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Artificial Intelligence and Regulation: Total Quality Management for Mental Health Services[1]

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Abstract

Artificial Intelligence becomes increasingly embedded in various forms in organizational processes and business activities, transforming the structures that support organizations and industries at global scale. The advance of Artificial Intelligence is expected to shift paradigms in several sectors. Technological innovations bring the need for regulatory institutions and frameworks to be introduced to monitor and control Artificial Intelligence applications, such as ChatGPT and other similar platforms in their current and future forms.

This paper contributes to the literature on regulation of the services of Artificial Intelligence platforms. Through a Multivocal Literature review, the paper argues for the need for such regulations. We suggest that Artificial Intelligence needs to be regulated, and that this will be beneficial for the development of the quality of the services. Through direction of the

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regulatory institution, proper implementation of Artificial Intelligence in mental health services leads to business performance effects for the mental health providers and to health improvement outcomes for the patients, and eventually to the transformation of the paradigm of this sector's services.

We propose directions for the implementation of a TQM model, normalized in the standards of Industry 5.0, and adapted for the Mental Health Services sector. Through the EFQM Model, the paper argues for the approach that can be implemented in regulating the Artificial Intelligence industry to ensure high performance and quality assurance. We suggest that results can be affected by stakeholder's perceptions, and we focus on the challenge of fast-moving Artificial Intelligence mental health services platforms coexisting as stakeholders with slow-moving medical bodies which establish practices and protocols. Medical bodies are identified as key stakeholders restrained by their commitment to uphold deontological ethics.

Keywords: Economic Regulation, Artificial Intelligence, Technological Change, Total Quality Management, Health Economics

JEL Classification: I110; L510; L520; O330

1. Introduction

Artificial Intelligence (AI) is an emerging Disruptive Technology, and it is anticipated that it will result in a paradigm shift for the operation of several sectors and industries (Păvăloaia & Necula, 2023). The scope for the use of AI, in conjunction with human capabilities, is very broad and to a great extent unknown (Seghatchian, 2020), as this technology is currently evolving at a fast pace and has not reached its full potential. Demand for Mental Health services has sharply and rapidly increased during the COVID-19 pandemic and the lockdowns and other social distancing restrictions imposed in several first-world countries (Brunier & Drysdale, 2020), indicating the need for introduction of a policy framework for better mental health systems and services for the future (Tausch et al., 2022). Although there are no clear evidence for long-term impact of COVID-19 on mental health among the general public (Ahmed et al., 2021; Bourmistrova et al., 2022), there is a strong call from the academic community for

constant monitoring and critical evaluation on the subject (Shi et al., 2021). Moreno *et al.*, (2020), in their seminal position paper, viewed COVID-19 "as an opportunity to improve mental health services", with increased demand for mental health services being sustained during the post COVID-19 period, which suggests that the sector needs to focus on medium-term and long-term effects. The sector should also consider the impact of other drivers of demand for Mental Health services.

Artificial Intelligence presents novel capabilities that can assist the provision of Mental Health services, introducing opportunities for implementation of new approaches in Mental Health services delivery (Dadi et al., 2021). AI technologies constitute unknow and potentially powerful factors that can permanently alter the industries that adopt these, reshaping their operation and resetting service performance standards. These AI Technologies have to be regulated by competent bodies and institutions, to ensure the safety and the proper and appropriate use of them (Justo-Hanani, 2022; Stahl et al., 2022; Truby et al., 2022). In the case of Mental Health services sector, the need for regulation is even stronger, as any practices and approaches of Artificial Intelligence have to be in line and in compliance with existing regulation of medical practices, including medical protocols, regulations and ethical considerations (Kooli & Al Muftah, 2022; Rubeis, 2022).

The paper examines potential issues and implications that can emerge from a very fast shift towards use of Artificial Intelligence technologies in Mental Health services, without proper preparation from sector regulators, who face various levels of uncertainty, ranging between "known unknowns" and "unknown unknowns" (Courtney et al., 1997; Kormanski, 1988) which is being introduced to a sector that has very well-established need for regulation aiming to deliver quality and excellence through conformance to specifications. Artificial Intelligence tools became accessible and widely available for public use only recently with the release of ChatGPT (De Angelis et al., 2023). These AI tools are fast advancing, becoming updated and more enhanced as time goes by, acquiring increased technological capabilities every few months as their platforms progress to more updated versions. At the same time, medical practices and protocols are being updated in slower paces and are subject to significant rigorous checking, making it challenging to remain up to speed with the most recent Artificial Intelligence technologies and platforms. Update in acceptable medical practices might take years to be introduced, and these might not even be introduced simultaneously across all global jurisdictions. Also, the understanding of the implementation details of medical practices might involve expensive and rigorous length training of medical professionals, and this also might

introduce time lags, as well as opportunities for new practices to be resisted and challenged. The use of AI in Mental Health services provision has the potential to introduce significant changes and a "cataclysmic" shift in the way in which Mental Health services provision and standards of practice are regarded.

We suggest that regulatory bodies and institutions (either existing or newly established) need to act quickly to understand, monitor and regulate the use and the applications of Artificial Intelligence in Mental Health services, as well as in other industries, health-related or beyond, that might face similar issues. We suggest that regulators adopt TQM frameworks of EFQM 2020 during their operation and the exercise of their regulatory powers, to ensure high levels of performance for the regulators and high levels of safety and quality in the industry's services delivered via Artificial Intelligence platforms.

2. Purpose of this paper

This paper focuses on the Artificial Intelligence technologies and their application on the Mental Health services industry. This study identified a gap in the literature and proceeded to examine the needs and peculiarities of the combination of aforementioned topics. This study proposes two theoretical TQM frameworks for the regulation of applications of Artificial Intelligence in Mental Health services industry. Given that this area experiences active interest in practical implementations, which can be potentially imminent, the value and the need for this study become profound.

3. Literature review

Existing academic literature examines Artificial Intelligence, Total Quality Management, Mental Health Services as three separate topics. In some cases, there is literature combining the two of the three topics. However, there is very limited to almost non-existent academic publications examining all three topics at the same time, and doing so from the perspective of Economic Regulation.

3.1 TQM in healthcare

Total Quality Management (TQM) is a management approach that seeks continuous improvement in all aspects of organizational operations. Over the past few years, the healthcare

sectors witnessed challenges such as escalating costs, demand variability, and service quality issues, prompting a need for transformative solutions (Hermes et al., 2020; Keehan et al., 2020; Zhu et al., 2020). Early in 2000's, Yasin & Alavi (1999) highlighted the competitive benefits of implementing TQM in healthcare. TQM in healthcare implies an integrated approach, focusing on improving the quality of care, reducing costs, and enhancing customer satisfaction (Alshrbaji et al., 2022). It involves everyone in the healthcare system, from physicians, nurses and administrative staff to patients and their families. Despite the plethora of benefits that the adoption of TQM approaches brings to health sector, several obstacles might also emerge. These could be tensions between managers and professionals, difficulties involved in evaluating healthcare processes and outcomes, and strong departmentalized, bureaucratic and hierarchical structures which can compel the TQM efforts unsuccessful (Mosadeghrad, 2013).

Fostering a culture that encourages continuous improvements and rejects complacency comes as a necessity for healthcare organizations to promote a proactive approach for identifying and addressing inefficiencies and deviations from established standards of care (Gözükara et al., 2019). A systematic review of the literature by Alzoubi et al. (2019) identified education and training, continuous quality improvement, customer focus/satisfaction, top management commitment and teamwork as the core predictors for a successful TQM implementation in the healthcare context. Adding to the latter, a study by Talib et al. (2019) revealed five main category enablers for healthcare quality services improvement through the adoption and implementation of TQM with "leadership-based enablers" and "process management based enablers" being the two most important ones. TQM stands as an established tool for augmenting quality and increasing efficiency and enhancing performance in healthcare systems. TQM is also of high interest of research, in the context of healthcare, for academics publishing in relevant journals (Shrivastav, 2023).

3.2 Artificial Intelligence in TQM

The integration of Artificial Intelligence (AI) into Total Quality Management (TQM) is a burgeoning area of research with significant implications for various sectors. From the role of AI in the Total Quality Management in transfusion practice (Smit Sibinga, 2020) to cracks on buildings recognition and Total Quality Management based on deep learning (Wu & Liu, 2021), the integration of AI and TQM has emerged as a prominent research topic over the last years (Chiarini, 2020). The application of technologies such as IoT and AI can significantly improve

the various elements of TQM for continuous quality improvement (Muruganandham et al., 2023). Kim (2020), in an analysis of the effect of quality management and biga data management on customer satisfaction in the public sector, among other significant results, stated that the future of operations has on its core biga data and artificial intelligence.

Schiavone et al. (2022) conducted a seminal study investigating the relationship between total quality service and digitalization on a digital health organization. Integrating Artificial Intelligence and IoT sensors, in the context of digital health solutions, can lead to social innovation and a more humane and accessible to all health system, as a consequence of reduced costs. In a similar vein, Souza et al. (2022) explore the new concept of TQM 4.0, highlighting the need for integration of employees with Industry 4.0 technologies (artificial intelligence, robots etc.) for both human resources and technologies to be active in the development process based on total quality, in an industrial scenario. Additionally, Tamer (2022) investigating the relationship of total quality management and supply chain management in healthcare services in the context of a digital environment,

3.3 AI and Economic Regulation

Artificial intelligence has permeated various facets of modern society, with its applications extending from autonomous vehicles to personalized advertising and intricate financial transactions. As AI continues its trajectory of rapid evolution and integration into daily life, the necessity for efficacious regulation becomes increasingly salient (Wirtz et al., 2020). A primary challenge in the regulation of AI is the inherent complexity of the technology (Buiten, 2019) and the vast array of its applications (Ruschemeier, 2023). AI systems often exhibit autonomy, making decisions and executing actions devoid of human intervention. This autonomy engenders questions pertaining to foreseeability and causation, as the prediction of AI actions or the determination of the rationale behind its decisions can be arduous (Abaimov & Martellini, 2020). Additionally, the development of AI is frequently characterized by opacity, with many systems being developed in a discreet and diffuse manner (Wright, 2021). This complicates the application of traditional regulatory approaches. In addition to this, there has been a notable dearth of comprehensive research, towards comprehensively identifying challenges (or inhibitors) of AI adoption in the public services (Misra et al., 2020).

Considering these challenges, certain scholars have proposed the establishment of international – or in other studies national - AI regulatory agency (Ellul et al., 2021; Erdélyi & Goldsmith,

2018; Stahl et al., 2022; Wallach & Marchant, 2019). This agency, drawing of interdisciplinary expertise, could construct a unified framework for the regulation of AI technologies. This could serve to address the global nature of AI, whose development and deployment often transcend national borders. An international agency could also inform the development of global policies, ensuring a consistent approach to AI regulation. However, the establishment of such an agency is not without its own set of challenges. It necessitates international cooperation and consensus on a multitude of complex issues, including the definition of AI, the scope of the agency's authority, and the mechanisms for enforcing its regulations (European Parliamentary Research Service, 2022). Moreover, the rapid pace of AI development could pose a challenge for such an agency to remain abreast of the latest advancements and challenges.

In addition to the establishment of an international agency, de Almeida et al. (2021), through systematically reviewing relevant scientific literature on AI regulation, noted a concurrent need for national regulations. For instance, in the context of autonomous vehicles, questions of liability in the event of an accident arise (Taeihagh & Lim, 2019). In the same context, Barfield (2018) examines liability allocation in instances where autonomous robots cause property damage or personal injury highlighting the complexity of the matter. National laws could provide clarity on these issues and offer a framework for addressing them (Gerke et al., 2020). Lasty, there is an increasing recognition of the potential for AI to be utilized in cyber warfare (Zhang et al., 2022). This underscores the need for regulations to avert a cyber arms race and to delineate an international doctrine for cyberspace skirmishes before they escalate into conventional warfare (Lancelot, 2020).

4. Methodology

4.1 Multivocal Literature Review (MLR)

Given the rapid evolution of the Artificial Intelligence industry, the inclusion of "grey literature" is of paramount importance in the process of assessing extant knowledge and expertise in the field. Traditional academic literature often necessitates substantial waiting periods prior to publication (Beller et al., 2013), thereby introducing a temporal lag that may render these papers obsolete and redundant for subsequent researchers. This is particularly pertinent in the field of Artificial Intelligence, where technological advancements occur at a swift pace, necessitating researchers and regulators to remain abreast of all current developments.

The process of publishing in peer-reviewed academic journals can be laborious and time-consuming. Consequently, many industry experts, leaders and practitioners opt to disseminate their work in various formats (videos, vlogs, blogs, white papers, discussion papers, podcasts) through several mediums. Those type of publications as commonly referred as "grey literature" (Soldani, 2019). Given the wealth of contemporary knowledge and up-to-date information accumulated in these mediums, the have become a valuable recourse. Therefore, the authors of this paper deemed it essential to incorporate such literature to glean its contemporary insights on Artificial Intelligence.

Considering the aforementioned, we systematically approached the literature, employing the methodology of Multivocal Literature Review (MLR) as proposed by Benzies *et al.* (2006) and Adams, Smart and Huff (2017). In essence, a multivocal literature review is a Systematic Literature Review (SLR) that incorporates Grey Literature (GL) alongside peer reviewed published literature (Garousi et al., 2019). As described by Adams, Smart and Huff, (2017) GL consists of three tiers. From the outermost to the innermost, the third tier includes blogs, presentations, emails and tweets. The second tier of GL includes annual reports, videos, wiki articles, news articles and NGO studies, while the first tier, books, magazines, government reports and white papers. Transitioning from "white literature" to the third tier, there is a marked decrease in the control over the outlet and the credibility of the sources or sources expertise, shifting from significant to low. Conversely, the volume of literature experiences an increase. In this context, the application of Artificial Intelligence in the realm of personal selling is examined. Specifically, two search engines were employed for the retrieval of the publications. Google search was favored for the location of grey literature, given its capacity for convenient customization throughout the search process (Godin et al., 2015). Words used for the grey literature searches conducted through Google were "Artificial Intelligence regulation" and "Artificial Intelligence regulation mental health". Regarding the white literature, Gusenbauer (2019) identifies Google Scholar as the "most comprehensive academic search engine", providing extensive coverage of academic publications (Jacsó, 2008).

4.2 The EFQM Model

The EFQM Model is a Total Quality Management framework which is offered by the European Foundation for Quality Management (https://efqm.org/the-efqm-model/) and which focuses on managing change and improving performance in organisations. In this paper, as we do not

introduce any assumptions for the involvement of pre-existing organisations to take on the responsibility of regulating AI in the economy, our approach and discussions for implementation of the EFQM Model are directed towards achievement of strong performance by the AI regulator, which subsequently produced positive outcome for other stakeholders.

Figure 1: EFQM Model 2020 – Innovation lens, https://efqm.org/efqm-lens-series/innovation/

5. Research Question

The aim of this paper is to understand, through a Systematic Literature Review, the necessity for the introduction of a regulator for the Artificial Intelligence industry. This necessity is with respect to the overall operation of the industry, as well as with respect to the role of AI in provision of mental health services specifically. To investigate this topic, the paper introduces a research question:

RQ: Does the necessity for the regulation of AI exist?

Establishing the inclusion/exclusion criteria

As an integral component of the research protocol, the establishment of inclusion and exclusion criteria is indispensable in the process of source evaluation and selection. The criteria employed are as follows:

- *Inclusion Criteria*
  - The literature must bear relevance to the research question.
  - The literature should explicitly reference Artificial intelligence and Regulation.
  - Literature that highlights the need for regulating Artificial Intelligence.
  - The web page should be text-based.
  - Literature that appears within the first seven pages of Google Search results.
  - The literature must be composed in the English language.
- *Exclusion Criteria*
  - Web pages whose main content comprises audio files, videos or images.
  - Literature that is inaccessible.
  - Literature that contains only a summary.

6. Results and discussion

Results in Table 1 and Table 2 are indicative of the recognition in the white literature and the grey literature of the necessity for regulation of AI. Also, the sources identified by this search suggest that AI can have significant applications in the provision of mental health services.

This paper proposes the introduction of regulation for AI, through the EFQM Model. A particular area of focus for the paper is the use of AI in the mental health services industry.

Table 1: Primary studies in academic literature

ID	Title	Venue	Year	Ref.
D1	The Dark Sides of Artificial Intelligence: An Integrated AI Governance Framework for Public Administration	Jour.	2020	(Wirtz et al., 2020)
D2	Towards intelligent regulation of artificial intelligence	Jour.	2019	(Buiten, 2019)
D3	AI as a challenge for legal regulation – the scope of application of the artificial intelligence act proposal	Jour.	2023	(Ruschemeier, 2023)
D4	Artificial Intelligence in Autonomous Weapon Systems	Book chapter	2020	(Abaimov & Martellini, 2020)
D5	Suspect AI: Vibraimage, Emotion Recognition Technology and Algorithmic Opacity	Jour.	2021	(Wright, 2021)
D6	Public Policy and Regulatory Challenges of Artificial Intelligence (AI)	Conf.	2020	(Misra et al., 2020)
D7	Regulating artificial intelligence: A technology regulator's perspective	Conf.	2021	(Ellul et al., 2021)
D8	Regulating Artificial Intelligence Proposal for a Global Solution	Conf.	2018	(Erdélyi & Goldsmith, 2018)
D9	A European Agency for Artificial Intelligence: Protecting fundamental rights and ethical values	Jour.	2022	(Stahl et al., 2022)
D10	Toward the agile and comprehensive international governance of AI and robotics	Conf.	2019	(Wallach & Marchant, 2019)
D11	Artificial Intelligence Regulation: a framework for governance	Jour.	2021	(de Almeida et al., 2021)
D12	Ethical and legal challenges of artificial intelligence-driven healthcare	Book Chapter	2020	(Gerke et al., 2020)

Table 2: Studies in grey literature. Table A in the Appendix shows hyperlinks for these sources.

ID	Year	Title	Type	Company/ Organization
[G1]	2023	Regulatory framework proposal on artificial intelligence	Policy article	European Commission
[G2]	2022	The impact of Artificial Intelligence on the Future of Workforces in the EU and the US	Policy paper	European Commission
[G3]	2023	AI regulation: a pro-innovation approach	Policy paper	UK Government
[G4]	2023	AI regulation around the world	Article	TaylorWessing
[G5]	2023	Artificial Intelligence Regulation	Insight publication	Norton Rose Fulbright
[G6]	2023	The European Union's Artificial Intelligence Act - explained	Article	World Economic Forum
[G7]	2023	Europe is leading the race to regulate AI. Here's what you need to know	News article	CNN
[G8]	2023	Who is going to regulate AI?	Article	Harvard Business Review
[G9]	2023	The US government should regulate AI if it wants to lead on international AI governance	Commentary	Brooking Institute
[G10]	2023	Artificial Intelligence and Digital Regulations Service	Article	NHS – Health Research Authority
[G11]	n.d.	Understanding AI regulation – A collection of resources to help developers of AI for health and care	Resources collection	NHS England – Transformation Directorate
[G12]	n.d.	Blueprint for an AI Bill of Rights	Blueprint	The White House
[G13]	2021	The wellness industry's risky embrace of AI-driven mental health care	Commentary	Brooking Institute
[G14]	2019	The incredible ways Artificial Intelligence is now used in Mental Health	Article	Forbes
[G15]	2023	Can AI Chatbot Therapists Revolutionalise Mental Health Care?	Article	Innovation Origins
[G16]	2023	Artificial Intelligence in Behavioral Health and Suicide Prevention: Opportunities, and Challenges	Article	The Centre for Community Solutions
[G17]	2023	AI-powered companion robots could end loneliness in older adults	Article	Interesting Engineering

7. The EFQM Model supporting AI regulator's performance

This paper identifies two lenses proposed from the EFQM as most relevant: the lens of Innovation and the lens of Net Zero. The Innovation lens allows for the main themes of Direction, Execution and Results to be included. These themes are illustrated in Figure 1, which has the Organisation (i.e. the AI regulator) at the centre, and presents these three themes as part of an ongoing cyclical process (with arrows moving clockwise and anti-clockwise). Effective organisations work on continuously improving themselves through the use of prior Results to shape their future Direction; these future Directions lead to Execution of actions; and these actions bring on Results. These Results are considered in the process of shaping future Direction, restarting this continuous cycle of improvement and of organisational learning through experience.

The regulator of AI faces the demanding task of working on understanding, monitoring a controlling a very innovative industry which can also be difficult to understand as externals due to the complexity of the operations. It is also likely that competitive advantage of the organisations that partake in the industry is based on operational aspects of the AI platforms, and thus regulated organisations can be reluctant to disclose and share any aspects of their operations. It is also possible that the business models used by AI firms are not fully understood, as a multitude of business models can be in motion, with some of these being more visible than other ones. This realisation has to be reflected in the Direction taken, involving relevant Vision and Leadership for achievement of the regulator goals, whilst adopting an Innovation Culture that helps achieve Strategy alignment and deep understanding of the workings and future plans of the regulated industry.

Execution is crucial, as this is where the AI regulator has to produce value, which is going to be sustainable, and embedded in the continuous nature of the role assigned. To ensure this, all stakeholders have to be engaged and included in the process, and the AI regulator has to be properly resourced, and has to build and execute activities oriented towards performance enhancement. Resources might involve going beyond the traditional 6Ms of production (Kaufman, n.d.) 8Ms (ConceptDraw, n.d.) to also include institutional-level resources, such as legislative, political and geopolitical resources to attempt to regulate firms with global operations and abilities to distribute these operations in remote jurisdictions.

Results for the AI regulator are not focused on the internal of the regulator's organisation, but are instead primarily directed to outcomes and impacts manifested on the Business and Market

Impact that regulator's actions have. With several stakeholders being involved in the AI industry, the full scope of outcomes and impacts have to be considered in order for relevant understandings of the AI regulator's performance to be drawn.

Figure 2 illustrates the Regulator's Artificial Intelligence Regulation Objectives mapping, which is based on the Net Zero lens of the EFQM model. That approach, which was amended for the AI regulation on which this paper is focused, was originally aimed at implementing the EFQM Model to efforts to implement Net Zero policies and strategies. This paper suggests that this framework can be combined with the framework shown in Figure 1 and that it can be applied on the operation of the AI sector.

In the illustration provided in Figure 2, the process commences with understanding and including Expectations and Interests of Key Stakeholders in the objectives of the regulator. This is followed by understanding and factoring in the emerging regulatory conditions in which the regulator is asked to operate. These might include political, economic, social, technological, environmental, legal considerations as per the PESTEL Analysis approach (Dudovskiy, 2015) in the sector which is to be regulated. The analysis which has to be done at that stage should include gaps and conflicting agendas, all of which have to be mapped and understood so that the impact of regulation can be appreciated. The Continuing Financial Sustainability and Future Value coming from the AI sector is achieved as a result of this process, and is also a contributing factor to the success of the regulatory efforts, and thus this is included as the third element of the framework of Figure 2.

With AI being a disruptive technology (*Disruptive Technology*, n.d.), which is expected to lead to paradigm shifts across several industries and sectors, it is imperative that its potential impacts become understood imminently. This can help facilitate transitionary arrangements that might be necessary to avoid demand and supply shocks across these industries and across economic sectors and industries, including changes and disturbances in labour markets, especially in those in which labour can be substituted by AI. It is understood that AI can be the element behind the 5th Industrial Revolution (Adel, 2022; Noble et al., 2022), leading to significant levels of sectoral and global economic disturbance and creating requirements for rearrangement of resources and processes (in industrial and services sectors alike). Given this, it is understood that the need for AI sector regulation is of imperative importance and urgent.

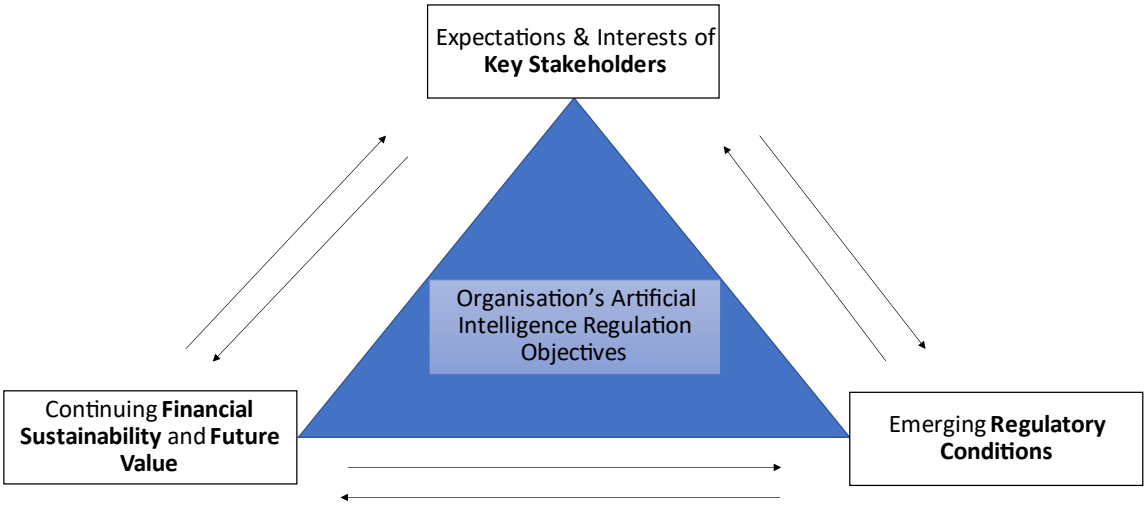

Figure 2: Regulator's Artificial Intelligence Regulation Objectives mapping. Based on EFQM Model – Net Zero lens, https://efqm.org/efqm-lens-series/net-zero/

8. Mental health services and AI – A regulatory perspective

One of the several sectors which are expected to be affected by the use of AI is the health services provision. A broad scope of possibilities is present, including diagnosis options and treatment options for telemedicine. One area which can be particularly labour-intensive and consuming significant amount of medical professionals time and attention is the diagnosis and treatment of mental health services. This presents opportunities for the introduction of mental health services through AI platforms, allowing platforms to interact with patients for significant length of time and through standardised approaches, gathering relevant data and supporting patients at the same time. These data could have been deemed non-economical to collect in more traditional approaches of mental health services provision, thus providing a unique opportunity for improvement of the performance of the services. The data collection done through AI platforms' interactions with patients, and these interactions not only could potentially provide support and monitoring, but it is understood that these would have been the times in which the patient would be queuing for services. This queuing could have given rise to patient dissatisfaction and could have allowed for symptoms of mental health conditions to worsen.

The regulatory approach to the actions and approaches for provision of mental health services could be implemented following the EFQM Model, as introduced above, with the stakeholders including as key actors the medical bodies and medical professionals, who would input to the regulatory process their protocols and deontological ethics. The AI regulator is in this case called upon to ensure that AI platforms which operate under profit-maximisation or value-maximisation agendas will be delivering services through conformance to specifications set up by the medical bodies. Independent data collection and analysis by the regulator, in addition to in-house expertise will be required to ensure appropriate levels of enforceability of the regulatory framework that is used.

9. Conclusions

We conclude that Artificial Intelligence needs to be regulated, to ensure the quality and the safety of the services provided through it. Through implementation of the EFQM Model, proper regulation of the Artificial Intelligence technologies in the mental health services industry is expected to improve business performance of mental health providers, improving outcomes for the patients, and leading the transformation of the paradigm for mental health services. We suggest that results can be affected by stakeholders' perceptions and agendas and these can be captured effective through the EFQM Model. We also suggest that Artificial Intelligence technological evolutions can shift paradigms in several sectors.

APPENDIX

Grey Literature sources hyperlinks

Table A: Grey Literature URLs.

ID	URL
[G1]	https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai
[G2]	https://digital-strategy.ec.europa.eu/en/library/impact-artificial-intelligence-future-workforces-eu-and-us
[G3]	https://www.gov.uk/government/publications/ai-regulation-a-pro-innovation-approach
[G4]	https://www.taylorwessing.com/en/interface/2023/ai---are-we-getting-the-balance-between-regulation-and-innovation-right/ai-regulation-around-the-world
[G5]	https://www.nortonrosefulbright.com/en/knowledge/publications/a473a1c1/artificial-intelligence-regulation
[G6]	https://www.weforum.org/agenda/2023/06/european-union-ai-act-explained/
[G7]	https://edition.cnn.com/2023/06/15/tech/ai-act-europe-key-takeaways/index.html
[G8]	https://hbr.org/2023/05/who-is-going-to-regulate-ai
[G9]	https://www.brookings.edu/articles/the-us-government-should-regulate-ai/
[G10]	https://www.hra.nhs.uk/planning-and-improving-research/research-planning/how-were-supporting-data-driven-technology/artificial-intelligence-and-digital-regulations-service/
[G11]	https://transform.england.nhs.uk/ai-lab/explore-all-resources/understand-ai/understanding-ai-regulation/
[G12]	https://www.whitehouse.gov/ostp/ai-bill-of-rights/
[G13]	https://www.brookings.edu/articles/the-wellness-industrys-risky-embrace-of-ai-driven-mental-health-care/
[G14]	https://www.forbes.com/sites/bernardmarr/2019/05/03/the-incredible-ways-artificial-intelligence-is-now-used-in-mental-health/
[G15]	https://innovationorigins.com/en/can-ai-chatbot-therapists-revolutionise-mental-health-care/
[G16]	https://www.communitysolutions.com/artificial-intelligence-in-behavioral-health-and-suicide-prevention-opportunities-and-challenges/
[G17]	https://interestingengineering.com/science/ai-powered-companion-robots-could-end-loneliness-in-older-adults

REFERENCES

Abaimov, S., & Martellini, M. (2020). Artificial Intelligence in Autonomous Weapon Systems. In M. Martellini & R. Trapp (Eds.), *21st Century Prometheus* (pp. 141–177). Springer, cham. https://doi.org/10.1007/978-3-030-28285-1_8

Adams, R. J., Smart, P., & Huff, A. S. (2017). Shades of Grey: Guidelines for Working with the Grey Literature in Systematic Reviews for Management and Organizational Studies. *International Journal of Management Reviews*, *19*(4), 432–454. https://doi.org/10.1111/ijmr.12102

Adel, A. (2022). Future of industry 5.0 in society: human-centric solutions, challenges and prospective research areas. *Journal of Cloud Computing*, *11*(1). https://doi.org/10.1186/s13677-022-00314-5

Ahmed, G. K., Khedr, E. M., Hamad, D. A., Meshref, T. S., Hashem, M. M., & Aly, M. M. (2021). Long term impact of Covid-19 infection on sleep and mental health: A cross-sectional study. *Psychiatry Research*, *305*(May), 114243. https://doi.org/10.1016/j.psychres.2021.114243

Alshrbaji, M., Mohammed, M., & Shamayleh, A. (2022). The Impact of Total Quality Management and Perceived Service Quality on Patient Satisfaction in Healthcare: A Systematic Review. *2022 Advances in Science and Engineering Technology International Conferences, ASET 2022*, 1–6. https://doi.org/10.1109/ASET53988.2022.9734872

Alzoubi, M. M., Hayati, K. S., Rosliza, A. M., Ahmad, A. A., & Al-Hamdan, Z. M. (2019). Total quality management in the health-care context: Integrating the literature and directing future research. *Risk Management and Healthcare Policy*, *12*, 167–177. https://doi.org/10.2147/RMHP.S197038

Barfield, W. (2018). Liability for autonomous and artificially intelligent robots. *Paladyn*, *9*(1), 193–203. https://doi.org/10.1515/pjbr-2018-0018

Beller, E. M., Chen, J. K. H., Wang, U. L. H., & Glasziou, P. P. (2013). Are systematic reviews up-to-date at the time of publication? *Systematic Reviews*, *2*, 36. https://doi.org/10.1186/2046-4053-2-36

Benzies, K. M., Premji, S., Hayden, K. A., & Serrett, K. (2006). State-of-the-evidence reviews: Advantages and challenges of including grey literature. *Worldviews on*

Evidence-Based Nursing, *3*(2), 55–61. https://doi.org/10.1111/j.1741-6787.2006.00051.x

Bourmistrova, N. W., Solomon, T., Braude, P., Strawbridge, R., & Carter, B. (2022). Long-term effects of COVID-19 on mental health: A systematic review. *Journal of Affective Disorders*, *299*(October 2021), 118–125. https://doi.org/10.1016/j.jad.2021.11.031

Brunier, A., & Drysdale, C. (2020). COVID-19 disrupting mental health services in most countries, WHO survey. *World Health Organization*, 2006–2021.

Buiten, M. C. (2019). Towards intelligent regulation of artificial intelligence. *European Journal of Risk Regulation*, *10*(1), 41–59. https://doi.org/10.1017/err.2019.8

Chiarini, A. (2020). Industry 4.0, quality management and TQM world. A systematic literature review and a proposed agenda for further research. *TQM Journal*, *32*(4), 603–616. https://doi.org/10.1108/TQM-04-2020-0082

ConceptDraw. (n.d.). *Manufacturing 8 Ms fishbone diagram - Template*. Retrieved July 13, 2023, from https://www.conceptdraw.com/examples/8m-method-machine-man-material

Courtney, H., Kirkland, J., & Viguerie, P. (1997). *Strategy Under Uncertainty*. Harvard Business Review.

Dadi, K., Varoquaux, G., Houenou, J., Bzdok, D., Thirion, B., & Engemann, D. (2021). Population modeling with machine learning can enhance measures of mental health. *GigaScience*, *10*(10), 1–16. https://doi.org/10.1093/gigascience/giab071

de Almeida, P. G. R., dos Santos, C. D., & Farias, J. S. (2021). Artificial Intelligence Regulation: a framework for governance. *Ethics and Information Technology*, *23*(3), 505–525. https://doi.org/10.1007/s10676-021-09593-z

De Angelis, L., Baglivo, F., Arzilli, G., Privitera, G. P., Ferragina, P., Tozzi, A. E., & Rizzo, C. (2023). ChatGPT and the Rise of Large Language Models: The New AI-Driven Infodemic Threat in Public Health. *SSRN Electronic Journal*, *April*, 1–8. https://doi.org/10.2139/ssrn.4352931

Disruptive Technology. (n.d.). Cambridge University Press. Retrieved July 10, 2023, from https://dictionary.cambridge.org/dictionary/english/disruptive-technology

Dudovskiy, J. (2015). *PESTEL Analysis*. Business Research Methodology. https://research-methodology.net/theory/strategy/7137-2/

Ellul, J., Pace, G., McCarthy, S., Sammut, T., Brockdorff, J., & Scerri, M. (2021). Regulating artificial intelligence: A technology regulator's perspective. *Proceedings of the 18th International Conference on Artificial Intelligence and Law, ICAIL 2021*, 190–194. https://doi.org/10.1145/3462757.3466093

Erdélyi, O. J., & Goldsmith, J. (2018). Regulating Artificial Intelligence Proposal for a Global Solution. *AIES 2018 - Proceedings of the 2018 AAAI/ACM Conference on AI, Ethics, and Society*, 95–101. https://doi.org/10.1145/3278721.3278731

European Parliamentary Research Service. (2022). *EU Legislation in Progress Artificial Intelligence Act*. *January*, 1–12.

Garousi, V., Felderer, M., & Mäntylä, M. V. (2019). Guidelines for including grey literature and conducting multivocal literature reviews in software engineering. *Information and Software Technology*, *106*(May 2018), 101–121. https://doi.org/10.1016/j.infsof.2018.09.006

Gerke, S., Minssen, T., & Cohen, G. (2020). Ethical and legal challenges of artificial intelligence-driven healthcare. In *Artificial Intelligence in Healthcare*. INC. https://doi.org/10.1016/B978-0-12-818438-7.00012-5

Godin, K., Stapleton, J., Kirkpatrick, S. I., Hanning, R. M., & Leatherdale, S. T. (2015). Applying systematic review search methods to the grey literature: A case study examining guidelines for school-based breakfast programs in Canada. *Systematic Reviews*, *4*(1), 1–10. https://doi.org/10.1186/s13643-015-0125-0

Gözükara, İ., Çolakoğlu, N., & Şimşek, Ö. F. (2019). Development culture and TQM in Turkish healthcare: importance of employee empowerment and top management leadership. *Total Quality Management and Business Excellence*, *30*(11–12), 1302–1318. https://doi.org/10.1080/14783363.2017.1366266

Gusenbauer, M. (2019). Google Scholar to overshadow them all? Comparing the sizes of 12 academic search engines and bibliographic databases. In *Scientometrics* (Vol. 118, Issue 1). Springer International Publishing. https://doi.org/10.1007/s11192-018-2958-5

Hermes, S., Riasanow, T., Clemons, E. K., Böhm, M., & Krcmar, H. (2020). The digital transformation of the healthcare industry: exploring the rise of emerging platform ecosystems and their influence on the role of patients. *Business Research*, *13*(3), 1033–1069. https://doi.org/10.1007/s40685-020-00125-x

Jacsó, P. (2008). Google Scholar revisited. *Online Information Review*, *32*(1), 102–114. https://doi.org/10.1108/14684520810866010

Justo-Hanani, R. (2022). The politics of Artificial Intelligence regulation and governance reform in the European Union. *Policy Sciences*, *55*(1), 137–159. https://doi.org/10.1007/s11077-022-09452-8

Kaufman, G. (n.d.). *Adding 6Ms of Production (man, machine, material, method, mother nature and measurement)*. Kaufman Global. Retrieved July 13, 2023, from https://www.kaufmanglobal.com/glossary/6ms-production-man-machine-material-method-mother-nature-measurement/#:~:text=Menu-,6Ms of Production (man%2C machine%2C material%2C,method%2C mother nature and measurement)&text=The 6Ms of production – Manpower,effect" problem-solving sessions

Keehan, S. P., Cuckler, G. A., Poisal, J. A., Sisko, A. M., Smith, S. D., Madison, A. J., Rennie, K. E., Fiore, J. A., & Hardesty, J. C. (2020). National health expenditure projections, 2019–28: Expected rebound in prices drives rising spending growth. *Health Affairs*, *39*(4), 704–714. https://doi.org/10.1377/hlthaff.2020.00094

Kim, G. S. (2020). The effect of quality management and Big Data management on customer satisfaction in Korea's public sector. *Sustainability (Switzerland)*, *12*(13). https://doi.org/10.3390/su12135474

Kooli, C., & Al Muftah, H. (2022). Artificial intelligence in healthcare: a comprehensive review of its ethical concerns. *Technological Sustainability*, *1*(2), 121–131. https://doi.org/10.1108/techs-12-2021-0029

Kormanski, L. M. (1988). Using the Johari Window to Study Characterization. *Journal of Reading*, *32*(2), 146–152. http://www.jstor.org/stable/40029904

Lancelot, J. F. (2020). Cyber-diplomacy: cyberwarfare and the rules of engagement. *Journal of Cyber Security Technology*, *4*(4), 240–254. https://doi.org/10.1080/23742917.2020.1798155

Misra, S. K., Das, S., Gupta, S., & Sharma, S. K. (2020). Public Policy and Regulatory Challenges of Artificial Intelligence (AI). In *IFIP Advances in Information and Communication Technology* (Vol. 617). Springer International Publishing. https://doi.org/10.1007/978-3-030-64849-7_10

Moreno, C., Wykes, T., Galderisi, S., Nordentoft, M., Crossley, N., Jones, N., Cannon, M.,

Correll, C. U., Byrne, L., Carr, S., Chen, E. Y. H., Gorwood, P., Johnson, S., Kärkkäinen, H., Krystal, J. H., Lee, J., Lieberman, J., López-Jaramillo, C., Männikkö, M., … Arango, C. (2020). How mental health care should change as a consequence of the COVID-19 pandemic. *The Lancet Psychiatry*, *7*(9), 813–824. https://doi.org/10.1016/S2215-0366(20)30307-2

Mosadeghrad, A. M. (2013). Obstacles to TQM success in health care systems. *International Journal of Health Care Quality Assurance*, *26*(2), 147–173. https://doi.org/10.1108/09526861311297352

Muruganandham, R., Venkatesh, K., Devadasan, S. R., & Harish, V. (2023). TQM through the integration of blockchain with ISO 9001:2015 standard based quality management system. *Total Quality Management and Business Excellence*, *34*(3–4), 291–311. https://doi.org/10.1080/14783363.2022.2054318

Noble, S. M., Mende, M., Grewal, D., & Parasuraman, A. (2022). The Fifth Industrial Revolution: How Harmonious Human–Machine Collaboration is Triggering a Retail and Service [R]evolution. *Journal of Retailing*, *98*(2), 199–208. https://doi.org/10.1016/j.jretai.2022.04.003

Păvăloaia, V. D., & Necula, S. C. (2023). Artificial Intelligence as a Disruptive Technology—A Systematic Literature Review. *Electronics (Switzerland)*, *12*(5). https://doi.org/10.3390/electronics12051102

Rubeis, G. (2022). iHealth: The ethics of artificial intelligence and big data in mental healthcare. *Internet Interventions*, *28*(March), 100518. https://doi.org/10.1016/j.invent.2022.100518

Ruschemeier, H. (2023). AI as a challenge for legal regulation – the scope of application of the artificial intelligence act proposal. *ERA Forum*, *23*(3), 361–376. https://doi.org/10.1007/s12027-022-00725-6

Schiavone, F., Pietronudo, M. C., Sabetta, A., & Ferretti, M. (2022). Total quality service in digital era. *TQM Journal*, *35*(5), 1170–1193. https://doi.org/10.1108/TQM-12-2021-0377

Seghatchian, J. (2020). An introductory commentary on the use of artificial intelligence, machine learning and TQM, as novel computational tools in big data patterns or procedural analysis, in transfusion medicine. *Transfusion and Apheresis Science*, *59*(6),

102985. https://doi.org/10.1016/j.transci.2020.102985

Shi, L., Lu, Z.-A., Que, J.-Y., Huang, X.-L., Lu, Q.-D., Liu, L., Zheng, Y.-B., Liu, W.-J., Ran, M.-S., Yuan, K., Yan, W., Sun, Y.-K., Sun, S.-W., Shi, J., Kosten, T., Bao, Y.-P., & Lu, L. (2021). Long-Term Impact of COVID-19 on Mental Health among the General Public: A Nationwide Longitudinal Study in China. In *International Journal of Environmental Research and Public Health* (Vol. 18, Issue 16). https://doi.org/10.3390/ijerph18168790

Shrivastav, S. K. (2023). How The TQM Journal has addressed "quality": a literature review using bibliometric analysis. *TQM Journal*. https://doi.org/10.1108/TQM-10-2022-0308

Smit Sibinga, C. T. (2020). Artificial intelligence in transfusion medicine and its impact on the quality concept. *Transfusion and Apheresis Science*, *59*(6), 103021. https://doi.org/10.1016/j.transci.2020.103021

Soldani, J. (2019). Grey Literature: A Safe Bridge Between Academy and Industry? *ACM SIGSOFT Software Engineering Notes*, *44*(3), 11–12. https://doi.org/10.1145/3356773.3356776

Souza, F. F. de, Corsi, A., Pagani, R. N., Balbinotti, G., & Kovaleski, J. L. (2022). Total quality management 4.0: adapting quality management to Industry 4.0. *TQM Journal*, *34*(4), 749–769. https://doi.org/10.1108/TQM-10-2020-0238

Stahl, B. C., Rodrigues, R., Santiago, N., & Macnish, K. (2022). A European Agency for Artificial Intelligence: Protecting fundamental rights and ethical values. *Computer Law and Security Review*, *45*, 105661. https://doi.org/10.1016/j.clsr.2022.105661

Taeihagh, A., & Lim, H. S. M. (2019). Governing autonomous vehicles: emerging responses for safety, liability, privacy, cybersecurity, and industry risks. *Transport Reviews*, *39*(1), 103–128. https://doi.org/10.1080/01441647.2018.1494640

Talib, F., Asjad, M., Attri, R., Siddiquee, A. N., & Khan, Z. A. (2019). Ranking model of total quality management enablers in healthcare establishments using the best-worst method. *TQM Journal*, *31*(5), 790–814. https://doi.org/10.1108/TQM-04-2019-0118

Tamer, G. (2022). The Effect of Total Quality Management on Supply Chain Management in the Digital World: Case of Healthcare Services. In *Handbook of Research on Cyber Approaches to Public Administration and Social Policy* (pp. 298–320). IGI Global.

Tausch, A., e Souza, R. O., Viciana, C. M., Cayetano, C., Barbosa, J., & Hennis, A. J. (2022).

Strengthening mental health responses to COVID-19 in the Americas: A health policy analysis and recommendations. *The Lancet Regional Health - Americas*, *5*, 100118. https://doi.org/10.1016/j.lana.2021.100118

Truby, J., Brown, R. D., Ibrahim, I. A., & Parellada, O. C. (2022). A Sandbox Approach to Regulating High-Risk Artificial Intelligence Applications. *European Journal of Risk Regulation*, *13*(2), 270–294. https://doi.org/10.1017/err.2021.52

Wallach, W., & Marchant, G. (2019). Toward the agile and comprehensive international governance of AI and robotics. *Proceedings of the IEEE*, *107*(3), 505–508. https://doi.org/10.1109/JPROC.2019.2899422

Wirtz, B. W., Weyerer, J. C., & Sturm, B. J. (2020). The Dark Sides of Artificial Intelligence: An Integrated AI Governance Framework for Public Administration. *International Journal of Public Administration*, *43*(9), 818–829. https://doi.org/10.1080/01900692.2020.1749851

Wright, J. (2021). Suspect AI: Vibraimage, Emotion Recognition Technology and Algorithmic Opacity. *Science, Technology and Society*, *2021*, 1–20. https://doi.org/10.1177/09717218211003411

Wu, X., & Liu, X. (2021). Building crack identification and total quality management method based on deep learning. *Pattern Recognition Letters*, *145*, 225–231. https://doi.org/10.1016/j.patrec.2021.01.034

Yasin, M. M., & Alavi, J. (1999). An analytical approach to determining the competitive advantage of TQM in health care. *International Journal of Health Care Quality Assurance*, *12*(1), 18–24. https://doi.org/10.1108/09526869910249640

Zhang, Z., Hamadi, H. Al, Damiani, E., Yeun, C. Y., & Taher, F. (2022). Explainable Artificial Intelligence Applications in Cyber Security: State-of-the-Art in Research. *IEEE Access*, *10*(July), 93104–93139. https://doi.org/10.1109/ACCESS.2022.3204051

Zhu, G., Chou, M. C., & Tsai, C. W. (2020). Lessons Learned from the COVID-19 pandemic exposing the shortcomings of current supply chain operations: A long-term prescriptive offering. *Sustainability (Switzerland)*, *12*(14), 1–19. https://doi.org/10.3390/su12145858