The Unseen Hand

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CURRENT OPINION

The Unseen Hand: AI-Based Prescribing Decision Support Tools and the Evaluation of Drug Safety and Effectiveness

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Abstract
The use of artificial intelligence (AI)-based tools to guide prescribing decisions is full of promise and may enhance patient outcomes. These tools can perform actions such as choosing the 'safest' medication, choosing between competing medications, promoting de-prescribing or even predicting non-adherence. These tools can exist in a variety of formats; for example, they may be directly integrated into electronic medical records or they may exist in a stand-alone website accessible by a web browser. One potential impact of these tools is that they could manipulate our understanding of the benefit-risk of medicines in the real world. Currently, the benefit risk of approved medications is assessed according to carefully planned agreements covering spontaneous reporting systems and planned surveillance studies. But AI-based tools may limit or even block prescription to high-risk patients or prevent off-label use. The uptake and temporal availability of these tools may be uneven across healthcare systems and geographies, creating artefacts in data that are difficult to account for. It is also hard to estimate the 'true impact' that a tool had on a prescribing decision. International borders may also be highly porous to these tools, especially in cases where tools are available over the web. These tools already exist, and their use is likely to increase in the coming years. How they can be accounted for in benefit-risk decisions is yet to be seen.

1 Introduction: Artificial Intelligence (AI)-Based Tools—A New Aid to Prescriber Decision Making

Prescribing the most safe and effective medication to a patient is a highly complex task, and clinical decision support system (CDSS) tools can assist in this activity. CDSS tools based on artificial intelligence (AI) may help inform prescription choices using complex combinations of patient attributes. This article focuses on the impact that these AI-based tools may have on established approaches for monitoring medicine safety and effectiveness in the real world. This article is a summary of three virtual workshops held from January to February 2023 with a focus on how the field of pharmacoepidemiology could react to the introduction of these tools. The workshop series was called 'Actionable AI for treatment' and prospective participants were invited to attend via email. All workshop participants also later contributed to this work as authors, representing academic, pharmaceutical industry and technology company organisations. In advance of the workshops, a list of proposed subtopics was generated and ranked in importance by poll, and each workshop followed a structured agenda. The first workshop focused on sources of bias and unfairness in treatment predictions, the second on the regulation and monitoring of AI-based tools that assist treatment selection, and the third on the impact that AI-based CDSS tools have on medication use and evaluation of drug benefit-risk. The minutes from each workshop were circulated and edited, and the key themes from the discussion were used to construct this manuscript.

2 The Current State of Play of AI-Based Prescribing Support Tools

A great deal of valuable medical information is available within the patient records, including previous diagnoses, procedures, genetic testing, and medication use. These data can be utilised by AI-based tools to help prescribers select the right medication for an individual patient [1]. The use of these tools in clinical practice is relatively

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Key Points

Artificial intelligence-based clinical decision support tools have the ability to promote better patient outcomes by making use of patient-level data. However, these sophisticated tools may alter our understanding of medicine benefit-risk in the real world.

The differential uptake of these tools may lead to 'surveillance artefacts' in real-world data, whereby the safety of a medicine appears worse or better than we would expect it to due to the hidden influence of these tools.

These tools may reduce or restrict medicine access for some groups of patients if off-label use is prohibited, which could disadvantage pregnant people, infants or the elderly.

It may be challenging to demonstrate that these tools are having an impact on prescribing during discussions with regulators.

opaque—anecdotal evidence shows that many of these tools fall outside of official medical device reporting channels, are restricted to single hospitals [2, 3], or, alternatively, are used for short periods within research studies [4].

The applications of these tools vary widely across the prescribing lifecycle [4–6]. Some tools aim to prevent prescription errors, such as MedAware, which uses AI to detect and flag potential errors in prescription [7]. Other tools focus on improving safety outcomes, such as the CMM-Wrap program used in high-risk Medicaid patients to predict the likelihood of adverse events (AEs) based on proposed treatment plans [8]. Some tools focus on drug effectiveness outcomes, such as the Antidepressant Response Prediction Network (ARPNet) tools, which predict treatment success in patients with depression [9], G-Net, which is able to predict individual patient treatment success under different counterfactual treatment plans [10]), or IBM Watson and Tempus's xT Platform for oncology treatment recommendations [11, 12]. Other tools may also use patient-level data to predict potential issues with addiction [13] or are able to predict non-adherence by using real-time measures of dosing [14]. Some tools will be used to enhance prescriber decision making during medication reviews, such as DynAIRx, a tool that visualises the risk of future hospital admissions according to different proposed treatment plans [15]. Other tools may be used to support tapering or de-prescribing, such as those seen in the describing of opioids [16, 17]. The clinical applications of these tools are numerous and are likely to expand as more AI developers are able to demonstrate increased return on investment or improved patient outcomes [2].

3 Integration of AI Prescribing Tools into Clinical Practice May Alter Prescribing Trends

The level of integration of these AI-based tools into standard clinical practice varies greatly. Some tools will be directly integrated into the Electronic Medical Record (EMR) system itself, while others will be available through external 'web-checker' browser-based tools, which operate on abstracted patient data. The tools may also differ in their impact and intrusiveness; some tools may either prevent prescription entirely (hard-stop alerts), or simply act as a checkpoint or warning flag in the prescribing process (e.g., requiring an additional sign-off for prescription) [18]. The regulation of these tools also varies according to the strength and specificity of the recommendations made. Tools that provide explicit treatment guidance would be required to follow the software as a medical device (SaMD) US FDA approval pathway. However, many AI-based tools may fall outside this rigorous framework, and some are considered non-device CDS by the FDA. The dividing line between SaMD eligible and ineligible tools remains highly contentious, and updated guidance was made available by the FDA in 2022 [19, 20].

4 Could these Tools Impact the Benefit-Risk Assessments of Medicines in the Real World?

The licencing and approval of medications is a complex and highly regulated process. After approval, marketing authorisation (MA) holders in the US and EU will implement some form of risk-based monitoring of real-world safety and effectiveness through a Risk Management Plan (RMP). These carefully crafted agreements monitor the safety and effectiveness of a medication in the real world through a range of predetermined post-authorisation safety studies (such as enhanced surveillance studies or drug utilisation studies). The RMP also contains any specific risk evaluation and mitigation (REMs) procedures deemed necessary to protect patients, such as educational campaigns or the restriction of prescription within certain groups (e.g., pregnant people). The question considered here is whether these benefit-risk monitoring activities

will be impacted by the use of these AI-based prescribing tools. Depending on the quality of these tools, a medication could either be prescribed correctly more often, prescribed inappropriately more often, prescribed in a biased way, or simply not prescribed at all. The MA holder has little control over which AI-based tools will be paired with their medication, and it is unlikely that MA holders will be aware where and when these tools are being used. Many hospitals and insurance companies do not disclose that they are using these tools or fail to release information on the algorithms and data used. It could also mean that traditional approaches used in REMS may be less effective (e.g., prescriber behaviour change campaigns).

5 AI-Based Clinical Decision Support System Prescribing Tools May Enhance the Apparent Safety Profiles of Medications

The reporting rate of suspected AEs may be affected by the use of AI-based tools. For example, after the MA of a drug, if a drug–drug interaction (DDI) checker is used to influence prescription, then this tool may increase the apparent safety of the medicine. However, if this tool were then to be discontinued or unavailable, then this could result in a sudden spike in DDIs, negatively impacting the safety profile. Thus, the presence or absence of the tool in the prescription decision process could influence the observable risk profile of the drug. Furthermore, as any unexpected AEs are routinely investigated by the MA holder and regulators as part of standard safety signal detection processes, it can be challenging to go back and fully understand why an AI-based recommendation was made (i.e., what benefit-risk evaluation did the tool logically make?). It can also be hard to determine whether the AI-based tool would make the same decision next time and whether any corrective action should be taken.

6 Like Humans, AI-Based Tools are Vulnerable to Bias

One important and unintended consequence of these algorithmic tools is that they may introduce bias or unfairness into prescribing decisions. Prescription is both a social and a medical phenomenon, and substantial evidence is already available in the literature attesting to the devastating impact of tools built on biased and unfair data towards certain ethnic groups or special populations [21]. AI-based tools may also introduce new patterns of data recording and testing in healthcare systems, and this may have downstream impacts on the evaluation of medicine safety and effectiveness. For example, if an AI-based tool can only function if certain laboratory test results are available, then this may result in a dramatic increase in these tests being conducted just to ensure eligibility for the tool. Efforts have already been made to ensure that the minimum information required to ensure the functionality of an AI-based tool is routinely collected (e.g., the minimum Common Oncology Data Elements [mCODE] initiative) [22]. However, a tool may fail to function if the patient does not have the right attributes or access to diagnostic equipment, and this has the potential to dramatically reduce minority and underserved group access to services. Several techniques exist to measure and mitigate bias in AI-based algorithms, but this is only possible if bias is proactively looked for in the first place [23].

7 Prescribing 'Beyond the Label'

AI-based tools may also have the unique ability to guide its users to prescribe '*beyond the label*' by using latent complex logic patterns that are only perceivable to a machine. AI-based tools may also make use of information that does not currently have an established role in prescription, such as wearable device data, which could be of great predictive value but is currently not utilised by prescription guidelines. AI-based tools are also able to integrate far more historical patient information than a prescriber can obtain in a single visit, and through the learning process, a model can create its own complex proxies and subgroups that are not transparent to the tool user. These proxies may just be artefacts (e.g., due to a biased dataset), or they may in fact represent valuable previously undetected subclasses that can optimise prescription. In theory, an AI-based tool may even encourage prescribing in black-box warning situations if its recommendations are not constrained by the label or if new guidance is introduced and the tool is not updated (AI-based tools cannot usually read or interpret 'Dear Doctor' letters). This may be particularly problematic if prescribers rely solely on the recommendation of the tool (known as 'automation bias'). This interaction between a recommendation tool and prescriber behaviour is the subject of ongoing research [24] and is also explicitly mentioned as a concern in the FDA's guidance around CDSS [20].

8 Care Providers at All Levels will be Impacted by the Advent of AI-Based Tools

These tools may create challenges for care providers, with significant impacts for civil liability and the 'freedom to practice medicine'. If a prescriber prescribes against an AI recommendation, then it raises difficult questions around accountability and harm. The Hawthorne Effect (whereby

a subject behaves differently when they are aware they are being observed), may come into play where AI-based tools are used, resulting in prescribers acting more cautiously. This is particularly the case if a prescribing checkpoint is implemented for special populations or off-label use. Off-label use of medication is very common (especially in pregnant persons and children), and the use of AI-based tools may invoke prescription hesitancy, leading to reduced medication access for these patients and also vastly limiting our understanding of real-world safety in these groups. To illustrate this, automated algorithms to identify problematic opioid prescription patterns in patients have proliferated in clinical settings in the US. Despite the wide adoption of some of these risk scores that rely on AI for estimation, little evidence exists on the real-world performance and clinical validation of these measures to correctly identify which patients are at high risk for opioid overdose. The result has been a significant decrease in opioid medication use that may harm patients with chronic pain and disabilities needing access to these therapies [25].

Also invoked are challenging ideas around who is accountable for maintaining an algorithm and identifying safety signals. Serious harms have already occurred due to AI-based tools [21], yet outside of the SaMD system, these AI-based tools are relatively unmonitored and often poorly described [26]. Despite this, such tools are still likely to remain attractive to hospitals and insurers due to potential cost savings and greatly enhanced clinical outcomes. Furthermore, in resource-limited settings, they may change expected patterns of prescribing due to increased confidence in prescription being given to non-specialists. This could even result in 'blurring' of lines of therapy, as confidence may be given to skip early lines of therapy that are deemed unlikely to work by the tool [27].

9 AI-Based Tools are Potentially Sensitive to Both Population and Location

AI-based tools may also be specific to the location where they were created and may not translate well across borders. Borders could be highly porous to these tools, especially if these tools can be actively sought out online. Different regions are likely to have different guidelines for testing as well as differential access to medicines, and this is almost certain to result in geographical differences in testing and prescribing behaviour. A recent study indicated that 71% of health algorithms used in the US were trained on patient data from only three states, and the majority of states do not contribute any data at all [28]. In this context, it is also important to consider that the intersection between cultural and environmental differences may have a significant effect. For example, the behaviours and health state of a person of Chinese heritage in the US are likely to be different to a person of similar heritage living in China. Additionally, Regulators in Asia often require medicine MA holders to conduct additional safety and effectiveness studies using local participant data. However, if a safety-based AI tool is unavailable in Asian countries, but is still available in the US, then the drug may artificially appear to be less safe or have lower effectiveness in certain ethnic populations. Furthermore, if an AI-based tool is able to continuously learn with new data, then regional differences may evolve with time, even to the point where it would generate different recommendations for the same person in different locations.

The uptake of any AI-based tool is unlikely to be evenly spread, even within a single country. The uptake of an AI-based tool may be higher in more digitally mature or 'innovative' hospitals. This could appear to show that some drugs have a worse safety profile depending on the care setting in which they were prescribed. Channelling bias (i.e., whereby newly available medicines are prescribed to an unusual or unrepresentative set of patients) [29] may also impact the performance of continuously learning algorithms, as the case mix of exposed patients will evolve slowly over time (changing the apparent safety/effectiveness of the medication as time goes on). Tied into this, algorithms may be subject to 'drift', a process whereby they become outdated as a result of changing practices and standards of care [30].

10 The Response of the Pharmaceutical Industry

Pharmaceutical companies are likely to regard these tools with a mixture of enthusiasm and trepidation. These tools may impact pricing (where AI-based tools are used to identify the cheapest and most effective drug), or even affect the lines of therapy used in clinical practice. The opportunity also exists for AI-based tools to be co-developed as a companion diagnostic, requiring a positive recommendation from the tool for access to the drug. These tools may even become associated with the use of value-based agreements, with a positive recommendation for the tool required to be eligible for the scheme.

A significant challenge will be to address both the plurality of the tools that are created and any potentially conflicting outputs (especially when choosing between medications with the same indications). Of course, many of these tools will be proprietary or company confidential, which can make it hard to evaluate a study design objectively and assess the data generated by the associated tool. Furthermore, a lack of transparency may also present an opportunity for bad actors to increase or decrease the likelihood of prescription

of drugs from specific companies. Providing evidence of such ethical transgressions would be extremely challenging. Certainly, it is possible to point authorities towards these tools and to perform drug utilisation studies, but it is difficult to show conclusively that the tools had a material impact on prescription decisions.

11 Conclusions: The New World of AI is Already Here

AI-based tools have the potential to bring both extraordinary benefits and very significant harms to patients, and our understanding of real-world safety and effectiveness is likely to be influenced by their use. In many cases, these sophisticated tools will ensure that patients receive optimally safe and effective medications, identifying the 'right drug' for the patient. There will however also be instances where these tools encourage a wrong or manipulated decision, leading to harm and artificially poor medication profiles. The data and study design elements involved in the development of an AI-based tool are the principal contributors to bias, and it is crucial that all parties (academia, regulators, competent authorities, tool developers, care providers and MA holders) have a clear understanding of the processes underpinning the functioning of these tools. Reporting initiatives such as DECIDE-AI are paving the way for a more standardised way to compare these tools, but such guidelines must be widely adopted and used by the community in order to provide value [31]. Even armed with such knowledge of these tools, the contribution of the 'unseen hand of AI' may provide pharmacoepidemiologists and safety professionals with both opportunities and challenges in the future.

Declarations

Funding This project was unfunded and workshops were conducted on personal time.

Conflicts of interest Taichi Ochi, Macarius Donneyong, Enriqueta Vallejo-Yagüe, Arti V. Virkud and Juan M. Hincapie-Castillo have no conflicts of interest to declare. Harriet Dickinson is an employee and stockholder in Gilead Sciences Inc. Jan Feifel is an employee and stockholder of Merck KGaA. Katoo M. Muylle is an employee of AstraZeneca BeLux and her PhD research was supported by a grant from the Research Foundation Flanders (FWO) under grant number 1S39820N. Joseph Zabinski is an employee and stockholder of OM1. Victoria Y. Strauss is an employee of Boehringer Ingelheim Pharma GmbH & Co. KG. Philip Hunt was an employee and stockholder of AstraZeneca at the time of writing. Dana Y. Teltsch is an employee of Takeda, and owns stocks in Takeda and Aetion.

Ethics approval Ethical approval was not required as this work does not contain any human subjects or patient-level data. Ethics approval was not sought for these workshops as no human data were involved.

Consent to participate Consent to participate was also not required as no human subjects were involved.

Consent for publication Consent for publication is not applicable as no patients were involved.

Availability of data and material (data transparency) Data sharing is not applicable to this article as no datasets were analysed during the current study. No electronic supplementary material is provided.

Code availability Code sharing is not applicable to this article as no code was generated during the current study. No electronic supplementary material is provided.

Authors' contributions HD conceived the idea for this manuscript and organised structured workshops. All authors decided on key themes and defined the scope of the manuscript, and HD, DT, JF, JZ, EVY, AV, KM, TO, MD, PH, VYS and JHC participated in workshops and subsequent offline discussions around key concepts. HD wrote the first draft from notes taken in the workshops. All authors reviewed the manuscript and approved the final version before submission.

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