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A recent case of a flawed medical AI system that was backed with public funding provides an opportunity to discuss the impact of government policies and regulation in AI.

Sweden, like many other countries, has ambitions to become a leading country in the race to realize the potential of AI[1]. However, caution is needed as there are many potential legal, ethical and political issues to tackle, as demonstrated by a recent attempt to implement an AI system in a third of primary public healthcare centres in Sweden. The system received a European grant, despite its design flaws and incorrect details in the grant application. In addition, the procurement process suffered from several irregularities, eventually leading to criminal convictions. In what follows, we will describe this particular case and use it to illustrate the need for high standards in scrutinizing government funding and implementation of AI systems in society, especially in healthcare.

Rise and fall of a flawed AI system

Vårdexpressen, which can be translated as 'Healthcare Express', is an (allegedly) AI-based system developed by the Swedish company Vårdinnovation. It consists of a questionnaire, which is completed by patients from home or at a healthcare centre[2]. Based on patients' answers the software generates a summary and recommendations relating to further examination, tests and treatment, which are accessed by the physician. Vårdexpressen was meant to support physicians in decision-making and to reduce their workload[2]. Between 2018 and 2020 the company which developed the system won public procurement contracts in three Swedish regions[3], and in 2019 it also received a nearly EUR 2 million grant from the European Commission to further develop the system[4].

Soon after the pilot testing of Vårdexpressen had started in a few Swedish health centres, some physicians expressed concerns about it. For example, in one case it reportedly 'overlooked' a patient in a serious condition, who had to be immediately transferred to an emergency ward[5]. Swedish television investigated the company and surrounding issues, revealing, thanks to the insights of former employees of Vårdinnovation, serious concerns about the procurement process[6]. The reporters presented the evidence they had collected to the primary care management of Skåne – one of the regions that had purchased the system. This persuaded the region to cease collaboration with Vårdinnovation and launch an independent investigation into suspected irregularities[6].

In April 2022 the CEO of Vårdinnovation was convicted of bribery and aiding and abetting breach of trust. Two local officials involved in the procurement process, similarly, were convicted of bribery and breach of trust. All were sentenced to prison and required to pay damages to the regions[7]. It also was revealed that the grant application Vårdinnovation made to the European Union (EU) included false information both about the qualifications of the company's CEO and about the system[8]. The grant agreement between the European Commission and the company was subsequently terminated[4]. Additionally, it was found that

the company had created and used a LinkedIn profile for what appeared to be a non-existent communications director[9,10].

Ethical, legal and political issues raised

First, should AI systems of questionable quality such as Vårdexpressen be permitted to enter the market? In the EU, there is a legal framework that regulates the market entry of medical devices, including medical AI. This framework has recently been revised, with the Medical Device Directive being replaced by the Medical Device Regulation. The regulation, which applies from May 2021, tightens many requirements[11]. Central features of the legal framework, however, remained unchanged. Both the directive and the regulation set requirements that must be met by the manufacturers wishing to place their devices on the market. The compliance of the lowest-risk devices with the requirements can be self-declared by the manufacturers. Meanwhile, the conformity of higher risk devices is verified by thirdparty private entities called 'notified bodies', which are designated by Member States. What has changed with the adoption of the new regulation is, among other things, the risk classification of the devices. Under the directive, Vårdexpressen qualified as a lowest-risk device[3], with the implication that it did not have to undergo external evaluation, being instead self-certified by the manufacturer. If Vårdexpressen were to enter the market today it would be likely classified, under the Medical Device Regulation, as higher-risk device and would need to pass a conformity assessment made by a notified body.

This higher level of scrutiny, and in particular the evaluation of clinical data, which should demonstrate the claimed performance and safety of the system, might have prevented Vårdexpressen from entering the market. From this point of view the new regulation seems to be a positive development. Its effectiveness, however, will depend on adequate enforcement. Jarman *et al*. have argued that the accountability mechanism under the regulation is inadequate, and that the incentive for notified bodies to ensure appropriate scrutiny of the devices is weak[12]. It is also important to recognise that demanding regulatory requirements may have a negative impact on the innovation of medical devices because they increase compliance costs for the companies and lead to longer development times 'from bench to bedside'[13]. Trades-offs between costs and benefits should, therefore, be carefully considered in any discussion of medical AI regulation. Importantly, the European Commission has recently proposed another regulation, the AI Act[14], which, if adopted, would introduce further requirements for medical AI, relating, for example, to the quality of data used for training and cybersecurity (Articles 10 and 15). These requirements would further raise the bar for entrants to the market. Again, however, this may not be straightforward, since compliance with the requirements would also be evaluated by notified bodies, reintroducing the issues noted above.

Second, Vårdinnovation received a large EU grant. Was the review process adequate, with enough scrutiny? The grant application stated that the applicant held a PhD title, which was untrue[8]. The project description on the EU website also states, falsely, that the system was implemented in 30% of Swedish public primary healthcare providers, and it presents data on (cost-)effectiveness set out in the context of that assertion[4]. One could argue that grant

evaluation procedures should include verification of this kind of rather crucial information, especially when a large sum of money is at stake.

The case also highlights a larger question about whether a state (or in this case the EU) should intervene in the market for new technologies by funding the research of private for-profit companies. The idea of the entrepreneurial state – that is, of a state that is 'a lead risk taker and market-shaper' of the kind necessary for the development of innovations[15] – has gained popularity. It has been put into practice by various states and organizations[16]. Horizon Europe, a flagship EU funding programme, for example, supports SMEs (small and medium enterprises) in developing 'innovations with potential breakthrough and disruptive nature with scale-up potential that may be too risky for private investors.'[17] Although at first sight it is appealing, this strategy does not seem to bear scrutiny when it comes to theoretical validity and empirical evidence[18,19]. The criticisms revolve around several questions. Is the allocation of public money to risky research and development a fair and reasonable use of scarce public money? Are state actors better able to pick technologies that will be of value to consumers than private investors (who, unlike government actors, personally bear costs of a failure)? How are the risks of opportunistic behaviours (e.g. bribery) of interests groups (e.g. tech companies) to be handled? And how will EU funding for selected technologies impact the development of other, potentially as or more useful, technological solutions? Considering these and related issues, the current approach of the EU to the funding of technologies through support for private for-profit enterprises may be worth rethinking.

Third, academic researchers, governments and the media are all at times implicated in hype around AI – that is, excessive publicity that focuses on benefits and understates risks and costs. It has been shown that research publications on medical AI include exaggerated claims about the capabilities of the systems[20], and that popular UK and US news outlets have tended to frame AI as outperforming or replacing doctors in recent years[21]. Governments of leading countries in AI also contribute to the hype. The national strategies on AI of China, Germany, France and the USA portray it as an 'essential social good' and consider its adoption inevitable[22]. Similarly, Swedish policy documents on AI from both governmental and nongovernmental actors incorporate 'overly optimistic' discourse[23].

Hype may contribute to a distorted view of technology. Eventually, it may lead to the implementation of unreliable systems if those responsible for that implementation are not knowledgeable in the subject. Government policies may also create direct pressure for a technology to be taken up – something that may lie behind a statement of the chair of a primary healthcare committee in one Swedish region: '[i]f we were not to make these investments [in Vårdexpressen], Region Skåne would fall far behind in digital development. Region Skåne is currently a world leader.'[24] On the bright side, there were doctors who were sceptical about the system from early on[25,26], and whose scepticism may be attributed to their accurate knowledge of the state of the art of medical AI, including its limitations. The media also played a crucial role in this case. The evidence they collected during a journalistic investigation prompted the region to cancel its collaboration with the company and commission an external investigation[6].

Last, but not least, the Vårdinnovation case illustrates the way in which AI software that generates non-existent face images, can be used for ethically dubious purposes. As touched upon above, after concerns about the Vårdexpressen system had been publicised, someone purporting to be a company communication director reportedly answered emails from various media outlets[9]. The LinkedIn profile of this employee had over 500 contacts. However, at some point the fact that she refused to meet in person, as well as some features of her profile photo on LinkedIn, raised the concerns of journalists. Reverse image search with the photo did not return any results, prompting further doubts about whether the profile was genuine. It has been suggested that the photo was artificially created using AI[9]. Under police interrogation, the CEO of Vårdinnovation admitted that the communication director did not exist. However, during the ensuing court trial he evaded questions about the issue[10]. This very probably fake profile helped the firm to appear trustworthy. It also enabled some of its employees to remain anonymous to public while they were engaging in fraudulent activities.

To prevent these kinds of abuse of AI technology, the proposed EU AI Act[14] requires professional users of software for image manipulation to ensure that such deepfakes are accompanied by information that the image has been artificially created (Article 52). Under the new regulation, public bodies called 'market surveillance authorities' would be tasked with looking for such deepfakes on social media (Article 63)[27]. It is, however, unclear whether such bodies will be provided with the expertise and other tools needed for this[27]. Nor does the regulation provide a mechanism for persons affected by deepfakes (e.g. a client of the responsible company) to lodge a complaint to the market surveillance authorities. It is therefore far from certain whether the provision on transparency about deepfakes will be enforced effectively[27].

Conclusions

Governments and the EU play significant roles in the adoption of AI, not only as legislators, but also as main investors, as well as actors shaping public discourse. Unfortunately, it seems that at least some of their activities in these areas serve not patients and society more generally, but rather the private interests of the AI industry and public officials. The recently proposed AI Act has serious shortcomings, among others in enforcement mechanisms, and in fact, as concluded by Veale and Zuiderveen Borgesius, it 'may contribute to deregulation more than it raises the regulatory bar'[27]. The EU's funding for private for-profit companies also raises questions about the adequacy of grant review processes and fair use of public money. Excessively optimistic and deterministic depictions of AI in policies and national strategies contribute to a distorted view of it and, arguably, the adoption of unreliable systems. This means, as the case of Vårdexpressen shows, that individual responsibility and appropriate levels of education among stakeholders in AI, especially medical doctors, are vital if we are to resist the hype and identify abuses in the implementation of medical AI systems.

Competing interests
The author declares no competing interests.

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