THE LONDON SCHOOL OF ECONOMICS AND POLITICAL SCIENCE

Predictive Analytic Techniques and Big Data for Improved Health Outcomes in the Context of Value Based Health Care and Coverage Decisions: A Scoping Review

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February 2021

This research was commissioned via LSE Consulting which was set up by the London School of Economics and Political Science to enable and facilitate the application of its academic expertise and intellectual resources.

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List of abbreviations

ACP - Algorithm Change Protocol

AI - Artificial Intelligence

AJCC - American Joint Committee on Cancer

ALP - Alkaline Phosphatase

APACHE - Acute Physiology And Chronic Health Evaluation

AUC - Area Under the Curve

BD4BO - Big Data for Better Outcomes

CNN - Convolution Neural Network

CPM - Combined Predictive Model

DL - Deep Learning

eFI - Electronic Frailty Index

EFPIA - European Federation of Pharmaceutical Industry Association

EHR - Electronic Health Records

ER - Estrogen Receptor

FDA - Food and Drug Administration

GDPR - General Data Protection Regulation

GMLP - Good Machine Learning Practice

ICS - Inhaled Corticosteroids

ICU - Intensive Care Unit

IMDFR - International Medical Device Regulators Forum

MACE - Major Adverse Cardiac Events

MELD - Model End-stage Liver Diseases

ML - Machine Learning

NHS - National Health Service

NIH - National Institute of Health

NLP - Natural Learning Process

OS - Overall Survival

PARR - Patients-at-risk-of-hospitalization

PCA - Principal Component Analysis

PCAWG - Pan-Cancer Analysis of Whole Genomes

PGL - Primary gastrointestinal lymphoma

PLR - platelet/lymphocyte ratio

POLARS - Pre-Operative Low Anterior Resection Syndrome

PRISM - Predictive risk stratification model

PWV - Pulse Wave Velocity

RESCUE - Real-World Estimator of Survival in Catheterized STEMI Patients Following Unsuccessful Earlier Fibrinolysis

RWP - Real-World Performance

SaMD - Software as Medical Device

SAPS II - Simplified Acute Physiology Score

SOFA - Sequential Organ Failure Assessment

SPARRA - Scottish patients at risk of readmission and admission

SPS - SaMD Pre-Specifications

SS - Scoring systems

SVM - Support Vector Machine

TGCA - Cancer Genome Atlas

WHO - World Health Organization

Executive Summary

Background

In the recent years, predictive analytics tools have been increasingly investigated and adopted in healthcare. When effective, these tools can successfully identify and stratify patients based on their individual risk of incurring in a specific health outcome. In this sense, predictive analytics tools differ from traditional descriptive analytics as the latter try to explain already existing processes and functions. This innovation can potentially reshape risk management in healthcare, since it can allow clinicians, patients, administrative staff and health care decision makers to predict potential events and therefore change the traditional decision-making processes. The development of these predictive tools is complemented by the advancement in the use and availability of big data, which represent the basis of a new and more accurate data infrastructure. The hypothesis of this scoping review is to investigate if predictive analytics are effective in identifying patients at risk of poor health outcomes, and if their development is actually improving patient outcomes for providers and enhancing the transition to different reimbursement models, such as the value-based ones. This scoping review also tries to set up a taxonomy of the available predictive analytics tools based on the identified literature, and to list the techniques and sources of data used to develop them.

Methods

A scoping review has been conducted to gather evidence in favour or in opposition to the broad research hypothesis, which is the following: "The use of predictive modelling to proactively identify patients who are at highest risk of poor health outcomes and will benefit most from intervention (also assuming that this intervention is happening early) is one solution believed to improve an efficient resource allocation and patient outcomes." The over-arching theme is therefore the following: implementation of predictive algorithms/analytics and/or artificial intelligence in health care can support population health management, predict and improve health outcomes, optimise care delivery, develop precision medicine and new therapies, help structure value-based agreements between payers and suppliers, reduce unnecessary expenditure and improve efficiency in resource allocation across the value-based care continuum

The review has been developed following the PRISMA guidelines for scoping reviews. Four databases have been used (Ovid Medline, PubMed, Web of Science and Scopus), and a grey literature search has been performed using a similar search strategy. The search included all the relevant publications from January 1992 to April 2019, limited to the English language. Included studies were categorized based on disease area of interest, type of predictive tool(s), clinical treatment outcome and disease stage. The taxonomy of predictive tools reported in this research is based on the included studies and does not intend to be a univocal classification of these tools.

Included literature and Evolution of Predictive Analytics

Based on the 198 included articles, the review summarises the predictive analytics tools adopted over the years, what techniques are used to develop them, and how they are commonly adopted by healthcare providers.

Seven predictive tools categories are identified: 1. Scoring systems; 2. Risk index/scores; 3. Staging/Grading systems; 4. Algorithms; 5. Modelling (i.e., single tools); 6. Machine Learning; 7. Deep Learning. Also, 11 techniques were found: 1. Algorithms; 2. Association rules learning; 3. Convolutional Neural Networks; Decision Trees; 4. Deep Belief Network; 5. Deep Neural Network; 6. Hazard models (e.g., Cox proportional hazard model); 7. Linear/Logistic regression; 8. Naïve Bayes; 9. Neural Networks; 10. Nomograms; 11. Random Forests. Common big data sources are the following: Administrative claims, Clinical Trial Data, Electronic Health Records (EHR), Personal Genome Services, Smartphone applications, Social media, Wearable devices.

Scoring systems are among the first predictive tools, as they started to be developed at the end of 1960s for trauma patients. They are also predominant in the literature of 1990s and early 2000s (34 of the 48 included studies between 1992 and 2009 are related to scoring systems). Together with scoring systems, risk index, risk scores, staging and grading systems can be considered traditional tools as they are not fitting or are very marginal in the machine learning spectrum, and are mostly supervised tools, while many of the recent predictive modelling and artificial intelligence tools are unsupervised. Supervised tools are based on a known set of input data and on a specific output, with the goal of generating a predicted output with different input data. Unsupervised tools instead are developed without a specific output, and have the goal of exploring the input data, allowing the tool to find potential unknown correlations.

Based on the included literature, it is not possible to rank the efficacy of different predictive tools, as so far research has only focused on comparing a specific set of predictive tools, and mostly only for certain disease areas. Synthesis from the scoping review is showing that there isn’t a broader attempt of comparing all the available predictive tools or techniques in the literature, and this is a symptom of a prevalent fragmentation of interests from the stakeholder community. However, it emerges that artificial intelligence is the area where most of the ambitions of developing more accurate, generalisable and reliable tools are concentrated.

Scoring systems are by far the most commonly investigated predictive tools (113 out of 198 articles). This is likely caused by the fact that they are quite easy to be developed, do not necessarily need a large amount of data and can be easily understood by patients and healthcare providers. 24 articles instead are related to algorithms, 17 to artificial intelligence (9 regarding machine learning tools and 8 to deep learning tools), 18 articles analyse risk index and risk scores, 17 are based on generic predictive modelling, and finally only 9 out of 198 are related to staging and grading systems.

Oncology is the disease area where most predictive analytics tools are adopted (73 out of 198 articles), followed by cardiovascular diseases (38 articles), liver diseases (17 articles) and kidney diseases (11 articles). Other areas which are investigated to a lesser extent are surgical techniques (9 articles), digestive system (9 articles), haematology (6 articles), infectious diseases (6 articles), neurodegenerative diseases (5 articles) and orthopaedics (5 articles). Only 14 articles are not focussing on a specific disease area.

With regards to the disease stage, most of the studies (119 articles) are related to secondary care, while 59 are based on prevention or primary care. Most common investigated clinical treatment outcome is related to surgery (75 out of 198 articles), followed by survival (63 articles), and occurrence of diseases (28 articles).

Challenges

Overall predictive analytics tools have found to be a useful resource for key stakeholders, as most of them shown to be useful complementary tools for healthcare providers and patients in predicting health outcomes and comparing risks of different treatments at an individual level. However, different challenges emerge from the included literature. The review identified challenges related to 1) Predictive tools external validation and data quality; 2) Governance and regulation; 3) Data infrastructure, exchange and interoperability; 4) Healthcare workforce education and adaptation; 5) Predictive tools and healthcare financing; 6) Data privacy and ethics; 7) Patient safety.

1. **Predictive tools external validation and data quality.** Regarding predictive analytics tools efficacy and reliability, the first challenge is related to the generalisability of their performance. Generalisability, or external validation of predictive analytics tools is required to scientifically

prove that a specific tool would be effective and reliable in a heterogeneous population, and this is lacking for most of the predictive tools. Also, data quality can be an issue in the accuracy of models to infer correct relationships or generalize results. This can be caused by many factors, starting from the way data is collected (patients' or providers' biases), data readability for the model (that as said can be sorted with NLP tools), or because of time frames over which the model predicts an event.

2. **Governance and regulation.** As of today, there is no scientific consensus over which tools or techniques are suggested based on disease area or type of diagnosis/treatment. However, attempts by national agencies are currently done to close this gap. The American FDA is an example as they developed and updated their regulatory framework for artificial intelligence and machine learning based software as medical devices (SaMD) to adapt regulation to new innovations, improve transparency and enhance tools validation.

3. **Data infrastructure, exchange and interoperability.** Currently, there is a lack of incentives that allow a major and stable data exchange, and this represent a crucial limit particularly for AI tools, since they need to be continuously fed with new data from clinical studies to perform better.

4. **Healthcare workforce education and adaptation.** Digital maturity amongst health care employees needs to be a priority to enable health care systems to manage genomic and AI tools. According to the Watcher Review, within the English NHS, it is expected that all Trusts will achieve by 2023 a high level of digital maturity. This means that local Trusts will have to be able to develop and manage infrastructures where new digital technologies will be implemented. The Topol Review remarks how, by 2040 at least the 80% of the health workforce will have to be able to understand and manage genomics and AI tools. Also, it will be a challenge to find good quality expertise in data analysis and science, both in clinical organisation and in other organizations.

5. **Predictive tools and healthcare financing**. The included literature provides no evidence directly examining how risk management for providers based on predictive tools could enhance a transition to value-based payments. Out of 198 studies there is hardly any evidence on how predictive tools could enhance a transition to value-based payments. However, a few examples are available, like the Buurtzorg Neighbourhood Care insurers in the Netherlands, where they are trying to simultaneously collect behavioural, demographic, health, and engagement data to provide an opportunity for machine learning and development of novel AI tools. This infrastructure could be useful for them to enhance the development of patient-centred and value-based systems.

6. **Data privacy and ethics.** Not everywhere the legislation is well updated for the most recent predictive analytics tools. GDPR (General Data Protection Regulation) in Europe or the California's Consumer Privacy Act are two good examples of setting up a data privacy regulation framework, however the high costs for regulatory compliance could still limit small organisations' growth in this sector. Ethics challenges in this topic can arise when suggested treatments from the predictive tool can be in conflict with physicians' ethical obligations or patient's preferences.

7. **Patient safety.** Safety and efficacy of predictive analytics, particularly for the AI driven ones, is strictly related to how updated the regulatory framework is. The already mentioned reforms carried by the FDA represent an example of updating regulatory standards for safety and efficacy assessments.

Case studies as examples of action

Flat Iron. Flat Iron is one of the fastest growing companies in the sector, which has set a goal of having an automatic system that gathers millions patient data in a readable format for AI tools. Intergovernmental organizations and policymakers could look at these realities to build collaborations.

Case studies from national organizations. NHS digital in England represents an example of how a national healthcare provider and insurer can set up a specific area of work for AI and predictive tools implementation. The idea of creating sustainable infrastructures in local trusts and promoting a development effort at all levels of the organizations, from national management organization to local trusts, is an example of how national health insurers and providers could collaborate on a national level.

In USA instead, the Food and Drug Administration (FDA) published in 2019 a guide to evaluate AI tools and a discussion paper called proposed regulatory framework for modifications to AI/ML based software as Medical Device (SaMD), that looks at how changing algorithms can be more efficiently assessed in premarket development and post market performance assessment. The discussion led in 2021 to an updated framework and an action plan that encourages data harmonisation, transparency and safety.

Big Data for Better Outcomes. This project sees the collaboration of a large number or universities, national and local insurers and regulators and pharmaceutical companies. It is an example of creating a vast collaboration with key stakeholders and of breadth in analysis, since it looks at all the main disease areas. Results from this project can lead to tangible progress in big data management and therefore in how it could be implemented in AI tools.

INF-ACT. Similarly, this project, promoted by the European Commission, involves 40 partners in 28 countries, and represents an example of how intergovernmental organizations could promote international collaborations on big data research.

Maccabi Biobank. Maccabi Health Services and TIPA Biobank established in 2017 the TIPA Biobank Research Initiative, with the goal of collecting biological samples that can be used for research. The project strives to collect a solid set of data as it is linked to Maccabi Health Services, which is one of the main insurer organization in Israel. So far they have collected samples from 2.5 million members among 350 different labs, allowing the possibility of using this data for longitudinal studies for a wide range of clinical conditions.

Conclusions and policy recommendations

To the authors' knowledge this study provides the first comprehensive taxonomy of predicting tools focusing on health outcomes. Predictive analytics tools have found to be a useful resource in healthcare, however different challenges, particularly for the most recent analytics tools, still have to be addressed. In the next two decades is expected a massive increase in AI, genomic and robotic tools implementation in healthcare, so a lot is still to be developed to address the ambitions and objectives of the various stakeholders.

Five policy recommendations are reported in this review:

1. **Integration of predictive tools is required.** It is unlikely that a one size fits all tool will be developed for every disease area. However, a major concerted research effort (academia, healthcare providers, national regulators and the private sector) would bring benefits in creating more effective predictive tools and would provide a clearer framework.

2. **Data exchange requires incentives to materialise.** There are no incentives in sharing data on a company or national level; this trend needs to be reversed. Policymakers, companies and healthcare providers could try to create a common space where data could be continuously gathered, since for AI tools is not feasible to be developed on a limited dataset.

3. **Regulation relating to data issues needs to take a pro-active stance and advance faster.** The idea of improving national regulatory frameworks to enhance pre-market development and post-market performance assessment from FDA represents an innovative and fundamental example of how regulators and company can try to create a framework that can speed up the R&D and improve safety. Inter-governmental organizations, companies and other national regulators need to follow this still on-going process to make progress on this issue. Positive examples exist from individual health insurers who have resolved data issues, including obtaining prospective consent from members on data usage.

4. **Creation of common platforms that could help enhance data-pooling and the predictive power across settings.** Cross-country collaboration or collaboration across settings could have beneficial effects (e.g., Inf-Act). Private sector initiatives could help advance technology development and methods, although benefits also need to be more widely diffused.

5. **Risk mitigation strategies as part of complementing predictive tools in the context of coverage decisions.** Predictive tools and evidence generated thereof can be combined with innovative payment agreements, which can be adapted in circumstances where the predictive modelling engages in generating evidence slightly outside the remit of treatment use proposed by HTA and clinical guidance in a forward-looking way, in order to incentivise truly innovative contracting and fall in line with approaches to population health, patient segmentation and early intervention of at-risk patents.

Abstract

Background: The recent development of and access to large samples of digital data, together with increasing research and adoption of technological tools (such as predictive analytics techniques), are constantly changing healthcare at all the stages of medical practice.

Objective: To develop a taxonomy of predictive tools used for diagnosis or for the evaluation of disease progression and health outcomes using big data sources.

Methods: A scoping review was performed to identify relevant peer-reviewed and grey literature. The research design was guided by the following hypothesis: predictive modelling can proactively identify patients who are at highest risk of poor health outcomes and will benefit most from intervention. Articles and grey literature were included in the review if they provided evidence in favour of or in opposition to the hypothesis. Development and current use of each technique, tool and data source is discussed and analysed based on the collected information. Also, 6 case studies related to research and regulation from governments, academia and companies are reported and discussed in a separate section.

Results: The review included 198 studies, which were categorized by predictive tool type, disease area, clinical treatment outcome and disease stage. A taxonomy of predictive techniques, tools, and big data sources was created with classification based on key features. The review identified 7 predictive tools categories (i.e. 1) scoring systems; 2) risk index and risk scores; 3) staging and grading systems; 4) algorithms; 5) modelling; 6) machine learning; 7) deep learning). Each tool's development and performance has been analysed based on the included literature. Also, the review identified 8 challenges areas related to the further development and implementation of predictive tools: 1) Predictive tools external validation and data quality; 2) Governance and regulation; 3) Data infrastructure, exchange and interoperability; 4) Healthcare workforce education and adaptation; 5) Predictive tools and healthcare financing; 6) Data privacy and ethics; 7) Ethical challenges; 8) Patient safety.

Conclusion: Most predictive analytics report good performance levels in improving treatment management and in forecasting health outcomes. It is expected that their predictive value will increase with new technology advancements and further availability of big data. In order to realise of the full potential of predictive analytics in healthcare, challenges around regulation, data quality, infrastructure, exchange and interoperability, data privacy, health workforce education and patient safety will need to be overcome.

Keywords: Predictive analytics; predictive techniques; predictive tools; big data analytics; artificial intelligence

1. Background

In recent years, big data analytics capabilities in healthcare organisations have developed significantly, leading to a switch from basic descriptive analytics to predictive analytics (Galetsi and Katsaliaki, 2018). The innovation of predictive analytics lies in the use of statistical methods to identify predictive patterns, while descriptive analytics tries to explain already existing processes and functions (ibidem). Predictive analytics allow all healthcare stakeholders, including clinicians, patients, administrative staff, health policy decision makers and financial experts, to more accurately foresee potential events and optimise decision-making. The importance of being able to predict events is most clearly seen in the realms of intensive care, surgery, emergency care, and pharmaceutical use. The correct positioning of pharmaceutical products, amongst other types of intervention, within a patient's disease pathway can have considerable effects on patient outcomes. An accurate predictive pathway for the disease and fine-tuned sense of when something is going wrong can help optimise patient outcomes.

Provider and payer organizations can apply predictive analytics tools to help address a range of challenges (financial, administrative, and healthcare provision). Successful implementation can improve health outcomes, efficiency in resource allocation, health system financial sustainability and user/patient satisfaction. Countries have started setting national plans and strategy to encourage development, implementation, and harmonisation of these new technologies and big data sources. Big data generation initiatives in healthcare are increasingly being promoted, such as the Cancer Genome Atlas (TCGA), Pan-Cancer Analysis of Whole Genomes (PCAWG), and neuropsychiatric diseases (PsychENCODE) (Agrawal and Prabakaran, 2020). The UK launched a personalised health and care 2020 strategy, with the goal of explaining how new technologies and new sources of data will be used to develop personalized treatments (NHS, 2020). At an international level, the WHO released a global digital health strategy for the 2020-2025 period, with the goal of harmonising the uptake of digital health infrastructure across countries, and to coordinate innovation, knowledge transfer and vision on the topic (WHO, 2020).

In light of the above, the objective of this research is to analyse existing predictive analytics tools and data infrastructure, in order to: a) develop a taxonomy of the available existing tools; b) assess the strengths and weaknesses of different types of tools; and c) identify ability to detect high-risk patient groups. This research is performed with the view of producing recommendations for the improvement of potential future models, for setting up adequate systems and to enable optimization of outcomes. Having conducted a selective literature review, in the following section, we outline a number of areas where predictive algorithms and analytics have been applied and define potentially actionable hypotheses to be tested.

1.1. Defining area of interest

How are healthcare organizations deploying predictive capabilities to extract actionable, forward-looking insights from their growing data assets? Based on a selective literature review, we investigate how predictive algorithms can accurately and reliably predict health outcomes, to improve disease management and population health.

Across all reimbursement models, the identification, stratification, and management of high-risk patients is central to improving quality and cost outcomes. Organizations that can identify individuals with elevated risks of developing chronic conditions as early in disease progression as possible have the best chance of helping patients avoid long-term health problems that are costly and difficult to treat. Creating predictive tools based on lab testing, biometric data, claims data, patient-generated health data, and the social determinants of health can give healthcare providers insight into which individuals might benefit from enhanced services or wellness activities.

The actionable hypothesis to study in this context is: The use of predictive modelling to proactively identify patients who are at highest risk of poor health outcomes and will benefit most from early intervention improves patient outcomes and results in a more efficient resource allocation.

2. Methods

2.1. Hypothesis

In light of the area of interest reported we want to test the following hypothesis:

- The use of predictive modelling to proactively identify patients who are at highest risk of poor health outcomes and will benefit most from intervention (also assuming that this intervention is happening early) is one solution believed to improve an efficient resource allocation and patient outcomes.

Based on this hypothesis, the research question is the following: are there predictive tools enabling early identification of high-risk patients? The over-arching hypothesis/theme, therefore, is as follows: implementation of predictive algorithms/analytics and/or artificial intelligence in health care can support population health management, predict and improve health outcomes, optimise care delivery, develop precision medicine and new therapies, help structure value-based agreements between payers and suppliers, reduce unnecessary expenditure and improve efficiency in resource allocation across the value-based care continuum.

2.2. Research design

A scoping review has been conducted in order to identify materials, reports and case studies providing evidence in favour of or in opposition to the research hypothesis. This enables identification of the volume of evidence available on the implementation of predictive algorithms/predictive analytics/artificial intelligence/machine learning in the areas identified above.

The scoping review has been developed following the PRISMA guidelines for scoping reviews (PRISMA, 2018). Notably, the goals of the research are to map the identified evidence by therapeutic area and over time, to underline the advantages and disadvantages of the main tools, and to assess their overall performance in terms of reliability and accuracy.

2.3. Search strategy and eligibility criteria

A search for peer-reviewed literature was performed on Ovid Medline in April 2019 with the following search strategy:

Table 1 - General search strategy

Step	Search
1	(predict* (algorithm* OR analytic* OR tool* OR system* OR method*)
2	Exp treatment outcome/
3	#1 and #2
4	Limit to English language

The search included all the relevant publications from January 1992 to April 2019. This was accompanied by manual searches for specific topics on Ovid Medline and other platforms, i.e., PubMed, Web of Science, Scopus, and grey literature databases using a similar search strategy.

2.4. Data Extraction and synthesis

Search results from Ovid Medline were exported to EndNote for title and abstract screening. Selected studies were then supplemented with studies identified through manual searches. An excel template was created to facilitate full text screening. The included studies were categorized based on disease area of interest, type of predictive tool(s), clinical treatment outcome and disease stage. The taxonomy of predictive tools reported in this research is based on the included studies and does not intend to be a univocal classification of these tools.

3. Results

3.1. Search results

393 studies were identified through Ovid Medline. Of these, 198 were included after title and abstract screening. 33 studies additional studies were identified through manual searches. Results have been categorised by type of predictive tool(s) (Table 2).

Table 2 - Study results from the Ovid Medline search categorised per predictive tool type, disease area, clinical treatment outcome and disease stage

Disease area		Clinical treatment outcome		Disease stage	
Oncology	73	Surgery	75	Prevention/ Primary	59
Cardiovascular	38	Survival	63	Secondary	119
Liver	17	Occurrence of disease	28	Generic/Reviews	20
Kidney	11	Multiple outcomes/Reviews	12		
Surgical Techniques	9	Treatment efficacy	6		
Digestive system	9	Survival and surgery	2		
Haematology	6	Other (letters, hospital retention, neurological effects)	12		
Infectious	6				
Neurodegenerative	5				
Orthopaedics	5				
Other disease areas	5				
Generic studies	14				
Total	198	**Total**	198	**Total**	198

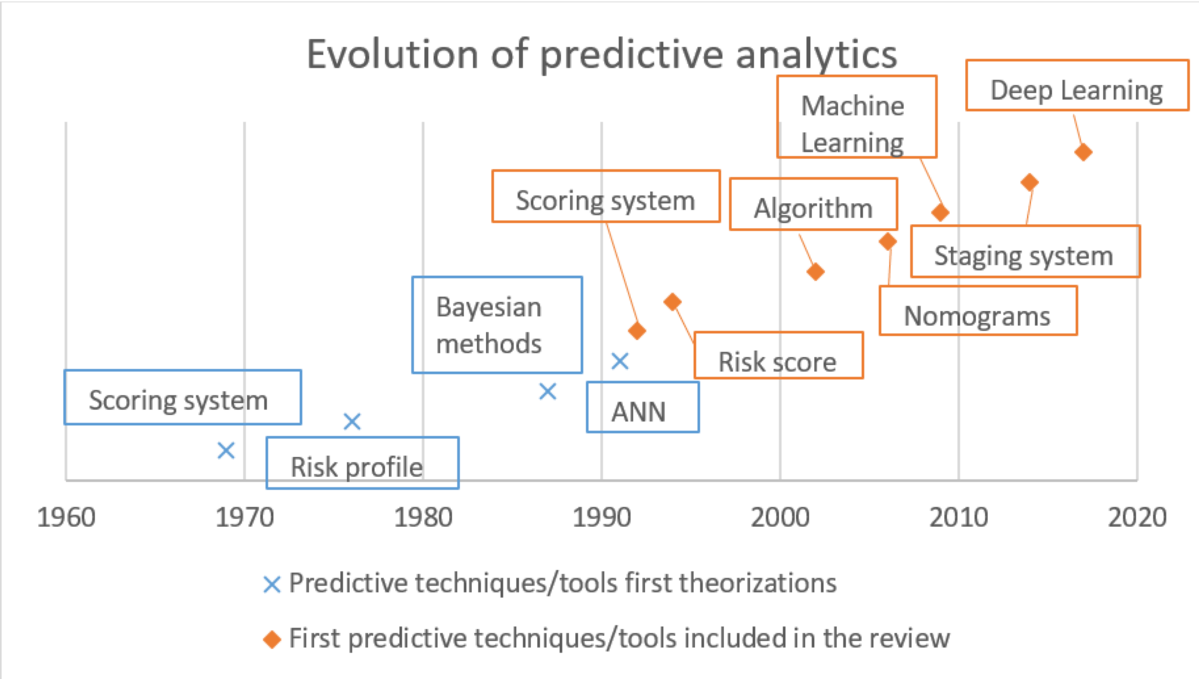
The table above summarises the number of included studies by disease area, clinical treatment outcome and disease stage. Publication dates range from 1992 to 2019. Oncology and cardiovascular diseases are the most frequently investigated disease areas. The most frequently studied clinical treatment outcomes for predictive tools are surgery and survival, covering more than half of the included studies. The most frequent disease stage studied in the context of predictive tools was later stage disease involving secondary care (hospital care setting).

The most common outcome measure for assessing predictive tools performance used in the literature is the AUC-ROC curve, which is a binary metric that assess the discriminative ability of a tool. It ranges from 0.5, where there is no discriminative ability, to 1, where there is perfect discrimination (Cantor et al. 2000). A tool with a higher AUC score has better performance in predicting a health outcome.

3.2. Types of predictive analytics tools, predictive techniques and big data

Predictive analytics are defined as methods of analysis adopted to face and manage the challenges related to big data sources (Hernandez et al. 2017). These methods use past and current data with the goal of predicting future or unknown events.

Figure 1 - Evolution of predictive analytics



Predictive analytics have evolved considerably over the past 50 years. Scoring, staging and grading systems emerged in the 1970s and represent the first types of predictive techniques. More sophisticated techniques have increasingly been developed from the 2000s onwards to improve the use of big data and enhance prediction accuracy. This includes predictive modelling (e.g. logistic regression), mathematical methods (e.g. nomograms) and Artificial Intelligence (AI), through the use of machine learning or data mining.

Table 3 - Predictive techniques, tools and big data sources lists. Numbers in the predictive tools' column reflect the number of articles that are related to each tool.

Predictive tools		Predictive techniques		Big data sources
Scoring systems	113	Algorithms	Linear/Logistic regression	Administrative claims
Risk index/scores	18	Association rules learning	Naïve Bayes	Clinical trial data
Staging/grading systems	9	Convolutional Neural Networks	Neural Networks	Electronic Health Records (EHR)
Modelling	17	Decision Trees	Nomograms	Personal Genome Services
Algorithms	24	Deep Belief Network	Random Forests	Smartphone applications
Machine Learning	9	Deep Neural Network		Social media
Deep Learning	8	Hazard Models		Wearable devices

Based on the 198 included studies, this scoping review identified 7 predictive tools categories (1. Scoring systems; 2. Risk index/scores; 3. Staging/Grading systems; 4. Algorithms; 5. Modelling (i.e. single tools); 6. Machine Learning; 7. Deep Learning). These tools can be developed with the use of different techniques. Scoring systems are the most investigated predictive tools, particularly in the 1990s and early 2000s; 34 of the 48 included studies published between 1992 and 2009 are related to scoring systems. Predictive tools can be also categorised as supervised or unsupervised tools. Supervised tools use a known set of input data to generate a specific predicted output. Unsupervised tools are adopted when there is not a specific output and involves exploring input data to find potential unknown correlations.

This review also identified the following predictive techniques: 1. Algorithms; 2. Association rules learning; 3. Convolutional Neural Networks; Decision Trees; 4. Deep Belief Network; 5. Deep Neural Network; 6. Hazard models (e.g. Cox proportional hazard model); 7. Linear/Logistic regression; 8. Naïve Bayes; 9. Neural Networks; 10. Nomograms; 11. Random Forests. Each category of predictive tool type may encompass a range of different predictive techniques. The following sections of the results will group the included literature based on the identified predictive tools categories.

Big data can be referred to as large and complex databases with a varied and complex structure (Sagiroglu et al. 2013). These datasets are characterized by high variable specificity for each endpoint, by long observation timelines, and by data originating from many sources. In healthcare, this data is mainly collected via Electronic Health Records (EHR), administrative claims, clinical trial data, genomic services, social media, and by personal common tools such as smartphone applications and wearable devices. Big data datasets have 3 peculiarities: large sample sizes, high heterogeneity and high dimensionality (i.e. many variables per each endpoint) (Hernandez et al. 2017). However, big data evolution and adoption generates challenges for predictive analysis. Variables errors can accumulate from various sources leading to noise accumulation and poor predictions or classifications. Even partially-biased sources can contribute to noise accumulation. Another issue that requires human monitoring and correction is spurious correlation. Unsupervised predictive tools in particular have the potential to show high correlation between variables that are not actually correlated, leading to wrong inference and false predictions.

3.3. Predictive tools

3.3.1. Scoring systems

Scoring systems (SS) are among the first predictive tools implemented, initially developed to analyse clinically relevant surrogate outcome measures in intensive care units, in order to evaluate the effectiveness of treatment practices (Rapsang et al. 2014). The first scoring systems were created at the end of the 1960s for trauma patients. (Gunning et al. 1999).

Table 4 - Predictive techniques that can be utilised to develop scoring systems

	Predictive tool
	Scoring systems
Predictive Techniques	**Algorithms**
	Association rules learning
	Convolutional Neural Networks
	Decision Trees
	Deep belief network
	Deep neural network
	Hazard models
	Linear/Logistic regression
	Naïve Bayes
	Neural Networks
	Nomograms
	Random forests

SS are made up of two components: the score which represents disease severity, and the probability model that can match groups of patients and make a quantitative comparison analysis.

Logistic regression was initially adopted to create models looking at probability of death. The ideal probability model should be based on three factors: validity, calibration and discrimination (Rapsang et al. 2014), Validity refers to the quality of the model performance, based on a test assessment. Calibration is related to the how accurate the model is. An example of calibration could be to assess the gap between the actual mortality and the probability of mortality estimated by the model. Discrimination refers to the ability to distinguish between dead and alive patients, based on the model estimation. A good discrimination assessment can be measured with metrics such as "sensitivity, specificity, false positive rate, false negative rate, positive predictive power, misclassification rate, area under the receiver operating characteristic curve and concordance" (Champion 2002).

SS can be distinguished according to purpose, specificity or assessment type (Gunning et al. 1999) (Table 4).

Table 5 - Scoring systems conceptual framework

Scoring systems		
Roles	**Types**	**Assessment**
Comparative audit	Specific	Anatomical
Evaluative research	Generic	Physiological
Clinical management		

The first SS adopted were specific anatomical models. Specific SS look to analyse only a certain group of patients, while generic SS aim to provide generalised results. Anatomical SS evaluate the extent of injury, providing fixed results, and are depending on an accurate measurement or description of the disease, while physiological SS are stemming from observation and measurement of vital signs, and are looking at the impact of injury on function, leading to results that vary as the response to injury changes.

The roles of SS include comparing predicted and actual health outcomes (comparative audit), improving observational or non-randomised or RCTs datasets (evaluative research) and providing support for healthcare professionals' decision-making process (clinical management).

As SS are amongst the most traditional available predictive tools, there is a vast number of studies that explain their development and provide an assessment of their effectiveness. One of the most widely adopted SS is APACHE (Acute Physiology And Chronic Health Evaluation). The first version was developed in 1981 and was revised a number of times, leading to the introduction of APACHE IV in 2006 (Zimmerman et al. 2006). This SS has been used in different diseases areas, including cardiovascular disease and oncology (Hu et al. 2013), and is generally utilised to predict clinical outcomes such as survival rate and length of hospitalisation. Many studies have compared APACHE with other SS. Hu et al. compared APACHE with MELD (Model End-stage Liver Diseases) to predict the risk of mortality after orthotopic liver transplantation, highlighting how the former SS showed a higher prognostic value (APACHE area under the curve (AUC) was 0.937 while MELD AUC was 0.694). Another study compared APACHE IV with SOFA (Sequential Organ Failure Assessment) and SAPS II (Simplified Acute Physiology Score) to predict short-term mortality in patients with acute myocarditis. SAPS II had a slightly higher prognostic value (AUC: SOFA 0.920, APACHE IV 0.934, SAPS II 0.942) (Hu et al. 2013). Another study focusing on cardiovascular diseases assessed the NCDR-RESCUE (Real-World Estimator of Survival in Catheterized STEMI Patients Following Unsuccessful Earlier Fibrinolysis) scoring system and reported that this SS can successfully be used to assess the risk of mortality after percutaneous coronary intervention (Burjonroppa et al. 2011).

Together with cardiovascular diseases, oncology is the main area in which SS are developed and applied. Prostascore, a prognostic model, allows providers to predict health outcomes of patients with advanced prostate cancer that have to decide what therapeutic path to choose (e.g. chemotherapy or surgery) (Abdel-Rahman et al. 2017). This is just one of the SS available for this specific disease, and it is hard to assess what is the most effective predictive tool. Issues relating to the depth and width of data, study follow-ups and generalisability limit the external validity of prostascore. The American Joint Committee on Cancer (AJCC), which proposed a staging system for the same disease, has conducted comparisons of the available predictive tools. The AJCC has reported limitations in generalisability of most SS, as they are frequently adopted for small cohorts of patients in specific areas with unique socio-economic features.

The AAAP scoring system is used to predict overall survival rates of patients with unresectable metastatic colon cancer that incurred a primary tumour resection. A study tested the prognostic scoring system based on four clinical risk factors (age, alkaline phosphatase (ALP), ascites, and platelet/lymphocyte ratio (PLR) on a cohort of 110 patients, divided in three risk groups (low, medium and high risk). The overall survival rate varied significantly across risk groups (low risk: 57.1%; medium risk: 10.7%; high risk: 0.0%. $P < 0.001$). This prognostic scoring system has proven to be a reliable tool for, outcome prediction of primary tumor resection and so to help providers and helps patients with metastatic colon cancer in choosing the best treatment path.

One study examines a SS that predicts health outcomes of patients with Crohn's diseases taking vedolizumab (Dulai et al. 2018). The SS was able to identify patients in clinical remission after vedolizumab therapy with an AUC of 0.67 (92% sensitivity), patients with mucosal healing with a AUC of 0.72 (98% sensitivity), patients in corticosteroid-free remission with an AUC of 0.66 (94% sensitivity), patients with both mucosal healing and clinical remission with an AUC of 0.75 (100% sensitivity), and patients with corticosteroid-free clinical remission with mucosal healing with an AUC of 0.75 (100% sensitivity). Another SS for Crohn's disease, the PROSPECT model, has been developed through univariable and multivariable Cox's proportional hazards model to build a web-based tool for providers and patients to help in predicting the risk of contracting Crohn's disease, based on genetic, clinical and serologic variables (Siegel et al. 2016). 243 patient were involved in the validation study to assess the web-based tool, and the model has proven to be reliable in predicting Crohn's disease complication over time. The model was also tested for external validity on two cohorts (adults and paediatric patients), which reported a concordance index of 0.73 and 0.75 respectively. A strength of the PROSPECT model is the generation of individualised risk prediction based on accessible and easy-to-collect data.

Another study developed a nomogram and online tool to predict postoperative bowel dysfunction severity in patients that received a restorative anterior resection for rectal cancer, based on an international patient-reported outcome measure, LARS (Low Anterior Resection Syndrome) (Battersby et al. 2018). The tool, POLARS (Pre-Operative LARS) has been tested on two different national datasets of patients that have to undergo a restorative anterior resection, in terms of capacity to predict long-term bowel dysfunction (mean LARS scores of 26 and 24 with a standard deviation of 11 in the two cohorts). The study also assessed how some factors (e.g. age or sex) can relate to diseases progression, but was unable to control other factors such as socioeconomic status, comorbidities, social support, and self-management. The European Society of Coloproctology also reports an overview of studies (8 in the last update in January 2018) in different national settings that tested and validated score systems (European Society of Coloproctology, 2019), with the aim of harmonising research on SS for colorectal cancer across different settings.

Overall, early SS were limited to making comparisons between observed and predicted health outcomes within a small subset of patients, while more advanced SS rely on the larger datasets to assist healthcare providers in care and treatment choices. Based on the evidence collected, there is still considerable room for improvement in the ability of SS to manage and leverage big data. Scoring systems are by far the most investigated predictive techniques in this scoping review. These however do not represent the latest predictive analytics techniques developed, and a comparison with other types of predictive tools is needed in order to identify the optimal use of SS.

3.3.2. Staging and grading systems

Staging and grading systems are usually pooled in the same category of scoring systems. These tools are mostly adopted for cancer diagnosis as decision-making support tool for clinicians or for patients and as classification criterion in clinical trials.

Table 6 – Predictive techniques utilised to develop staging or grading systems

	Predictive tool
	Staging/grading system
Predictive Techniques	**Algorithms**
	Association rules learning
	Convolutional Neural Networks
	Decision Trees
	Deep belief network
	Deep neural network
	Hazard models
	Linear/Logistic regression
	Naïve Bayes
	Neural Networks
	Nomograms
	Random forests

Few studies included in the scoping review addressed grading and staging systems. Focus was limited to evaluation of individual systems or a small number of systems in highly specific disease areas. No evidence on the broader rationale of these systems was identified. Grading and staging systems are generally related to disease severity. The most adopted staging system in US is the TNM system (primary tumor (T), regional lymph nodes (N) and distant metastases (M)), which groups three disease features together in one staging system. The Lugano and the Ann Arbor systems were compared to TNM in predicting the overall survival of patients with primary gastrointestinal lymphoma (PGL) (Chang et al 2015). TNM has the best performance in predicting 5-year overall survival rates in aggressive and indolent PGL (TNM stages: I 100%, II 87.18%, III 75.17% and IV 16.69% p<0.0001) compared to Lugano (stages: I: 100%, II 80%, IIE 64.96%, IV 49.90%) and Ann Arbor (IE 95.83%, IIE 55.34%, 66.67%, IV 0%).

Another study, integrated the TNM system with a gene signature analysis to predict tumor relapse within 3 years for patients with colorectal cancer (Peng et al 2010.). The integrated model has proven to be more effective than a predictive tool utilising only TNM (AUC of 0.664 vs 0.647). Also, survival analysis showed that the 3 years relapse free survival was 100% in low risk, 74% in medium risk and 52.4% in high-risk groups. The development of big data availability could help to create integrated systems of predictive tools including staging systems (Edge et al. 2010).

3.3.3. Risk Index and risk scores

Risk stratification tools (risk indexes and risk scores) are also often pooled in the same category as scoring systems. Risk models assess the individual patient risk by adapting individual patient data into a multivariable risk prediction model (Moonesinghe et al. 2013).

Table 7 - Predictive techniques to develop risk index or risk scores

	Predictive tool
	Risk index/scores
Predictive Techniques	**Algorithms**
	Association rules learning
	Convolutional Neural Networks
	Decision Trees
	Deep belief network
	Deep neural network
	Hazard models
	Linear/Logistic regression
	Naïve Bayes
	Neural Networks
	Nomograms
	Random forests

Cardiovascular and oncological diseases are the common disease areas where risk indexes were implemented. One of the most adopted tools in this category is the Framingham risk score. This tool builds on a long history of research that started at the end of the 1940s. The Framingham Heart Study was a long-term investigation which aimed to improve preventive and treatment research for cardiovascular diseases (Mahmood et al. 2014). The Framingham risk score was first published in 1998, and is widely utilised to predict the risk of incurring cardiovascular diseases. It is also utilised to assess the impact of cardiovascular risk factors on other diseases, such as multiple sclerosis (Moccia et al. 2015). Another study uses the Framingham risk score to explore the link between breast cancer could and cardiovascular diseases, showing that women with breast cancer have a 1.77 times higher risk of contracting cardiovascular diseases than women who have never had breast cancer (Geernat et al 2018). One research team integrated a 70-gene signature, a clinical tool, to different risk prediction algorithms, to predict outcomes in early stages of breast cancers (Drukker et al. 2014). PREDICT integrated with 70-gene signature (AUC: 0.662) was the best predictive tool compared to AOL, NPI, St. Gallen, CBO and NABON. The authors report that integration of 70-gene signature and risk prediction algorithms can improve risk estimation and help providers improve management of early stage breast cancer.

Another study assessed PREDICT 2.0 as a prognostic tool in 8834 breast cancer patients. The tool reported an AUC of 0.80 for 5-year overall survival (OS) and an AUC of 0.78 for 10-year OS

(Van Maaren et al. 2017). A subgroup analysis of the cohort was performed based on age and on oestrogen receptor subtype (ER). The tool was less accurate in some subgroups (patients older than 75 years and ER negative patients) but was reported to be an overall reliable predictive tool. Despite promising results, low adoption of risk indexes remains an issue. Lack of use can be caused by poor clinician awareness, limited evidence on the robustness, and by concerns over tool complexity and accuracy (Moonesinghe et al. 2013). Other examples of risk stratification tools implemented in broader contexts include four programmes implemented in England, Wales and Scotland to reduce emergency hospitalisation rates: PARR (Patients-at-risk-of-hospitalization) and CPM (Combined Predictive Model) in England; PRISM (Predictive Risk Stratification Model) in Wales and SPARRA (Scottish patients at risk of readmission and admission in Scotland). These programmes were adopted between 2006 and 2010 and consisted of risk stratification models based on linear and logistic regressions that could identify individuals at high risk of hospitalisation (Hutchings et al. 2013).

3.3.4. Predictive modelling and algorithms

Predictive modelling and algorithms are the most broadly defined category of predictive tools. A wider range of tools and techniques are captured under these terms within the literature.

Table 8 - Predictive techniques that can be used to develop predictive tools based on algorithms

	Predictive tool
	Algorithms
Predictive Techniques	Algorithms
	Association rules learning
	Convolutional Neural Networks
	Decision Trees
	Deep belief network
	Deep neural network
	Hazard models
	Linear/Logistic regression
	Naïve Bayes
	Neural Networks
	Nomograms
	Random forests

Predictive modelling techniques include both older techniques captured under scoring systems and more recent ones related to AI. Generally, predictive modelling projects do not referring to a specific analytics technique, but rather to a broader project that can involve more than one tool (e.g. national programs for health prevention). Predictive modelling can be broadly analysed in four ways: through the event that it is predicting; through the set of patient predictor variables available; through the time frame considered to make a prediction; or through the type of statistical technique adopted (Panattoni et al. 2011). The accuracy of predictive modelling evidence is related to the patient predictor variables adopted, including socio-demographic; diagnostic; prior utilisation or costs; pharmacy data; health status and functionality; clinical data (Panattoni et al. 2011). Some literature categorises predictive analytics or prescriptive analytics as predictive modelling tools. These tools focus mainly on cancer and cardiovascular diseases.

One study developed a mathematical method (Radial basis functions and particle swarm optimization RBF-PSO) to predict the final height of patients with growth hormome deficiency (Migliaretti et al. 2018). The tool was found to be reliable in predicting final patient's height. Another study examined if clinical PWV score (pulse wave velocity) can be a prognostic tool for detecting major adverse cardiac events (MACE) in patients after percutaneous coronary intervention (Chen et al. 2015). The tool was reliable in predicting 3-year MACE (AUC 0.72). A comparative study focusing on breast cancer assesses different mathematical methods (Logistic regression, decision trees, and random forests) to identify the best predictive tool for detecting adverse events (Lindsay et al 2019). The study reports that ensemble methods (random forests) are more effective than single-model methods (decision trees, logistic regressions). Ensemble methods had an average AUC of 0.053 vs single-model methods AUC of 0.034.

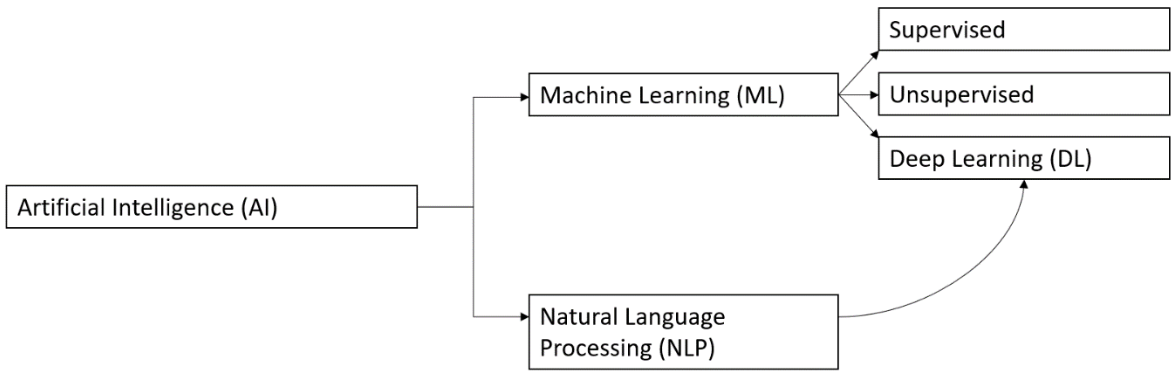
Another study adopted a model based on logistic regression to predict which children affected by asthma can be treated with inhaled corticosteroids (ICS) (Wu et al. 2017). The scaled Brier score was used to evaluate the overall prognostic value of model, while AUC curve was used to assess the model's predictive responsiveness. Tool validation was performed on a cohort of 158 children, reporting an AUC of 0.763 and a Brier score of 0.23 (where zero is no prediction and 1 indicates perfect prediction). The study provides an example of how specific techniques can be used to develop a model which is difficult to classify within a taxonomy.

Algorithms for predictive tools development and implementation can be utilised as single predictive techniques and can be both implemented in non-AI and AI tools. Algorithms development and implementation involves 5 stages: 1) acquiring data; 2) building and validating the model; 3) applying in a real-world setting; 4) testing it in practice and 5) scaling the model to generalize implications (Amarasingham et al. 2014). Recent examples of algorithm utilisation as predictive tool can be found in Martinez-Gimenez et al. (2018), Andres et al. (2018), and Zhu et al. (2018). The first study investigated how algorithms could predict treatment modalities based on temperature differences in burn wounds, analysed with thermographic scans (Martinez-Gimenez et al. 2018). The algorithm was reliable, correctly predicting the best treatment option with an accuracy of 85.35%. The second study developed a software tool, PSSP, based on a learning algorithm, to predict individual survival after liver transplantation for primary sclerosing cholangitis (Andres et al. 2018). The authors also developed an evaluation measure called D-calibration, to assess tool effectiveness. PSSP is a reliable tool in estimating the survival probability over time. The study also compares this algorithm-based tool with risk scores and other models, such as the Cox proportional hazard model, arguing that algorithm-based tools are more effective for screening tasks and more accurate in prospective cohort analysis. The final study developed an algorithm-based tool (ALR, ALP-to-lymphocyte ratio) that predicts survival and microvascular invasion in patients with hepatocellular carcinoma (Zhu et al 2018). Based on a cohort of 165 patients, ALR had an AUC of 0.73 in predicting microvascular invasion, had the highest accuracy when compared with three other tools (PLR, AUC: 0.632; APRI, AUC: 0.554; Fib-4, AUC: 0.572). Also, ALR proved to be a reliable independent predictor of survival for patients with hepatocellular carcinoma.

3.3.5.Artificial Intelligence: machine learning and natural learning process (NLP)

In the last few years scientific literature has increasingly focused on AI tools for predictive analysis in health (Jiang et al. 2017). The two predominant types of AI are machine learning and natural learning processes (Figure 2).

Figure 2 - Artificial Intelligence framework



AI analytics rely on algorithms to create tools that can "learn" features from larger healthcare datasets, while older predictive tools involve a process where the input, output and outcome are specifically set by humans (Panesar 2010). The two main AI subgroups, ML and NLP, through the use of algorithms, are trained from extensive volumes of datasets to find associations between subject features and outcomes of interests (Jiang et al. 2017). There is not a rigid threshold that can distinguish what tools can be considered AI or not. Rather, tools can be positioned on a spectrum in terms of level of human specification vs level of learned features from available data. (Beam et al. 2017). AI tools tend to have less the human involvement and more independent learning from data. Machine learning is the broadest AI subgroup and includes supervised ML, unsupervised ML and dep learning. NLP involves converting non-machine-readable information into a language that can be understood by AI tools (i.e. the extraction of information of unstructured data, such as clinical notes or medical journals contents) (Jiang et al. 2017). Overall NLP has an ancillary role for ML proper functioning.

Table 9 - Predictive techniques that can be used to develop Machin Learning predictive tools

	Predictive tool
	Machine Learning (Supervised/Unsupervised)
Predictive Techniques	**Algorithms**
	Association rules learning
	Convolutional Neural Networks
	Decision Trees
	Deep belief network
	Deep neural network
	Hazard models
	Linear/Logistic regression
	Naïve Bayes
	Neural Networks
	Nomograms
	Random forests

The older predictive analytics tools (scoring, grading systems, nomograms, risk index) are all considered supervised techniques, and do not fit or only very marginally fit within the AI spectrum. A general advancement of machine learning is that it can handle greater volumes of data and has a tendency to produce more generalizable results through both supervised ML or unsupervised ML tools. Classic machine learning techniques are supervised. Common supervised ML tools include decision trees, association rules learning, linear and logistic regression, naïve Bayes, random forests, discriminant analysis, support vector machine (SVM) and neural network (Jiang et al. 2017; Gianfrancesco et al. 2018). SVM and neural networks are the most frequently used supervised ML techniques and rely on imaging, genetic and electrophysiological data (Jiang et al. 2017). These tools are categorised as supervised because researchers must introduce input data and a specific set of outputs or outcomes of interest. The aim is to infer ex-ante the probability of a specific outcome based on a clustered dataset (patients' traits). Generally inputs are composed of baseline data (i.e. patients' age, gender, disease history) and the health outcomes are disease indicators, survival times, and quantitative disease levels (Jiang et al. 2017).

Unsupervised ML techniques don't include any outcome of interest in their algorithm. The rationale is to use a tool that can learn features from data and autonomously infer associations between similar groups of subjects. The most common unsupervised techniques adopted as predictive tools are clustering and principal component analysis (PCA).

Table 10 - Predictive techniques that can be adopted to develop deep learning predictive tools

	Predictive tool
	Deep Learning
Predictive Techniques	**Algorithms**
	Association rules learning
	Convolutional Neural Networks
	Decision Trees
	Deep belief network
	Deep neural network
	Hazard models
	Linear/Logistic regression
	Naïve Bayes
	Neural Networks
	Nomograms
	Random forests

Deep learning (DL) can be considered as a statistical extension of classical supervised and unsupervised ML techniques. In particular, they extend the capacity of classical neural networks by developing more layers of representation from which a learning algorithm can discover and develop new patterns (Esteva et al. 2019). DL occurs without supervision techniques (without including specific outcomes of interest). The automatic composition of multiple layers allows DL tools to handle even greater volumes of data compared to a classic machine learning technique. Unsupervised and DL techniques are the most powerful tools when there is the need to reduce data dimensionality and to identify unknown subgroups (Jiang et al. 2017). The most commonly used deep learning technique is convolution neural network (CNN), which is mainly used to handle and reduce high dimensionality in imaging data (Lecun et al. 2009). Other DL techniques for predictive analytics development are recurrent neural network, deep belief network and deep neural network. Deep learning techniques can be integrated with NLP to create automatic tools that can constantly generate sources of raw data, clean data and use it for the required purpose.

As for the previous discussed tools, cancer and cardiovascular diseases are the most common disease areas of interest for AI application. These recently developed techniques can greatly support providers in prescriptive decisions (diagnosis and treatment) and in predicting risk in health outcomes. In some cases, ML tools have exceeded provider's ability in prediction or prescription decision-making. One study focused on DL use cardiovascular disease utilised artificial neural networks (multilayer perceptron, MLP, and radial basis function networks, RBF) and Bayesian networks to assess tool accuracy, sensitivity and specificity in the prediction of hospital mortality in patients with abdominal aortic aneurysm (Monsalve-Torra et al. 2016). ANN tools have the highest overall accuracy (95.1% for MLP and 92.9% for RBF) but have low sensitivity rates (MPL: 65.5%, RBF: 69.5%), while Bayesian networks had a sensitivity of 86.8%. A combination of all three methods led to a higher sensitivity (87%). Overall, there is still no agreement over the best predictive tool or technique for this disease. While the authors report that Bayesian network algorithms is the technique with the best overall results, other studies claim that ANN and multiple regression are the best DL predictive techniques in the context of this disease area.

Artificial Neural Networks have been also used in the context of kidney diseases. One study developed an ANN system to predict postoperative outcomes after percutaneous nephrolithotomy (PCNL). Based on a cohort of 254 patients, the system was able to accurately predict stone free rates complications (AUC: 0.861), with predictive accuracy and sensitivity of postoperative variables between 81% and 98.2% (Aminsharifi et al. 2017). Previous research suggests that this machine learning system has a prognostic accuracy at least as accurate as previously implemented statistical models (eg. regression analyses) in this disease area (Aminsharifi et al. 2017). Despite this, there is still no comparison of different tools in the literature for prognostic accuracy.

A systematic review and meta-analysis of machine learning algorithms to predict therapeutic outcomes in depression was performed (Lee et al. 2018). 26 studies were included in the qualitative review and 20 in the meta-analysis, most of them with a retrospective study design. Classification algorithms had an overall accuracy of 0.82 (95% CI) in predicting therapeutic outcomes. ML algorithms have capacity to include a large volume of data types and sources, which enables consideration of a broader conceptual and analytical research framework. Nevertheless, an integrative approach, which combines multiple techniques produces the most effective predictive tool (Lee et al. 2018).

An artificial neural network and SVM based tool was developed to predict brain arteriovenous malformation caused by a surgical technique with a 97.5% accuracy. This was a considerable improvement over standard regression analysis in the same setting which yielded an accuracy of 43% (Asadi et al. 2014). Another study adopted logistic regression to successfully predict the outcome of a 3-month treatment after a stroke (Zhang 2013). In the context of cancer research, IBM developed Watson, which assembles ML and NLP techniques to assist providers in treatment decision. Watson suggestions matched provider decisions in 99% of cases. This tool also supports clinical research through identification of genetic associations in different types of cancer (Jiang et al. 2017).

4. Case studies

4.1. NHS Digital Platform in the UK

The UK NHS in UK is actively promoting research and implementation of predictive tools for both patients and providers. By 2040, more than 80% of the NHS workforce will have to be able to understand and manage genomic, AI and robotics tools (Topol 2019). The ability to read genomes, use speech recognition and NLP programmes and manage predictive analytics tools will be a critical component of healthcare delivery. Currently NICE has approved the following data-derived tools used for population risk stratification within the NHS: QCancer, adopted to calculate the absolute risk of a patient having an undiagnosed cancer; QRisk, which evaluates a patient's risk of incurring in cardiovascular diseases over their life; electronic frailty index (eFI) scores, that predicts primary care adverse outcomes risks based on a patient's underlying vulnerability; and QAdmissions, which predicts the risk of an emergency hospital admission. Many other projects at a local level are promoted. Royal Free NHS Trust and Google DeepMind are in partnership for a project on real-time EHR data, to develop apps for healthcare professionals that can predict patient deterioration. In Berkshire (Connected Care in Berkshire), 17 health and social care organisations are sharing EHR records to promote data exchange and to enhance predictive tools management within local hospitals.

NHS digital in England represents an exciting example of how a national healthcare provider and insurer can set up and support a project for AI and predictive tools implementation. NHS digital has aspired to create sustainable infrastructures in local trusts and to promote development at all levels of the organization, from national management organization to local trusts, providing a good example of how health insurers and providers can collaborate on a national level in the context of digital health and predictive tools.

4.2. Flat-Iron Health and Roche partnership

Flat-Iron Health is an oncology-based company that specialises in health-related data analytics, with a particular focus on recent data designs (big data and EHR). This company is highly innovative in their approach to collecting, analysing and managing data. One of the main features that distinguished them is the ability to collect unstructured clinical data from a range of sources (laboratories, cancer treatment centres, research repositories, payer networks) for use in AI tools (Sprenger et al. 2016). Their work aims to address some of the main challenges related to clinical development: how to improve clinical trial results and eligibility assessment, and how to help pharmaceutical companies in strengthening and stepping up their innovation process?

Flat-Iron Health was acquired by Roche in 2018. One of the main goals of this partnership is to link new methods in gathering, analysing and providing continuous complex data (mainly through the EHR design), to more effective and comprehensive AI predictive tools. These efforts help to generate AI tools with enhanced prognostic effectiveness in order to better support provider and researcher decision-making. FlatIron's ambitious approach to data integration, with a goal of having an automatic system that gathers millions patient data in a readable format for AI tools, could be a ground-breaking development in the field of predictive analytics. While still at an early stage, Flat Iron is a great example of a company adopting a long-term perspective. Collaborations with intergovernmental organizations and policymakers could help to further promote this initiative.

4.3. Inf-act.eu

The Inf-act project is an ambitious joint collaboration between European governmental and research institutions to address fragmentation, lack of comprehensiveness and limited access to health data in Europe. The Inf-act project consists of 10 working packages which aim to: a) Set up a framework of the health information systems in Europe; b) provide guidance on how to integrate these systems with national policies; c) review the reliability and volume of evidence available on innovation in health information; d) determine the level of interoperability of available health data; and e) provide recommendations on tools and methods to support health information systems. The overarching objective of the 10 working packages is to create a unique framework of business cases, analyses and proposals that provides a common and sustainable research infrastructure, reduces health information inequalities and improves interoperability of health information within the European Union. This collaboration plans to give political support to national countries in developing and implementing best practices, build capacity within and across countries and provide common health information tools. Inf-act, in collaboration with European Research Infrastructure Consortium on Health Information for Research and Evidence-based Policy (HIREP-ERIC), represents one of the most ambitious projects in predictive analytics given a wide-ranging approach to creating harmonised and coordinated data infrastructure in health information and data generation within Europe.The project was launched in 2018 and will end in March 2021.

4.4. LSE Big data for better outcomes

Big Data for Better Outcomes (BD4BO) is another European research programme involving national governmental bodies, academia, research institutions and companies involved in the pharmaceutical sector. The aim of this comprehensive programme is to foster the development of platforms for big data, to enhance interoperability and improve the level of analysis in big data. The programme has four disease specific projects: ROADMAP on Alzheimer's disease; Harmony on hematologic malignancies; PIONEER on prostate cancer and BigData@Heart on cardiovascular diseases such as atrial fibrillation, acute coronary syndrome and heart failure. The overall programme is managed by DO-IT, a coordination platform within the Innovative Medicines Initiative 2, which is a joint programme promoted by the EU and European Federation of Pharmaceutical Industries and Associations (EFPIA). This project sees the collaboration of a large number or universities, national and local insurers and regulators and pharmaceutical companies. It is a great example of creating a vast collaboration with key stakeholders and of breadth in analysis, given a focus on multiple key disease areas. Results from this project can lead to tangible progress in big data management and, by extension, in how it could be implemented in AI tools.

4.5. Maccabi Biobank

Maccabi Health Services and TIPA Biobank represent another interesting case of how health insurers' organizations can deal with data collection and quality. In 2017, Maccabi established the TIPA Biobank Research Initiative (Maccabi, 2019) with the goal of collecting biological samples that can be used for research. The project strives to collect a comprehensive set of biologic data linked to Maccabi Health Services, which is one of the main insurer organizations in Israel. So far they have collected multiple samples from 2.5 million members across 350 different labs. This creates the possibility of using this data for longitudinal studies for a wide range of clinical conditions. The TIPA Biobank can provide start-up companies with digital, genetic and biological data to improve research and to help support the development of validation of new tools, such as predictive analytics. The collaboration between a national healthcare organization and local research centres improves the quantity and quality of data collection, and represents a crucial first step for promoting the development of innovative and complex predictive tools. The TIPA biobank serves as a case study which could enable an effective subsequent collaboration on an international level to improve data exchange.

4.6. FDA proposed regulatory framework for modifications to AI/ML based software as Medical Device (SaMD) and the Artificial Intleligence/Machine Learning (AI/ML)-based Software as a Medical Device (saMD) Action Plan

In 2019 the U.S. Food and Drug Administration (FDA) published a guide to evaluate AI tools and a discussion paper called 'Proposed regulatory framework for modifications to AI/ML based software as Medical Device (SaMD)' (FDA, 2019), that looks at how changing algorithms can be more efficiently assessed in premarket development and postmarket performance assessment (FDA) (FDA, 2019). The FDA is already a leading regulatory body in dealing with the innovations brought by AI in healthcare. It currently proposes flexible and tailored premarket authorisations for these tools (premarket clearance (510(k)) or De Novo classification).

Machine learning tools present challenges to regulators, as the scope and performance of the algorithm is dynamic and changes as more data is analysed. The FDA discussion paper, called on all the interested stakeholders to join and support a debate on proposed reforms in AI/ML software regulation. In January 2021, the FDA published an Action Plan based on the discussion paper and subsequent stakeholder discussion. The FDA outlined 5 actions: 1. Tailored regulatory framework for AI/ML-based SaMD; 2. Good Machine Learning Practice (GMLP); 3. Patient-Centered Approach Incorporating Transparency to Users; 4. Regulatory Science Methods Related to Algorithm Bias & Robustness; 5. Real-World Performance (RWP).

The updated regulatory framework outlined in the action plan is based on the SaMD Pre-Specifications (SPS) (that describes what aspects the manufacturer intends to change through learning) and the Algorithm Change Protocol (ACP) (that reports how the algorithm will learn and change) (FDA, 2021). The GMLP encourages harmonization of best practices in data management, training, interpretability, documentation and evaluation. A patient-centered approach aims to increase transparency for users by holding public workshops to discuss device labelling features. Also, the FDA commits to support new methodologies for the evaluation and improvement of machine learning algorithms, and to collaborate with stakeholders who are piloting real-world performance processes for AI/ML-based SaMD (FDA, 2021).

5. Discussion

The results of this scoping review suggest that predictive tools are a useful resource for patients, providers and insurers. To the authors' knowledge this is the first study that has established a taxonomy of predictive tools used to inform research and decision-making in healthcare. Most of the predictive tools analysed in the included literature were shown to be useful ancillary tools for healthcare providers and patients in predicting the risk of incurring in specific consequences if undertaking certain treatments, or in predicting the overall survival rate in a cohort of patients. Among the articles analysed through the Ovid Medline search, the vast majority of the studies focus on older generation tools, mainly used for oncology and cardiovascular diseases. While AI driven predictive tools show tremendous potential, they are a relatively recent development implementation in healthcare thus far is limited. There is an on-going debate on how AI driven tools can reshape healthcare management and on identifying the current challenges, but relatively few articles were identified that validate the performance of AI driven tools.

In many disease areas, scoring systems or application of single techniques already provide significant predictive value, potentially limiting the need for AI driven tools. Nevertheless, researchers are increasingly looking at ways of integrating different techniques or tools, including traditional ones, in order to maximise the prognostic performance. Innovation in the field of predictive analytics remains complex. While researches aim to develop tools with high accuracy, sensitivity, and precision, limitations are still present in terms the level data complexity that can be managed by a tool. Both supervised and unsupervised predictive techniques have been successfully developed and implemented, yet both approaches have strengths and weaknesses. Further, it is still hard to generalise the validity of a specific technique or tool above others. There is still no scientific consensus over which techniques are perform best in a specific disease area or type of diagnosis/treatment and a broader attempt to compare all available predictive tools or techniques in the literature is lacking. Fragmentation of interests from the stakeholder community remains a barrier to developing consensus on predictive tools.

The scoping review provided only partial answers to our main hypothesis. While some evidence is present on how predictive modelling can stratify patients based on the risk, very little is available on how these tools could support the transition to value-based payments. One of the few authors that links these two issues is Panesar (2019). In the *Shifting from volume to value* chapter the author reports the case of Buurtzorg Neighbourhood Care in the Netherlands, as an example of this paradigm shift. The simultaneous collection of behavioural, demographic, health, and engagement data can provide an opportunity for machine learning and development of novel AI, to rapidly improve, and learn from, user behaviour and outcomes. This in turn could enhance the development of patient-centered and value-based systems. However, further research is needed in assessing the potential links between predictive analytics tools and healthcare financing issues.

With the currently available information it is not possible to rank all tools or techniques in a unique classification. Nevertheless, a number of pros and cons of individual tools emerge from the research and it is possible to make inferences about the use of one tool in lieu of most others. Scoring systems are the most investigated tools not only because they were among the first tools developed, but also because they are relatively easy to be set up, do not require large amounts of data and can be easily understood by patients and healthcare providers. However, due to their simplicity they cannot manage complex and large data sets and have frequently faced limitations in demonstrating generalisability and external validity. The same applies for other old-generation tools (i.e. risk scores, staging and grading system). As a result, current ambitions for developing more accurate, generalizable and reliable tools are largely concentrated on machine learning driven tools. Machine learning driven tools can handle an impressive amount of data, can be developed as unsupervised tools, and have the capacity to adapt their analysis as more data becomes available. Outstanding challenges in the context of predictive analytics tools, particularly for the most recent analytics techniques, are related to governance, regulation, data quality, data exchange and interoperability, privacy and ethics, health workforce education and patient safety (He et al. 2019, Panch et al 2018, Parikh et al 2019).

Governance and regulation. As reported in the FDA case study, efforts are currently being made by regulators to keep pace with the level of innovation in predictive tools and deliver effective regulatory frameworks. A number of debates and proposal have emerged in the past few years, particularly in the context of algorithm-based tools. One proposal outlines five criteria to update the regulatory framework for algorithm-based predictive tools (Parikh et al. 2019). The five criteria are related to the performance endpoints, benchmarks, interventions, specification and audit mechanisms. The applicability of these criteria were demonstrated with the WAVE Clinical platform, the first surveillance system to receive FDA clearance for clinical practice (Parikh et al. 2019).

Data quality. Poor data quality directly reduces the accuracy of a model and limits generalisability of results. Without accurate and correct data, predictive tools cannot perform well. Issues in data quality arise from many factors, including the way data is collected (patients' or providers' biases), data readability for the model (NLP tools may offer a solution in this context), or the timing/duration of data collection. Typically, models that attempt to predict events further in the future have lower predictive accuracy given limitations in available data. (Mukamel et al. 1997). A predictive tool generates more accurate results with a time frame of less than one year compared to multiannual time frames. However, short time periods may be less relevant for risk prediction or patient identification in some disease areas (Panattoni et al 2011). These are relevant limitations for predictive tools and can significantly hamper the development of one-size-fits-all tool.

Data infrastructure, exchange and interoperability. The lack of free exchange of data presents another limitation to the development of predictive tools. Currently, incentives are lacking to promote a major and stable data exchange. This affects AI tools in particular, given their need to be continuously fed with new data from clinical studies to learn and improve performance (Jiang et al. 2017). Further debate on this issue is needed across all stakeholders in order to improve accuracy and robustness of predictive techniques, specifically unsupervised techniques. The development of national platforms to improve data collection (including the reported cases in UK and Israel) bode well for future developments in data exchange at the international level. Without coordinated efforts between national health insurers, healthcare providers and patient organizations, it hard to foresee resolution of issues in data fragmentation and interoperability. Examples of data aggregation amongst organisations are limited. Within the USA, data aggregation in Intensive Care Units and Veterans Administration have helped to accelerate AI development in healthcare (Panch et al. 2019).

Interoperability and data exchange also underlie the broader issue of data property, data responsibility and utilisation. Data property rights composition can significantly impact the process of promoting interoperability. Possible solutions to deal with data infrastructure issues include: a) creating generalized data infrastructures based on already existing cases, such as the STRIDES initiative promoted by the National Institute of Health (NIH, 2019) or the MIMIC initiative from the Massachusetts Institute of Technology (Johnson et al. 2016); or b) to convince all the healthcare companies, through legislation, to commercialize their clinical data in accessible clouds (Panch et al. 2019). Despite continued efforts regulatory bodies and healthcare organizations, data infrastructure is likely to remain a key barrier to promoting free exchange and interoperability of data.

Data privacy. The use of individual patient data for personalised medicine presents another challenge to regulators, providers and healthcare companies. Data privacy issues have always been present, but the issue has come under increased scrutiny with the advent of machine learning and big data sources. In many settings, data infrastructure legislation does not adequately reflect the most recent developments in predictive analytics tools. The GDPR (General Data Protection Regulation) in Europe and the California's Consumer Privacy Act are two good examples of effective data privacy regulation frameworks. Howeve high costs for regulatory compliance could limit the growth of small organisations in this sector (Panch et al 2019).

Ethical challenges. Ethical challenges can arise when the suggested treatments from a predictive tool conflict with a physician's ethical obligations or a patient's preferences. A comprehensive conceptual framework of the legal and ethical challenges in managing predictive analytics tools has been developed, including data collection, development, validation in real world settings and final implementation, underlying how data infrastructure regulation and policy decisions shape development and implementation of predictive tools (Cohen et al. 2014).

Health workforce education. According to the Watcher Review, all Trusts within the English NHS, are expected to achieve a high level of digital maturity by 2023. Local Trusts will have to be able to develop and manage infrastructures where new digital technologies will be implemented. The Topol Review forecasts that by 2040 at least the 80% of the health workforce will have to be able to understand and manage genomics and AI tools. As big data sources accumulate, it will be a challenge to find good quality expertise in data analysis and science, both in clinical organisation and in other organizations. Some argue that it will not be reasonable to expect that physicians will be able to reach this level of understanding, but that it will be inevitable that medical schools will have to provide informatics programs and adequate training for the future student cohorts (He et al. 2019). Others stress how the developments of AI, particularly in the area of diagnostic image analysis, will lead to a demise of radiologists and a likely merging of into a single specialty called information specialist (Panch et al. 2018). This new specialty would focus predominantly on managing AI tools results and tailoring them to individual patients, rather than diagnostic image analysis.

Patient safety. Safety and efficacy of predictive analytics, particularly for the AI driven technologies, requires frequent updating of regulatory frameworks. The FDA reforms in regulatory frameworks for AI predictive tools present an excellent example of updating regulatory standards for safety and efficacy assessments. In the US, predictive analytics fall under the SaMD label, defined by the International Medical Device Regulators Forum (IMDFR). This differentiation from other medical devices allows a more tailored and rapid premarketing authorisation process. Regulation should balance the need for patient safety and efficacy with facilitating quick access to new techniques.

Risk mitigation strategies as part of complementing predictive tools in the context of coverage decisions. Predictive tools and evidence generated thereof can be combined with innovative payment agreements, which can be adapted in circumstances where the predictive modelling engages in generating evidence slightly outside the remit of treatment use proposed by HTA and clinical guidance in a forward-looking way, in order to incentivise truly innovative contracting and fall in line with approaches to population health, patient segmentation and early intervention of at-risk patients.

6. Conclusion

Predictive analytics can be very useful tools for detecting health outcomes. Evidence shows that most tools are accurate enough to help providers and patients with treatment management and with forecasting health outcomes. Innovations in recent years suggest that they will be increasingly important in the shift to personalised treatments. Little evidence is available in assessing the relationship between predictive analytics tools and the transition to value-based payments systems. Substantial increases in AI, genomic and robotic tools implementation in healthcare are expected over the next two decades. Undoubtably, addressing the ambitions and objectives of all stakeholders for implementation of predictive tools will require a coordinated and collaborative international effort.

7. References

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