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A Review of Clinical Research Incorporating Artificial Intelligence Analyses

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Abstract: ***Artificial Intelligence is increasingly being used in medical research and certain clinical practice areas. This article examines selected literature to identify common themes with an idea to understanding the impact, concerns and opportunities afforded by such technology. Such research is markedly different from established research methodologies and so is challenging to assess and evaluate. The complexity of the analytics and applied statistics makes it difficult for many to understand and yet conclusions drawn can have a significant impact on clinical practice and policy, funding and recording practices. The key themes identified are those of accuracy, population bias, database limitations, cost- and time-savings, and the ability to use artificial intelligence to predict future events or outcomes. In addition, certain dangers are highlighted and a few recommendations made.***

Keywords: Artificial intelligence, Machine learning, Delivery of health care, Deep learning

1. Introduction

Public health policies are informed by research into best practice and this is determined through evidence-based research. Research relies on the analysis of various kinds of data which is generated through carefully designed studies, but also through the provision of healthcare services where it is saved in a multitude of databases from pathology laboratories to funder systems and electronic health records. Vast quantities of information are now available for interrogation and new methods which increasingly rely on complex digital processes are impacting the health industry in a tangible way.

The technology behind the utilisation of data in this way is artificial intelligence (AI) which is a branch of computer science that enables computers to simulate intelligent behavior. Machine learning on the other hand is “the science of getting computers to learn and act like humans do, and improve their learning over time in autonomous fashion, by feeding them data and information in the form of observations and real-world interactions” [1]. This is a departure from rules-based programming that instead relies on the scripting of very detailed and complex algorithms to evaluate data. The computerised deep learning process that takes place makes use of neural network architectures to enable machine learning that improves analysis over time and with the expansion of the database. A key contribution of machine learning relies on its ability to uncover hidden relationships between data entries.

This article explores published literature to ascertain the extent to which AI is being used and accepted in current medical research, and also to determine the accuracy of such applications. Furthermore, an indication of the cost savings is a point of interest. These are thought-provoking questions which impact directly on the healthcare working environment but more importantly, as they are increasingly embraced and accepted within industry, so the need for non-IT professionals to have a working understanding of AI increases.

The Lancet [2] aptly states: “2017 has marked a step change for AI in health care… With this change, the skills required to understand the informatics of large datasets, and the insights that can be drawn from them, have become an essential pillar of clinical practice, alongside evidence-based medicine.”

The aim of this review is to present themes identified in healthcare research so as to understand the evidence- and financial- impact of the use AI interrogation in current clinical research.

2. Methods

The strategy used to guide the literature search identified articles published in English between 2013 and 2018. PubMed and Google Scholar were searched using combinations of relevant key words: machine learning, delivery of health care (and healthcare), and deep learning. Given that AI is a relatively new field, numerous variations in definitions and terminology abound and so very specific search terms were avoided. Figure 1 presents the search results. When the articles were reviewed and the definitions of in- and exclusion applied, the material identified was found not to be very numerical in nature, excluding the need for statistical analysis. This article therefore presents and discusses the key themes distilled.

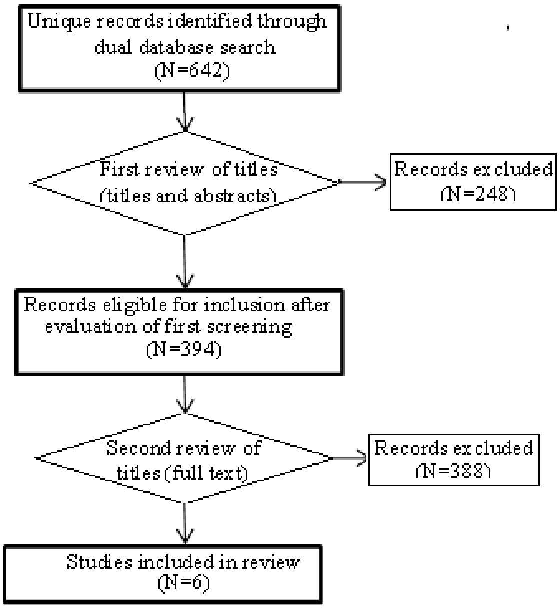

Figure 1: Search method applied

Only articles freely available, written in English, published between 2013 and 2018 and researching material from human clinical trials or studies was included, thus ensuring relevance within the public health space.

3. Results

The research into AI and machine learning marks a clear departure form standard research methodology in that enormous amounts of data already exist. The data is generally quantitative in nature but can also be qualitative. In addition large image databases exist and these have been used to draw conclusions via AI interrogation with a high degree of accuracy. The use of machine learning in the analysis and diagnoses of radiology scans is a particularly successful application. Significantly though, no matter the type of data, it must all be digitally labelled and curated in order for it to be useable within the AI arena.

A second significant fact is that the database needs to be very large and able to store information gained from different kinds of studies and diagnostic tests.

Given these realities, it was not possible to evaluate the evidence utilised in the identified studies, or to place them within the accepted academic hierarchy of evidence. On examination of the research findings presented, as well as the discussions by the authors, it was clear that the computer analytics and statistical interpretations are incredibly complex, and difficult to understand and interpret by a clinician not trained to critically appraise the mathematics and computer science underpinning these. Similarly, the study designs and methodology used in each article are not comparable with traditional research approaches designed to assess clinical evidence.

4. Discussion

A number of themes were identified in the articles even though the focus of investigation was diverse. The themes of accuracy, bias, database limitations and cost- and time-saving were uppermost. The ability of AI to predict future trends also came to the fore.

4.1 Accuracy

The accuracy of AI analyses is completely reliant on data quality, and if this is lacking, then so will be the results. Furthermore the repetition of investigations through robust testing should produce similar results, but if the data available is limited, then the ability to test is affected and levels of accuracy become difficult to determine. When multiple results are evaluated, the research team must be able to conclusively state that the AI is sufficiently accurate to be useful when applied in the field. However, this particular challenge results in an interesting paradox as the detailed nature of AI analyses expose inconsistencies within the database, resulting in it not being able to consistently perform the task at hand. On the surface this appears to be a problem of accuracy when in reality it speaks to inconsistencies in the data.

4.2 Population bias

The fact that AI research relies on datasets introduces a population bias by default as the population sample excludes everyone whose results are not uploaded into the database. Where health inequity or dual healthcare systems exist, datasets could exclude significant segments of a population which would skew results. Minority populations could either be excluded, or their unique circumstances not captured within the data. For example, an analysis of the Twitter stream investigating public perception to certain vaccines produced valuable information but its insights are limited to Twitter users and are not necessarily generalisable to the broader public [3].

4.3 Limitations of database

The limited nature of databases was found to impact on the results, accuracy and transferability of conclusions drawn from the data. Although the ability to predict clinical risk (e.g. an asthma attack or cardiovascular event) by using machine learning analyses of clinical data has shown promise [4], [5], its usefulness has been diluted by insufficient potentially relevant data. Digital information on environmental, behavioural, genomic or cultural factors are not often recorded and so not factored into the algorithm applied to the data.

4.4 Cost- and time-saving

In instances where positive results were produced from the algorithms, it was shown to deliver cost savings. In one institution, the ability of an algorithm to successfully predict objective remission with thiopurines reduced the need for a pathology test which resulted in a cost saving of $75 000 [6]. In Japan, machine learning was successfully used to develop a virtual health check-up which was able to predict hyperuricemia amongst high risk individuals [7]. If implemented in Japan, it will largely eliminate the need to administer a serum test which could lead to a saving of around $408,960 per annum.

By extension, the analysis of additional datasets once an algorithm has been developed can be achieved with relative ease. The successful analysis of public sentiment to certain vaccines in Twitter data produced valuable information which was used to inform public health campaigns. These algorithms could for example be modified to examine sentiment in response to other public health initiatives such as the sugar tax.

It is clear that in instances where an algorithm extracts value from relationships between pieces of data, it can lead to cost savings in clinical practice and also be modified so as to identify other relationships of clinical significance. Large investments in time and expertise in the initial research lessens over time as the methodology is replicated in subsequent projects.

4.5 Ability to predict

Chronic diseases and comorbidities are an increasing problem in healthcare and any automated process to predict the need for intervention will help to manage conditions and avoid treatment in an advanced disease stage. In the literature analysed, a number of AI algorithms were designed to predict specific exacerbations (e.g. asthma attacks) or disease progressions (e.g. diabetic retinopathy) with varied levels of success. An examination of the challenges experienced highlighted the importance of quality, complete and well curated datasets, and the impact of the clinical complexity being investigated. The different machine learning approaches and statistical models currently available have been used to generate predictive risk models and the relative strengths of each have been contrasted. In some instances, these were successful and could be implemented within a clinical setting where improved care and cost savings could be realised. Others were inconclusive and instead areas of improvement were identified to ensure future progress.

As healthcare systems are required to meet the needs of growing numbers of people with increasing disease burdens, so the need for a reliable assessment tool that can generate a credible problem list from data routinely entered into an electronic health record becomes imperative. Additional tools like virtual health check-ups which are able to flag people with imminent health needs will enable qualified practitioners to act on high risk individuals timeously. As the ability of AI to predict outcomes and disease progression improves, so too will these tools, and their ultimate impact on health systems will be immense.

5. Conclusion

AI and machine learning tools interrogate existing databases and so traditional evidence based research methodologies, interventions and outcomes measures are no longer directly applicable. Each published article reviewed here adopted a unique approach to examine the chosen dataset so as to identify trends and draw conclusions around the accuracy, generalisability and transferability of the new methods of analyses across data. In essence, new standards and norms for future healthcare research are being established through such groundbreaking work.

Looking to the future, it is recommended that healthcare practitioners embrace the drive to ensure that data is collected in such a way that it can be used for machine learning. Furthermore, it is important that practitioners in the clinical space be trained to understand this new research field so that they can critically assess its usefulness, accuracy and applicability. There is a great danger that the lack of skills to evaluate and critique such information will lead to a manipulation of results in favour of secondary agendas. This would defeat the gains made and could cause great harm to public health. Ultimately however, clinical research cannot rely only on statistical analyses of databases. It must integrate these insights together with aspects of being human that cannot be assimilated into data fields as these are often critical and able to influence the overall interpretation of a study. A close, mutually respectful relationship must therefore exist between the programmer designing the algorithm, data analyst and clinician when AI is implemented in medical research.

6. Declarations

The authors declare that they have no competing interests

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