ORIGINAL ARTICLE

Protecting Your Patients' Interests in the Era of Big Data, Artificial Intelligence, and Predictive Analytics

SA-CME

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Abstract

The Hippocratic oath and the Belmont report articulate foundational principles for how physicians interact with patients and research subjects. The increasing use of big data and artificial intelligence techniques demands a re-examination of these principles in light of the potential issues surrounding privacy, confidentiality, data ownership, informed consent, epistemology, and inequities. Patients have strong opinions about these issues. Radiologists have a fiduciary responsibility to protect the interest of their patients. As such, the community of radiology leaders, ethicists, and informaticists must have a conversation about the appropriate way to deal with these issues and help lead the way in developing capabilities in the most just, ethical manner possible.

Key Words: Artificial intelligence, machine learning, ethics, big data, informatics

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When Google DeepMind needed to test an app to provide alerts for patients at risk for worsening renal disease, it gathered the records of 1.6 million patients from the Royal Free Hospital. The Information Commissioner's Office, an "independent authority set up to uphold information rights in the public interest, promoting openness by public bodies and data privacy for individuals" in the United Kingdom, disapproved, finding that the arrangement between the two entities broke the law and failed to uphold the data privacy rights of individuals [1,2]. Although disclosures of patient information for direct patient care are widely accepted, otherwise identical disclosures for research and development require informed consent. The distinction between patient care and research is widely recognized, yet its proper application in the setting of new techniques can elude even the most capable organizations.

Imaging is a robust source of phenotypic information suitable for the application of big data, artificial intelligence, and personalized medicine methods. Industry has taken notice of this relatively unexplored frontier and spent considerable resources surveying options to harness the power of imaging data [3,4], eagerly seeking partners in health care. Although some have forged ahead, others have reconsidered their initial forays into this space with industry partners [5,6]. Because the conversation often begins with imaging and the radiology department, it behooves any health care provider, department, or system to consider important questions regarding their big data and artificial intelligence efforts, whether internally or in partnership with external partners.

We have long subscribed to ethical and regulatory frameworks to guide our use of patient and research subject data. In many cases, we seem unsure of how to

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apply these conventions in the era of big data and artificial intelligence, with their seemingly insatiable appetite for more information. These methods have real consequences, with the potential to affect the lives of individuals and populations in ways that could benefit some while harming others. Here, we touch on the major principles of existing applicable frameworks in this setting, explore known issues when dealing with big data and machine learning in health care, explore perspectives from key stakeholders, and pose questions for discussion for imaging health care professionals to consider as they embark on their own big data and artificial intelligence ventures.

BRIEF DEFINITIONS

The expressions big data, artificial intelligence, personalized medicine, population health, and predictive analytics represent a family of concepts that are related but not synonymous. For those being first introduced to the field, a brief delineation of these terms follows.

Big Data

Still a vaguely defined term [7], "big data" consists of at least three increasingly accepted characteristics of data, the "3 V's": volume, variety, and velocity [8]. These are especially suitable for radiology data, which include large volumes of images and reports, in a variety of imaging modalities, body parts, and formats (unstructured text and structured DICOM), that are rapidly generated and potentially analyzed in real time or near real time.

Artificial Intelligence

Artificial intelligence is a branch of computer science that encompasses the automation of intelligent behavior [9]. Machine learning, a subfield of artificial intelligence, is composed of data-driven techniques, such as deep learning, used to uncover patterns and predict behavior accomplished with minimum human intervention [10]. The machine "learns" by analyzing training data and then making predictions on a new data set [10]. This technology holds promise in radiology for preliminary lesion detection and differential diagnosis generation, potentially augmenting the sensitivity and accuracy of radiologists. Natural language processing, also a subfield of artificial intelligence, focuses on understanding the full meaning of written or spoken text by integrating concepts and methods pulled from various domains [11].

Precision or Personalized Medicine

Precision or personalized medicine involves prevention and treatment strategies that take individual variability into account [12], for example, scheduling earlier mammographic and MRI breast cancer screening for patients with *BRCA* gene mutations. Precision and personalized medicine is increasingly dependent on big data and artificial intelligence techniques.

Population Health

Population health and *public health* are often interchangeably used terms and refer to the health of a group of individuals, rather than the individuals themselves, organized into many different units of analysis, depending on the research or policy purpose [13].

Predictive Analytics

Predictive analytics is a broad term used to describe a variety of statistical techniques, such as modeling, machine learning, and data mining, that analyze current and historical data to predict future events or behaviors [14]. When artificial intelligence algorithms have access to big data, they may facilitate the advancement of predictive analytics in population health or personalized medicine.

EXISTING FRAMEWORKS

> *I will respect the privacy of my patients, for their problems are not disclosed to me that the world may know.*
>
> —Hippocratic oath [15]

Numerous legal precedents, ethical frameworks, and historical milestones have contributed to our current understanding of how to appropriately interact with human subjects, patients, and clients. From these, two of the most well known in health care are the Hippocratic oath and the Belmont report, which articulate foundational principles for how physicians ethically treat patients and deal with research participants.

The Hippocratic oath is one of the earliest known calls to respect the privacy of patients and respect the confidentiality of the information with which they entrust their physicians. In this regard, the Hippocratic oath's call to respect privacy and confidentiality predates the US constitution, the European Union Charter of Fundamental Rights, and HIPAA, all of which allude to privacy of individuals, if not the confidentiality of their data.