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Clinical risk prediction models: the canary in the coalmine for artificial intelligence in healthcare?

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Clinical risk prediction models (CRPMs) are statistical models that aim to improve medical decision making by providing an objective measure of potential health outcomes based on data.[1] In recent years, there has been an explosion in the development of such models across all areas of medical care. Additionally, the adjunct of artificial intelligence (AI), which builds on traditional statistical prediction methods using machine learning, models are increasing in complexity and potential accuracy.[2] However, the adoption pathway of CRPMs and AI models is similar, with both requiring access to data for model development, regulatory approval and effective implementation into the workflow of clinicians.

Despite significant potential, only few CRPMs have been implemented into practice and achieved patient benefit.[3] In this editorial we explore the incentives of producers, intermediaries and users of CRPMs and discuss how a lack of alignment has failed to realise their potential to achieve intended benefits. AI in healthcare faces a similar threat and we propose a novel solution to mitigate this for the future.

Currently, models are mainly produced in the academic context, where there is access to data and methodological expertise. Researchers are incentivised by traditional academic objectives, such as published papers, conference presentations or other scientific accolades. This results in a failure to pursue a successfully validated model beyond these goals. If further motivation (and often funding) allows, efforts are focused on improving the statistical accuracy or undertaking external validation studies, rather than exploring implementation or clinical usability.

Furthermore, any software, such as a CRPM or a clinical AI model, is by definition a medical device.[4] This means that they are subject to conformity assessments and regulatory approval prior to being placed on the market.[5] Most researchers will not have the expertise to undertake this, or have access to the relevant support to navigate this process. Additionally, software requires regular updates and maintenance, which may come with considerable running costs. Currently, there is no clear understanding of whom to attribute these to, yet they are critical to the longer-term safety, efficacy and viability of a CRPM.

Clinically validated and approved models are typically implemented as stand-alone web or mobile applications. This creates usability barriers, as users access an external interface and manually transcribe data to receive results.[6] In reality, electronic health record (EHR) vendors could act as intermediaries and integrate models directly into their systems, complementing the clinical workflow. However, the vendors would have to take responsibility for the medical device regulation, maintenance and associated costs. The value proposition for vendors to foot these costs and risks is currently not there, especially as clinical stakeholders do not yet expect such functionalities in EHRs. An alternative could be for vendors to provide third party companies an application programming interface (API) to their EHR. However, as there is no single API standard, third party model suppliers would have to integrate with each EHR individually. This would be compounded with ongoing licensing fees, making for a precarious business model for what are usually small enterprises.

ALIGNING INCENTIVES WITH BLOCKCHAIN TECHNOLOGY

The individual incentives of the producers (researchers), intermediaries (EHR vendors) and users (healthcare providers) are

currently unaligned. The academic environment or EHR market has not incentivised the conversion of technical discovery to integrated product development, limiting the 'bench-to-bedside' pathway of CRPMs. To prevent a similar experience for AI models, we must develop strategies that align incentives and create a value proposition for all involved parties.

A potential solution could be a national infrastructure; a marketplace for models, all clinically validated and compliant with medical device regulations. Blockchain, a form of distributed ledger technology (DLT), may facilitate such an infrastructure by securely hosting the marketplace and allowing the producers to be remunerated when their model is used through smart contracts.

Blockchain is an open network of distributed data stored in secure blocks, which are available to all participants (known as 'nodes') on a network.[7] By distributing blocks across all nodes, the data in the network is difficult to hack, change or corrupt, creating a traceable, immutable and secure record of transactions between nodes.[8] Blockchain has therefore been widely discussed in the context of sharing electronic patient records.[9] Smart contracts are a digital technology that execute an financial transaction recorded in a blockchain when a predefined condition is met.[10]

Blockchain and DLT could support the implementation and financial reward for CRPMS: models could be published to the national marketplace, hosted on the blockchain and clinical data could be entered securely to receive results with a micro-payment triggered at every use, via smart contracts. Defining a national vendor-neutral API standard for models would make the marketplace accessible from all EHRs that implement it. A recognised body could regulate this process alongside an established framework, such as the UK government's guide to good practice for digital and data-driven health technologies.[11] The traceability provided through a DLT-based solution would build trust among all stakeholders and allow a shared interest to develop.

An example of a CRPM that this could apply to is the CHA(2)DV(2)-VASc score, which is used to predict the risk of stroke in patients with atrial fibrillation, and thus guide the need for blood-thinning medication.[12] The producers would publish their model to the marketplace, who would take the responsibility of assessment conformity and regulatory approval. Once the model is live, EHR vendors could integrate it into their interface using the standardised API.

This would increase the use of CRPMs by clinicians as they are incorporated into their workflow, provide a monetary incentive for researchers to pursue models to implementation and integration and finally, make EHRs that integrate CRPMs more attractive for healthcare providers to procure. Figure 1 illustrates this concept, highlighting how blockchain technology can align incentives and operationalise current and future CRPMs and AI models.

The traditional medical research path is linear with rigid objectives and little concern for commercialisation. However, it is evidence-focused and rightly, prioritises safety and regulation. In contrast, technology

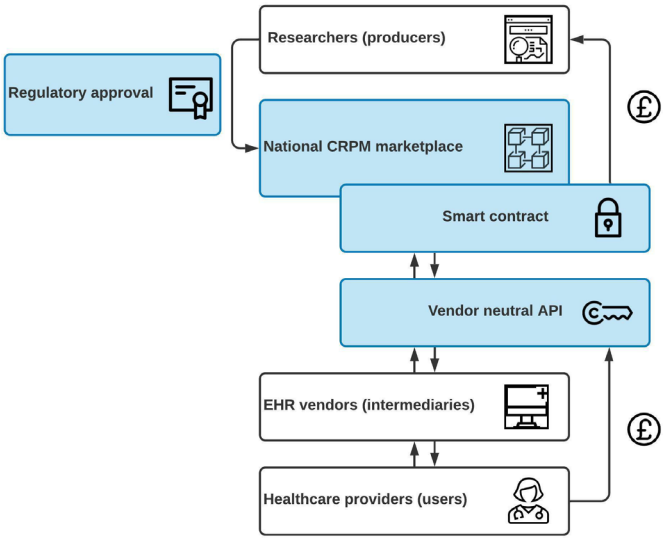

Figure 1 Conceptual representation of a vendor-neutral distributed ledger-based CRPM marketplace to maintain data security with the use of smart contracts to facilitate micro-payments. API, application programming interface; CRPMs, clinical risk prediction models; EHR, electronic health record.

development is agile, iterative and focused on real-world application.[13] There remains a need to create a joint culture across academic and industry stakeholders to harmonise expertise and develop meaningful digital health solutions. Recent efforts, such as the proposed Decision-support systems driven by artificial intelligence guidelines, support this by calling for early clinical evaluation with a view to bridging the current implementation gap of AI models.[14]

The introduction of Chief Clinical Informatics Officers and digital strategies by healthcare providers will help regulate and adopt these technologies going forward,[15] however, a collaboration across the vendor industry remains essential. A drive towards business success may incentivise researchers, vendors and healthcare providers appropriately to pursue solutions and achieve intended benefits. Interdisciplinary and cross-industry health research, with a long-term focus on clinical impact can thus unlock the potential of CRPMs and AI, leading to radical change in patient care and outcomes.

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