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PRECISION MEDICINE AND ITS CONTRADICTIONS: A SOCIOLOGICAL APPROACH TO THE HIDDEN IMPLICATIONS¹

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Abstract

Several countries have initiated programs for the development of precision medicine, also known as genomic, individualized, or personalized medicine. With thousands or millions of health data, prioritizing genetic maps, artificial intelligence is used to develop algorithms that identify subpopulations with susceptibility to certain diseases, and establish the pharmacogenomic correspondence with the appropriate medicines. This article briefly characterizes this proposal and systematizes critical aspects for its implementation from a public health perspective. The

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text focuses on the main trends driven by the technical and socioeconomic characteristics of precision medicine. The article also highlights the misleading advertisement that suggests an individual healing approach, when precision medicine is not on individuals and their organisms, but on genetic subpopulations. Given the arguments presented, it is likely that personalized medicine will lead to greater inequality between countries and regions and within different social sectors.

Keywords: precision medicine, genomic medicine, artificial intelligence, genetic subpopulations

Introduction

A rtificial Intelligence (AI) has penetrated many economic sectors in the last decade. This is the case of medicine. Various terms are used to identify the application of AI to the sector, such as precision medicine also called genomic medicine, individualized, or personalized medicine. It is a very recent area if we consider its formal institutionalization. In the United States and Europe, it burst in starting in the second half of the 2010s, although the scientific basis and research on the subject can be traced back to the beginning of this century (Stoykova and Koeva-Dimitrova 2019).

The purpose of the article is to frame the development of precision medicine in the context of current and potential social, political, and economic contradictions. The text does not intend to provide a detailed description of this medicine, as there is abundant literature on genomic or precision medicine from a scientific, technical, and biomedical perspective (World Economic Forum 2020). However, there is scarce literature on the interrelationship of this medicine with social, political, ideological, and economic factors (Iriart 2019; Iriart et al. 2002).

The second section explains the logic of precision medicine from a critical socioeconomic and political perspective, rather than from its biomedical characteristics. It points out the main elements necessary to understand the economic and social trends caused by this medicine. The third section analyzes the trends driven by technical relations themselves, followed by the ones driven by social production relations resulting from competition and the struggle for profit. The chapter ends with general conclusions.

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1. Characteristics of Precision Medicine from a Critical Approach.

Precision medicine lies in the application of AI to the health sector and medical care (Parexel n.d.). A brief characterization of precision medicine is given in the following paragraph:

Precision medicines are those which target known genetic, molecular or cellular markers and can be tailored to the individual characteristics of individuals, helping in providing a more personalized approach to patients." "The potential to stratify patients by disease subtypes holds much promise in improving care and often requires modification of traditional trial designs and innovation in order to better evaluate these medicines" (Parexel n.d.).

Precision medicine is part of a medical culture that prioritizes patient care without considering the social context in which the patient is found. Some authors suggest that this medicine is an update of the germ theory as the cause of disease, which emerged at the beginning of the 19th century, although now replacing the germ with the genes (Sun and Ching, 2021). It is not surprising that in a social context where innovation is the purpose of scientific research, medicine is oriented towards therapies that accelerate diagnosis, monitoring, drug development, and patient treatment, such as precision medicine promises (Kenny et al., 2021). The use of AI showed its fruits during the COVID-19 pandemic with the development of RNA vaccines in record time (Gote et al., 2023), and modern gene editing techniques are even more representative of that trend (Doudna and Sternberg, 2017).

AI is increasingly being utilized in the medical sector. It is employed to improve access to healthcare using chatbots, apps connected to devices that monitor patients in real time, and remote physician attendance. These technologies reduce the time and distance required to access medical care. AI is also employed for making diagnoses, by gathering patient medical information (medical history, test results, lab images, and omics - omics (genome-wide genetic information or full transcriptome analysis) and contrasting it with vast databases that suggest matching patterns. This process makes diagnosis and treatment suggestions more accurate. Alowais et al. (2023) refer to cases of reduction of false positives and negatives in mammogram interpretation in the UK. In South Korea, AI has been found to detect cancer diagnoses earlier and more accurately than X-ray results.

The starting point of this medicine is the databases of biomedical information and clinical histories of millions of people, with genetic maps as the central objective and propaganda battle horse. With this digitized and labeled information, algorithms are developed that show correlations between diseases, genetic sequences, biomarkers, and drugs. It should be noted that this medical pathway does not start with sick individuals but begins with genetic information of all possible people, both healthy and sick. This is what allows the diagnosis to detect possible structural weaknesses of an organism even before a disease manifests itself; and it also allows automatic diagnosis of sick person. Finally, the drugs for therapy would also be digitally articulated to the characteristics of the different groups of sick people (pharmacogenomic).

The term "personalized" or "individualized" should not be taken literally, because the correlation established by the pharmaceutical corporation is based on algorithms that identify subpopulations. The diagnosis is based on identifying the patient within a genetically similar subpopulation, and the disease in question. There is no individualization at this stage of diagnosis. Specific personal information such as potential telomere effects do not enter the algorithms, although they may be key in the development of some diseases. Patient-specific epigenetic information is not included either, although some components that adhere to the genetic sequence analyzed can influence different functions of the organism, including diseases, even if the nucleotide sequence is not modified. Epigenetics is not yet included with biomarkers for disease because it is more difficult to detect its markers. Nevertheless, important advances are going on in this field (Santaló and Berdasco, 2022).

The next stage is based on the identification of drugs appropriate to the subpopulation and disease, a result of pharmacogenomic correlations. This stage is also not personalized as advertised.

To understand this lack of correlation between terminology and reality, it is necessary to note that for more than 150 years modern medicine has had the disease as its object of study, not the patient. Therefore, the term individual or personal is about a particular disease or a genetically similar subgroup to which the patient belongs but does not mean the analysis of the patient as a holistic organism. When speaking of individualized drugs, it should be interpreted as individualized for a disease, not for a specific patient (Bynum, 2020; Picard, 2022).

Precision medicine diagnostics will confront the clinician, who will be faced with the difficult decision of either prescribing what she considers best for her patient based on her professional experience or prescribing the drug indicated by the software. For a physician, subject to the vicissitudes of a disease, the adverse effects of drugs, potential patient lawsuits, and the government and hospital agreements to join precision medicine, there are administrative and labor pressures that should not be dismissed. Therein lies the contradiction between the subjective action of the physician and the objective pressure of software and government contracts with pharmaceutical companies; the machine confronts the human.

In biomedical terms, precision medicine that privileges the gene-disease relationship has its critics (Galea 2016). One of the arguments in favor of modern precision diagnostics is the possibility of anticipating diseases, to treat them before they manifest themselves. However, genes require sequences that control their expression and respond to a context and circumstances that activate them during the life of the organism. Therefore, the use of biomarkers to detect a disease in advance assumes that the organism does not change, that there is no mutation in the cells, and that there will be no unpredictable epigenetic changes between the anticipation of the disease and its manifestation. In such cases, the self-expression, and regulatory capacity of genes (production of enzymes and proteins) may well be altered. Anticipating a disease based on biomarkers may imply that the body's own metabolism and biological repair and defense system will not be able to modify the future course of the organism. This is true for a few diseases linked to genetic alterations, but not for most diseases. The possibility of overdoses due to anticipating disease is also part of precision medicine therapy (Carter et al., 2016; Vogt et al., 2019). Precision medicine tends to treat the patient without considering the organism, but by applying prescriptions of standardized algorithms based on millions of cases. In most common diseases the relationship of the disease to the genes, if any, is the result of tens or hundreds of genes and multifactorial individual circumstances that "turn them on" or "off" depending on the person. David Taylor-Robinson, professor of public health at the University of Liverpool, points out:

... the extent to which meaningful individual prediction is even possible remains unclear. The inconvenient truth in the risk-prediction industry is that we are predicting outcomes for groups of people like our patient; we are not predicting the outcome for an individual (quoted by The Economist Intelligence Unit Ltd. 2020:32).

This bias towards treating the illness instead of the person is in the basis of many of the following trends driven by precision medicine.

2. Socioeconomic Trends Driven by Precision Medicine

Under capitalist relations, technological development tends to replace living labor with equipment and machinery (Rubin, 1987).

To facilitate the analysis of the trends in precision medicine, we distinguish, on the one hand, those that are more closely related to technical relations. These are the relations between humans and technology. For example, an employee may be displaced by a robot. On the other hand, we identify those that depend more directly on capitalist social relations that have to do with competition and struggle for profit. For example, a corporation expanding its monopoly by buying small and medium-sized enterprises. Technical and social relations form a dialectical unity and are all social relations of production in the broad sense.

Trends driven by technical relations

Several authors have highlighted the consequences of AI as a technical process. Many of these also occur in precision medicine.²

• *Ethical conflicts.* In many cases automatically elaborated algorithms (machine learning) are impossible to be traced, generating a black box (Pasquale 2015). Their traceability, when feasible, can result in costs greater than the process of creating the algorithms (Mittelman 2022; Pasquale 2015; Pasquinelli 2019; World Health Organization 2021). When applied to healthcare, ethical principles of medical care are violated. One of the most important documents on ethical guidelines

² A WHO report systematizes the challenges of applying AI to health (World Health Organization 2021).

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regarding biomedical research is the 1978 Belmont Report of the United States (Inf. Belmont 1979). One of its main principles is Respect for Persons. This principle considers that the researcher and clinician should be able to reasonably judge the scope and significance of her actions, and that the patient should be able to receive all relevant information to be able to make decisions autonomously (Buisan Espeleta 1996:114-15). With personalized medicine, this principle shows serious implementation difficulties because the algorithms are automatically processed by robots that obtain untraceable results. Trust in technology must supplant any relevant information offered to the patient, who decides based on faith in technology without relevant information or reasoned knowledge. There is also no transparency in the procedures leading from diagnosis to therapy and drugs, a process that is also largely automated (World Economic Forum 2020:104). Through a comprehensive literature review, Ahmed et al. (2023) systematize the ethical concerns for precision medicine patients.³

- *Technological errors.* The technical process is based on statistical models that distinguish patterns. It is an inference that creates a rule from quantities of analyzed data. In these statistical processes, there is a percentage of error. In real cases of the application of artificial intelligence to warfare, innocent civilians died because of an erroneous assessment of lethal weapons that carry autonomous decision to use them (LAWS- Lethal Automatic Weapons Systems) (Gibson 2021). The possibility of an error in the adjudication of a drug selected by the model for a given disease and subpopulation is theoretically feasible; but, as long as it is not discovered it can multiply the error in countless patients to whom the model is applied (Nicholson Price II 2019).
- Reproduction of inequality of class, race, gender, ethnicity, and so on. The algorithms and models created by AI use data that already carry differences of class, race, gender, ethnicity, etc., of the moment that were captured. These differences have no choice but to be reproduced by the software, so the technique itself implies the reinforcement of social differentiation, and even its deepening once resources are



³ See also (Bostrom and Yudkowsky, 2018).

allocated on that basis. An example is the already paradigmatic case of racist deviation in health care detected by a research team from Berkeley, California. The researchers discovered that if the same information is entered into the program for two people who have the same medical situation, but are of different races, the system assesses as requiring special care for whites rather than African-Americans. Among other variables that the database contains is the annual health expenditure of each patient. The algorithm used the economic information to assume that those who spent more were sicker and required more treatment. The case is that many African Americans were not receiving treatment because they spent little due to a lack of economic resources and, therefore, the intelligent machine interpreted that they were healthier (Ledford 2019).

Hijacking of personal data. By making personal data independent and • integrating them into information chains, the possibility of capturing, using, and selling them to third parties or institutions for financial gain is feasible. There are currently several systems that concentrate patients' health information. In some cases, the patients themselves provide the information directly through an app on their cell phones or from devices incorporated into the body or used for regular health monitoring. Some examples of these systems are PatientsLikeMe, u-Motif, Voluntis. Some of them are in collaboration with big pharma such as Roche or Sanofi (Deloitte 2017). The possibility of hijacking individual information is present at all stages of these processes. During 2022 and 2023 several health databases were stolen and exposed for sale in breach forums (Newman, 2023). This is one of the critical aspects first questioned about health and there is a large volume of publications on the subject and concern about establishing regulatory criteria (Hunter 2016; Wetsman 2021). In political and legal terms, the bases of millions of personal data captured for free and converted into proprietary algorithms create an information security problem, something recognized by the World Economic Forum 2020: "...no common frameworks for the privacy and ownership of precision health data" (World Economic Forum 2020).

Trends arising from competition, profits, and capital accumulation process

The AI techno-scientific revolution could radically change the economic context in which medicine develops. Precision medicine requires huge volumes of capital. There must be satellite connection and fast Internet to enable information traffic; server farms to store the energy-intensive information; computer equipment and personnel capable of processing millions of data, elaborating algorithms and creating software and models. It is not a technology for small or medium-sized companies. It is for large international corporations such as Amazon, Google, Microsoft, Alibaba, and some other smaller ones. In a few years these large coporatoins and communication corporations will likely partner with Big Pharma to enter the healthcare sector.

• *Concentration and centralization of capital.* These are trends intrinsic to capitalist competition tending towards monopoly of strategic sectors and amalgamation with other sectors of the supply chain. They are already visible in precision medicine, despite the short period of activity. An example of the centralization of capital is the growing process of convergence between the clinical diagnostics and drug production sectors. Two economic sectors with different objectives. The diagnostics sector has been considered a stepchild of Big Pharma, with revenues close to one-fifth of the latter. However this has been changing with the growth of AI (Kling 2007). Kling suggests that Big Pharma will absorb the diagnostics sector:

This could shift the focus of the healthcare industry from therapeutics to diagnostics and, if that happens, the 'poor stepchild' of the medical industry-as Randy Scott, Chief Executive Officer of Genomic Health, refers to diagnostics-will reshape the economics of medicine (Kling, 2007).

Big Pharma's eyes are set on buying or controlling diagnostic companies or creating its own competition. In fact, almost all Big Pharma is already doing so, accentuating the centralization of capital (Data Journalism Team 2022).

The growing subordination of diagnostics companies to Big Pharma is joined by another notorious sector in the economic fray. AI corporations such as Google,

Amazon, and Apple are entering the health diagnostics market with an eye to pharmacogenomics, taking advantage of the fact that many of them already have huge individual databases. Here the difficulty for Big Pharma is much greater than with the diagnostic stepdaughter. These are corporations that compete in economic terms *vis-a-vis* with many of the major pharma companies.⁴ We are likely to see new alliances, acquisitions, and furious competition that, in any case, will lead to even greater concentration and centralization of the global capital and power of the winners (Hirschler 2018, 2018; Little 2005). The chief executive of the Roche corporation acknowledges as much in this way:

Roche Chief Executive Severin Schwan believes data is the next frontier for drugmakers and he is betting that the Swiss group's leadership in both cancer medicine and diagnostics will put it in pole position. "There's an opportunity for us to have a strategic advantage by bringing together diagnostics and pharma with data management. This triangle is almost impossible for anybody else to copy (Hirschler 2018).

The purpose of corporations and companies is profit. This is achieved by accelerating the processes of diagnosis, therapy, and drug production and by identifying biomarkers that make it possible to anticipate diseases, particularly rare and degenerative diseases for patients with high purchasing power.

• Deepening the development - underdevelopment gap. Genomic medicine means economic benefits for Big Pharma, because, as long as these methods do not reach most of the country's population, precision medicine will continue to be, as it is today, for a few developed countries and specific diseases and patients with high purchasing power. Some analysts suggest that as algorithms and information increasingly narrow the pool of susceptible subpopulations at risk, Big Pharma may be discouraged from continuing, due to the consequent reduction of the market. A telling fact is the case of anti-cancer drugs, which is the disease most investigated by precision medicine and where more drugs have been developed specifically for smaller and smaller subpopulations. The IQVIA institute identified 97 new anticancer drugs that were

⁴ See, for example, the distribution between 2017 and 2022 of the global market among the major cloud-owning corporations (Amazon, Microsoft, Google, etc.) some of which such as Microsoft's Azure has a specific sector for healthcare data (Statista 2022).

approved since 2011, and a 2018 *Jama* journal article noted that the cancer drugs based on genetic analysis in use in 2018 were 31. Even more questionable, in terms of profitability, is the American Medical Association study in oncology, which estimated that only 8% of cancer patients were eligible for precision medicines and, of these, only 5% would benefit medically. The same author notes that the IQVIA institute estimates that 87% of new anticancer drugs are used by fewer than 10,000 patients annually (Cutler 2020).

In purely technical terms, precision medicine requires sophisticated equipment, many of them nanotechnological equipment for atomic and molecular manipulation, such as sensors, access to Big Data, nanoencapsulation, and distribution of nanodrugs and implants (Fornaguera and García-Celma 2017; Herrmann and Rösslein 2016). These are highly sophisticated technologies that bet on early and, at the same time, site-specific treatment, be it cells, an organ, tissues, bones, etc. In addition, precision medicine requires qualified personnel. All this requires national planning and public resources for professional training, infrastructure and equipment, and an appropriate telecommunication network (e.g. 5G, 6G, and soon 7G), which in the global race will probably deepen the world's health inequity (The Economist Intelligence Unit Ltd. 2020).

• Pressure from pharmaceutical corporations on governments. In countries where governments establish agreements with different corporations to promote precision medicine, there are no economic cost-benefit studies for its application in public health. This does not exist worldwide. Although the still initial state of precision medicine does not allow global evaluations, the uncertainty about the use of public resources for such purposes constitutes, in some cases, a barrier to its introduction (The Economist Intelligence Unit Ltd. 2020:25). In its incipient decade of take-off precision medicine is very expensive, it is aimed at affluent sectors of society and the treatment of some specific types of cancer and other degenerative and rare diseases, ignoring neglected epidemic diseases or diseases of poor countries (*neglected diseases*) (Bosetti 2015). It would not be a surprise that, as happened with the COVID-19 vaccines, this medicine will deepen the global health gap between and within countries.

The Microsoft Azure clouds that centralize millions of health data from the most diverse countries are an example of these uncertainties. In Europe, as well as in Australia, New Zealand, and other countries where governments have made agreements with Microsoft to use its cloud, critical voices have arisen regarding the possibility of Microsoft using these databases for its purposes, given that they are the ones who encrypt health data and create the proprietary algorithms (Pollet 2021). The impetus for precision medicine comes from Big Pharma, as illustrated by the latest GlobalData report on the subject (Data Journalism Team, 2022 based on GlobalData) which ranks corporations according to indicators that estimate the winners in the sector. GlobalData places among the first and in hierarchical order the well-known Novartis, Pfizer, Catalent, Johnson & Johnson, Roche, AstraZeneca, Sanofi, Bristol Myers Squibb, Amgen, Gilead Sciences, Patheon, Lonza, Takeda Pharmaceutical, Merck, Eli Lilly, IQVIA, AbbVie, and Parexel. The purpose of these corporations is that states and private companies will be forced to buy access to knowledge, rely on the drugs they indicate, and even guide the trajectory of biomedical research and education. Microsoft Azure is penetrating Latin American countries by offering its cloud to centralize health data (Microsoft Azure 2015).

Although this medicine can be highly successful in treating certain diseases, it remains unknown whether it results in an advantage for the public health of a country and, particularly, for a developing one subject to control and pressure from big pharma and associated corporations (Kwame Sundaram and Chowdhury 2018).

For countries with large populations of non-European origin, there are information gaps that represent a challenge for Big Pharma. 95% of existing algorithms work with population databases of European genetic origin (Garcia de Jesus 2022); that is why corporations are eager to extend their databases to as many different populations as possible. Mexico is an eloquent example and there are studies on genetic variation that show a high degree of difference between regions or states of the country (Moreno-Estrada et al., 2014). This being so, precision medicine is more inclined, for now, towards people of European origin, since with little characterization of other populations, the pharmacogenomic effectiveness of drugs is unknown (The Economist Intelligence Unit Ltd. 2020).

Conclusions

Genomic medicine, precision medicine, or personalized medicine is based on the development of extensive databases with personal health indicators, biological characteristics, genetic maps, etc. Statistical methods are used to identify subpopulations susceptible to certain diseases, for which specific drugs are developed. This is supposed to reduce the adverse effects of the drugs and to achieve a faster diagnosis and therapeutic process. At the same time, the development of individual devices would allow patients to follow up on their disease and, therefore, to participate in biomedical research systematically; it would mean real time monitoring of the evolution of people's health and the possibility of detecting potential diseases based on biomarkers and genetic sequences in advance of their manifestation. Of course, for all this, the existence of genetic maps of the populations to be treated is a prerequisite far from being achieved in developing countries.

In addition to the biomedical advantages are the economic ones, a priority for the profit-driven pharmaceutical corporations that are the sponsors of this precision medicine. There would be savings in pharmacological raw materials; the patented algorithms would facilitate monopoly and thus the concentration of capital. The databases held by Big Pharma would oblige governments to establish collaboration agreements to have access to this information; and the possibility of extending treatment to people who do not yet manifest disease, and who would be impossible to treat. The only way to know if they will suffer from it, if left untreated is, perhaps, in a few cases of diseases that are proven to be linked to specific genes.

In scientific terms, precision medicine deals with smaller and smaller parts of the organism (e.g. genes), something increasingly far from the attention of the person as an organic unit, blocking alternative therapeutic developments (Marcum 2008; Tauber and Sarkar 1993; Yuan 2016); in theoretical-ideological terms, these technologies reinforce formal logic and mechanistic methodologies, depositing knowledge in automated processes, making them more complex and difficult to regulate (Klein et al. 2021). In parallel, propaganda is aimed at convincing the consumer that products are no longer massive, that technoscience and the capitalist economy that commands it are adjusted to satisfy personal needs, when it is a matter of applying statistical standards of thousands or millions of individuals of genetic subgroups.

Although the potential advantages of genomic or precision medicine may well outweigh its non-applicability to certain diseases that are not yet common, the advantage for public health, which cannot ignore the most common diseases that are not very profitable from a corporate point of view but have a great social impact, remains under discussion.

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