall within Class A, as well as Classes B, C, and D, require the involvement of a notified body for conformity assessment.

Crucially, for software to be regarded as a medical device, its location and mode of operation are irrelevant. Namely, whether they are applications on a computer or a phone, whether they are cloud-based, or whether they are embedded in a particular technology. Moreover, different interconnections are possible, e.g., Bluetooth or Wi-Fi, as well as those that do not bear on the classification.

### 3.2.3 *AI as an AI System under the AI Act*

The AI Act regulates the development, placing on the market, and putting into use of AI systems within the EU.<sup>71</sup> Its scope covers, among others, providers<sup>72</sup> that place on the market or put into service AI systems or general-purpose AI models in the Union, regardless of whether those providers are established or located within the EU or outside it.<sup>73</sup> Moreover, it also applies to those classified as deployers of AI systems, namely, those who use an AI system under their authority except where the AI system is used in the course of a personal non-professional activity,<sup>74</sup> if they have their place of establishment or are located within the EU,<sup>75</sup> for example, hospitals, as well as AI system providers and deployers that are established or located in a third country, if the output produced by the AI system is used in the EU.<sup>76</sup>

AI systems under Article 3(1) of the AI Act are defined as a machine-based system (i.e., AI systems run on machines)<sup>77</sup> “that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments”, where environments are considered to be the contexts in which the AI systems

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<sup>71</sup> Article 2.1(a) AI Act.

<sup>72</sup> A provider is the one “that develops an AI system or a general-purpose AI model or that has an AI system or a general-purpose AI model developed and places it on the market or puts the AI system into service under its own name or trademark, whether for payment or free of charge”.

Article 3(3) AI Act.

<sup>73</sup> Article 2.1(a) AI Act.

<sup>74</sup> Article 3(4) AI Act.

<sup>75</sup> Article 2.1(b) AI Act.

<sup>76</sup> Article 2.1(c) AI Act.

<sup>77</sup> Recital 12 AI Act.

operate.<sup>78</sup> The adaptiveness as fleshed out in Recital 12 relates to “self-learning capabilities, allowing the system to change while in use”.

The capability to infer is a key characteristic of an AI in order to be regarded as an AI system under the AI Act. Pursuant to Recital 12, the capability to infer covers the following two facets. First, the process of obtaining the outputs, such as predictions, content, recommendations, or decisions, can influence physical and virtual environments. Second, a capability of AI systems to derive models or algorithms, or both, from inputs or data. By way of illustration, the recital notes what techniques can enable inference within the meaning of the AI Act. Those include “machine learning approaches that learn from data how to achieve certain objectives, and logic- and knowledge-based approaches that infer from encoded knowledge or symbolic representation of the task to be solved. The capacity of an AI system to infer transcends basic data processing by enabling learning, reasoning or modelling.” Crucially, the AI Act applies to stand-alone AI systems, also known as non-embedded systems, as well as those that are components of a product, known as embedded systems.<sup>79</sup>

The AI Act adopts a risk-based approach to AI systems.<sup>80</sup> The applicable legal requirements vary, depending on the risk classification of the AI in question. Firstly, it sets out a range of AI practices considered prohibited.<sup>81</sup> Pursuant to Article 5, prohibited practices cover an “AI system that deploys subliminal techniques beyond a person’s consciousness or purposefully manipulative or deceptive techniques, with the objective, or the effect of materially distorting the behaviour of a person or a group of persons”. Moreover, it covers “the placing on the market, the putting into service for this specific purpose, or the use of AI systems to infer emotions of a natural person in the areas of workplace and education institutions, except where the use of the AI system is intended to be put in place or into the market for medical or safety reasons.”

<sup>78</sup> Recital 12 AI Act.

<sup>79</sup> Recital 12 AI Act. For an analysis of inference, see Maximilian Poretschkin, Tabea Naeven, When Do Data-Driven Systems Exhibit the Capability to Infer?, <https://arxiv.org/pdf/2606.11769>. For an examination of the regulatory challenges surrounding the EU approach on inference, see Maria L. Mena-Durán, Antonio Falcó Montesinos, Inference as the defining criterion of AI: rethinking the EU AI Act, *Law, Innovation and Technology* 2026 p. 1.

<sup>80</sup> See in that regard, e.g., Johanna Chamberlain, The Risk-Based Approach of the European Union’s Proposed Artificial Intelligence Regulation: Some Comments from a Tort Law Perspective, *European Journal of Risk Regulation*, vol. 14, 2023 p. 1 and Martin Ebers, Truly Risk-based Regulation of Artificial Intelligence How to Implement the EU’s AI Act, *European Journal of Risk Regulation*, vol. 16, 2025 p. 684.

<sup>81</sup> See Rostam J. Neuwirth, Prohibited Artificial Intelligence Practices Revisited. I: Vera Lucia Raposo (ed.) *The European Artificial Intelligence Act*, Springer 2025.

A significant part of the AI Act's legal requirements applies to AI systems classified as high-risk.<sup>82</sup> Pursuant to Article 6.1, points a and b, if “the AI system is intended to be used as a safety component of a product, or the AI system is itself a product, covered by the Union harmonisation legislation listed in Annex I”; and if it is required to undergo a third-party conformity assessment under the MDR or IVDR prior to placing on the market or putting it in service, the respective device will be classified as a high-risk device. The consequences of this are the applicability of heightened requirements set out in the AI Act. These requirements include, for example, a risk management system, data and data governance requirements, technical documentation, and record-keeping.<sup>83</sup>

On the other hand, low- and minimal-risk AI in healthcare, namely, those that do not require external conformity assessment under the MDR or IVDR, need to comply with certain transparency requirements if the systems are intended to interact with natural persons,<sup>84</sup> e.g., chatbots. General-purpose AI models, such as LLMs, are subject to different rules.<sup>85</sup> The models are not considered AI systems, and different requirements apply. The AI Act sets out requirements for general-purpose AI models that pose systemic risk.<sup>86</sup> For all general-purpose AI models, certain obligations apply, particularly those related to transparency.<sup>87</sup>

### 3.3 On the EU Requirements and Their Limitations for AI

As elaborated above, medical devices falling into IIa, IIb, and III class categories, as well as *in vitro* diagnostic medical devices falling in Class B, C, and D, with rare exceptions, will be regarded as high-risk AI systems. Most AI systems that fall into MDR Class I and IVDR Class A will remain low-risk under the AI Act. The implications are thus self-certification by a manufacturer under the MDR or IVDR. This leads to the conclusion that, under the AI Act, such devices will be regarded as low risk. While it would only be reasonable to expect that those systems are also adequately developed and that healthcare

<sup>82</sup> For a comprehensive insight, see Dariusz Szostek, Rafał Tomasz Prabucki, High-Risk AI Systems. I: Vera Lucia Raposo (eds.) *The European Artificial Intelligence Act*, Springer 2025.

<sup>83</sup> See Articles 8–11 AI Act. For a comprehensive account on the obligations, see Chapter III Section 2 AI Act.

<sup>84</sup> Article 50.1 AI Act.

<sup>85</sup> See in that regard, e.g., Oskar J. Gstrein et al., General-purpose AI Regulation and the European Union AI Act, *Internet Policy Review* vol. 13, 2024 and Michael Veale, João Pedro Quintais, The Obligations of Providers of General-Purpose AI Models in Zanfir Fortuna et al. (eds.), *The Artificial Intelligence Act – A Thematic Commentary* (Hart, 2026).

<sup>86</sup> Article 51 AI Act.

<sup>87</sup> See Chapter V, Section II AI Act.

professionals can ensure their oversight, that is not a legal requirement *per se* in such a case. Moreover, this also applies to all AI used in healthcare that is not regarded as a medical device or an *in vitro* diagnostic device. Consequently, AI-enabled healthcare devices that are relevant for patient safety may not meet these AI Act's legal thresholds yet still support patient care.

Furthermore, both MDR and IVDR envisage an in-house exemption.<sup>88</sup> This exemption is crucial as it allows, on the one hand, flexibility in developing individualized AI solutions. On the other hand, this also comes with limited regulatory requirements under EU law and national oversight. Under EU law, the general safety and performance requirements must be met, and requirements are further clarified by the Medical Device Coordination Group.<sup>89</sup> Under national law, the manufacturer of such devices is responsible for notifying the Health and Social Care Inspectorate about their manufacture and use, and for providing details of the healthcare provider.<sup>90</sup> Furthermore, such devices shall have a documentation requirement and instructions for use.<sup>91</sup>

Finally, and potentially most importantly, the AI Act distinguishes between general-purpose AI models and general-purpose AI systems. Whereas the large language model is regarded as a general-purpose AI model, the user interface renders it a general-purpose AI system. General-purpose AI systems are adaptive by their nature. As a result, they currently do not meet the requirements set out in Annex I of the MDR and IVDR, and they cannot bear a CE mark. However, there are various international efforts to overcome the regulatory challenge.<sup>92</sup>

#### 4. Healthcare Actors' Obligations Regarding the Use of AI in Patient Care

##### 4.1 Mix of National and EU Legal Requirements

The obligations of healthcare actors in relation to the use of AI in patient care stem from both Swedish national law and EU law. The Swedish national law sets out such central pillars for AI use as the requirement of good care,

<sup>88</sup> Article 5.5 MDR and Article 5.5 IVDR.

<sup>89</sup> See Medical Device Coordination Group, Guidance on the Health Institution Exemption under Article 5(5) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746, 2023-1, 2023 [https://health.ec.europa.eu/system/files/2023-01/mdcg\\_2023-1\\_en.pdf](https://health.ec.europa.eu/system/files/2023-01/mdcg_2023-1_en.pdf).

<sup>90</sup> See Chapter 4, Section 2 HSLF-FS 2021:32.

<sup>91</sup> See Chapter 4, Section 3 and 4 HSLF-FS 2021:32.

<sup>92</sup> Ugur Ilker Atmaca et al., Data-driven medical devices and the EU MDR: Mapping Gaps in Standards for Regulatory Compliance, *npj Health Systems* vol. 3, 2026 p. 1.

compliance with the requirement of science and proven experience, and the requirement of information and consent. To this, the EU AI Act adds two important requirements that apply to deployers and trickle down to health-care personnel: AI literacy and human oversight.

#### 4.2 Good Care

Pursuant to Chapter 5, Section 1 of the Patient Safety Act, healthcare must be organized so that a requirement for good care can be ensured. This requirement – understood as an obligation<sup>93</sup> – is also enshrined in Chapter 5, Section 1 of the Health and Medical Care Act. While the law does not define what constitutes good care, it lists several key elements that are fundamental to it and must be followed within healthcare.<sup>94</sup> They cover, among other things, that the care provided must be of good quality and satisfy patients' needs for security, continuity, and safety.<sup>95</sup> The preparatory works of 2016 point back to the preparatory works of 1981, where considerable emphasis was placed on the need to meet basic requirements to consider care to be of good quality. Among other things, it is indicated that it shall have the necessary technical and medical quality, meet the requirements for good care (god omvårdnad), and be adjusted to the individual patient's needs.<sup>96</sup> The National Board of Health and Welfare (Socialstyrelsen) further guides that quality entails compliance with the applicable legal requirements.<sup>97</sup> Consequently, although this requirement makes clear that AI may be used in patient care if it has the necessary technical and medical quality, and complies with the applicable law, what this quality is remains unspecified.

Crucially, EU law does not prescribe what technical and medical quality is necessary in healthcare. It merely regulates AI as a medical device and AI as an *in vitro* diagnostic device to ensure that safe products are available on the market within the EU. On the other hand, the EU regulatory approach

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<sup>93</sup> Kavot Zillén, *Hälso- och sjukvårdspersonalens religions och samvetsfrihet – En rättsvetenskaplig studie om samvetsgrundad vägran och kravet på god vård*, Uppsala universitet juridiska fakulteten: Uppsala 2016 p. 47.

<sup>94</sup> Applicable not only to the regions, healthcare providers and principals, but also of relevance to healthcare personnel. See in that regard Denniz Sabo, *Hälso- och sjukvårdspersonalens skyldigheter och patientens "rättigheter"*, I: Kavot Zillén, Titti Mattsson, Santa Slokenberga (eds.), *Medicinsk rätt*, vol. 3, Stockholm 2025 p. 96.

<sup>95</sup> See Chapter 5, Section 1 point 2 of the Patient Safety Act.

<sup>96</sup> Government Bill (Regeringens proposition) 2024/25:167, p. 55.

<sup>97</sup> Latest version of The National Board of Health and Welfare's regulations and general advice on management systems for systematic quality work (Senaste version av Socialstyrelsens föreskrifter och allmänna råd om ledningssystem för systematiskt kvalitetsarbete) SOSFS 2011:9 Chapter 2 Section 1.

may not be ignored when considering the necessary technical and medical quality, as it anchors its regulatory requirements in the state of the art of the field.<sup>98</sup> At the same time, oversight of compliance with these requirements differs depending on whether it is an in-house AI, AI that is of such a classification that it does not meet the thresholds of external assessment, or AI that meets these thresholds. Nonetheless, against the loose national requirements, it could be argued that if the AI that is used in patient care complies with the requirements that are applicable to it, a strong argument for meeting the requisite of quality can be made. However, AI in healthcare requires not only consideration of the requirements applicable to the AI as software, but also how that software is deployed in a particular case.

### 4.3 Science and Proven Experience

The use of AI in patient care can be viewed in the context of healthcare quality regulation. For healthcare professionals, the key requirement is science and proven (or carefully tested) experience,<sup>99</sup> a requirement found in both Chapter 6 Section 1 of the Patient Safety Act and Chapter 1 Section 7 of the Patient Act. As a key rule dating back to the 1890s,<sup>100</sup> it still governs what care may be provided to patients, including which treatment methods, medicinal products, and devices a healthcare professional may use in a particular situation.

Despite science and proven experience not being a new requirement in the Swedish legal system, ambiguity remains about its exact legal content.<sup>101</sup> Scholars have tried to deconstruct the notion,<sup>102</sup> examine its different components and their coexistence,<sup>103</sup> and place it in the context of scientific progress,<sup>104</sup> evidence-based medicine,<sup>105</sup> specific interventions, for example, off-label use

<sup>98</sup> See Annex I of the MDR and Annex I of the IVDR.

<sup>99</sup> Government Bill 1993/94:149 expanded from medical doctors to healthcare professionals, see Government Bill (Regeringens Proposition) 1993/94:149, p. 65.

<sup>100</sup> See 1890-years medical instruction (1890 års läkarinstruktion).

<sup>101</sup> For inquiries about the content of this provision, see, for example, Lena Wahlberg and Johannes Persson, Importing Notions in Health Law: Science and Proven Experience, EJHL vol. 24, 2017 p. 565. The preparatory works of 1989 indicate that the preparatory works behind the first regulation in 1890 are not available, see Swedish Government Official Reports (Statens offentliga utredningar) 1989:60 p. 59.

<sup>102</sup> Jameson Garland, *On Science, Law, and Medicine – The case of gender-“normalizing” interventions on children who are diagnosed as different in sex development*, Uppsala Universitet, 2016.

<sup>103</sup> See Johannes Persson, Sten Anttila, Nils-Eric Sahlin, Hur förstå ”och” i ”vetenskap och beprövad erfarenhet”?, *Filosofisk tidskrift*, 2018 nr 1, p. 44–54, p. 52.

<sup>104</sup> See Elisabeth Rynning, *Samtycke till medicinsk vård och behandling: en rättsvetenskaplig studie*, 1994 p. 130.

<sup>105</sup> Johannes Persson et al., Science and Proven Experience: A Swedish Variety of Evidence-based Medicine and a Way to Better Risk Analysis?, *Journal of Risk Research*, vol. 22, pp. 1–11, see p. 2.

of medicines,<sup>106</sup> and unestablished care.<sup>107</sup> Yet, there is no guidance on how EU law regulating medical devices, *in vitro* diagnostic medical devices, and AI fits under this umbrella standard of care. Thus, disregarding the difficulties with the term, to proceed with examining the use of AI in healthcare, it is important to attempt to contextualize it against the legal status of AI that is used in healthcare.

To begin with, one can distinguish a case where a CE-marked AI that is a medical device or a diagnostic medical device and that has undergone external conformity assessment is used on-label, i.e., according to the manufacturer's intention, covering the intended patient group and the intended purpose of use, and has had its evidence assessed by an external party. This could arguably be the closest to the requirement on science and proven experience, due to the EU legal requirements that must be fulfilled prior to affixing a CE mark.

Thereafter, two categories follow that are somewhat close to each other, but which one most closely meets the science and proven experience requirements depends on the particular case at hand. Firstly, low-risk AI medical devices and low-risk AI *in vitro* diagnostic medical devices rely on manufacturer self-certification and trigger only voluntary AI Act requirements, which also cover the state-of-the-art requirements under the MDR and IVDR. However, the assessment is not made externally prior to affixing the CE mark. The MDR and IVDR do not envisage enforcement measures, such as sanctions. Nonetheless, market controls are envisaged. These self-certified systems could arguably be viewed as ranking below AI medical devices and AI *in vitro* diagnostic medical devices that undergo external assessment. However, this category of devices presumably accounts for only a fraction of what is available on the market. Secondly, in-house AI medical devices and AI *in vitro* diagnostic medical devices. These are also subject to the general safety and performance requirements, including the state of the art in science. However, the MDR and IVDR modalities associated with bringing devices to market or into service do not apply. Instead, an assessment is conducted locally in Sweden by the Health and Social Care Inspectorate. Crucially, neither the MDR nor the IVDR expressly excludes adaptive AI from the definition of in-house technology and the general safety and performance requirements.

Finally, the furthest from science and proven experience is potentially technology that is not subject to MDR and IVDR quality requirements but

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<sup>106</sup> Santa Slokenberga, The Standard of Care and Implications for Paediatric Decision-making: The Swedish Viewpoint. I: Clayton Ó Néill et al. (eds.), *Routledge Handbook of Global Health Rights*, Routledge 2021 pp. 122–152.

<sup>107</sup> Lena Wahlberg & Nils Eric Sahlin, Om icke vedertagna behandlingsmetoder och kravet på vetenskap och beprövad erfarenhet, *Förvaltningsrättslig tidskrift*, 2017, 1 p. 45.

still falls under the AI Act, namely, general-purpose AI systems.<sup>108</sup> While there are evolving datasets on the use of large language model user interfaces in health-related contexts, and various technologies are being built on large language models, such as chatbots, adaptive AI currently cannot meet the standards prescribed by the MDR and IVDR. However, this also highlights the vulnerability of this approach, as adaptive models have demonstrated their strengths in healthcare.<sup>109</sup>

#### 4.4 AI Act Requirements for the Use of AI in Healthcare

The AI Act adds two already noted important requirements to AI in clinical care: AI literacy and human oversight. These requirements apply to the deployers as healthcare providers, and they trickle down to healthcare personnel.

##### 4.4.1 AI Literacy

Literacy, in its original conception, was widely understood to be the ability to read and write.<sup>110</sup> However, over time literacy has acquired multiple dimensions, including health literacy, digital literacy, and AI literacy.<sup>111</sup> AI literacy is particularly crucial as the uncritical use of AI in healthcare risks leading to errors and inefficiencies. On the other hand, well-trained healthcare professionals can use AI to enhance healthcare quality, use resources more efficiently, and improve outcomes.<sup>112</sup>

As the legislative process of the AI Act advanced, the EU legislator opted to include the notion of AI literacy as one of the AI Act's fundamentals.<sup>113</sup> Under the AI Act, AI literacy aims to equip providers, deployers, and affected persons of AI systems with the necessary knowledge to make informed decisions.<sup>114</sup> Article 3(56) of the AI Act thus defines AI literacy as "skills, know-

<sup>108</sup> For a comprehensive analysis of the concept, see David Fernández-Llorca et al., *An Interdisciplinary Account of the Terminological Choices by EU Policymakers Ahead of the Final Agreement on the AI Act: AI System, General Purpose AI System, Foundation Model, and Generative AI*, *Artificial Intelligence Law* vol. 33, 2025 pp. 875–888.

<sup>109</sup> For an account of this, please see the introduction of this article.

<sup>110</sup> Davy Tsz Kit Ng et al., *Conceptualizing AI literacy: An exploratory review*, *Computers and Education: Artificial Intelligence* vol. 2, 2021 p. 100041 (cross-references omitted).

<sup>111</sup> Davy Tsz Kit Ng et al., *Conceptualizing AI Literacy: An Exploratory Review*, *Computers and Education: Artificial Intelligence* vol. 2, 2021 p. 100041.

<sup>112</sup> Elena Bignami, *Artificial Intelligence in Healthcare: Tailoring Education to Meet EU AI-Act Standards*, *Health Policy and Technology*, vol. 14(6), 2025 p. 1.

<sup>113</sup> For an account of the evolution of Article 4 AI Act, see Manuela Paolini e Silva et al., *AI Literacy Under the AI Act: Tracing the Evolution of a Weakened Norm*, preprint, 2025, [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=5099834](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5099834).

<sup>114</sup> Recital 20 AI Act.

ledge and understanding that allow providers, deployers and affected persons, taking into account their respective rights and obligations in the context of this Regulation, to make an informed deployment of AI systems, as well as to gain awareness about the opportunities and risks of AI and possible harm it can cause”.<sup>115</sup>

Article 4 of the AI Act sets out the details of AI literacy.<sup>116</sup> It focuses on those who develop and use AI systems and strives to ensure that the people involved in AI work (staff and other persons, such as healthcare personnel) have a sufficient level of AI literacy. As a means, “[i]n the context of the application of this Regulation, AI literacy should provide all relevant actors in the AI value chain with the insights required to ensure the appropriate compliance and its correct enforcement”.<sup>117</sup> As elaborated by Palmieri et al., “[o]n the surface, this appears to be a straightforward requirement: anyone working with or affected by AI systems must be educated about them. However, a closer reading reveals several interpretive challenges that complicate its practical implementation, especially in complex institutional settings like healthcare organization.”<sup>118</sup> One such is that the literacy obligation, accounting for Recital 20, captures even literacy raising vis-à-vis persons impacted by AI decisions, for example, patients.<sup>119</sup> The AI Omnibus amendments add that there is no specific literacy level that must be guaranteed. Instead, the Commission shall publish practical compliance examples.<sup>120</sup>

Disregarding the ambiguities,<sup>121</sup> the core idea of AI literacy is straightforward. It seeks to equip key concerned actors, such as healthcare personnel, with the necessary knowledge and skills to operate AI in healthcare. However, the AI Act does not impose direct responsibilities on individual healthcare personnel but rather on deployers, e.g., hospitals or outpatient care institutions. Through them, they will reach the healthcare personnel. Within the Swedish healthcare sector, various initiatives are underway to promote AI literacy.<sup>122</sup>

<sup>115</sup> Article 3(56) AI Act.

<sup>116</sup> For a detailed insight into the concept, see Sofia Palmieri, *AI Literacy in Healthcare Organisations: Implementing Article 4 of the EU AI Act with M-SHALF*, npj Health Systems vol. 3, 2026 p. 1. Since then, the AI Act amendments have been passed.

<sup>117</sup> Recital 20 AI Act.

<sup>118</sup> Sofia Palmieri, *AI Literacy in Healthcare Organisations: Implementing Article 4 of the EU AI Act with M-SHALF*, npj Health Systems vol. 3, 2026 p. 1.

<sup>119</sup> See Sofia Palmieri et al., *AI Literacy in Healthcare Organisations: Implementing Article 4 of the EU AI Act with M-SHALF*, Health Systems, vol. 42, 2026.

<sup>120</sup> Article 1(5) Digital Omnibus on AI.

<sup>121</sup> These are also highlighted by the Digital Omnibus on AI amendments for Article 4.

<sup>122</sup> See e.g., Uppsala och Örebro i projekt för att lära läkarstudenter mer om AI, *Läkartidningen*, 2024, <https://lakartidningen.se/nyheter/upsala-och-orebro-i-projekt-for-att-lara-lakarstudenter-mer-om-ai/>.

#### 4.4.2 Human Oversight

Closely related to the requirement for AI literacy is the requirement for human oversight set out in Article 14 of the AI Act. It applies only to high-risk AI systems and mandates that such systems be designed and developed to be effectively overseen by natural persons during their use.<sup>123</sup> The aim of such an oversight is “to prevent or minimise the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse”.<sup>124</sup> As derived from Article 14.3 of the AI Act, “[t]he oversight measures that are taken must be commensurate with not only the risks, but also with the level of autonomy and context of use of the respective high-risk AI system”.

The regulation of human oversight goes further by prescribing the actions that natural persons, to whom human oversight is assigned, such as health-care personnel, are required to perform. Five sets of actions are specified in Article 14.4 of the AI Act. Firstly, to properly understand the high-risk AI system and its relevant capacities and limitations, and be able to duly monitor its operation. Secondly, to remain aware of automation bias, namely, the tendency to automatically rely on, or over-rely on, the output produced by a high-risk AI system. This is particularly relevant to high-risk AI systems used to provide information or recommendations for decisions made by natural persons. Thirdly, “to correctly interpret the high-risk AI system’s output, taking into account, for example, the interpretation tools and methods available”. Fourthly, to take decisive decisions regarding the use of the high-risk AI system in any particular situation: not to use or to otherwise disregard, override or reverse the output that the system has provided. Finally, “to intervene in the operation of the high-risk AI system or interrupt the system. This may be done via a ‘stop’ button or a comparable procedure that allows the system to halt in a safe state. As derived from Article 14.4, these sets of actions are not cumulative. Instead, their appropriateness and proportionality must be assessed in each case. This is where the AI literacy gets particularly important.

#### 4.5 Informed Consent for the Provision of Care

Finally, the use of AI in patient care directly concerns patients as the recipients of healthcare services. One of the key aspects of healthcare from a patient perspective is the protection of their autonomy and self-determination, which are also important facets of protecting personal integrity under human rights

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<sup>123</sup> Article 14.1 AI Act.

<sup>124</sup> Article 14.2 AI Act.

law.<sup>125</sup> This is clearly affirmed in Chapter 4, Section 1 of the Patient Act, which states that the patient's self-determination must be respected. This idea is reflected in the rules on information and consent, both within international human rights standards<sup>126</sup> and Swedish national law. The former affirms personal autonomy as the right to make choices about one's body, as established in *Pretty v. the United Kingdom* and affirmed thereafter.<sup>127</sup> As elaborated by the ECtHR, "respect for personal autonomy is a general and fundamental principle. It is safeguarded notably by the universally recognised rule of free and informed consent."<sup>128</sup> This entails that "[t]he legally competent patient who has been duly informed about his or her health condition and the available treatments, as well as the implications if no treatment is accepted, has the right to freely decide whether to give consent to treatment or to withhold it".<sup>129</sup> In this spirit, Swedish national law stipulates that healthcare may not be provided unless the patient has given consent, except where provided by law.<sup>130</sup> These rules equally apply to the use of AI in patient care.

While it is clear that informed consent requirements are relevant to AI in healthcare, the central question is when the requirements set out in the Patient Act become relevant. Pursuant to Chapter 4, Section 2 of the Patient Act, the object of consent is healthcare that is deemed medically necessary and offered to a patient. For the purposes of the Patient Act, healthcare, understood against the backdrop of the Health and Medical Care Act,<sup>131</sup> is defined as measures to prevent, investigate, and treat diseases and injuries, as well as to provide patient transport. The preparatory works to the previous Health and Medical Care Act place specific focus on "pure healthcare", covering outpatient care and hospital care, as well as care in connection with injuries, bodily malformations, and childbirth, abortion, and sterilisation.<sup>132</sup> The definition of healthcare in itself does not set boundaries for what should be treated as

<sup>125</sup> See Article 8 ECHR, for example, which covers both facets.

<sup>126</sup> *S.O. v. Spain* (Application no. 5742/22, 17 September 2024) para 38. As a matter of human rights protected under the ECHR, the Court has drawn a distinction between medical care that is a well-established standard of care, and interventions that bring about sensitive moral and ethical concerns, and mandate discretion from the signatories, para 125. AI in healthcare is likely to fall within the former as it increasingly finds its place in medical care, except for cases which give rise to sensitive ethical and moral concerns. See in that regard, *Pindo Mulla v. Spain* (Application no. 15541/20, 17 September 2024) paras 125–128.

<sup>127</sup> For reiterations, see *Pindo Mulla v. Spain* (Application no. 15541/20, 17 September 2024) para 137.

<sup>128</sup> *Pindo Mulla v. Spain* (Application no. 15541/20, 17 September 2024) para 138.

<sup>129</sup> *Pindo Mulla v. Spain* (Application no. 15541/20, 17 September 2024) para 138.

<sup>130</sup> Chapter 4, Section 2 Patient Act.

<sup>131</sup> See Government Bill (Regeringens proposition) 2013/14:106 p. 111.

<sup>132</sup> See Government Bill (Regeringens proposition) 2013/14:106 p. 111.

the object of consent. It merely marks the spectrum of measures that can fall within the scope of consent, e.g., using AI to investigate an injury. However, more concrete borders of the object of consent can be inferred from the idea of patient self-determination, rooted in autonomy,<sup>133</sup> and its expression in the Patient Act.

The validity of informed consent is strongly related to the information provided to the patient.<sup>134</sup> At its core is the idea that each patient decides for themselves whether to accept the care being offered to them.<sup>135</sup> While patients cannot decide what care will be given, they can decide to accept or decline the care offered.<sup>136</sup> This marks clear boundaries for the operationalization of informed consent and the extent of patients' self-determination. Whereas patients cannot decide whether AI may be used in managing their healthcare administratively as part of this right, they can decide whether they are willing to accept the use of AI in the direct care offered to them. Admittedly, there could be cases where a line between these two ends is not easy to draw. This does not limit the duties and possibilities to provide more general information to patients as a group.

Chapter 3 in the Patient Act sets out the information that shall be provided to a patient. Chapter 3, Section 1 specifically focuses on the details of a medical intervention offered to a patient and, in a non-exhaustive way,<sup>137</sup> and not a challenge-free way,<sup>138</sup> lists key elements. Among those in point 2, "the methods available for examination, care and treatment" are listed, and in point 5, "the expected course of care and treatment," as well as in point 6, "significant risks of complications and side effects". This promotes transparency for the patient regarding how the offered examination is conducted and how care and treatment are provided. Moreover, it covers treatment details and captures key dimensions, including risks and side effects. These dimensions apply equally when AI is involved in the care offered to a patient.

The provision does not, in itself, dictate whether a patient shall be informed that an AI is being used as part of the healthcare offered. The underlying principle of this provision is the necessity to provide sufficient information to a particular patient to enable them to make a decision. If a particular patient

<sup>133</sup> *Pretty v. the United Kingdom* (Application no. 2346/02, 29 April 2002) para 61.

<sup>134</sup> See in that regard Government Bill (Regeringens proposition) 1998/99:4 p. 23–4.

<sup>135</sup> See Government Bill (Regeringens proposition) 1981/82:97 p. 50.

<sup>136</sup> See Government Bill (Regeringens proposition) 1981/82:97 p. 50.

<sup>137</sup> See Government Bill (Regeringens proposition) 2013/14:106 p. 114.

<sup>138</sup> Jameson Garland, *Informed Consent as a Right: Regulatory Challenges in the Swedish Legal Framework*, FT, 2018 p. 246.

needs additional information, that shall be provided. The information must thus be tailored to the specific patient in question.<sup>139</sup>

The provisions thus do not, in themselves, mandate disclosure of the fact that AI is being used. However, they do create a framework where such disclosure is possible. For example, just as a patient needs to know whether a prescribed medication is a pill or a liquid, it would be relevant to know whether a specific AI device will be used. However, the requirements for methods may also be satisfied without disclosing the AI component as a matter of fact. For example, AI falls under the broader category of software as a medical device or an *in vitro* diagnostic medical device. Formally, Chapter 3, Section 1 of the Patient Act does not prohibit providing general information that omits the specific AI component, unless it is clearly relevant to a particular patient (for instance, if the patient has explicitly inquired about it). Nevertheless, this non-disclosure approach would fail to raise awareness, including awareness of the enjoyment of scientific progress and its applications, protected as part of the right to benefit from scientific progress and its applications,<sup>140</sup> as well as awareness among end users or end-service recipients to further the acceptance of AI as a new technology.

When information about an AI system is disclosed to a patient, it is crucial that the healthcare provider has the necessary knowledge and skills to understand the AI system offered to the patient for their healthcare. This is where the AI literacy requirement gains additional relevance. However, healthcare personnel are highly dependent on the AI providers to supply the required and necessary information to patients. As Kiseleva et al., in connection with AI medical devices, have emphasized, the legal framework places transparency requirements on the manufacturer, particularly with regard to products placed on the market or put into service pursuant to the MDR,<sup>141</sup> which also applies to the IVDR. These requirements are subsequently reflected on the device label. It is then the healthcare professional's responsibility to deliver this necessary information to the patient to enable informed consent. However, for AI that is not a medical device or an *in vitro* diagnostic medical device placed on the market or put into service, a label is not required. In-house devices would normally have the general safety and performance

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<sup>139</sup> See Government Bill (Regeringens proposition) 2013/14:106 p. 114.

<sup>140</sup> International Covenant on Economic, Social and Cultural Rights 1966, Article 15, see General Comment No. 25 (2020) on science and economic, social and cultural rights (article 15 (1) (b), (2), (3) and (4) of the International Covenant on Economic, Social and Cultural Rights).

<sup>141</sup> Anastasiya Kiseleva, Transparency of AI in Healthcare as a Multilayered System of Accountability: Between Legal Requirements and Technical Limitations, *Frontiers in Artificial Intelligence*, vol. 5, 2022 p. 10.

requirements documented,<sup>142</sup> but it is unclear whether this documentation is readily accessible to healthcare professionals using these devices. As far as national legal requirements extend, no explicit obligation has been placed on the manufacturer of the devices to equip end-users with relevant information. As far as EU law stretches, such a requirement has also not been imposed. Consequently, systems that have not undergone the process of being placed on the market or put into service risk failing to support healthcare professionals in delivering it to patients, unless this risk is adequately managed within the healthcare institution.

#### 4.6 On the Limitations Surrounding Healthcare Actors' Obligations Regarding the Use of AI in Patient Care

While good care, science, and proven experience are fundamental pillars for ensuring the quality of healthcare in Sweden, how these apply to AI systems used in patient care is not directly regulated by law. An attempt to shed light on this has been made; however, it has limitations. Healthcare providers, when providing care in each particular case, must be aware of the modalities surrounding the AI as outlined in Section 3 above, and assess how the intended AI meets the requirements of science and proven experience. Moreover, healthcare providers must ensure that the healthcare personnel working in their institutions have sufficient literacy and can ensure the required human oversight. Crucially, the requirement for human oversight applies only to AI in healthcare that is a medical device or an *in vitro* diagnostic medical device and has undergone an external conformity assessment. The use of other systems remains unregulated by the EU, and it is a question that falls within the remit of the national legislator's competencies. In the absence of any further specifications from the legislator, it could be argued that the requirement for good care, science, and proven experience implies a duty for healthcare professionals to be competent in choosing relevant technology and operating it responsibly vis-à-vis the patient. However, whether all the requirements prescribed in Articles 4 and 14 of the AI Act can be fully integrated into the Swedish standard of good care, science, and proven experience mandates remains to be seen.

While informed consent is a powerful human rights tool, on its face, it affords relatively limited control for patients over AI use in their healthcare. While the law does not expressly mandate the disclosure of the use of AI, the disclosure falls within the information elements prescribed in the Patient

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<sup>142</sup> See HSLF-FS 2021:32.

Act, for example, as part of the methods. It should be encouraged to support patient acceptance of new technologies and transparency in the care provided. However, in these disclosures, considerable dependence is on the available information about a particular AI in question, as well as AI literacy levels. While the AI Act is strong on healthcare providers' literacy, that of patients is in a significantly different position, heavily depending on the preconditions that each individual patient has. Therefore, further guidance for healthcare professionals might be needed to better manage informed consent procedures to support medical decision-making and further the acceptance of the technology.

## 5. Concluding Remarks

Despite the Swedish law not regulating the use of AI in healthcare expressly, there are layers of legal norms relevant for the use of AI in patient care. As this article shows, there is a complex interaction between the EU's approach to regulating AI in healthcare, and the national norms regulating the provision of care.

More concretely, this article has argued that the more limited the EU's regulatory intervention is in ensuring the quality of AI in healthcare, the more difficult it may be to meet the national requirements of good care, science, and proven experience. The growing evidence of self-learning AI systems in healthcare poses a challenge to this approach. At the same time, there are currently no direct and uniform ways to integrate large language models into clinical care in a way that consistently meets the requirements of good care, science, and proven experience. This issue must be further examined, especially considering evolving capacities, the evolution of explainable AI, and difficult cases where established interventions or built knowledge are constrained.

The complex interplay between how EU law approaches the regulation of AI in healthcare and the requirements for AI use specified by the Swedish and EU legislatures has a bearing on how healthcare professionals are equipped to support the exercise of patients' autonomy through informed consent. While the four-tier hierarchy in the context of science and proven experience is a starting point to disentangle the interplay between EU law and national law, deeper legal inquiries in each of the flagged areas are necessary to support patient protection. Likewise, further investigations into other relevant questions that have been delimited due to space constraints are necessary, such as the importance of data subjects' rights in connection with AI use in healthcare.

