

AI and decision-making: dilemmas of regulation and methodological implications

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1. WHY TO FOCUS ON DATA-DRIVEN DECISION MAKING

This paper focuses on data-driven decision-making, i.e. how present technological developments affect the way we take decisions either in scientific research or in the social, ethical and legal domains.

Exploring decision-making seems to be a productive approach in the light of an interdisciplinary experience, both theoretical and practical¹.

The main facets of current technological landscape are well known: a) the *Internet of everything*, which includes, on one side, the (let's say "old") Internet of things, i.e. the fast connection through cloud (and 5G in the next future) of services, industrial activity, hospitals and all aspects of smart cities, and, on the other side, the Internet of people, when the entities connected are humans; b) the *huge quantity of data* all these connections produce; c) *Big Data analytics* as a means for governing all this data and exploit them through the use of machine learning technologies, i.e. Artificial intelligence and data science.

Of course, being all these facets part of the same interconnected environment does not mean they are a unique entity. They have to be explored and studied in different ways and the result will largely depend on the research focus, e.g. if the connectivity or Artificial intelligence *per se* or social applications and so on.

Hereinafter I firstly outline the state of the art on big data and its opportunities in European documents, deserving some attention to the discussion about the kind of regulation to be introduced for new technologies. In the following paragraph, two main lines of exploration are presented, where the data-driven revolution crosscuts health policies and even the law, as an autonomous field of big data research. A final paragraph is dedicated to the importance of an interdisciplinary approach and to a proposed list of topics to be shared between bioengineers and jurists.

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¹ I take advantage of previous research on the issue lastly published in A. Santosuosso, G. Pinotti (Eds), *Data-Driven Decision-Making. Law, Ethics, Robotics, Health*, Pavia University Press, 2020.

2. THE CURRENT DEBATE ON AI, BIG DATA AND REGULATIONS

Current times witness an unprecedented generation of amounts of data of different nature, also called Big Data. This ranges from an ever-increasing amount of data from social media and Internet and mobile applications, to the growing digitization of all human activities (books, legal archives and medical records), to multimodal sensors data collected by robots and digital assistants.

Big Data have pushed technologies towards new paradigms for their collection, storage and analysis. In particular, big data analytics uses machine learning methods and tools extensively, which makes possible to examine large amounts of data, to uncover hidden patterns, to find correlations and to infer other insights. Big data analytics is also useful to design new automated and autonomous data-driven reasoning and decision systems.

2.1. The position of the EU

Some documents and reports by European Union institutions and public-private actors dedicate great attention to the so called “big data revolution”.

According to the European Parliament, in its *Towards a thriving data-driven economy*, in European countries and EU institutions it is a shared opinion that Big Data “has the potential to boost economic productivity and improve consumer and government services; [...] may bring more business opportunities and increased availability of knowledge and capital, as long as governments and stakeholders work together in a constructive manner”².

In addition, the EU Commission delivered in 2017 a communication *Building a European Data Economy*³, where the importance of the huge amount of collected data is clearly underlined: “as the data-driven transformation reaches into the economy and society, ever-increasing amounts of data are generated by machines or processes based on emerging technologies, such as the Internet of Things (IoT), the factories of the future and autonomous connected systems. [...] The enormous diversity of data sources and types, and the rich opportunities for applying insights into this data in a variety of domains, including for public policy development, are only beginning to emerge. To benefit from these opportunities, both public and private players in the data market need to have access to large and diverse datasets”⁴.

Also private actors and industries are aware of the importance of Big data: “the increased volume, velocity, variety, and social and economic value of data signal a paradigm shift towards a data-driven socio-economic model. The significance of data will only grow in importance beyond 2020 as it is used to make critical decisions in our everyday lives”⁵.

² European Parliament, *Towards a thriving data-driven economy*, <https://www.eesc.europa.eu/en/our-work/opinions-information-reports/opinions/towards-thriving-data-driven-economy>). See also the Big Data Europe project, and the activity of the Consortium of European Social Science Data Archives CESSDA <https://www.cessda.eu>.

³ https://eur-lex.europa.eu/content/news/building_EU_data_economy.html.

⁴ See also the European Commission Project CORDIS- Data-driven decision making for a more efficient society. https://cordis.europa.eu/project/rcn/204374_en.html.

⁵ Big Data Value Association, *European Big Data Value Strategic Research and Innovation Agenda*, Introduction, available at https://businessdocbox.com/Business_Software/71308945-European-big-data-value-strategic-research-and-innovation-agenda.html.

2.2. Some remarks on the EU regulation and its potentially universal application.

Among the current legislative priorities and commitments to implement a connected Digital Single Market, the European Commission attributes great importance to the General Data Protection Regulation (GDPR, entered into force in 2018), an essential tool in order to “safeguard individuals fundamental right to the protection of personal data in the digital age”.

The European Parliament in its *Towards a thriving data-driven economy* “stresses that the processing of certain kinds of data, in particular personal data, falls under the scope of EU data protection law; urges, in this connection, the swift adoption of the Data Protection Package; [...] Believes that more effort is needed with regard to the anonymization and pseudo-anonymization of data as a precondition for creative data innovation and a major step in lowering market entry barriers for start-ups and SMEs; believes that uptake technologies, including text and data mining, will be an important factor in deriving added value from open datasets; points out, however, that a clear distinction must be made between the processing of personal data and other kinds of data, and that technological solutions that are privacy-enhancing by design must be devised; [...] Stresses that all the principles laid down in EU data protection law, such as fairness and lawfulness, purpose limitation, the legal basis for processing, consent, proportionality, accuracy and limited data retention periods, must be respected by Big Data providers when processing personal data; recalls, in this context, the opinion of the European Data Protection Supervisor on privacy and competitiveness in the age of Big Data”⁶.

In a technological global scenario, unquestionably dominated, in terms of investments and political power, by the USA and China, some interesting interstitial phenomena are emerging.

European legal and ethical regulations (and especially the above mentioned GDPR) are one of them. It is worth noting that in the general present claim for regulating in some way Artificial intelligence and its applications the European GDPR is considered a possible model for universal application. There is also who, as Mark Zuckerberg (no matter how much this man might be in conflict of interest)⁷, proposes to apply the GDPR to the United States, something that only few years ago was unimaginable.

The EU Commission has taken a further step forward and has appointed a High-Level Expert Group on Artificial Intelligence. The group has delivered a document, *Ethics Guidelines for Trustworthy AI*, suggesting some ethical rules, which start from a not usual and interesting assumption: ethical AI should be lawful according to EU legislation, which includes the Treaties of the European Union and its Charter of Fundamental Rights, the General Data Protection Regulation, the Regulation on the Free Flow of Non-Personal Data and more, the European Convention on Human Rights and more.

On 19 February 2020, the European Commission published a White Paper aiming to foster a European ecosystem of excellence and trust in AI and a Report on the safety

⁶ European Parliament, *Towards a thriving data-driven economy*, cit.

⁷ Mark Zuckerberg, *The Internet needs new rules. Let's start in these four areas*. The Washington Post, 2019 March 30. Other interesting interventions on the discussion about regulation are Reed C. 2018 *How should we regulate artificial intelligence?* *Phil. Trans. R. Soc. A* 376: 20170360. <http://dx.doi.org/10.1098/rsta.2017.0360>; Wendell Wallach; Gary Marchant, *Toward the Agile and Comprehensive International Governance of AI and Robotics [point of view]*, *Proceedings of the IEEE* (Volume: 107, Issue: 3, March 2019); Yochai Benkler. *Don't let industry write the rules for AI*; *NATURE* 01 MAY 2019, *Nature* 569, 161 (2019) doi: 10.1038/d41586-019-01413-1 (Yochai Benkler is a law professor and co-directs the Berkman Klein Center for Internet & Society at Harvard University in Cambridge, Massachusetts).

and liability aspects of AI. The White Paper proposes: “Measures that will streamline research, foster collaboration between Member States and increase investment into AI development and deployment; Policy options for a future EU regulatory framework that would determine the types of legal requirements that would apply to relevant actors, with a particular focus on high-risk applications”⁸.

Well, it is worth noting that all this legal stuff, traditionally considered an excessive burden, seems now to have turned into the object of the (US and global) desire.

A further example of global approach is given by the UNESCO Recommendation on rules to be applied to AI⁹. UNESCO claims the uniqueness of its perspective “thanks to its universality in membership and drawing on its multidisciplinary expertise”. And really the document develops some considerations about cultural minorities, multilingualism as a way of preserving cultural diversities, the effect of AI on arts and more. At the end the drafters conclude “It is not only desirable but urgent that measures be taken to set up a non-binding global instrument in a form of a recommendation. A recommendation – considering its non-binding character and its focus on the principles and norms for the international regulation of any particular question – would be a more flexible method and better suited to the complexity of the ethical questions raised by AI”. The elaboration of an instrument on ethics of artificial intelligence is currently in progress and has the ambition to elaborate the first global standard-setting instrument on ethics of artificial intelligence¹⁰.

What seems worth noting is that the level of complexity of the present technological turn is so high to leave room, beside the unquestionable superpower of US and China, to other entities and initiatives that can contribute to a real debate about the future of the humanity.

2.3. *Strategies of Regulation*

The question of the best strategies in order to take the best and avoid the worst side-effects is crucial. In the case of AI and Big Data the field might be defined as the area of human and economic relations where the development of new systems of connectivity plays a decisive role. This is easier said than done, because of the speed of change and the increasing pervasiveness of connectivity. Indeed, present reality looks like a “scurrying prey” and would require the attitude of a hawk when swooping down to capture it¹¹, rather than the slow, reflexive, supposedly rational attitude of ordinary rule-making processes.

⁸ Source: <https://ec.europa.eu/digital-single-market/en/artificial-intelligence> (Visited May 21, 2020).

⁹ UNESCO World Commission on the Ethics of Scientific Knowledge and Technology (COMEST), Preliminary Study on The Technical and Legal Aspects Relating To The Desirability Of A Standard-Setting Instrument On The Ethics Of Artificial Intelligence, Paris 21 March 2019, available at <https://unesdoc.unesco.org/ark:/48223/pf0000367422?posIn-Set=1&queryId=3cbc48e0-b3bd-488e-879b-84c382cd577d>. [the author of this paper, is a COMEST member].

¹⁰ This is the decision of UNESCO’s General Conference at its 40th session in November 2019 <https://en.unesco.org/artificial-intelligence> (Visited May 21, 2020). It is an inclusive and multidisciplinary process, which will include consultations with a wide range of stakeholders, including the scientific community, people of different cultural backgrounds and ethical perspectives, minority groups, civil society, government and the private sector.

¹¹ The metaphor is taken from Selmer Bringsjord – Naveen Sundar Govindarajulu, Artificial Intelligence, 2018, <https://plato.stanford.edu/archives/fall2018/entries/artificial-intelligence/>, visited May 1, 2020).

We know different systems of norms, the principal of them are Ethics, Law (legislation and/or judge-made law) and Technology. Each of them has pros and cons.

Ethics might be preferred for its being less rigid, even though it is exposed to the criticism of being not well defined and hardly enforceable. This is the main reason of a critical point of view on ethics: *'human rights'* are preferable rather than *'ethics'*, because human rights, even though protecting very similar values, have a clearer legal frame (e.g. the EU Charter of fundamental rights). In addition, there is no universal agreement on what is ethical, and several ethics have similar legitimacies. In short, it is unclear what ethics should be followed and what authority might control their application¹².

On this position, it has to be noted that the norms of the Universal Declarations of Human rights or the EU Charter of Fundamental Rights are twofold and share with law their phrasing and wording and with ethics the difficulty to be enforced. In addition, if we move from the very general level of Universal Declarations to specific regulations, such as the ownership and commercialization of data, public/private interface, license, open source and more, we find not less differences from one country and another than in the ethical field.

Indeed, the traditional conceptual scheme of establishing norms (whatever their nature, legal, ethical or even technical), waiting for social behavior, then reacting to their violations might be largely ineffective. In addition, the old rule-making systems hardly work in societies like ours and in technological matters. New strategies have to be invented.

An interesting normative technology is that of rules embedded in tech. For instance, the *privacy by design* and *by default* (art. 25, GDPR) impose to designers and producers a duty to conceive the products in a way that automatically reduces the impact on privacy of people.

Privacy by design and *by default* are an interesting novelty in the international ethical debate and also in the legal scenario after the inclusion in the GDPR (art.25). They impose to designers and producers a duty to conceive the products in a way that reduces the impact on privacy of people and suggest them “to implement appropriate technical and organizational measures, such as pseudonymization, which are designed to implement data-protection principles, such as data minimization, in an effective manner and to integrate the necessary safeguards into the processing in order to meet the requirements” of the Regulation and protect the rights of data subjects. Furthermore, “the controller shall implement appropriate technical and organizational measures for ensuring that, by default, only personal data which are necessary for each specific purpose of the processing are processed. That obligation applies to the amount of personal data collected, the extent of their processing, the period of their storage and their accessibility. In particular, such measures shall ensure that by default personal data are not made accessible without the individual’s intervention to an indefinite number of natural persons”.

It has also to be noted that the GDPR has a potentially area of application which goes beyond the EU countries. According to Art. 3, the Regulation applies to the processing of personal data in the context of the activities of an establishment of a controller or a processor in the Union, regardless of whether the processing takes place in the Union

¹² This is the opinion presented by OECD representative at the Conference on the Ethics of Science & Technology, And Sustainable Development (6 July 2019), 11th (Ordinary) Session Of The World Commission On The Ethics of Scientific Knowledge and Technology of Unesco (COMEST), Bangkok, Thailand, 2-7 July 2019. See also OECD, Recommendation of the Council on Artificial Intelligence, OECD/LEGAL/0449 (22 May 2019).

or not. In addition, the Regulation may apply in some cases also to the processing of personal data of data subjects who are in the Union by a controller or processor not established in the Union.

A further radical approach puts technology at the forefront and works on technological options. These options share with traditional ethical and legal regulations the goal of protecting freedom of people and reducing the overwhelming power of few huge companies, but pursue it using technological innovation that can change the game, without external regulatory intervention. It is the case of Tim Berners-Lee and a group of people at the Berkman Klein Center (Harvard) who are working on a change of the technology underlying the WEB¹³.

At the end there is the provocative thesis of who proposes just to wait: “Masterly inactivity in regulation is likely to achieve a better long-term solution than a rush to regulate in ignorance”¹⁴.

In conclusion, the Tim Berners-Lee radical technological approach (when possible) has the great advantage of being immediately effective without any need of further (sometimes questionable) legal or ethical intervention. In these terms it seems to be preferable wherever it is possible. Nevertheless, there are cases where mere technological changes are not possible or sufficient and the recourse to internationally recognized and enforceable instruments is unescapable. In the EU there is a general legal instrument, regulating some aspects of AI and connectivity: the General Data Protection Regulation (GDPR enacted 2018). However, the GDPR covers only some aspects and is binding only in the territory of EU (even though with some potential extensions). UNESCO is the only international organization having a global view and an attention to all aspects of human life and culture.

3. THE CASE OF PUBLIC HEALTH

The health information systems must generate, analyze and disseminate data.

At the Public health level, several issues need to be addressed: what are the best strategies to collect data really relevant for decision-making, given the introduction and implementation of new technologies? Which principles should guide the algorithm implementation to analyze the data and to take the intervention decisions? What kind of modeling can be useful for this purpose? Are simulation and agent-based modeling proper tools to support decision making?

Even in developing countries important applications are possible, ranging from agriculture to smart city applications till to health monitoring. The prospect seems to be globally positive and important for these countries¹⁵.

¹³ Berkman Klein Center, *The future of the decentralized web*, at <https://medium.com/berkman-klein-center/the-future-of-the-decentralized-web-707915f12360>; Jonathan Zittrain e Tim Berners-Lee; Ethan Zuckerman, *Thinking in Solid*, in Medium, at <https://medium.com/@EthanZ/thinking-in-solid-85e4f2c974c9>.

¹⁴ Chris Reed, How should we regulate artificial intelligence?, in «Phil. Trans. R. Soc., A», 376, 2018, <http://dx.doi.org/10.1098/rsta.2017.0360>.

¹⁵ Miazi, Md Nazmus Sakib, et al. «Enabling the Internet of Things in developing countries: Opportunities and challenges.» *2016 5th International Conference on Informatics, Electronics and Vision (ICIEV)*. IEEE, 2016. See also Rohokale, Vandana Milind, Neeli Rashmi Prasad, and Ramjee Prasad. «A cooperative Internet of Things (IoT) for rural healthcare monitoring and control.» *2011 2nd International Conference on Wireless Communication, Vehicular Technology, Information Theory and Aerospace & Electronic Systems Technology*

3.1. About data and datafication

The availability of data in order to take decisions is a crucial point of modern societies. Indeed, the birth of modern statistics is strictly related to the emergence of the modern nation state. Centralized states needed to know what human and physical resources existed on their territories. In the XVII century, in England, Political arithmetic (William Petty, *Political arithmetic*, 1690) applied to the numerical observation of births, deaths and other demographic phenomena, allowing an assessment of the population and of the economic power. Further progresses came from the application of the rules of the calculation of probabilities (P.-S. Laplace, *Théorie analytique des probabilités*, 1812).

Today the worldwide spread of IoT and connectivity produces a huge quantity of data, which allow a deep and finely granular knowledge of any human and physical phenomenon and are available for further processing (AI). In addition, public life today has both a national and an international and transnational dimension. This implies that IoT is strictly connected with the present political sphere and shows as an essential part of national and global governance.

In health management there are important shortcomings, with a general, diffuse inability to generate the data needed for a real progress in ameliorating the public health service. Solutions might come from the creation of a Health Information Network, in the frame of a EU and/or global collaboration.

However, deciding according to data is not a neutral choice, as the debate about datafication, in general and in public health signals. As it has been noted “statistics work from data, but these first need to be produced. Data are not raw materials; they are, as suggested by Latour, achievements”. Indeed “to datafy a phenomenon is to put it into a quantified format so it can be tabulated and analyzed”. Thus, there is a need to understand better when it is valuable, for whom, and for which purposes. In some instances, new data infrastructures can create visibility, and in others they involve forms of decontextualization of information in ways that facilitate deliberate or unintended unknowing or ignorance¹⁶.

4. DECISIONAL PROCESSES AND DATA-DRIVEN DECISION-MAKING: CROSSCUTTING INTERDISCIPLINARY CRITICAL POINTS

Data-driven decision-making as a field of research both in science-tech and in the social (and thus ethical and legal) domains has just been opened and, despite the vast concern, is still largely unexplored in depth.

Decisions are currently distributed along the scale from rule-based decision making to statistical reasoning to machine learning and AI. As a matter of fact, data-driven decision-making and traditional knowledge-driven decision making (such as rule-based systems) coexist in different combinations according to the fields of application, the situations and, largely, the availability of data.

(Wireless VITAE). IEEE, 2011. Rainfall monitoring and flood prediction are another field where IoT can be extremely helpful for developing countries Gosset, Marielle, et al. “Improving rainfall measurement in gauge poor regions thanks to mobile telecommunication networks.” *Bulletin of the American Meteorological Society* 97.3 (2016): ES49-ES51. Routray, Sudhir K., et al. “Internet of Things Based Precision Agriculture for Developing Countries.” 2019 International Conference on Smart Systems and Inventive Technology (ICSSIT). IEEE, 2019.

¹⁶ Klaus Hoeyer, Susanne Bauer, Martyn Pickersgill, Datafication and accountability in public health: Introduction to a special issue, *Social Studies of Science* 2019, Vol. 49(4) 459-475.

However, this coexistence is not simply complementary, being the two systems different in kind, assumptions and inspiration. Are new ethical and legal paradigms necessary to tackle these challenges?

On the line from knowledge-based towards data-driven decision-making some well-known problems incrementally arise:

- i. **Biases in dataset.** Quality and characteristics of the dataset used: where do data come from? How are they collected and selected? (see above the problem of datafication);
- ii. **Biases in applied algorithms.** Quality and characteristics of applied algorithms. How do we deal with inherent human biases? Can or should this mimicking process remove human bias? What are the dangers of this process? How can a legal system safeguard the security and privacy of personal data needed to train such algorithms? Which is the current legal framework?
- iii. **Explainability of AI produced results.** The fact that these processes are not always transparent and explainable raises new ethical and regulatory challenges. This is true in many fields, such as in scientific research, where at least a relevant part of success appears to be in the hands of the researcher rather than relying on automatic processes, or in medicine, where diagnostic and treatment decisions depend on the accountability of the single medical practitioner or of a professional team. And this is true even for law, where public (administrative and/ or legislative) decisions have to be explainable, and ethics, where traditionally any decision process derives from an interindividual confrontation aimed at solving ethical dilemmas.

4.1. Rule-based and data-driven decision-making: understanding the point

The use of big data analytics may affect the inner nature of law: i.e. law-making and application.

Data-driven decision-making originally is a use of analytics in business for the purpose of taking decisions based on verifiable data and achieving productivity gains. Nowadays, data-driven decision-making has moved towards all social activities and is becoming a general model. The effects are sometimes positive and in other cases problematic.

All this calls for ethics and law as systems of regulation of these new technologies. However, ethics and law, while regulating Big Data induced social phenomena, are, at the same time, challenged by the applications of Big Data tools within their own areas. Namely, legal decision-making, as traditionally based on rules (even though their nature may be different), is challenged by decision-making systems, which are based on data analytics.

All this requires a deeper analysis and understanding of what the real issue at stake is.

Data-driven and rule-based decision-making systems have different pros and cons. The typical problem of data-driven decisions is the quality of the data gathered, its analysis and interpretation, so that whatever mistake and/or bias in one of the steps can heavily affect the decision.

The problem of decision systems based on rules is that being based on rules simply means that rules have been followed, whatever the quality and/or efficiency of the taken decision. In any case, if applied to rule-based decision-making systems, data-driven ap-

proach might produce some positive effects, such as a reduction of the arbitrariness of the starting point and of some critical decisional steps.

4.2. Notes for an interdisciplinary dialogue

Points to be clarified are as follows:

- a. Rule-based decision-making is not synonymous of decision made in a legal way. Rule-based decision-making is a more complex field. In its proper and strict sense, it is the way of deciding according to a written, clearly defined rule. Frederick Schauer, who is the author of a fundamental study on *playing by the rules* is very clear saying “rule-governed decision-making is a subset of legal decision-making, rather than being congruent with it”¹⁷. According to his very demanding definition, a decision taken by a legitimately appointed court according to criteria such as “best interest” of the child or of the patient, or the system of equity or the sentencing process (where an unlimited range of factors may play a role) are all legal decisions even though they are not rule-based decisions, because of the nature and intrinsic quality of the rule/criterion to be applied.
- b. In the broader field of legal rule-based decisions we can find also an important divide/opposition, such as legal formalism and realism, where the crucial point is that of the role the rules play in the decision: if they are the master and guide to establishing/distributing rights and wrongs or they are an ex-post justification of a decision taken according to other (personal, political, social, emotional and more) reasons¹⁸. The divide legal formalism vs realism is another twist of the old opposition between rational approach and empirical/historical approach.

Taking advantage from these legal arguments and assuming an interdisciplinary point of view we might ask: are these categories applicable to the medical field? For instance, following the Guidelines can be considered a rule-based approach? Is data-driven approach rational (see above the scurrying prey)?

- c. Data-driven is not equivalent of data-based decision-making, as if it were synonymous of evidence based in opposition to arbitrary decision. Data-driven decision-making means to decide accordingly to what emerges from the application of machine learning algorithms. Taking advantage of the “distinction between a forward and an inverse problem” (where the forward approach –from the model to the observable– is that used in experimental or quasi-experimental approaches), “the inverse approach is the heart of machine learning”, where “one uses the observables to build the model rather than using the model to assign causal weight to those observables”¹⁹.

Again, are these categories applicable also to the medical field? The reply seems to

¹⁷ Frederick Schauer, *Playing by the Rules: A Philosophical Examination of Rule-Based Decision-Making in Law and in Life*, Clarendon Press, Oxford, 1991, p. 11.

¹⁸ Well-known advocates of the American legal realism are Edward. H. Levi (E. H. Levi, *An Introduction to Legal Reasoning*, The University of Chicago Press, Chicago-London, 1949) and Oliver W. Holmes (O.W. Holmes, *The Path of Law*, 10 *Harvard Law Review* 457, 1897).

¹⁹ Daniel Martin Katz, *Quantitative Legal Prediction – or – How I Learned to Stop Worrying and Start Preparing for the Data Driven Future of the Legal Services Industry*, *Emory Law Journal*, Vol. 62, 2013.

be *yes*²⁰. The problem is the *how* (see below under d). A pure quantitative approach raises similar problems in health and law?

- d. In theoretical terms the question of the nature and interpretation of the results of algorithms is at the forefront. Following Kevin Ashley's (2017) detailed analysis of the situation, we can stress that "since a Machine Learning (ML) algorithm learns rules based on statistical regularities that may surprise humans, its rules may not necessarily seem reasonable to humans. ML predictions are data-driven. Sometimes the data contain features that, for spurious reasons such as coincidence or biased selection, happen to be associated with the outcomes of cases in a particular collection. Although the machine-induced rules may lead to accurate predictions, they do not refer to human expertise and may not be as intelligible to humans as an expert's manually constructed rules. Since the rules the ML algorithm infers do not necessarily reflect explicit legal knowledge or expertise, they may not correspond to a human expert's criteria of reasonableness²¹".

The question is how to combine the intrinsic nature of patterns emerging from legal analytics (and their limited explainability) and the right to explanation of public (and sometimes even private) decisions, which basic constitutional provisions recognize to humans.

The application of methods of quantitative prediction to legal materials is at its beginning and has to face (among several others) a crucial problem: how and when to combine mere statistical results with legal contents, i.e. legal semantic. How medical practitioners and researchers manage this kind of problem?

²⁰ Riccardo Bellazzi, Francesca Bellazzi, *Data-driven and knowledge-driven decision-making in clinical medicine: the necessary approach*, in A. Santosuosso, G. Pinotti (Eds), *Data-Driven Decision-Making. Law, Ethics, Robotics, Health*, Pavia University Press, 2020, available at <http://www.paviauniversitypress.it/catalogo/data-driven-decision-making-law-ethics-robotics-health/5637>.

²¹ Kevin D. Ashley. "Artificial Intelligence and Legal Analytics: New Tools for Law Practice in the Digital Age", 2017, p. 111.