Patient Data-Sharing for AI: Ethical Challenges, Catholic Solutions

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Abstract

Recent news of Catholic and secular healthcare systems sharing electronic health record (EHR) data with technology companies for the purposes of developing artificial intelligence (AI) applications has drawn attention to the ethical and social challenges of such collaborations, including threats to patient privacy and confidentiality, undermining of patient consent, and lack of corporate transparency. Although the United States Catholic Conference of Bishops' *Ethical and Religious Directives for Health Care Services* (ERDs) address collaborations between US Catholic healthcare providers and other entities, the ERDs do not adequately address the novel concerns seen in EHR data-sharing for AI development. Neither does the Health Insurance Portability and Accountability Act (HIPAA) privacy rule. This article describes ethical and social problems observed in recent patient data-sharing collaborations with AI companies and analyzes them in light of the guiding principles of the ERDs as well as the 2020 *Rome Call to AI Ethics* (RCAIE) document recently released by the Vatican. While both the ERDs and RCAIE guiding principles can inform future collaborations, we suggest that the next revision of the ERDs should consider addressing data-sharing and AI more directly.

Summary: Electronic health record data-sharing with artificial intelligence developers presents unique ethical and social challenges that can be addressed with updated United States Catholic Conference of Bishops' *Ethical and Religious Directives* and guidance from the Vatican's 2020 *Rome Call to AI Ethics*.

Keywords

Artificial intelligence (AI), Catholic health care, Data-sharing, Electronic health records (EHR), *Ethical and Religious Directives* (ERDs), Ethics, Patient confidentiality

Artificial intelligence (AI)¹ is changing healthcare delivery. To date, innovative AI tools have led to robotic surgeries, assisted radiology and pathology diagnosis, improved administrative workflow coordination, robotic prostheses, fraud detection, and dosage error reduction, to list only a few applications (Rigby 2019; Yu, Beam, and Kohane 2018). The economic impact of AI in health care is significant. The combined US public- and private-sector investment in AI for health care is estimated to reach \$6.6 billion by 2021, and implementation of key AI software applications could potentially save \$150 billion annually by 2026 (Kalis, Collier, and Fu 2018). AI software development relies upon

access to very large amounts of data to “teach” its underlying algorithms² to make accurate predictions, so technology companies are increasingly

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turning to healthcare institutions for access to patients' data-rich electronic health records (EHRs) to support the development of AI products (Laraki 2019). Given the growing application of AI in health care, the significant investments anticipated, and the collaboration across sectors, there is a need for clear ethical guidance for all parties involved.

Several recent, high-profile instances of data-sharing between healthcare institutions and AI technology developers in the United States and abroad have elicited ethical concerns as well as legal or regulatory actions. In 2015, Google UK obtained access to a wide range of existing and future health data from 1.6 million patients of the National Health Service (NHS), ostensibly to develop an app to monitor patients with kidney disease (Hodson 2016). Critics claimed this arrangement lacked transparency about the extent of the data-sharing as well as its potential future use (Hodson 2016). The UK's Information Commissioner's Office determined that the agreement failed to comply with UK data protection law (Kharpal 2017). In 2018, the NHS granted Amazon permission to access governmental health records in order to develop AI health information technology for use in its Alexa and Echo Virtual Assistant products (Das and Gregory 2019). This partnership was criticized for breach of patient confidentiality, lack of informed consent, and a small economic return for use of the data (Bernal 2019; Das and Gregory 2019).

In 2017, the University of Chicago Medical Center (UCM), Stanford, and the University of California San Francisco sold access to EHR patient data to Google. A 2019 class-action lawsuit claims that UCM shared EHRs without appropriate removal of identifiable data³ and physician notes (Wakabayashi 2019). The lawsuit also claims that UCM should have obtained patient consent for such sharing of identifiable data (*Matt Dinerstein v. Google LLC and the University of Chicago Medical Center and the University of Chicago* 2016).

In 2018, Ascension, the second-largest healthcare system in the United States and the largest Catholic healthcare provider, entered into a collaboration with Google. Ascension operates 150 hospitals as well as 2,500 doctors' offices and other health facilities in 20 states and Washington, DC (Ascension 2020). This may well be the largest instance of EHR data-sharing in the United States to date, involving an estimated 50 million or more patient records. The collaboration attracted negative publicity in November 2019, when a Google whistleblower claimed that Ascension shared EHR data without proper de-identification, including patient names and dates of

birth as well as lab results, diagnoses, and hospitalization records (Copeland 2019). Reports described the arrangement as "secretive" (Reynolds 2019; Pilkington 2019) since it was not until the Google whistleblower contacted the *Wall Street Journal* that any details about the sharing of EHR data were publicly revealed (Copeland 2019; Anonymous 2019). As a result, the US Department of Health and Human Services' (DHHS) Office for Civil Rights opened an investigation into whether the arrangement violated HIPAA in any way (Copeland and Needleman 2019). The partnership between Ascension and Google also generated discussion about the involvement of Catholic healthcare entities in AI and big data research given their specific values and mission (Mongoven 2019).

Amid rapid growth in AI, controversy, and uncertainty, several different groups have recently developed or are in the process of developing ethical guidance for AI. For example, in May 2019, the Organization for Economic Cooperation and Development (OECD), an international standard-setting body, released its *Recommendation on Artificial Intelligence*. In June 2019, the G20 adopted a set of principles for AI that draws heavily on the OECD recommendations. Of particular interest for Catholic health care, the Vatican has also recently released the *Rome Call for AI Ethics (RCAIE)*; Pontifical Academy for Life [PAV] 2020).

In the remainder of this article, we will discuss ethical and social considerations for EHR data-sharing partnerships with AI companies, with attention given to how Catholic healthcare institutions can best navigate such partnerships. First, we will present general ethical concerns relevant to AI in health care. Next, we will discuss how ethical principles articulated in the *Ethical and Religious Directives for Health Care Services (ERDs)*; United States Catholic Conference of Bishops [USCCB] 2018), and the newly released 2020 *RCAIE* can provide guidance for healthcare institutions considering sharing EHR data with technology companies for the purposes of developing AI for health care. Lastly, we will recommend considerations for future ethical guidance for healthcare-related AI research and development.

EHR Data-Sharing, AI, and Health Care: Ethical and Social Issues

The sharing of EHR data for developing healthcare AI tools poses unique ethical challenges in terms of patient privacy and confidentiality, informed consent, and institutional transparency. To be sure, these

concerns warrant attention, and healthcare systems and AI technology companies must respond to the public's demands for greater transparency. However, AI also poses additional social risks, and Catholic healthcare systems as well as others should consider the broader range of ethical ramifications that may result from data-sharing for the development of health-related AI technology products.

Patient Privacy and Confidentiality

As discussed above, in some recent high-visibility collaborations, it is not clear whether the involved parties complied with HIPAA. Obviously, any data-sharing partnerships must follow relevant laws. However, it is unclear whether current laws are sufficient to protect patient privacy. Reidentification may be easier than previously thought (Parasidis, Pike, and McGraw 2019; Crigger and Khoury 2019), especially given the vast amounts of data, including location data, that companies like Google and Amazon have from other sources such as social media, search engines, and consumer purchases (Cohen and Mello 2019).

The HIPAA privacy rule allows data-sharing with third-party "business associates" for services that are necessary for provision of standard healthcare services such as billing, as long as it is used "only to help the covered entity carry out its healthcare functions" or for research (US Health and Human Services 2003). In the Ascension/Google collaboration, Google was reportedly planning to use EHR data "... in part to design new software, underpinned by advanced artificial intelligence and machine learning, that zeroes in on individual patients to suggest changes to their care" (Copeland 2019). It is debatable whether EHR data-sharing for such purposes meets HIPAA requirements.

Furthermore, the HIPAA privacy rule only applies to medical records from healthcare service providers. HIPAA does not apply to other companies or their products that include consumer healthcare information such as apps, retailers, search engines, and social media. HIPAA also does not cover de-identified data; once HIPAA identifiers have been removed from the data, regulatory oversight does not apply. Only when a collaboration proposes human subjects research that falls under the Common Rule or Food and Drug Administration (FDA) regulations is IRB review required, but most data analytics projects involving data-sharing between healthcare organizations and tech companies do not fall under these regulations (Parasidis, Pike, and McGraw 2019). The HIPAA privacy rule was last revised before the rise in machine learning

or the possibility linking of EHR data with social media data, and therefore, it needs to be updated (Cohen and Mello 2018).

Informed Consent and Transparency about Collaborations with Third Parties

Even if collaborating third parties do not have access to individual patient records and will not try to link with other records, healthcare institutions should still inform patients and clinicians that they will share de-identified data with the company developing the AI in exchange for payment and that this company may profit from products developed using the data. Healthcare institutions should also inform patients and clinicians about the specific goals of the data-sharing partnership. Transparency is critical to trust; lack of trust in AI on the part of patients, healthcare providers, and the general public may undermine the potential of AI to address critical health issues. In the Ascension case, reports claimed that clinician employees did not know about the collaboration with Google (Copeland and Needleman 2019). This lack of transparency can negatively affect the provider-patient relationship. Providers must be able to honestly and accurately answer questions from patients about any data-sharing partnerships and refer patients to the appropriate parties if there is a question they cannot answer.

A related issue is whether, in the absence of an ethical or legal requirement for informed consent, patients should be able to "opt out" of data-sharing. In many cases, opting out may be impractical or the logistics required might actually increase the risk of a breach of confidential information. However, it is also possible that research could use data for purposes that individual patients find objectionable or in ways that the initial authorization does not cover, strengthening the argument for an option to opt out.

Replicating Bias and Exacerbating Inequality

Algorithms are social tools that can be used to make decisions that have significant effects on people's lives: whether to grant a homeowners' loan, how long a prison sentence will be, whether a particular college will admit a student, whether a patient will be screened for or diagnosed with a particular illness, or which treatment a physician will prescribe.⁴ Algorithms can also be trained to cheat, discriminate, or prioritize certain outcomes or goals (e.g., profit) over others (e.g., quality of patient care; Char, Sharh, and

Magnus 2018). Some have argued that, “Societal fairness dictates that health data be used to advance the public good and not in ways that cause or exacerbate inequities” (Parasidis, Pike, and McGraw 2019, p. 1494). Arguably, AI projects that support public health surveillance efforts or intend to identify optimal resource allocation in an epidemic aim to advance the public good, while projects to establish insurance premiums that work in insurance companies’ favor advance corporate rather than public interests. Generally, the public supports AI for medical research and public health but not for marketing and advertising (Grande et al. 2013). Healthcare institutions should enter into data-sharing agreements with a clear understanding of what the data will be used for (e.g., the purpose of the algorithms being developed from the data), what knowledge will be gained, and who may stand to benefit.

There is also the potential for unintended bias in algorithms that are built into AI products that use EHR data, in that these algorithms may exacerbate social and healthcare inequalities or otherwise threaten patient safety and well-being (Char, Sharh, and Magnus 2018). Algorithms that purposely discriminate are obviously unethical, but bias can enter into AI inadvertently in a multitude of ways (Gianfrancesco et al. 2018). AI-derived algorithms reflect the data used to develop them. Ample evidence suggests that data in EHR are far from being free of bias (Beam and Kohane 2018). For example, implicit racism and sexism can find their way into providers’ diagnoses, treatment plans, and other notes (Smedley, Stith, and Nelson 2003). Algorithms developed from such biased EHR data can then result in AI diagnostic and/or predictive tools that are less accurate for certain population segments (Obermeyer et al. 2019). Additionally, a great deal of information that contributes to health is *not* in the medical record, and this may further bias algorithms (Maddox, Rumsfeld, and Payne 2019). Bias can also result from the exclusion or lack of representation of certain groups in the primary data set on which the AI is developed (Maddox, Rumsfeld, and Payne 2019). Fortunately, promising research is underway to determine how best to detect and correct for bias (Chen, Szolovits, and Ghassemi 2019; Obermeyer et al. 2019), but this will be an ongoing challenge.

Caution in Moving from “Bench” to “Bedside.”

Like any drug, device, or diagnostic tool, an algorithm or other AI product, once developed, should next be tested in a research setting before it is

disseminated (i.e., sold to healthcare organizations) and used in standard practice by clinicians (University of Chicago Medicine n.d.). There is a standard framework and accepted process for clinical trials, peer review, postmarketing surveillance for drugs and devices, and regulations in order to ideally prevent harmful products from getting to market. However, this is not currently the standard way of doing business in the technology world, where the goal is to get products to market quickly and then fix problems later, or, as Facebook’s Mark Zuckerberg famously said, “move fast and break things” (Taneja 2019). Health care needs clear evidentiary standards to guide the implementation of new AI tools into clinical practice (Maddox, Rumsfeld, and Payne 2019). The FDA has issued draft guidance (USFDA 2019) on clinical decision support software but is currently reconsidering its approach to regulating AI products (USFDA 2020).

Long-Term Impact of AI on Provider-Patient Relationships and the Practice of Medicine

The full potential of AI in health care has yet to be realized. Undoubtedly, AI will have significant impacts not only on patient health and outcomes but also on the practice of medicine, medical education, and the physician–patient relationship. Some have even speculated that AI could replace the physician altogether (Rigby 2019). While this is unlikely to happen in the near future, the highly valued provider–patient relationship may gradually erode as AI becomes more integrated into patient care, rendering the medical experience less personal and intimate, and more automated (Cabitza, Rasoini, and Gensini 2017). Automation may lead to a decline in clinical skills as physicians rely more on software and less on clinical experience and reasoning (Anderson and Anderson 2019). The American Medical Association (AMA) clearly argues that machine learning should be used to support rather than replace clinician diagnosis and advice to patients about treatment (Crigger and Khoury 2019). In fact, the AMA refers to AI as “augmented intelligence,” reflecting this belief (Crigger and Khoury 2019). Concerns have also been raised about liability. For example, if a patient is misdiagnosed, who is at fault, the algorithm or the healthcare provider (Sullivan and Schweikart 2019)? Ultimately, the rise in AI also has implications for medical education. In order to truly interpret the output of an algorithm, physicians will need to understand what goes into algorithms. This adds one

more topic to an already full medical curriculum (Wartman and Combs 2019).

The ERDs: Interpreted for AI Collaborations

The *ERDs* acknowledge that Catholic health care faces challenges on several fronts: economic, technological, social, and moral (USCCB 2018, Part 1, Introduction). Although the *ERDs* do not specifically reference data-sharing agreements or the ethics of AI development, they do reference several key principles of Catholic social thought that can guide thinking about the ethics of AI broadly, and data-sharing partnerships in particular. Relevant principles include (1) promoting and defending human dignity from conception until death, (2) contributing to the common good, (3) caring for the poor, and (4) exercising responsible stewardship over healthcare resources. We will discuss each of these principles briefly.

Promoting and Defending Human Dignity from Conception until Death

A commitment to human dignity is at the core of the Catholic healthcare mission. Central to dignity, as articulated in Part 3 of the *ERDs*: The Professional–Patient Relationship is “mutual respect, trust, honesty, and appropriate confidentiality” which “enables the patient to disclose personal information needed for effective care . . .” (USCCB 2018, 13). Healthcare systems must take care that their collaborative arrangements with outside entities do not jeopardize patient trust in the confidentiality of the information they share with their healthcare providers. *ERD* Directive 7 also clearly articulates that employees be treated respectfully and justly (USCCB 2018, 9). At a minimum, transparency with patients and employees regarding when and how healthcare institutions share data for research purposes is central to maintaining trust and promoting human dignity. However, given the potential for re-identification when combined with data from other sources, compliance with HIPAA may not eliminate all threats to confidentiality. Additional safeguards may be ethically required.

Contributing to the Common Good

The common good is another foundational principle of Catholic social teaching and closely related to human dignity. According to Part 1: The Social Responsibility of Catholic Health Care Services, the common good is realized when all persons are able

to “fulfill their common purpose and reach their common goals” (USCCB 2018, 8). The principle of the common good emphasizes the interdependence and social nature of all humans, indicating that our duties to each other are as important as our individual rights. The principle of the common good may justify research collaborations that carry potential social benefit even when they infringe upon individual privacy, as long as that infringement is proportional and transparent.

Caring for the Poor

Part 1: The Social Responsibility of Catholic Health Care Services states that “particular attention should be given to the health care needs of the poor” (USCCB 2018, 8). *ERD* Directive 3 states that “Catholic health care should distinguish itself by service to and advocacy for those people whose social condition puts them at the margins of our society and makes them particularly vulnerable to discrimination” (USCCB 2018, 9). A reasonable interpretation of this mandate is that data-sharing collaborations should not result in AI products that discriminate against already vulnerable groups or exacerbate existing inequalities.

Exercising Responsible Stewardship over Healthcare Resources

ERDs Directives 4 and 6 describe the duty of Catholic healthcare institutions to be “responsible stewards” of healthcare resources, particularly when collaborating with others. With regard to data-sharing/AI collaborations, patients’ EHR data should be used only as necessary, seen only by those who must see the data, and used only for purposes aligned with Catholic teaching. Good stewardship also dictates that research collaborations should have a clear purpose for the common good through improved patient care, healthcare access, or systems operations and not simply be “fishing expeditions.” The related principle of subsidiarity suggests that decisions about EHR data use for purposes other than direct patient care should be made with the input of patient representatives.

Avoiding Scandal

Avoidance of scandal is a concern expressed in Part 6 of the *ERDs*, which focuses on collaborative arrangements between Catholic healthcare systems and non-Catholic organizations and providers (USCCB 2018, 29–34). While avoiding scandal is

not a guiding principle of the *ERDs* per se, it is important to consider in any moral analysis of such collaborations. Although Part 6 focuses on health-care delivery and not data-sharing or research specifically, passages on cooperation are relevant to data-sharing for research on AI. Material cooperation⁵ with wrongdoing could occur on two levels: (1) the original manner in which the EHR data collection and sharing occurs and (2) the use or implementation of resulting AI applications. With regard to the first level, EHR data-sharing must adhere to high standards and best practices for protecting patient confidentiality, and the collaboration must be transparent to patients, employees, and the general public. In some cases, additional safeguards might be desirable, such as individual informed consent, allowing for opt in/out, or involving patient representatives in decisions about how data are used and

shared for research and other purposes. Regarding the latter level, collaborators must ensure that they address potential biases in data collection or algorithm development and that resulting AI software will not be intentionally used for purposes contrary to Catholic moral teaching.

Vatican Initiatives in AI Ethics

The Catholic Church has been at the global forefront of discussions concerning ethical and social considerations of AI, and its initiatives demonstrate an understanding of the great potential for this new technology to profoundly affect humanity, for better and for worse (see Table 1). Vatican initiatives have attracted international experts from all disciplines, including the late Professor Stephen Hawking, and ranking executives from high-profile technology

Table 1. Vatican Artificial Intelligence (AI) Initiatives.

Vatican Entity, Date	Initiative	Summary
Pontifical Academy of Sciences (PAS) and Pontifical Academy of Social Sciences (PASS) (2019)	Power and Limits of Artificial Intelligence	This meeting fostered discussion among experts from different fields to examine ethical and social questions in AI, robotics, brain modeling, and brain-computer interfaces.
Francis, Message of His Holiness Pope Francis to the Executive Chairman of the “World Economic Forum” on the Occasion of the Annual Gathering in Davos-Klosters (2018)	World Economic Forum 2018, Davos-Klosters	Pope Francis addressed international business and political leaders, stressing that AI applications must “. . . contribute to the service of humanity and to the protection of our common home . . . ”
Pontifical Academy of Life—Microsoft Scholarship (2019)	Vatican/Microsoft Scholarship Collaboration	In cooperation with Microsoft, this joint venture will award scholarships for doctoral dissertations in AI ethics.
Pontifical Academy for Life (2019)	Roboethics: Humans, Machine Learning, and Health	This workshop focused on ethical aspects of robotics in society, ethics, and health care.
Pontifical Academy of Sciences (PAS) & Pontifical Academy of Social Sciences (PASS) (2019)	Robotics, AI, and Humanity: Science, Ethics, and Policy	This conference examined frontiers in AI/robotics and societal impacts including peace, war, and development and discussed ethical and religious implications.
Dicastery for Promoting Integral Human Development (2019)	The Common Good in the Digital Age	This seminar fostered debate regarding the impact of new AI technologies on the common good in order to develop parameters to guide associated ethical problems.
Pontifical Academy for Life (2020)	Rome Call for AI Ethics” document	This landmark document provides an ethical framework for AI development. Initial signatories included representatives of Microsoft, IBM, the United Nations, and Italy.

Table 2. *Rome Call for AI Ethics: Six Guiding Ethical Principles Promulgated by the Pontifical Academy of Life, February 28, 2020.*

1	Transparency	In principle, AI systems must be explainable.
2	Inclusion	The needs of all human beings must be taken into consideration, so that everyone can benefit and all individuals can be offered the best possible conditions to express themselves and develop.
3	Responsibility	Those who design and deploy the use of AI must proceed with responsibility and transparency.
4	Impartiality	Do not create or act according to bias, thus safeguarding fairness and human dignity.
5	Reliability	AI systems must be able to work reliably.
6	Security and Privacy	AI systems must work securely and respect the privacy of users.

companies including Google, Facebook, IBM, and Microsoft (Battro and Dehaene 2017; PAV—Microsoft Scholarship 2019; PAV 2020). The common ethical consensus apparent in each initiative is that AI technology should first and foremost be placed at the *service* of humanity rather than replacing or dominating it. Further, the Vatican initiatives have emphasized that AI technology should be designed to uphold the inherent dignity of each person, the family unit, and the common good and should seek to improve the human condition while remaining free from economic and/or political motivations.

Pope Francis (2018) has personally reiterated these themes, stating that “... artificial intelligence, robotics and other technological innovations must be so employed that they contribute to the service of humanity and to the protection of our common home, rather than to the contrary, as some assessments unfortunately foresee.” Additionally, he has warned against “... the risk of man being ‘technologized’, rather than ‘technology humanized’” (Francis 2019).

RCAIE Landmark Document, 2020

The Vatican initiatives described in Table 1 culminated in the PAV issuing its landmark 2020 document, the *RCAIE*, which presents guiding ethical principles to assist AI technology companies in ensuring that their technology ethically serves society (PAV 2020). The *RCAIE* had its first signatories on February 28, 2020, which included the president of PAV, high-ranking executives at Microsoft and IBM, and representatives from the United Nations and the Italian government (PAV 2020; Gomes 2020). We hope that more leaders will sign on in the near future.

RCAIE and ERD Ethical Parallels

The six ethical principles outlined in the *RCAIE* are broad in scope (see Table 2). Additionally, in order to be applicable to all manner of AI development, the *RCAIE* does not incorporate faith-based language, but draws on the Universal Declaration of Human Rights (United Nations 1948). However, there is obviously intersection between *RCAIE* principles and foundational Catholic ethical and social principles relevant to health care expressed in the *ERDs*. For example, the *RCAIE* principles of transparency, responsibility, and security and privacy reflect human dignity and explicitly invoke human dignity to define the principle of impartiality. *RCAIE* principles of inclusion, responsibility, and impartiality represent the common good. Caring for the poor is implicit in the *RCAIE* principle of inclusion. Several times in the *RCAIE*, there is mention of ensuring that AI does not discriminate against the most vulnerable. A focus on stewardship of limited resources is in the *RCAIE* principles of responsibility and reliability. In the absence of specific mention of AI ethics in the *ERDs*, *RCAIE*’s six ethical principles can provide general guidance for Catholic healthcare collaborations with AI companies.

Recommendations

Based upon the preceding discussion, we make the following recommendations for various strategic parties responsible for regulating, providing guidance to, or approving EHR data-sharing collaborations with AI companies.

Recommendations for US Governmental Agencies

Existing HIPAA regulations that permit EHR data-sharing with outside “business associates” were

developed before current AI research was even a possibility. Updating these regulations can strengthen protections for confidentiality when personal EHR data are shared with commercial parties for AI purposes. The California Consumer Privacy Act and the European General Data Protection Regulation (GDPR) provide stricter rules than HIPAA for notification, consent, and rights and processes for opting out of data-sharing for products that collect consumer health data (California Legislature 2018; European GDPR 2016). These provide a good starting point for developing stronger regulations but may not go far enough. Regulatory revisions should consider requiring that patients are fully informed about how their data will be used and identify circumstances under which patients should be given the option to “opt in” or “opt out” or when individual informed consent may be required.

As noted above, the FDA is in the process of reconsidering its approach to regulating clinical decision software and other AI tools. DHHS research regulations must also at some point more explicitly address big data research broadly, and AI specifically. Given that the Common Rule was recently revised and the rulemaking process is quite slow, additional guidance prior to any substantive regulatory revision is critical.

Recommendations for Catholic Health Care

While the *ERDs* are grounded in sound ethical principles, they currently do not directly address EHR data-sharing for research and development in AI, nor do they address any of the broader ethical issues arising from the use of AI in health care. The next revision of the *ERDs* should update Part 6: *Collaborative Arrangements with Other Health Care Organizations and Providers* to address data-sharing with technology companies, specifically the need for maximum transparency as well as the financial implications of such collaborations. Any revision of the *ERDs* to include language specific to AI should review the *RCAIE* to ensure alignment with the ethical principles outlined therein.

However, because the *ERDs* will never be able to comprehensively address all ethical issues raised by AI and EHR data-sharing, we recommend a few other actions. First, Catholic healthcare institutions should require any AI software development companies wishing to enter into a data-sharing collaboration to sign the *RCAIE* (PAV 2020). Second, in addition to engaging with broader secular initiatives related to the ethics of AI in health care, the Catholic

Medical Association, the Catholic Health Association of the United States, Catholic healthcare systems, the National Catholic Bioethics Center, and other leaders in Catholic health care should build upon the *RCAIE* and develop similar ethical guidance specific to AI in Catholic health care, perhaps through the creation of a Catholic healthcare AI consortium. Tech companies should also be engaged in these efforts, as they were for the *RCAIE*, to ensure buy-in and relevance of ethical guidance for programmers and other frontline practitioners.

Recommendations for Catholic Institutions of Higher Education

A commitment to education is explicit in the *RCAIE*. Following this call, we recommend that Catholic institutions of higher education should become leaders in research and education related to the social and ethical impacts of AI. Programs of instruction in computer science, software engineering, data analytics, bio/informatics, and other specialties that train individuals who may work in AI-related fields should include robust ethics training. As the field grows and funding becomes available, Catholic institutions of higher education should create new research centers, academic majors and minors, academic chair positions, conferences, and scholarships for research in AI ethics.

Recommendations for AI Technology Companies

In the past, several high-profile technology companies have participated in Vatican-sponsored initiatives related to AI (see Table 1). These efforts are laudable, should continue, and should expand. Because Catholic healthcare institutions serve so many patients in the United States and their influence is far-reaching, AI technology companies need to engage with the Church around the ethics of AI, particularly if they desire access to EHR patient data. Signing the *RCAIE*, as Microsoft and IBM have already done, demonstrates agreement to be accountable to ethical standards in their use of shared data and AI development protocols.

Conclusion

AI will surely transform health care. Missteps in early EHR data-sharing collaborations with AI development companies have drawn attention to ethical challenges, while additional concerns will arise as research progresses and AI products appear

in clinical practice. Existing regulatory guidance has not kept pace with novel technological advances, and the *ERDs* lack specificity. The Vatican-initiated *RCAIE* fills a critical gap, but more collaboration between the Church and the private sector will be required as the field rapidly evolves.

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Notes

1. In computer science, artificial intelligence (AI) is demonstrated by machines. AI is a broad term used to describe different applications including machine learning, which is a subset of AI that applies algorithms and statistical models to large data sets in order to “learn” to perform specific tasks according to specific computer-coded instructions, relying on patterns and inference (Rigby 2019). For a more detailed description of AI, see Nichols, Herbert Chan, and Baker (2019) and Hinton (2018).
2. An algorithm is a highly specific set of instructions written in computer code that instruct a computer to act upon inputted data in a very specific way in order to yield a predetermined goal.
3. Per HIPAA guidelines, in order for data to be de-identified, the following identifiers must be removed, making it theoretically impossible to reidentify any individual in a data set: name, address, all date-related elements, telephone/fax numbers, email address, social security numbers, medical record numbers, health plan beneficiary numbers, account numbers, certificate/license numbers, vehicle identifiers and serial numbers (includes license plate numbers), device identifiers and serial numbers, web universal resource locators, Internet protocol address numbers, biometric identifiers, full face photographic images and comparable images, and any other unique identifying number, characteristic, or code (Office of Human Subjects Research—Institutional Review Board 2003).
4. For a comprehensive overview of the role of algorithms in our lives, and how they may promote discrimination, see Cathy O’Neil’s *Weapons of Math Destruction* (O’Neil 2016).
5. In this case, material cooperation occurs when one party (the Catholic hospital) neither intends the wrongdoing (immoral use of AI technology) nor agrees with the intention of the other party (the AI company) but nevertheless contributes in some fundamental way (providing EHR data) to the second party’s wrongdoing.

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