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AI-based clinical decision-making systems in palliative medicine: Ethical challenges

This is the final peer-reviewed author's accepted manuscript (postprint) of the following publication:

Published Version:
De Panfilis, L., Peruselli, C., Tanzi, S., Botrugno, C. (2023). AI-based clinical decision-making systems in palliative medicine: Ethical challenges. BMJ SUPPORTIVE & PALLIATIVE CARE, 13(2), 183-189 [10.1136/bmjspcare-2021-002948].

Availability:
This version is available at: https://hdl.handle.net/11585/994886 since: 2024-10-25

Published:
DOI: http://doi.org/10.1136/bmjspcare-2021-002948

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(Article begins on next page)

10 September 2026

ETHICAL CHALLENGES OF AI-BASED CLINICAL DECISION-MAKING SYSTEMS FOR PALLIATIVE CARE

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Introduction

Improving palliative care (PC) is a policy priority worldwide[1]. According to the most recent studies, we can expect an increase in people with PC needs at the end of life (EOL) over the next few years[2]. n Europe, more than 75% of people die from chronic diseases such as cancer, heart disease, stroke and dementia[3]. Chronic diseases are characterized by a slow progression, fluctuations in trajectory, a long duration and uncertainty in prognoses. In this context, PC is challenged by irreducible uncertainty and must be flexible. An early identification of PC needs becomes fundamental in the care approach of chronic disease and can also represent public health concerns worldwide[4].

A timely introduction of PC services provides effective patient-centered care and could improve outcomes such as patient quality of life, reduction of the overall length of hospitalization, survival rate prolongation, the satisfaction of both the patients and caregivers, and cost-effectiveness[7,8]. In achieving these goals of care, Advance Care Planning (ACP) represents an essential tool.

According to the most recent definition promoted by the European Association for Palliative Care (EAPC) "ACP enables individuals who have the decisional capacity to identify their values, to reflect upon the meanings and consequences of serious illness scenarios, to define goals and preferences for future medical treatment and care and to discuss these with family and health-care providers. ACP addresses individuals' concerns across the physical, psychological, social, and spiritual domains. It encourages individuals to identify a personal representative and to record and regularly review any preferences so that their preferences can be taken into account should they, at some point, be unable to make their own decisions"[21].

Despite the worthy objectives of the ACP, both health care professionals (HPs) and patients have expressed concerns about beginning an ACP conversation. As reported by Detering[22], the potential barriers to ACP include the availability of trained staff to discuss ACP with patients and the organizational commitment and policy locally implemented not only by the physicians involved but also by the organization. According to the literature, prognostic uncertainty is another barrier to beginning an ACP conversation. This must be coupled with difficulties in making the most appropriate decision for the future[23].

Increasing prognostic awareness can help overcome some of the reported difficulties, even if the ACP process also involves communicative, ethical and relational issues that require specific skills by health care professionals[24]. As shown by Detering[22], the benefits of ACP are not limited to promoting respect for the individual autonomy but include the opportunity of considering patients' wishes and values and strengthening relationships between all involved, such as relieving burdens on the family.

A physician's assessment is currently the main method in clinical practice for predicting adverse outcomes – including mortality, the appropriate timing for initiating an ACP discussion,and identifying PC needs[5]. However, evidence has shown that predictions of patient survival by clinicians can be imprecise and overly optimistic, even in metastatic cancer, where the prognosis is usually considered to be fairly accurate[6]. In addition, PC is often delivered late in the illness trajectory, resulting in an increase ofhospital mortality, a suboptimal symptom management, and possible delays in initiating ACP [10,11].

As also confirmed by Courtright et al. (2019), today "innovative and systematic strategies are needed to augment clinician referral of patients most likely to benefit from earlier palliative care consultation" (2019, 1841).

Currently, the implementation of new technologies in healthcare practice – particularly, Information Technologies (ITs) – has been credited with playing a major role in improving efficiency and ensuring higher accuracy in both diagnostic and therapeutic processes[12].

However, technological innovation in healthcare is often driven by a technological imperative that influence its social acceptability. Indeed, despite the impressive opportunities they bring to healthcare practice, the magnitude of their benefits has not been yet adequately assessed (Challen et al 2019, 231). In parallel, their introduction in care settings raise severe ethical concerns[13].

In this article, after briefly retracing the state of the art in the field of Artificial Intelligence (AI)-based clinical decision-making systems for PC and ACP, we identify and discuss some of the major ethical challenges related to their implementation in routine PC settings.

AI for PC and ACP: Where are we?

AI systems have already shown their potential to emulate human abilities by processing large data sets of health information (Wang and Preininger, 2019; Chen and Decary 2019). This is particularly evident with image-based diagnostics, arguably the most promising sector for the integration of AI in healthcare (Hosney et al. 2018; Pesapane et al. 2018). Specialties as radiology, neurology, cardiology, and oncology are among those that can benefit the most from the ability of AI to accurately process (i.e. assess, record, put in comparison, and therefore "learn" from) radiographies or statistical data, from which diagnostic and/or therapeutic indication can be extracted (Pinto dos Santos 2018; Tang et al. 2018).

Among the subsets of AI is Machine Learning (ML), which offers the opportunity to "train" sample data to enable them to "learn" automatically from the elaboration of large sets of anonymized (big) data. As has been previously argued[15], the deployment of ML techniques is becoming fundamental for analyzing large amounts of complex healthcare data.

ML has the potential to support clinicians in improving the decision-making process by identifying those at high risk of inappropriate care, poor outcomes and mortality. Evidence has shown the capacity of ML tools to provide accurate mortality predictions[16]. Indeed, ML can improve the ability
of health professionals to establish a prognosis and this could transform improve the timing of advance care planning for patients with serious illnesses (16).

Another branch of AI tools is natural language processing (NLP). NLP techniques allow for the recognition and analysis of human conversations, including clinical conversations[17]. NLP[18] can also enable the systematic analysis of unstructured free-text clinical notes, and electronic health records (EHRs), which could enhance the identification of patients with a poor prognosis[19].

It has been emphasized that routinely collected health data – e.g. death registries, hospital records, data from primary and palliative care registers – boast an intrinsic value in PC and are increasingly being used in this context (Davies et al 2016, p. 258): "The inherent value of routine data is that it already exists and often on a population basis, negating the challenges associated with primary data collection in [palliative and end of life care]" (davies et al 2016, 257)".

Another main source of information that could be relevant for AI in PC is currently represented by the proliferation of sensors or Internet of Things (IoTs). As has been argued, indeed, IoTs application boast the potential to shift forward the scope of data collection including not only sleep, movement and heart rate but also "eating and drinking habits and time spent on different types of activities" (Nowsu et al 2018, 165). Tanutsepro (2017) confirms that PC activation could benefit from automated processing of health data collected for the most diverse purposes, such as capturing emergency room visits, or sub-acute care hospitalizations and nursing home assessments, ambulatory care (Tanutsepro 2017, 489). However, the author also alerts that the information included in these databases cannot capture the patient experience, nor do they provide much detail about the progression of disease and " this limits our ability to infer when and to what level of palliative care might be appropriate" (Tanutsepro 2017, 489).

As of today, the introduction of AI-based services into PC settings has had a limited impact. For example, according to Storick[25], the improvement of decision-making at the end-of life requires more than simply improving the predictive power of mortality models.

Nonetheless, it is undeniable that mortality predictions provided by AI-based tools can have a significant impact on PC and EOL if used as one among a series of parameters to activate early PC. This is also shown by the reported experiences related to the current integration of AI into PC settings, including ACP.

Robbins[26] described the development and implementation of an automated mortality prediction model based on daily clinical data in several care settings. Automated lists of inpatients with a high risk of dying within 12 months are generated daily on the basis of large datasets. According to the authors, automated

prediction helps clinicians initiate ACP conversations in a timely fashion; without them, difficult communications start late or never.

The same goal is pursued by the app "Aspire Health"[27], which helps in identifying patients with a mortality prediction of less than 12 months. Hence, it can lead to timely access to PC assessment at home while reducing futile and inappropriate treatments.

"Palliative Connect"[28] is an experimental project which combines an analytical forecast of survival to an early assessment of PC needs with the purpose of improving EOL management. Preliminary results have shown an increase of 74% in in-hospital specialized PC compared to the control group; ACP documentation increased by approximately 38%, while PC home activations increased by approximately 61%. Moreover, fewer admissions to the ICU have been registered.

Finally, Wang[29] showed that a "deep neural network" supports mortality forecasts in 6-12-24 months, and it can be used to identify dementia patients with PC needs. Moreover, it can help in initiating ACP discussions, which represents a very important issue in caring for these patients, especially considering the clinical and cognitive decline intrinsic to dementia.

From an ethical point of view, the provision of these automated techniques raises a number of critical issues that deserve further exploration. In the next paragraph, we will illustrate some of the ethical challenges of the use of AI in PC and ACP.

The ETHICAL challenges of AI in PC

1. AI-based predictions and ACP decision-making process: opportunities and limits.

Uncertainty is one of the challenges that PC professionals have to address in their work, while the promise of certainty is part of the attraction of ML-based techniques and services[30]. As of today, however, the most plausible scope for the integration of the automated services into PC is enhancing the ethical decision-making process, not replacing clinicians with the “machine’s results”. As observed by Ngiam[15], indeed “the most ethically feasible scenario involves the use of AI to augment the capability of human doctors, rather than replace them”. In this perspective, Scott emphasized that patients always need to have empathic interactions with their clinicians, who have to tailor care to their individual circumstances ““which are unlikely to be fully captured by algorithmic application of Big Data” (Scott 2019, 128).

Accordingly, mortality predictions should not be used as a unique parameter to activate early PC and initiate an ACP. In contrast, they can signal the need for patients to obtain access to personalized communication or palliative care consultation[30]. Other factors must be included in the ethical decision-making process related to the initiation and stimulation of ACP conversations, among which are autonomy and quality of life, the risk of worsening health care status, the commitment by caregivers, the patients’ psychosocial and spiritual distress, and not least, requests by patients themselves to initiate EOL discussions[23].

It must be reminded that decision-making process focused on ACP is an ongoing process. Only during this process is it possible to determine what is important to patients and their desires and preferences to understand the originality of their "illness narratives". For some, ML mortality predictions can help motivate clinicians to start these personalized conversations (Ref. n.31). Others maintain a critical view on this technological innovation, as in the case of Sulmasy (2020), who wonder if instead of using AI to explore the hidden preferences of patients, doctors concentrating on becoming more fully human in the relationship of care and accepting the uncertainty inherent in all ethical decision-making (Sulmasy 2020, 814).

It is necessary to consider how the introduction of these new technologies will fit into conventional PC practice, and what the ethical balance between automated predictionsand professionals' autonomy in evaluating appropriateness and timeliness of PC could be.

2. The meaningfulness of automated predictions

The appropriateness of AI-based mortality predictions as a trigger to start EOL conversations is closely related to the discussion on their "meaningfulness", namely their intrinsic and extrinsic attitude to be used by healthcare professionals. As for the intrinsic value of automated predictions, it has been underscored that, if used alone, they could be not enough to inform decisions in the EOL because they "describe an outcome distribution among individuals with a particular set of characteristics" (Maley et al 2) but "they do not compare how that outcome distribution would change were different treatment decisions made" (Maley et al 2). Accordingly, they (Maley et al) conclude that the role of automated predictions should be limited to support for identifying a PC need, after which there would be need to estimate causal effects (Maley et al 2020, 3).

As for the extrinsic value of automated predictions, Scott (2019) highlights that the huge availability of big data in itself may be not of great help without a conceptual framework that guides data collection, curation and interpretation (Scott 2019, 127).

It is hard to say whether prediction results will be immediately usable – and eventually interpretable – by PC professionals in their routine. A risk exists that this innovation will turn into a new burden for PC professionals. It does not seem feasible nor ethically acceptable that they can be induced (or obliged) to find the time and develop the ability necessary to deal with the functioning of AI. This would mean asking them to turn – ever more – into medical informatics, i.e. to make a further step into the informational medicine paradigm mentioned above. In such a scenario, the barycentre of care would move from the doctor-patient relationships to the interaction between patients and technology.

3. The impact of AI on the responsibility of PC professionals

The integration of automated predictions in PC discloses radically new scenarios for what concerns responsibility and malpractice liability. Of course, the latter rest upon the technical features of AI-based tools, as well as on the concrete configurations through which they are implemented in practice. ML techniques can be supervised, semi-supervised or unsupervised depending on the room they leave to human oversight. Of course, to protect patients, the best would be to allow professionals to supervise the process, but this would give rise to a new responsibility in case the supervision leads to mistakes. Secondly, regardless of whether the prediction has been supervised by humans, the management of the prediction would trigger a further problem: To what extent are doctors entitled to discard AI-based predictions? At least three scenarios are conceivable when thinking at the integration of AI-based tools into routine PC: a) doctors are obliged to be consequent with the prediction's results; b) doctors are recommended to take into account the prediction's results; c) doctors are free to give value to prediction's results. Each of these scenarios would lead to a different type of responsibility: in a) doctors cannot be charged with the consequence of mistakes made by the algorithm; in b) doctors can be asked to face the consequence of a serious mistake unless they prove they could not be choose otherwise on the basis of the algorithm's input; in c) doctors would remain totally responsible for their choices.

Correlatively, from the side of patients, it must be wondered if have they a right to opt out from the inclusion of their case into the AI-based prediction mortality[12]?

4. INTEROPERABILITY of health data

As seen above, AI-based tools can tap at multiple sources for developing mortality predictions. Indeed, ML algorithms can obtain valuable information by examining diagnoses from the most diverse databases, including "those capturing emergency room visits, sub-acute care hospitalizations, nursing home assessments, ambulatory care, physician service billings, and supportive home care assessments. [They] can also take advantage of existing disease-based registries, for example, in cancer" (Tanutsepro 2018, 489).

This attitude of AI, however, must be considered in the light of the barriers posed by data interoperability, which cannot be taken for granted, especially when it comes to health data.

Today health data are collected on a myriad of platforms and through a countless range of formats. Not least, digital health data is just a small although growing part of the whole amount of health information collected and produced.

On the one hand, "harmonizing" these data could be an unbearable effort for current healthcare systems. On the other hand, to ensure accuracy and meaningfulness, automated predictions should process the hugest amount of data available. This calls for a global digital strategy (Nwosu et al 2018) that ensures the technical uniformity of health data formats and their compliance by technology developers.

5. Automation bias and the ensuing risks of inequalities and discrimination

Among the main concerns expressed by bioethics scholars when looking at the application of AI techniques in healthcare, is that they can induce biases or magnify those intrinsic to human decision-making. This would increase health inequalities in the EOL, sending patients from particular population groups down certain care trajectories or directing PC resources to those who are already most likely to get them[32].

Despite ML the algorithms are usually trained on an impressive amount of data, they could not necessarily reflectthe state of the art in the fields relevant to the prediction, or they could be not representative of certain population group. For example, consider the "oldest old" people. The main risk posed by automated mortality predictions is that they can condition intensive treatment decisions and recommendations solely on the base of one or more factors. This is what happened with the "age" factor with the allocation of ventilators in the COVID-19 emergency, which raised strong controversy at international level[33]. As has been argued, Big Data may remain poorly calibrated when quantifying risk in individual patients (Scott 2019, 127). Scholars have coined the term "distributional shift" to describe the gap between real-world data and ML-trained data (Huckvale et al 2019).

Not least, AI-based services can also influence the autonomy of doctors' clinical evaluations, inducing them to seek for compliance with automated results. Such phenomenon has been defined as "automation bias": a situation in which clinicians "accept the guidance of an automated system and cease searching for confirmatory evidence, perhaps transferring responsibility for decision-making onto the machine" (Challen et al 2019, 234)

6. Protecting patient's privacy

Respecting patient's privacy is pivotal when implementing digital healthcare services[37]. As described above, AI services for mortality prediction are based on the processing of large anonymized datasets, from which individual forecasts of survival are extracted. In virtue of its nature, The management of this information is a crucial point for respecting patients' privacy Due to its nature, knowing about a mortality prediction can trigger a very high and specific condition of vulnerability for concerned patients. This raises a series of questions: Who is entitled to access this information besides the concerned patients? If the prediction mortality services are offered by private providers, to what extent are they allowed to use the information for direct-to-patient commercial offers? Additionally, are they legitimized to reuse generated information for purposes unrelated to healthcare? Although the GDPR in Europe provides a strong framework to address these issues, conflicts between opposed interests, rights, values and practices are unavoidable in everyday practice, namely, when considering the vulnerability and frailty of patients in EOL and PC settings. In addition, bioethics scholars already warned about the desires of medical companies to expand their

influence by attracting users and thus being able to manage large pools of health information (Beck 2016, Caplan trovare__). This is especially true when considering that deployment of AI in healthcare seems to be driven by profit. As emphasized by Windisch et al (2020), the application of AI in healthcare "is still largely limited to projects with the potential for great commercial gain. In contrast, research on its impact in other fields such as global health is comparatively slow" (Windisch et al 2020, 1).

Conclusions

The use of AI-based tools to systematically identify patients with advanced progressive diseases, potential PC needs and ACP planning conversation could shift healthcare practice and relieve the physicians' burden in identifying these patients.

Nevertheless, several ethical challenges arose. Most of all, it is important to raise awareness of the ethical implications of integrating AI-based techniques into pre-existing EOL and PC settings. Undoubtedly, the progressive spread of IT-mediated services is reshaping the features, the ethics and the aesthetics of healthcare delivery. New technologies are designed to be attractive and seductive to the users' eyes – including to those of patients and of healthcare professionals – which contributes a great deal to foster their widespread use in routine practice. In the meantime, new technologies also reshape the way patients and healthcare professionals conceptualize the body, its expressions and the emotions (including e.g. suffering and pain), as well as the relationship between health and disease itself (Lupton 2016; 2013).

The evaluation of complexities in PC can benefit from these tools to lean on an ACP process, but, the research has to include not only survival estimations. It is crucial to analyzedifferent outcomes, such as the complexity of needs, patient preferences and values, deterioration of self-determination and autonomy, and moral and social distress. Last, it will be crucial to develop specific educational programs dedicated to HPS while engaging patients in those technologies.

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