

MITRE

**AN ETHICAL FRAMEWORK FOR
THE USE OF CONSUMER-GENERATED DATA IN
HEALTH CARE**



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EXECUTIVE SUMMARY

The Ethical Framework for the Use of Consumer-Generated Data in Health Care profiled in this document establishes ethical values, principles, and guidelines to guide the use of Consumer-Generated Data for health care purposes (i.e., diagnosis, prevention, treatment, payment, care operations, population management, health monitoring, and/or the delivery of essential public health services).

Consumers are largely unaware that organizations are acquiring and using their personal lifestyle data for health care purposes. Organizations may have benevolent intentions—such data can be used in productive ways that ultimately benefit consumers' health—but consumers can potentially be harmed if this data is used inappropriately or unethically.

Consumer-generated data (CGD) refers to individual lifestyle or behavior data generated by an individual's engagement in a non-clinical commercial, participatory, or social activity (e.g., an individual's online search history, social media activity, purchase transaction history, etc.). CGD is an undeniably valuable commodity for organizations. Whether analyzed alone or integrated with clinical data, CGD offers a tantalizingly rich trove of information from which organizations can glean critical insights about how lifestyle factors affect health outcomes, disease risk, and health services utilization. Organizations also may use CGD to develop more personalized and efficient health care experiences for their consumers.

However, CGD use also has the potential to harm individuals or populations. Use of

CGD may result in erroneous inferences about a consumer's health, exacerbate health disparities by perpetuating historical biases (e.g., structural inequities), or render certain populations invisible. Consumer segmentation and personalization of services based on CGD can restrict consumer choice or limit opportunities by making assumptions about consumer preferences or group classifications. Additionally, without certain protections, CGD use may negatively impact health insurance access by influencing plan pricing.

Though access to CGD offers unprecedented opportunities to organizations, serious ethical concerns exist surrounding privacy, consent, trust, data security, and data control. Moreover, to harness analytic insights from CGD and other data, organizations are increasingly crossing into the technological territory of increasingly complex algorithms and machine learning, which raises additional ethical concerns related to fairness, transparency, accountability, and autonomy.

Consumers expect organizations working in health to have sound ethical values and to invest in and promote their best health. Organizations have a responsibility to proactively evaluate and address ethical concerns surrounding the use of CGD for health care purposes to reduce potential harms to individuals and populations. By voluntarily adopting a consistent ethical decision-making approach whenever they use CGD, organizations can guard against reputational harm and prevent erosion of consumer trust and confidence stemming from perceived misuse of CGD.

The purpose of the Ethical Framework for the Use of Consumer-Generated Data in Health Care is twofold:

1. To guide organizations seeking to establish policies that promote the ethical use of CGD for health care purposes, including CGD acquisition, storage, disclosure/distribution, processing, analysis, and application
2. To motivate organizations to discuss the ethical implications of machine learning and develop appropriate governance processes to facilitate the ethical use of machine learning for analysis of CGD and other data

A wide range of health care stakeholders—providers, payers, health systems, population management vendors, and other industry organizations (e.g., technology, social media, or e-commerce companies)—providing products or services for health care can employ this Framework to ensure that they use CGD in an ethically defensible way.

By adopting this Framework, organizations can feel confident that they are handling CGD ethically and taking actions that will actively preserve and foster the trust of their consumers.

An Overview of the Framework

In developing this Framework, we considered existing cultural norms, ethical frameworks, and laws pertaining to health care. The comprehensive, multidisciplinary definitions of our guiding values and principles are informed by literature from philosophy, health, technology, and computing, promoting a robust, shared understanding of ethical terms and concepts.

The sections of the Framework are summarized below.

Framework FAQs | SECTION 1

Contains background information about the Framework, presented as a series of frequently asked questions. We include a comprehensive definition of CGD, address the emergent need for an ethical framework, and specify the Framework scope.

Introduction to Ethical Frameworks | SECTION 2

Introduces the purpose and elements of ethical frameworks, discusses the centrality of human decision making in applying such frameworks, and details the conceptual model of our Framework, which has three components:

1. A set of **values**—broadly applicable fundamental precepts that should be protected and promoted
2. A set of **principles**—prescriptive statements of high-level guidance about how to protect these values in relation to the use of CGD for health care purposes
3. A set of **rules or guidelines**—more specific and actionable guidance about how CGD should and should not be used for health care purposes.

The values, principles, and guidelines work together to guide decision makers toward ethical decision making: values motivate the principles, the principles protect the values and justify the guidelines, and the guidelines—derived from the values and principles—serve as more specific and actionable directives. Inevitably, ethical decision making requires occasional balancing of competing interests. Thus,

we also provide guidance for adjudicating trade-offs and conflicts, informed by tenets of biomedical ethics.

Developing the Framework

| SECTION 3

Explains the multidisciplinary, collaborative, and externally reviewed methodology we used to develop the Framework.

Determining Our Values and Principles

| SECTION 4

Describes how and why we selected the values and principles for the Framework.

Values

| SECTION 5

Details the core values that shape the Framework. Briefly and in no particular order, these values are:

- **Distributive Justice**—the idea that the burdens and benefits of social and economic life should be borne and accrued across a society.
- **Health**—the ability of individuals and populations to experience physical and psychological well-being.
- **Individual Self-Determination**—the ability to lead one's life according to one's own intentions.
- **Privacy**—the ability to preserve individual integrity, where personal boundaries, as defined by the individual, are protected from invasion or intrusion.
- **Trustworthiness**—the ability of an organization to be relied on by consumers as honest or truthful.

Principles

| SECTION 6

Details the principles that protect and promote the values of our Framework. Briefly and in no particular order, these principles regarding CGD use for health care purposes are:

- **Consider Fairness**—requires decision making to assume a basic equality between persons and to ensure that potential benefits and harms of policies and actions are fairly shared.
- **Consider Individual and Population Health**—requires that organizations consider tensions between meeting the needs of the individual vs. those of the population.
- **Respect Autonomy**—requires that organizations respect human beings as rational, moral agents, capable of and entitled to self-determination.
- **Empower Individuals and Communities**—requires that individuals and communities have the knowledge, ability, opportunity, support, and resources necessary to access and influence organizations.
- **Ensure Accountability**—requires that organizations or individuals be answerable for their actions and decisions.
- **Promote Transparency**—requires that organizations operate in ways that make it easy for others to see what actions they perform.
- **Promote Personal Data Protection**—requires that organizations not share or use CGD in a manner not authorized or for purposes not reasonably foreseeable by the consumer.
- **Promote Data Security**—requires that organizations keep CGD secure.

Guidelines | SECTION 7

Presents guidelines, each derived from specific values and principles described above. These guidelines provide more granular guidance to three types of organizational decision makers:

1. Executives (senior leaders, managers, and policymakers)
2. Data teams
3. Clinical and non-clinical end users

Each guideline is presented alongside special questions and considerations to inform and facilitate its application.

Conclusion

Proactive implementation of this Framework will give organizations that use CGD for health care purposes confidence that their decision-making processes are ethically sound. In a competitive marketplace, use of the Framework is a differentiator—it will strategically position these organizations as being committed to ethical data use to protect individuals and populations.

INTRODUCTION



Consult any major news source and you will likely come across an article about a high-profile organization that repurposed consumers' personal lifestyle information (e.g., social media data), using it in a manner that violated consumer trust.

Many of these organizations had good intentions but may not have fully considered the ethical implications of consumer data use. Such blunders cause irreparable harm to an organization's reputation. To date, these incidents have occurred predominantly outside the health care space, but the increasing use of consumer lifestyle data for health care purposes—including diagnosis, prevention, treatment, payment, care operations, and the delivery of essential public health services—puts health care organizations at risk of making similar missteps.

Consumer-generated data (CGD) refers to individual lifestyle or behavior data created as a result of an individual's engagement in a non-clinical commercial, participatory, or social activity or service (e.g., an individual's online search history, social media activity, or purchase transaction history). CGD is an undeniably valuable commodity for organizations. Whether analyzed alone or integrated with clinical data, CGD offers potentially critical insights into the influence and impact of lifestyle and behavioral factors on health. Organizations are beginning to leverage disparate and varied sources of CGD—from consumer loyalty card data to online search histories—to predict readmission risk, assign individual health risk scores, or detect cancer earlier.^{1,2,3} Though CGD may be directly collected from the consumer, it is primarily collected and aggregated by data brokers or vendors without any direct interaction with or awareness of the consumer.

For consumers and organizations working in health, the use of CGD holds the promise of a more personalized, efficient health care experience. Health care organizations—providers, payers, health systems, population management vendors, and other industry organizations (e.g., technology, social media, or e-commerce companies) that provide products or services for health care purposes—have seized upon the potential power of using CGD to achieve diverse goals. These goals include improving prevention, diagnosis, and treatment; addressing social factors impacting consumers' health; better forecasting health care utilization; and segmenting consumers for target interventions. As the health care sector increasingly harnesses the power of big data to improve value-based care,⁴ patient population management, and total population health, organizations that can perform robust analyses of CGD and other data will claim a competitive advantage in the market.

While there are obvious opportunities and advantages for both organizations and consumers associated with the use of CGD for health care purposes, potential harms include, but are not limited to:

- Violations of patient privacy and autonomy
- Disrupted trust in the patient-provider relationship
- Overemphasis on individual responsibility for health
- Exclusion, marginalization, or discrimination of individuals or populations

**The use of CGD
for health care
purposes raises
many questions.**

Consider a scenario where CGD is used to predict the medical costs of an employer's population, or to assess an individual's social support for suitability for organ transplant.

Will individuals and populations have concerns about how organizations acquired and are using their CGD? Is the relevant population represented in the CGD data set for the specified purpose (are certain segments of the population missing, and if so, why)? How do structural and social determinants of health influence the consumer lifestyles reflected in the CGD? In what ways will consumers' CGD influence how organizations choose to allocate resources?

Importantly, when integrating CGD with other clinical data, organizations have begun embracing more sophisticated algorithms and artificial intelligence (AI), such as machine learning—computer algorithms that learn automatically through experience without being explicitly programmed. Uncertainty in machine learning data inputs, models, and/or the “black box” opacity of algorithms raises additional ethical concerns regarding fairness, transparency, accountability, trust, and autonomy.^{5,6} If algorithm outputs fueled by CGD and other data generate erroneous classifications, predictions, or conclusions, health disparities could be introduced or exacerbated, and/or consumers and populations could suffer other inadvertent harm.

In light of the potential for adverse consequences, many questions arise with regard to the use of CGD for health care purposes. For example, should there be constraints on how organizations use CGD? What obligations do organizations using CGD have to consumers?

How can organizations use CGD in an ethical manner to protect individuals and populations from unintended consequences? It is critical that organizations anticipate and thoughtfully consider the ethical implications of CGD use for health care purposes to avoid inadvertent harms to individuals and populations and to avoid the damaging missteps made by other organizations outside health care.

To address the ethical concerns and potential harms associated with the increasing use of CGD for health care purposes and the emerging complexities of its use, we developed an Ethical Framework for the Use of CGD in Health Care.

When organizations make a commitment to use CGD ethically, the decision is in the best interests of all involved, from the consumers who generate it to the organizations that use it to make decisions about the health of individuals and populations. Although adoption of this Framework may require an upfront investment of time to craft policy and add a layer of complexity to an organization's decision-making activities, proactive implementation will positively differentiate the organization as one that cares about people—one committed to *taking action* to use CGD in an ethical manner. As consumer data privacy laws evolve, organizations' ability to acquire CGD may hinge upon consumer trust, as consumers elect whether or not to share their CGD with organizations. Proactively addressing ethical concerns will foster consumer trust, promote shared values and expectations, and build loyalty, allowing organizations to remain competitive as empowered consumers explore options to improve their health and health care.

The Ethical Framework for the Use of CGD in Health Care

1. Offers an actionable tool for three cadres of decision makers in organizations—executives, data teams, and end users—to promote ethical use of CGD for health care purposes
2. Advances the discourse on the ethical implications of CGD use and machine learning in health care
3. Encourages organizations using CGD for health care purposes to demonstrate a proactive commitment to reducing risk of harm to patients and populations.



SECTION 1

FRAMEWORK FREQUENTLY ASKED QUESTIONS



SECTION 1

FRAMEWORK FREQUENTLY ASKED QUESTIONS

The purpose of this section is to address some commonly asked questions regarding our definitions, scope, purpose, and target audience of the Framework.

What Is Our Definition of Consumer-Generated Data?

We define CGD as individual lifestyle or behavior data created as a result of an individual engaging in a non-clinical commercial, participatory, or social activity.

CGD may include, but is not limited to, data about an individual's buying behaviors, patterns, and preferences; memberships and subscriptions; participation in events; and/or online presence. It also includes health data from mobile health technologies collected from a user of a wearable or health app (i.e., patient-generated health data).

What Are Some Examples of CGD?

Common types of CGD include:

- Store loyalty card data
- Credit/debit card data
- Browser search or download history
- mHealth technologies data (apps, wearables)
- Social media posts
- TV/streaming data
- Internet of Things data (e.g., smart appliances)
- Blog/vlog posts
- Sensors/tracking information (e.g., geolocation data)
- Voter registration records
- Membership records

What Data Is Excluded from Our Definition of CGD?

Our definition of CGD generally excludes the following, which we refer to as clinical data:

- Individually identifiable and de-identified health care data generated by Health Insurance Portability and Accountability Act (HIPAA)-covered entities and their business associates

that relates to an individual's physical or mental health or condition, the provision of health care, and/or health care payment or operations.

- Identifiable and de-identified health data generated during a clinical research trial.
- Health care data generated from products and/or apps that meet the definition of a medical device under the Federal Food, Drug, and Cosmetic Act, in which the Food and Drug Administration intends to enforce compliance with its regulatory requirements.
- National health survey data and/or patient and disease registry data (e.g., Surveillance, Epidemiology, and End Results, National Health and Nutrition Examination Survey) that is governed by an existing statutory/regulatory framework.
- Genetic information, as defined by the Genetic Information Nondiscrimination Act, as the ethics surrounding this space require additional considerations.

Third-party data brokers that collect, analyze, and share CGD operate under a limited regulatory framework that has been criticized by privacy and security experts.

Clinical data is the data with which health organizations are most familiar and is often governed under an existing statutory/regulatory framework specific to its use for health-related purposes.

Why Is CGD Relevant to Health?

Health is significantly influenced by factors outside the health care system, with medical care contributing only 10% to 20% to the health outcomes of individuals and populations.⁷ Other social determinants significantly impact health, such as an individual's health-related behaviors (e.g., substance use, diet, physical activity), social and community context, economic factors, and built/physical environment. CGD provides critical insight into the lifestyle and behaviors of individuals and populations, and therefore is highly valuable for data aggregation, integration, and analysis.

For What Health Care Purposes Are Organizations Using CGD?

Organizations may use CGD for many reasons; however, we found that generally organizations are using CGD to make predictions or inferences about an individual's health status, risks, or behaviors; create digital profiles that provide insights into personal preferences, characteristics, and interests; and/or categorize individuals into data segments (e.g., motivated vs. sedentary patients, low risk-taking vs. high risk-taking patients) for targeted interventions.



What Distinguishes CGD from Clinical Data?

Several characteristics differentiate CGD from clinical data for health care purposes. First, consumers are generally aware of the use of their clinical data for treatment, payment, operations, and specific public health purposes; but consumers are often not aware that health care organizations are using CGD. Second, clinical data, while not infallible, is generally perceived to be of

sufficient quality and integrity and is trusted to inform decisions regarding an individual's health. In contrast, the quality and integrity of CGD may vary, leading to concerns about its usefulness, although some posit that CGD may be superior in terms of timeliness and completeness. Third, privacy ethics have been discussed extensively for clinical data, and the HIPAA Privacy Rule governs the use and disclosure of protected health information. In contrast, third-party data brokers that collect, analyze, and share CGD operate under a limited regulatory framework that has been criticized by privacy and security experts,^{8,9} and HIPAA does not adequately address the use of CGD in health care. Last, while health care data collected in the clinical context often directly relates to an individual's health care, it is less clear whether CGD collected in a non-clinical context can be used to make accurate inferences about an individual's health, either alone or when combined with data from a different context and/or time period. Moreover, CGD has the potential to be erroneously attributed to one individual when it was in fact generated by another individual (e.g., if two family members share a computer or a consumer rewards program account).

Why Focus on the Ethics of CGD Use for Health Care Purposes?

As more health care organizations pursue vertical integration and unique partnerships, CGD use will likely proliferate, especially as retailers, big data, and e-commerce giants enter the health care space. It is important that health care organizations use CGD in an ethical manner to foster trust between organizations and consumers; to promote shared interests and outcomes for organizations and consumers; and to minimize potential harms to individuals and populations.

What Do We Consider the Ethically Relevant Characteristics of CGD?

The defining and ethically relevant characteristics of CGD are:

1. The consumer "lifestyle" data is not provided directly to an organization by the data subject¹⁰ for health care purposes.¹¹ Instead, an organization may indirectly acquire the data subject's lifestyle data from other sources (e.g., third-party), and/or an organization may directly acquire (collect) the data subject's lifestyle data, but the data subject is not aware the data is used for health care purposes.
2. Use of the data is not controlled by the data subject.

What Is Artificial Intelligence and Machine Learning?

AI is the scientific field that attempts to perform or solve tasks normally requiring human cognition. Narrow AI systems focus on performing or solving specific tasks. General AI systems can autonomously or semi-autonomously perform across multiple tasks, emulating human intelligence. Whereas, the use of narrow AI is rapidly growing, most technologists agree that human-like, general AI is decades away. Machine learning is a subset of AI that enables systems to automatically learn and improve from experience based on data, without being explicitly programmed. Today, products that incorporate machine learning applications are improving rapidly in power and convenience.

How Is Machine Learning Relevant to the Ethical Use of CGD?

Machine learning algorithms can analyze very large data sets (of CGD and otherwise) to identify patterns and determine features (variables) relevant to predicting or optimizing an output of interest. To harness analytic insights from CGD and other data, organizations are increasingly embracing machine learning—both as a tool to classify individuals or populations, and to generate predictive modeling or optimization outputs to augment human decision making. Uncertainty in machine learning data inputs, models, and/or the “black box” opacity of algorithms raises ethical concerns regarding fairness, transparency, accountability, trust, and autonomy.

To harness analytic insights from CGD and other data, organizations are increasingly embracing machine learning.

What Are the Key Questions This Ethical Framework Seeks to Address?

The Framework seeks to address the following questions:

1. What core values, principles, and guidelines will promote organizations’ ethical use of CGD for health care purposes?
2. What ethical considerations and constraints should inform the use of machine learning outputs for augmentation of human decision making in health care?

We note that the ethical concerns, considerations, and constraints regarding the use of machine learning are not unique to CGD. However, in light of the increasing use of machine learning, we chose to briefly address some ethical considerations and constraints for its use vis-a-vis CGD and other types of data in health care.

What Is the Scope of the Framework?

This Framework focuses on promoting the ethical use of CGD for health care purposes.

The Framework is designed to:

1. Increase transparency about decision making
2. Reduce the likelihood of ethically questionable decisions that can be “rationalized away”
3. More thoughtfully consider the implications and consequences of using CGD prior to implementing targeted patient interventions or integrating CGD into population management strategies

This Framework is not designed to address the ethical use of CGD for non-health care-related purposes, and it does not address ethical data collection practices. While ethical data collection practices are critical, we chose to focus on ethical CGD use, given that this data is already readily available for use. This Framework does align with existing complementary efforts focused on data collection and individual data control.

How Does This Framework Differ from Other Documents Addressing Ethical Data Use and Machine Learning?

The Framework has been designed specifically for the health care domain, taking into consideration existing cultural norms, ethical frameworks, and U.S. and international data laws and regulations in health care. While constructing the Framework, we were cognizant of the obligations of health care organizations to the consumer, which may be governed by both clinical and organizational ethics. We sought to promote the interests of patients/consumers and populations, while also considering health care organizational needs. Our Framework is inspired by Principlism, which is discussed in Section 2, but does depart from it in important aspects by incorporating new values and principles, as well as highlighting existing bioethical principles, to address ethical issues arising from the use of CGD and machine learning in health care.

Who Is the Target Audience for This Framework?

Our target audience includes a range of actors engaging in the health care space by developing products or services for health care purposes, including providers, payers, health systems, and their population management vendors, as well as other industry organizations (e.g., technology, social media, or e-commerce companies), and individuals. In this document, we segment our target audience into three major groups:

1. Executives (senior leaders, managers, and policymakers) involved in the decision-making process regarding the use of CGD
2. Data scientists and developers specifying model inputs, outputs, and functionality of applications involving the use of CGD for health care purposes
3. Clinical and non-clinical end users (individuals who apply analytical outputs to augment their decision making)



How Does the Framework Help the Target Audience?

The Framework provides clearly articulated foundational ethical values and principles to guide the use of CGD for health care purposes, particularly when using machine learning data outputs. The Framework provides a set of actionable guidelines that, when proactively implemented, help organizations protect and promote the values and principles, with questions or considerations to guide ethical reasoning. These values and principles provide the underlying structure and foundation for the Framework and are what drive the guidelines.

Who Else Should Consider Reading the Framework?

Patients/consumers or their advocates who engage with organizations using CGD for health care purposes may be interested in reading the Framework to identify questions they should pose to organizations or otherwise consider regarding their use of CGD. We are developing supplemental materials specifically for consumers. These materials, informed by the Framework, will assist consumers in engaging with organizations using their CGD for health care purposes.

SECTION 2

AN INTRODUCTION TO ETHICAL FRAMEWORKS



SECTION 2

AN INTRODUCTION TO ETHICAL FRAMEWORKS

This section provides a high-level introduction to ethical frameworks in layperson's terms, for the non-ethicist.

Ethical frameworks are defined as "concrete analytical tools designed to assist professionals in deliberating about aspects of programs or policies to support decision-making before implementation."¹² Ethical frameworks are intended to encourage reflection on important ethical concerns to improve conscientious decision making at every step of the process.¹³

Components of the Ethical Framework

An effective ethical framework consists of both necessary and highly desirable features.

Necessary features of an effective ethical framework include:

1. Ethically defensible values
2. An internally consistent set of parameters that establishes a range of ethically permissible behaviors
3. Usability (i.e., the framework must be understandable, agile, and implementable by those with decision making authority)

Highly desirable features of an effective ethical framework include:

1. Broad applicability to various situations and flexibility to adapt to different levels of detail
2. Revisability based on experience in applying the framework
3. A process that acknowledges unavoidable trade-offs but that leaves decision makers with as little decision regret as possible

An effective ethical framework incorporating these necessary and highly desirable features typically comprises three components:

1. A set of values, fundamental precepts that ought to be protected and promoted
2. A set of principles, with guidance for adjudicating trade-offs that are specific to/contingent upon the subject area for which the framework is designed (in our case, the use of CGD in health care)
3. A set of rules or guidelines for applying the principles

Values are recognized by most ethical theories and most societies as inherent “goods” that ought to be protected. Values motivate principles, which are prescriptive statements of high-level guidance about how to protect the values on which the ethical framework rests. This distinction acknowledges that, by their nature, values (e.g., health) are timeless and broadly applicable, while permitting the articulation of principles that are more precisely related to the use of CGD in the context of an individual’s health care. Principles provide general, fundamental justifications for moral rules, or guidelines. “Moral rules are general guides governing actions of a certain kind; they assert what ought (or ought not) to be done in a range of particular cases.”¹⁴ Like principles, guidelines are derived from values, but are more specific and actionable. Guidelines are not intended to be mechanical or algorithmic, but instead ought to guide decision makers toward an ethical outcome. Due to the iterative nature of ethical decision making, framework outcomes should be evaluated regularly. Guidelines should be revised when it is clear, based on implementation experience, that modified guidelines might improve usability and reduce decision regret.¹⁵ No ethical framework can entirely eliminate or wholly mitigate all risks or prevent all harms, but effective frameworks will certainly reduce the likelihood of causing harm or decision regret.

The conceptual model in Figure 1 represents the key components of our ethical framework.

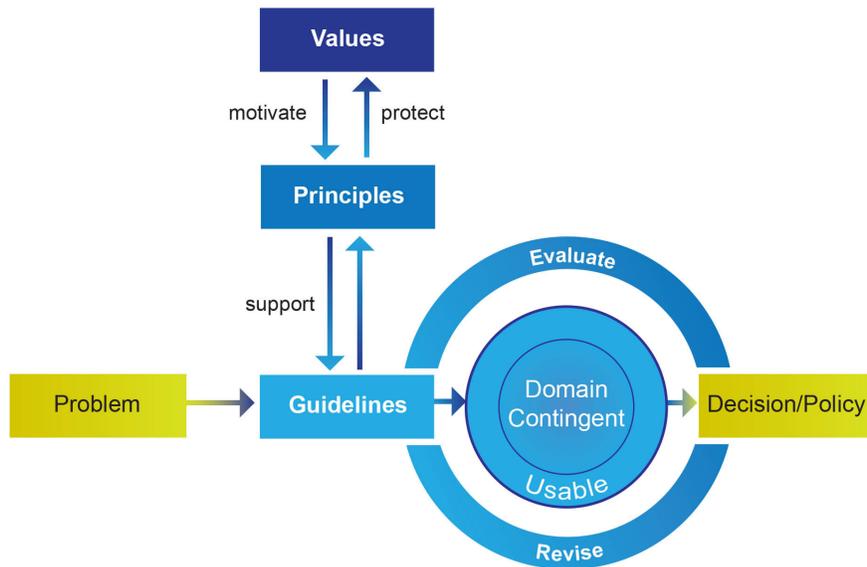


Figure 1. Ethical Framework Conceptual model

Occasions may arise in which values or principles conflict with one another. Some might be tempted to rank-order the values and principles to establish which value or principle ought to be prioritized when conflicts occur. However, as discussed in further detail below, universal rank-ordering of values and principles limits any framework’s flexibility. For the framework to be broadly applicable to various situations, different individuals and different cultures should be able to give different weight to values and principles when they conflict.

Balancing Principles: Trade-offs and Resolving Conflicts

The prevailing ethical framework in biomedical ethics largely relies upon the tenets of Principlism—an approach to provide ethical guidance for clinical decision making in morally complex situations. The Principlist approach respects “common morality” (the dominant moral consensus in a particular society), and tends to produce a less subjective, more consistent, and more efficient means of moral decision making than religion or individual intuition.¹⁶ Other methods, directed at more detailed and case-specific moral decision making, are available (e.g., casuistry). These methods might be preferred in clinical settings, which tend to be quite unique, and often focus on the case of a specific patient. However, with respect to decision making in large, complex organizations, where attention to individual-level detail is not always possible or desired, the Principlist approach has the following virtues: it is easy to understand, flexible enough to use in real situations, and is minimalist in terms of the number of principles. It comprises only four core principles (again, in no hierarchical order of importance): (1) respect for autonomy; (2) beneficence; (3) nonmaleficence; and (4) justice.¹⁷

Each of these principles articulates a moral obligation, but conflicts will inevitably arise when applying an ethical framework. Nevertheless, it is widely agreed upon in the literature that the four principles should not be rank-ordered. As Gillon notes, “...the fact that principlism in itself does not provide a universalisable method for prioritising the four principles, far from being a fatal blow to principlism, is on the contrary a major advantage.”¹⁸ Not prescribing a specific method for prioritizing the principles allows different people and different cultures to give different weight to these principles when they conflict. To retain flexibility, the principles intentionally do not embody enough specifics to arbitrate the trade-offs; they are intended to represent a first level of ethical guidance, to be given more specification in actual application. For example, the principle of respect for autonomy could be specified as respect for the autonomy of parents to make decisions for their minor children.



Critics of Principlism worry that this method lacks subtlety, nuance, and comprehensiveness when applied to complex moral problems. Beauchamp and Childress, who developed the Principlist approach, acknowledge that their framework alone is not sufficient to address complex moral problems, explaining, “the content of these rules and principles is too abstract to determine the acts that we should perform. In the process of specifying and balancing norms and in making particular judgments, we must often take into account factual beliefs about the world, cultural expectations, judgments of likely outcome, and precedents to help assign relative weights to rules, principles, and theories.”¹⁹

Balancing requires recognizing that the ethical permissibility of potential actions might involve weighting principles differently under different circumstances.

Still, at the level of large scale decision making (as opposed to the unique situation of the clinical encounter), ethical frameworks are meant to be decision-making tools that urge deliberative consideration and identify factors that ought to be considered—but do not definitively compel—a particular course of action. Principlism, when grounded in values and articulated in specific rules, provides a general and effective means of increasing the ethical defensibility of decisions at all levels of an organization.

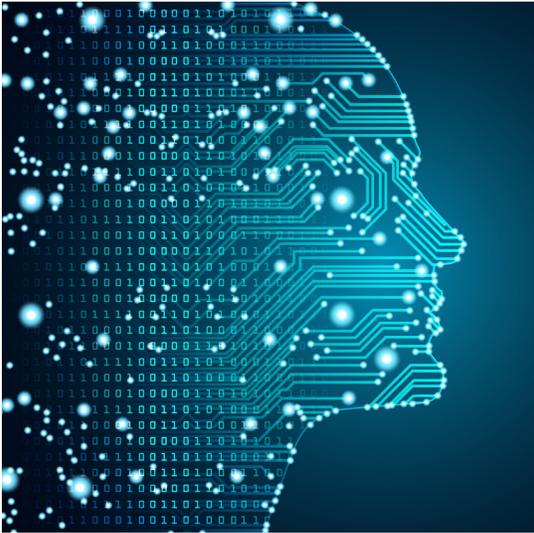
As an example, deep learning models that include electronic health record data and CGD have been used to accurately predict an individual's risk of in-hospital mortality upon arrival. The Principlist approach

presents a framework that could help determine whether this risk should be communicated to the patient. In applying the Principlist approach to this case, the principle of beneficence (prioritizing the general welfare of the patient) conflicts with the principle of respect for autonomy (which rejects the option of deceiving the patient). We have an obligation not to lie to the patient, yet we have an obligation to do what is best for the patient. If the evidence shows that revealing mortality risk to incoming patients actually increases their in-hospital mortality risk, then it may be appropriate to weight beneficence more heavily than respect for autonomy as the operative principle in this case. While deception by omission is still morally undesirable and requires moral justification, under these circumstances, beneficence outweighs autonomy in the moral calculus.

Balancing requires recognizing that the ethical permissibility of potential actions might involve weighting principles differently under different circumstances. Fact-finding and deliberation are also required in any practice guided by ethical principles. The principles are not absolute, but their moral valence is always present—that is, deception is always a wrong-making feature of an action, but that fact can carry more or less weight in any given decision-making situation.

Necessity of Human Decision Making in Applying the Framework

Some might be tempted to automate ethical decision making by completely “computationalizing” this ethical framework. Skilled human decisions may be viewed as too costly or limited when confronted by the need to make a large number of decisions, consider a large number of factors, and in areas where the decision maker may have emotional biases. Also, since human moral intuition may be used to disregard relevant information in favor of opaque decisions based on the justification that it “felt right,” some may believe that “computationalizing” the framework could lead to more objective ethical decisions.



However, ethical decision making cannot be completely mechanical because neither the set of relevant factors, nor the applicable moral norms and principles, can be coded fully and exhaustively. To teach algorithms to reliably “do the right thing,” one would need morality to be captured comprehensively in a data set, which is highly implausible. Programmers cannot manually identify and codify every salient detail that may be significant to make subtle adjustments to each principle sufficient to constitute a pattern that could be “learned.” Therefore, the output of a learning algorithm may be a very imperfect estimator of moral permissibility.

Machines also cannot engage in reflective discourse or deliberative consideration of nuanced expectations or situations. Learning algorithms generally do not recognize when their formulation is inappropriate to a situation, and they may not recognize that crucial information has not been included in the input set. Even technological optimists believe that algorithms will, for decades, be limited in handling subtle, nuanced situations.

For efficiency, it may be useful to apply some degree of automation (e.g., to quickly identify guidelines applicable to specific purposes). However, completely automated ethical decision making performed independently and exclusively by machines merits additional ethical scrutiny, specifically considering the following factors:

1. Avoiding unjustifiable confidence in machine “decisions”: Humans are prone to believe that the outputs of computations are more objective, freer of bias, and closer to the truth than human decisions, but there is no empirically verified reason to accept the generalization that learning algorithms make “better” decisions than humans do.
2. Remembering that some learning algorithms used in automated decision making cannot “justify” their decision making: Explanation relates to how a decision maker, or in the case of automated decision making, an algorithm, arrived at a decision. Justification explains why the decision maker (or algorithm) believes the decision is “right.” In many cases, an explanation of machine learning outputs may provide individuals with sufficient justification for a decision. However, some machine learning results are not sufficiently explainable, thereby hindering justification.

To summarize, while the flaws in human decision making are familiar, machine learning and algorithmic decision making are new. The potential unintended consequences, understanding of possible undesirable results, and the mechanisms to cope with them are not mature. For all of the above reasons, ethical decision making related to the use of CGD (and health care information technology [IT] more generally) will continue to require a human component, both to understand key issues and to decide how best to weigh and resolve them.

SECTION 3

DEVELOPING THE FRAMEWORK



SECTION 3

DEVELOPING THE FRAMEWORK

To develop the Framework, we employed a modified Delphi method.

We began by conducting multiple literature reviews to investigate the following:

- CGD use in health care
- Existing policies surrounding the use of CGD, consent, and privacy concerns in the United States and abroad
- Existing ethical frameworks in health care
- Ethical frameworks for data analytics, algorithms, machine learning, and AI
- CGD risk management

Sources included:

- Philosophical texts
- Domestic and international statutes and regulations
- Articles from Web of Science, PubMed, and Embase
- Gray literature, such as conference proceedings, government reports, and issue papers

Building upon the literature reviews, we conducted a comparative analysis of existing ethical frameworks addressing health or technology, including their associated principles, values, and rules/guidelines.

We reconciled terminology across disciplines, defined key terms, and drafted a preliminary set of values, principles, and guidelines for the Framework.

Subsequently, we hosted two consensus workshops, led by human-centered design subject matter experts. Each workshop consisted of approximately 20 participants from a variety of disciplines, including clinicians, lawyers, data scientists, ethicists, policy analysts, privacy experts, and health communication and marketing specialists. The first workshop focused on the underlying values and principles for the Framework, and the second workshop focused on discipline-

Participants from a variety of disciplines, including clinicians, lawyers, data scientists, ethicists, policy analysts, privacy experts, and health communication and marketing specialists.

specific guidelines. Between the two workshops, we held small focus groups comprised of three to six participants from a single discipline (e.g., clinicians, lawyers, etc.) to consider the types of decisions likely to be made within their discipline with respect to CGD, and to solicit feedback on guidelines for decision makers.

In addition, we conducted key informant interviews with data scientists and privacy scholars to ask additional questions to inform guideline development. Concurrent with the above activities, we reviewed and analyzed proposed and existing pertinent legislation at the international, national, and state levels to inform Framework development.

To refine the Framework, we used an iterative process that sought feedback through external stakeholder interviews and by incorporating multiple cycles of multidisciplinary expert review. We made an effort to infuse consumer/patient considerations throughout all aspects of the Framework.

SECTION 4

**DETERMINING
OUR VALUES
AND PRINCIPLES**



SECTION 4

DETERMINING OUR VALUES AND PRINCIPLES

Our approach to constructing the Framework began with a review of the literature in the fields of medical ethics, data ethics, AI ethics, public health ethics, and organizational ethics.

We consulted a wide range of frameworks and principle documents (see Appendix A). Appendix A is not exhaustive of all existing ethical frameworks; rather, it provides examples that represent the prevailing view of the core elements of ethical frameworks.

In our analysis of each framework, we evaluated elements by (1) whether they would be applicable to the use of CGD in the context of an individual's health care or population health; (2) the frequency with which they were included in various frameworks; and (3) whether they were redundant to other elements defined within the Framework. Based upon these criteria, we compiled a list of preliminary elements for consideration to include in our Framework.

Notably, our research identified wide variation in how ethical terms are defined and used across, and even within, disciplines. For example, some sources distinguished between what they defined as a value versus what they defined as a principle, while others used the terms interchangeably. Even those sources that distinguished between values and principles diverged in how they categorized ethical concepts (e.g., some frameworks classify "justice" as a value, while others refer to it as a principle).

According to the distinctions we articulated between values and principles in Section 2, we sorted the preliminary elements of the ethical Framework into two subsets: values and principles. Through extended discussion and debate and a series of multidisciplinary consensus and engagement activities, the preliminary set of elements were defined and iteratively refined into the current Framework, which consists of five values and eight principles. The values and principles were reviewed by individuals in the following domains: IT, data science, privacy, health communication, clinical care, public health, law, health insurance, and policy.

The purpose of developing this Framework is to minimize or prevent harm to individuals or populations by providing a concrete analytical tool to assist organizations in formulating programs or policies regarding the use of CGD and/or implementation of machine learning algorithms using CGD in health care. The use of CGD in health care has the potential to achieve some—even significant—good (e.g., precision medicine, improved consumer experience, and the ability to address structural and social determinant factors impacting health). However, focusing only on good outcomes (e.g., improving health, reducing cost), or the magnitude of such outcomes, may unwittingly or deliberately obscure the ways those outcomes were achieved. Such a selective focus may increase the risk of unforeseen or unintended consequences that negatively affect individuals or populations, particularly, the least well-off.

**The Framework
provides an ethical
“safety net.”**

The use of CGD in health care is in its infancy, and it is possible that new values and principles unique to this practice might emerge in the future. In the meantime, the Framework provides nuanced guidance and constraints for CGD use, while promoting consideration of potential harms. Any organization wishing to use CGD for health care purposes in an ethically defensible way can apply this Framework to (1) increase transparency about decision making; (2) reduce the

likelihood of ethically questionable decisions that can be “rationalized away”; and (3) more thoughtfully consider the implications and consequences of using CGD prior to implementing targeted patient interventions or integrating CGD into population management strategies.

Following the Principlist approach, our Framework presents a lean but comprehensive structure that establishes a minimum ethical threshold for decision making about CGD use in health care—one that promotes ethical deliberation and minimizes harm. In this sense, the Framework provides an ethical “safety net.” As noted in Section 2 (“Balancing Principles”), certain contexts might demand taking additional considerations into account. The Framework itself, with its strongly supported values, principles, and guidelines, provides the scaffolding necessary to fully evaluate additional considerations

SECTION 5
VALUES



SECTION 5

VALUES

The core values that ought to be protected and promoted in using CGD in the context of an individual's health care are as follows, in no hierarchical order of importance:

- ▷ Distributive Justice
- ▷ Health
- ▷ Individual Self-Determination
- ▷ Privacy
- ▷ Trustworthiness

Distributive Justice

Distributive justice refers to the idea that various burdens and benefits of social and economic life should be borne and accrued across a society. For the purposes of this ethical Framework, the value of distributive justice is assumed to require, at a minimum, procedural justice, or a system of articulated rules and procedures that apply equally to all members of society with regard to the use of their data. Mere procedural justice is not sufficient to determine the ethical use of CGD, since procedures by themselves cannot counter or correct for existing structural inequalities.

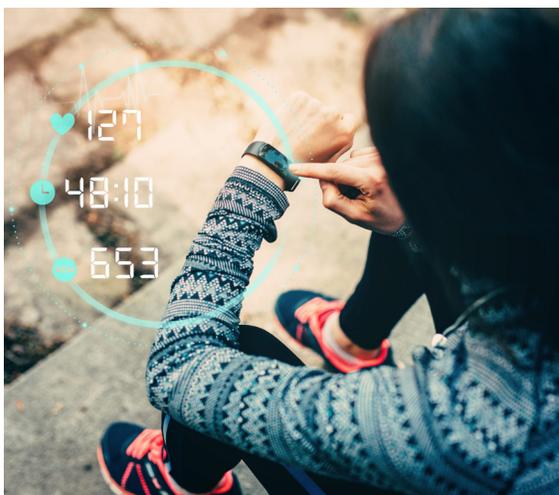
In *A Theory of Justice*, John Rawls articulated two elements relevant to determinations of distributive justice: (1) each person should have an equal right to the most extensive basic liberty compatible with a similar liberty for others; and (2) social and economic inequalities should be arranged so that they are both (a) reasonably expected to be to everyone's advantage, and (b) attached to positions and offices open to all.²⁰ While not all unequal health circumstances are necessarily unjust, health inequalities between groups become health inequities when they are unjust. Accordingly, health inequality is unjust when access to health

Not all unequal health circumstances are necessarily unjust, health inequalities between groups become health inequities when they are unjust.

care is inequitable or when other factors within the realm of the social determinants of health (e.g., education) are not distributed according to three considerations:

1. **Primary goods**—“what free and equal persons need as citizens” (e.g., certain civil rights, opportunities, income). The specific “primary goods” may change over time as social norms are influenced by technology and other factors that determine what individuals need to prosper.
2. **The Difference Principle**—“[S]ocial and economic inequalities are to be arranged so that they are . . . to the greatest benefit to the least advantaged.”²¹
3. **The Maximin Principle**—“[W]e are to adopt the alternative the worst outcome of which is superior to the worst outcomes of the others.”²² In other words, when presented with a variety of bad choices, the best choice is that which produces the least bad outcome.

Distributive justice in health care necessitates that in some cases, special mechanisms may be needed to correct unjust structural inequalities (inequities) and to protect the vulnerable (e.g., mechanisms to reduce or eliminate health disparities or achieve health equity²³). Health is of special moral importance because all other opportunities, and ultimately life itself, are predicated upon an individual’s health status.²⁴



Health

For the purposes of our ethical Framework, we adopt as a value Carr’s definition of health as “the experience of physical and psychological well-being.” Carr states, “good health and poor health do not occur as a dichotomy, but as a continuum. The absence of disease or disability is neither sufficient nor necessary to produce a state of good health.”²⁵

An individual’s health status exists on a continuum influenced by biology and genetics, individual health behaviors, and other social determinant factors over the course of their life. Our value

acknowledges that inferences about health based on an individual’s CGD may not only reflect their health behaviors and lifestyle choices, but also may be influenced by socioeconomic and political structural factors. To preserve the value of health, these structural factors should be considered when using CGD to assess an individual’s disease risk and health outcomes, as well as in the development of targeted individual, population, or structural interventions.

Our value of health also includes total population health, which is defined as the health outcomes of a group of individuals, including the distribution of such outcomes within the group.²⁶ Population health is not limited to the management of a subpopulation of patients that an organization serves (i.e., population management), nor is it simply the summation or

aggregation of the health status of individuals; rather, population health focuses on using CGD to promote the health of populations, which may or may not also result in the improved health of all individuals within the population.

Individual Self-Determination

For the purposes of this ethical Framework, the value of self-determination refers to the ability to lead one's life according to one's own intentions. Individuals are assumed to value the freedom to make decisions about their health and lives for themselves according to their own intentions. Individual choices by competent individuals are to be sought and respected. The ability to exercise self-determination is a defining characteristic of humanity. The value of self-determination may be permissibly infringed only when its exercise impedes on the ability of another to lead their life according to their own intentions.²⁷

Privacy

For the purposes of our ethical Framework, we define the value of privacy as individual integrity, where the boundaries of an individual are protected from invasion or intrusion. The boundaries of an individual are defined and understood in terms of what things individuals deem important to protect, which we refer to as the "protecteds." Protecteds may include the physical body, reputation, social networks or relationships, and/or communications and conversations, which may be impacted by an individual's personal data. Different individuals may assign varying degrees of importance to specific protecteds, such that different boundaries may apply for each individual. Additionally, some protecteds may matter more than others to a specific individual; it is the amalgamation of the protecteds that defines the boundaries of an individual.

As social norms evolve in response to developments in the digital ecosystem, the universe and weightings of protecteds will likely change over time. As new technologies emerge, individuals may be forced to reconcile the potential harms they may incur as the result of sharing their personal information for a particular use against the articulated benefits. Despite these changes, privacy will endure as a value because individuals will continue to care about, and want to protect, the boundaries of their person (and/or those of their minor dependents), even if the criteria that define the boundaries (the protecteds) change over time.

An individual's privacy is compromised when the "protected" boundary of their person is entered upon. This may occur with or without the individual's knowledge or consent.



An individual's privacy is compromised when the "protected" boundary of their person is entered upon. This may occur with or without the individual's knowledge or consent. In the case of a "permissible waiver," an individual may agree to share or allow access to "protected" information; the individual's boundary may be compromised **with** conscious²⁸ knowledge, but their privacy is not necessarily violated. An individual's privacy is **violated** when their boundary is compromised as a result of their data being used **without** their conscious agreement to share or allow access to their "protected" information. Violations are inherently unethical.

When it comes to an individual's personal data, including personal knowledge and insights derived from data analysis, it is important to consider that individuals fall along a spectrum with respect to how

much information they would consent to share. Privacy "maximalists" are reluctant to share information about themselves, or allow others access to their information, as they feel this breaches or intrudes on their boundaries. Privacy "minimalists" do not feel that sharing more information, or allowing others access to their information, breaches or intrudes on their boundaries. In considering the level of privacy protection to employ, users of individual data (whether CGD or clinical) should, where technically feasible, seek to satisfy each person's expressed privacy preferences. When satisfying each person's expressed preferences is not technically feasible, the organization should employ the highest level of protection with regard to the protecteds from the perspective of a privacy maximalist. Adopting a privacy maximalist standard ensures that both maximalists and minimalists will feel the boundaries of their person are protected. With this standard in place, minimalists may have to make an effort to contribute their data, or mechanisms will have to be in place to allow individuals to readily share health-relevant data (e.g., see Mikk et al.²⁹).

The "privacy paradox" describes a phenomenon in which some individuals demonstrate inconsistency between their expressed privacy concerns and their actual behavior by freely sharing information beyond their protected preferences.³⁰ Adopting a privacy maximalist standard ensures that individual privacy concerns are respected even if individuals do not always act in accordance with those concerns.

Separate but related to privacy, the concept of "confidentiality" often arises in the health care context. We view confidentiality as a characteristic that defines the nature of the relationship between an individual who has shared personal information and a third party. We may enter into a "confidential" relationship (e.g., doctor-patient), or we may ascribe information or

conversations as “confidential” based on the nature of the relationship. These confidentiality arrangements have emerged over time to facilitate trusting relationships, as well as honest and open communication designed to best serve the individual and, in some cases, society. In a social or professional setting, confidentiality imposes an obligation to not disclose privately shared information (limited disclosure) and an expectation that information shared within the context of the relationship will be given special treatment compared with ordinary information. Confidentiality presupposes that privacy is a value because confidentiality involves waiving certain protecteds within the context of the confidential relationship.

An individual’s decision to take the risk to access or accept care may hinge on an organization’s trustworthiness.

Trustworthiness

For the purposes of our ethical Framework, we define the value of trustworthiness as the ability of a health care organization to be relied on as honest or truthful, as determined by three correlated characteristics as conceptualized by Mayer et al. (1995): ability, benevolence, and integrity.³¹

1. Ability is the extent to which an organization possesses the knowledge, skills, competency, and/or influence to act within a specific domain (health care). It acknowledges that an organization’s trustworthiness may be domain-dependent or issue-dependent, wherein the organization may be viewed as trustworthy in one domain or activity (e.g., health care, diagnosis), but not in another (e.g., data science, financial projections), based on the organization’s actual and/or perceived abilities in the domain of interest.
2. Benevolence is the extent to which a trustor (trusting party) believes the organization has the desire to “do good,” independent of its own self-interest or extrinsic incentive. Benevolence is not the same as beneficence. Benevolence refers to an individual’s or organization’s intention to do good, whereas beneficence,³² a long-standing principle of medical ethics, refers to the specific action of actively promoting good for the purpose of benefiting others. We interpret “good” to be that which promotes health, longevity, alleviation of pain, and/or well-being.
3. Integrity is the extent to which an organization adheres to a perceived set of standards that the trustor deems acceptable. Social and moral norms may influence the set of standards a trustor deems acceptable, and/or guidelines or rules may explicitly outline organizational standards.



Individuals may appraise an organization's benevolence, integrity, and ability differently with respect to the relative importance of each characteristic, and the importance and/or unique effects of the three characteristics may vary in different contexts or change over time.

Separate but related to trustworthiness, the concept of trust refers to the act of trusting. Trustworthiness can be a precondition for warranted trust, but is not required. We define trust as the willingness of an individual to voluntarily commit to pursue a path with a perceived uncertain outcome, based on

the belief that the trusted individual or organization will act in a certain way to achieve a good/non-detrimental outcome on the trustor's behalf.³³ Trust has been shown to influence health care access and delivery.^{34, 35, 36} Trust can exist at multiple different levels (e.g., interpersonal, organizational, community, group), and individuals may feel differing levels of trust for the organization compared to individuals affiliated with the organization.³⁷ Most importantly, trust requires the trustor to take risks with regard to their health and accept being vulnerable to the organization. In most instances, the trustor voluntarily accepts being vulnerable; however, in the health care context, individuals may involuntarily remain in a position of vulnerability due to situational factors such as impaired health status, information asymmetry, or other health factors (e.g., health literacy). For this reason, organizations should routinely assess whether their behaviors, policies, standards, governance, and oversight mechanisms with regard to CGD engender such trust; an individual's decision to take the risk to access or accept care may hinge on an organization's trustworthiness.

SECTION 6
PRINCIPLES



SECTION 6

PRINCIPLES

The guiding principles that ought to be protected and promoted in using CGD in the context of an individual's health care are as follows, in no hierarchical order of importance:

- ▷ Consider Fairness
- ▷ Consider Individual and Population Health
- ▷ Respect Autonomy
- ▷ Empower Individuals and Communities
- ▷ Ensure Accountability
- ▷ Promote Transparency
- ▷ Promote Data Protection
- ▷ Promote Data Security

Consider Fairness

The principle to consider fairness requires decision making to assume a basic equality between persons and to ensure that potential benefits and harms of policies and actions are fairly shared. Any harms must be justified in terms of the efficacy of policies or actions to deliver significant benefits that far outweigh the harms and are not unjustly distributed. Further, decision makers should endeavor to make decisions that create a system they would consider fair were they among the least well-off in that system. To assess whether decisions about the use of CGD in health care disproportionately impact certain persons, decision makers may apply a balancing test to consider how well-off a person is with respect to three attributes (in no particular order):

1. Socioeconomic status

- Organizations ought to consider income, education, literacy, and occupation, as well as other relevant factors affecting an individual's position in society.

2. Health status

- Organizations ought to consider morbidity, disability, and quality of life.
- Organizations ought to consider health disparities, which are differences in health that are "closely linked with social, economic, and/or environmental disadvantage" and are associated with "groups of people who have systematically experienced greater

obstacles to health based on their racial or ethnic group; religion; socioeconomic status; gender; age; mental health; cognitive, sensory, or physical disability; sexual orientation or gender identity; geographic location; or other characteristics historically linked to discrimination or exclusion.³⁸

3. Information asymmetry

- Information asymmetry, in which some individuals have more or better information than other individuals or groups of individuals.
- Organizations ought to consider the “invisible” population that does not have access to technology/does not generate CGD and individuals’ differing levels of access to and ability to understand and control their information.

Agents in different roles may weigh certain of these attributes as more or less important, depending upon those roles. For example, an individual’s health status is probably the most significant attribute for some clinicians, but the other attributes also merit consideration. From the organizational data use perspective, information asymmetry might be the most important attribute to consider (how data is obtained, whether it is used equitably, etc.). In giving differential weight to these attributes, decision makers also should consider which underlying values are being protected by the application of the principle to consider fairness. While no one attribute supersedes the others, an individual who is least well-off compared with others in a society in all three of these attributes is more vulnerable to disproportionate negative impact from CGD use. The principle to consider fairness requires that the use of CGD not leave the least well-off worse off than they already are.

Decision makers should endeavor to make decisions that create a system they would consider fair were they among the least well-off in that system.

Consider Individual and Population Health

We value both individual and population health, but protecting individual health and promoting population health may at times be incongruent. Tension may exist between meeting the needs of the individual vs. those of the population. To determine whether the needs of the individual or the needs of the population should be weighed more heavily under a particular set of circumstances, the principle to consider individual and population health requires balancing two related concepts: beneficence and nonmaleficence.

Beneficence is actively promoting good. There is much debate in the literature with respect to what constitutes “good.” For the purposes of our Framework, we interpret “good” to be that which promotes health, longevity, alleviation of pain, and/or well-being. Nonmaleficence



is the related concept of doing no harm. These two concepts have a long history in medicine; the Hippocratic oath explicitly imposes an obligation of beneficence and nonmaleficence: “I will use treatment to help the sick according to my ability and judgment, but I will never use it to injure or wrong them.”³⁹

Ideally, agents should aim to promote the health of both individuals and populations. Often, promoting individual health contributes to improved population health because healthy individuals lead to healthier populations; similarly, promoting population

health may improve health outcomes among individuals because benefits to the population may extend to individual members. In both cases, organizations must be cognizant of the distribution of health outcomes within the population to assess and prevent health disparities. However, situations inevitably will arise where promoting total population health by using CGD may harm one or more individuals; conversely, promoting good health for an individual could be to the detriment of a particular population. When a conflict arises, the principle to consider individual and population health requires that decision makers consider the effect of their decisions on both individual and population health, balancing the requirements to actively promote good and to do no harm.

Organizations and agents may look to public health for guidance on balancing the needs of the individual against the needs of a particular population when using the outputs of CGD analysis (machine learning) for intervention, policy, or program development. Childress suggests five conditions to consider in determining whether promoting public health warrants infringing on individual health (in no particular order):⁴⁰

1. **Effectiveness**—An intervention, policy, or program that infringes on one or more moral considerations in the name of public health, but has little chance of realizing its goal, is ethically unjustified.
2. **Proportionality**—The probable public health benefits of an intervention, policy, or program should outweigh the infringed moral considerations.
3. **Necessity**—Not all effective and proportionate policies are necessary to realize the public health goal that is sought. The fact that a policy will infringe on a moral consideration provides a strong reason to consider alternative strategies that are less morally problematic.
4. **Least Infringement**—Even when a proposed intervention, policy, or program satisfies the first three justificatory conditions—that is, it is effective, proportionate, and essential in realizing the goal of public health—public health professionals should seek to minimize the infringement of moral considerations to the degree possible without compromising the effectiveness of the intervention, policy, or program.

5. **Public Justification/Transparency**—When a public health intervention, policy, or program infringes on one or more moral considerations, public health professionals have a duty to explain and justify that infringement to those affected by the infringement.

Other considerations for organizations include the following:

1. Does the population health intervention, policy, or program developed as a result of CGD analysis allow an opportunity for individual choice?
2. Does the population health intervention, policy, or program developed as a result of CGD analysis balance the benefits and burden across all individuals, or are certain individuals more vulnerable?
3. Should patients/consumers be involved in designing and monitoring the population health intervention, policy, and program developed as a result of CGD analysis?

Respect Autonomy

The principle to respect autonomy maintains that human beings are rational, moral agents, capable of and entitled to self-determination. Where the action in question is a decision or choice, then it is autonomous only if the individual has access to accurate and reasonably complete information. Respecting autonomy presents unique challenges with regard to use

of CGD by an organization in furtherance of its own ends. Specifically, use of CGD by an organization may lead to coercive situations, in which the individual generating the CGD supplies the CGD willingly for an inducement (for example, a coupon/discount on a product or service), without understanding that the benefit of the CGD to the organization far outweighs the value of the benefit offered to the individual. Moreover, if the organization is not transparent about the potential for the CGD supplied willingly by an individual to be paired with data acquired from other sources, the individual may not have an opportunity to make an autonomous decision because he or she does not have access to accurate and reasonably

complete information about how the CGD might be used. CGD users have a duty to minimize coercion, avoid deceptive practices, and disclose to CGD suppliers (data subjects) ostensibly complete information regarding how CGD will be used.

The principle to respect autonomy motivates the notion of informed consent. Informed consent requires that an agent voluntarily choose a particular course of action based on their demonstrated understanding of the information provided to them.⁴¹ Although websites,

Informed and meaningful consumer consent for CGD use is critical to promoting the principle to respect autonomy.

apps, wearables, and consumer rewards programs generally require consumers to sign a user agreement meant to satisfy the requirement for informed consent, consumers rarely read and/or understand the information provided to them because the language of these policies is often written in legalese of significant length and density to discourage active reading, engagement, and interpretation. Furthermore, consumers generally realize they don't have a choice: if they want to use the technology or website, they are required to sign the user agreement and they are not given an opportunity to object to any of its terms or conditions. Therefore, even in cases where a consumer signs a user agreement authorizing sale or use of CGD for purposes not directly benefiting the consumer, CGD poses a threat to autonomy when it is used for purposes not fully understood by the consumer. Organizations may also restrict autonomy by presenting an individual with no realistic alternative to not providing their CGD (i.e., all-or-none requirements for use of service or benefits). Informed and meaningful consumer consent for CGD use is critical to promoting the principle to respect autonomy; we discuss this further in our guidelines.



The principle to respect autonomy should also be considered with personalization of services, as personalization may create restricted options, wherein an individual's understanding and view of the world and freedom of thought and action are limited and/or defined by algorithmic filtering of information.

Empower Individuals and Communities

The principle to empower individuals and communities maintains that individuals and communities have the knowledge, ability, opportunity, support, and resources necessary to access and influence the systems using CGD or clinical data and its impact on their health care.

Empowerment is critical to improving health outcomes, including equity, quality of life, morbidity, and mortality. Empowerment not only encompasses an individual's or community's self-esteem, self-efficacy, and/or strength to achieve their definition of optimal health—more significantly, empowerment is the opposite of powerlessness. Our principle acknowledges that the health of individuals and communities is not determined in a vacuum. Health is influenced by socioeconomic and political forces and how the health care system uses data to make decisions affecting individual or community health. Thus, empowerment of individuals and communities depends on more than just individual or community change. Decision makers must implement system changes to share and/or give up power so that individuals



and communities have the opportunity to enhance and/or maintain their health. While organizations may be reluctant to share decision-making authority with consumers, balancing power between organizations and consumers may promote shared accountability and facilitate increased consumer engagement and trust with regard to CGD data use.

Many different mechanisms can facilitate individual and community empowerment. Inclusive participation and engagement are one mechanism whereby individuals,

especially those from underrepresented or vulnerable populations, are included, take action, and/or invest in activities and decision making about policies governing data use that affect them. Another empowerment-facilitating mechanism is health literacy promotion, whereby individuals have the capacity to meaningfully understand different types of CGD, the processes by which it is used to make decisions about their health, the potential impact of its use on their health, and the skills and knowledge to make decisions regarding CGD use in health care. Individuals and communities may also consider developing partnerships with advocacy organizations—formal and informal, internal and external—that help stakeholders understand and influence the forces, decisions, and actions impacting CGD use in health care. Empowerment may manifest differently for each individual or community. Organizations should understand what role individuals and communities want to play with regard to CGD use in health care and meaningfully respond to their needs and preferences. Organizations must also have processes that enable consumers to effectively influence systems using CGD in the context of their health.

A Note About Organization Empowerment—While our principle to empower individuals and communities is defined and is predominantly intended to represent the perspective of consumers/patients and communities, we acknowledge the importance of empowering individuals within the health care organizational context as well. Clinical and non-clinical end users must have the knowledge, ability, and resources to understand CGD use, and other IT processes, to meet their professional responsibilities in the job context, clinical or otherwise. They should be empowered to know and understand the strengths and weaknesses of the systems they use, and to ask questions where they lack knowledge. Managers, system developers, and data scientists should be empowered to understand the issues in their systems, and qualities of data sets they use, and they should be given the tools to better understand the shortcomings of the data where they exist.

Ensure Accountability

The principle to ensure accountability requires that organizations or individuals be answerable for their actions and decisions with regard to CGD use. Answerability does not presuppose that organizations or individuals are either blameworthy or praiseworthy for their actions or decisions, but rather that they are expected to be prepared to:

1. Provide an explanation for actions and decisions involving or affecting individuals
2. Justify actions and decisions
3. Accept responsibility for actions and decisions
4. Respond to and/or provide redress for any harms resulting from actions and decisions, impose sanctions on identifiable wrongdoers, and/or adjust standards and procedures to improve future actions and decisions based on the knowledge and insights gained from their assessment of outcomes

The purpose of the principle to ensure accountability is to promote trust and understanding, rather than solely to impose liability or penalty in the legal context. Accountability is required regardless of whether a decision process is human or automated.

Accountability and CGD Use for Algorithms/Algorithmic–Decision Making—CGD, and other big data, increasingly is being used in algorithms derived from machine learning and other AI techniques to augment human decision making; thus, we believe it is important to briefly discuss algorithm accountability in the context of our principle.

With regard to algorithm accountability, an organization's explanation for actions and decisions involving or affecting individuals may include explaining how an algorithm works (explainability) and/or documentation or assessment of the use of decision-making protocols for procedural regularity.⁴² Organizations should be prepared to explain and justify their actions and decisions

at several phases in the decision-making process. These decision-making phases include (1) the acquisition (or collection) and aggregation of CGD; (2) CGD analysis and use for model development; and (3) model use, including why a model is applied and its impact after implementation.⁴³

While algorithm transparency (disclosing the source code, inputs, and outputs) may be one mechanism to promote algorithm explainability, and in turn accountability, in many instances it is neither practicable nor feasible. Transparency is neither necessary nor sufficient to ensure accountability. Accountability requires that individuals be able to make sense of an output, even with incomplete information, so that they can understand what the output means

Organizations should be prepared to explain and justify their actions and decisions at several phases in the decision-making process.

for them. Additionally, organizations should implement rigorous technical and procedural mechanisms to ensure that algorithms are working as intended; this assessment should consider human-machine interaction (i.e., an algorithm may accurately provide an output to facilitate an outcome, but once humans begin to interpret and use the output, a different outcome may result than was anticipated). Organizations must ensure that the algorithm use and performance is in accordance with organizational goals and values.



Organization and Individual Accountability—All systems have the potential to harm individuals or groups. Design and implementation flaws often have their origins among multiple individuals, or even multiple organizations. With regard to accepting responsibility, sole responsibility does not adhere to a particular agent (clinician, developer, chief executive officer, etc.). Multiple individuals (or in some cases external organizations/vendors) may be involved in the decision to use CGD and/or involved in the design, development, and implementation of algorithms using CGD. As such, all agents are responsible for their own actions and decisions in light of their general awareness that their actions and decisions have the potential for downstream effects on individuals and populations. However, the extent to which agents are subject to praise, blame, or sanctions for their decisions may vary based on (1) whether they met the functional and moral obligations of their organizational role; and (2) the degree of harm they caused to individuals and/or populations.

Finally, organizations should establish and foster a culture of accountability, such that all decision makers are aware of the expectation that they are answerable for their actions and decisions.⁴⁴ This culture of accountability should promote system accountability to cultivate a supportive environment wherein individuals involved in the data-algorithm-model pipeline are motivated to report and discuss errors to address root causes and develop effective solutions. However, organizations also must develop accountability policies and standards for all individuals involved in CGD use and its associated algorithms, wherein certain standards for individuals are inviolable, and all individuals who violate those standards are held accountable. We refer readers to the guidelines for considerations about how to foster a culture of ethics and accountability.

Promote Transparency

The principle to promote transparency requires that organizations and individuals operate so that it is easy for others (either internal or external to the organization) to see what actions they perform. We define transparency as “the perceived quality of intentionally shared information from a sender.”⁴⁵ Whereas accountability is about “answerability,” transparency is about “visibility,” in which the actions of—or information from—an organization are perceived as visible. Decision-making policies and procedures ought to be visible and designed to uphold an organization’s values. Organizations and individuals have an obligation to openly communicate information to stakeholders in an accessible and easy-to-understand format. Additionally, organizations should make clear the processes in place for stakeholders to receive further information upon request.

With regard to organizations’ use of CGD, promoting transparency requires that both internal and external stakeholders have access to information about how and why an organization uses CGD, and resources to help them understand how the use of CGD might affect decisions or outcomes. This may include, but is not limited to, information about the details on which a decision using CGD is based (e.g., who made the decision, what procedures/processes were applied, what data was used, what was the data quality), or information about the outputs/consequences of CGD use (e.g., errors, outcomes, biases⁴⁶).

Transparency does not require organizations to share all information with all stakeholders, but rather that they restrict information (only when necessary) by considering the following: (1) cost, risk, and benefits of transparency; (2) governance and oversight responsibilities; and (3) options to help stakeholders understand a process, outcome, or decision, and how it is meaningful to them, even when it is based on proprietary information. Promoting transparency is critical to promoting and preserving the values and principles of the Framework.

**Promoting
transparency requires
that both internal and
external stakeholders
have access to
information about
how and why an
organization uses CGD.**

Promote Personal Data Protection

For purposes of our ethical Framework, data protection limits use of personal data only for the purposes and in the manner agreed upon from the perspective of the individual who supplied the data (i.e., the data subject). The principle to promote data protection necessitates that any CGD user, keeper, or processor should not share or use CGD in a manner not authorized or for purposes not reasonably foreseeable by the data subject. CGD use should be consistent with the organization’s obligations and promises to the data subject. However, the expectation that

an individual's personal data will be protected is not absolute, but must be balanced against other societal values, principles, or expectations with regard to health care (e.g., balancing individual health versus public health).⁴⁷

Promote Data Security

For purposes of our ethical Framework, data security is the obligation of the keeper or processor of information to keep that information secure. The principle to preserve data security requires any CGD user, keeper, or processor to take active steps to implement technical and procedural security measures to keep data safe from unauthorized access or breach, both internal and external to the entity keeping the information. If the user, keeper, or processor of the CGD hires a third party to maintain the data, the obligation to ensure the data is secure extends to the third party.

SECTION 7

GUIDELINES



SECTION 7

GUIDELINES

The guidelines in this section are derived from our values and principles and are intended to provide more granular guidance regarding CGD use to three organizational decision makers: (1) executives (senior leaders, managers, and policymakers); (2) data teams; and (3) clinical and non-clinical end users.

Executives refers to anyone involved in the decision-making process to acquire and use CGD; this includes individuals involved in selection of external vendors who process and analyze CGD on the organization's behalf. Data teams include anyone responsible for strategic and technical decisions and oversight regarding the use of CGD, including the analysis, design, development, implementation, and evaluation of machine learning algorithms; this may include data scientists, developers, privacy and security experts, or analytics strategic advisors. Clinical and non-clinical end users include individuals who use or apply the analytics outputs in the context of a consumer/patient interaction.

Organizations vary in their organizational structure; therefore, we leave it to the organization's discretion to determine the appropriate categorization of each decision maker.

We note that the guidelines:

1. **Are not intended to be exhaustive**—Organizations may develop supplemental guidelines based on implementation experience and specific contextual needs. We focus on areas where CGD usage may require customized consideration when compared to clinical data usage; however, we encourage organizations to create a governance environment that applies to all sorts of data.
2. **Are intended to provide some granular guidance** regarding the use of machine learning to extract analytics insights from CGD and other data.
3. **Are intended to be dynamic**—Organizations may update and customize the guidelines based on implementation experience and specific contextual needs. Framework outcomes should be evaluated regularly, and guidelines should be revised when it is clear, based on implementation experience, that modified guidelines might reduce decision regret.
4. **Do not replace general privacy and security best practices and standards.**
5. **Do not invalidate or supplant regulatory compliance procedures already in place.**

We acknowledge that organizations may be at different maturity levels with regard to CGD use and/or may have limitations (cost, structural, etc.) that prevent immediate implementation of recommended actions in the guidelines. Organizations should pursue staged implementation of the Framework by assessing organizational gaps, assets, needs, and opportunities for implementation. Additionally, we encourage early consumer engagement to guide organizations in identifying and prioritizing actions that would be most meaningful to consumers.

The three tables below display (1) the guidelines; (2) questions and considerations that may inform application of the guidelines; (3) the area of focus, which identifies at what point during the decision-making process (Strategic Planning & Governance, Analysis, Design & Development, Implementation, or Monitoring & Evaluation) a decision maker should apply the guideline; and (4) the aligned decision maker column, which identifies whether a particular guideline applies to more than one decision-making agent. Table 1 (blue) reflects guidelines for organizational senior leadership, managers, and policymakers (SL). Table 2 (green) reflects guidelines for data teams (DT). Table 3 (orange) reflects guidelines for clinical and non-clinical end users (EU).

For each guideline, we note the **strongly** aligned values and principles using the abbreviations noted below.

Values	Principles
· Distributive Justice (J)	· Consider Fairness (FA)
· Health (H)	· Consider Individual and Population Health (IP)
· Individual Self-Determination (S)	· Respect Autonomy (AU)
· Privacy (P)	· Empower Individuals and Communities (EM)
· Trustworthiness (T)	· Ensure Accountability (AC)
	· Promote Transparency (TR)
	· Promote Data Protection (DP)
	· Promote Data Security (DS)

In the future, we plan to develop a web application to promote usability of the framework, including an interface for agents to review and apply the guidelines as they engage in decision making.

Table 1. Guidelines for Organizations, Senior Leaders, Managers, and/or Policymakers

Guidelines	Questions/Considerations	Area(s) of Focus	Aligned Decision Maker
<p>The organization should assess whether the intended purpose, goals, and expected outcomes of CGD acquisition and use, for each specified purpose, align with:</p> <p>Framework core ethical values and principles</p> <p>Organizational values, mission, and vision.</p> <p>All values & principles</p>	<p>Does CGD acquisition and use conflict with Framework core ethical values?</p> <p>Does CGD acquisition and use conflict with your organizational values, mission, and vision?</p> <p>Do any conflicts exist between principles? If yes, consider how to balance conflicts.</p>	Strategic Planning & Governance	DT
<p>The organization should assess and document the specific intended purpose(s) for acquisition (or collection) or use of each type of CGD (e.g., social media data, loyalty card data etc.).</p> <p>H, T, AC, TR</p>	<p>Are there specific purposes for which you will not acquire or use CGD? Specifically, what are your organizational “hard stops” with regards to CGD?</p> <p>How will you justify pursuing CGD acquisition and use if unable to articulate the purpose?</p> <p>Is the purpose specified in as narrow terms as practicable (e.g., use to develop tailored interventions to reduce readmission)?</p>	Strategic Planning & Governance	DT
<p>The organization should assess the risks, costs, and benefits of CGD acquisition and use, including who might benefit and who might be harmed, particularly among the least well-off.</p> <p>J, H, TR, FA, IP, AC</p>	<p>Who benefits from CGD use?</p> <p>What is the value proposition (costs/benefits/risks) for the organization, patients/consumers, and other relevant stakeholders?</p> <p>Can you justify the value proposition, particularly for vulnerable or least well-off groups?</p> <p>Do those who potentially suffer harms or risks also receive benefits?</p> <p>Will the organization be the only one to benefit from CGD use?</p> <p>What are the privacy impacts of CGD use?</p> <p>What is the error tolerance based on the intended CGD use (e.g., marketing vs resource allocation)?</p>	Strategic Planning & Governance	DT
<p>The organization should assess consumer/patient attitudes regarding CGD use (type of CGD and purpose).</p> <p>S, EM, DP</p>	<p>How will you engage patients and other stakeholders in the decision-making process regarding the use of CGD?</p> <p>Will you conduct a patient/consumer survey or environmental scan to understand general attitudes regarding CGD use (type and purpose)?</p>	Strategic Planning & Governance	DT
<p>The organization should discuss and document the terms of disclosure for CGD acquired and/or collected for health care purposes.</p> <p>P, T, AC, TR, DS, DP</p>	<p>Under what circumstances will you redisclose CGD acquired or collected for health care purposes?</p> <p>To whom and/or for what purpose will you redisclose CGD?</p>	Strategic Planning & Governance	DT

Table 1. Guidelines for Organizations, Senior Leaders, Managers, and/or Policymakers (continued)

Guidelines	Questions/Considerations	Area(s) of Focus	Aligned Decision Maker
<p>The organization should obtain meaningful consent for CGD use from all consumers/patients.</p> <p>S, P, AU, EM, DP</p>	<p>How will you work with consumers and/or their advocates to define what meaningful CGD consent means to them?</p> <p>Will consent be obtained for a specific purpose rather than broadly (e.g., marketing)?</p> <p>Will consent be opt-in rather than opt-out? (Consent preferentially should be opt-in rather than opt-out).</p> <p>What will be included in your consent materials?</p> <p>Consider including the following: the type of CGD; purpose(s); conditions of use; access, retention, storage, and disposal policies and standards; and terms of disclosure.</p> <p>How will consent be obtained in an accessible format that takes into consideration the technical and health literacy needs of the population?</p> <p>Will you work with health communication, marketing, usability experts, and consumers to develop materials to supplement formal notice and consent policies to promote meaningful consent?</p>	<p>Strategic Planning & Governance</p>	<p>DT</p>
<p>The organization should ensure consumers/patients have the opportunity to opt-out of CGD use in the context of their health care, to the extent feasible.</p> <p>S, P, AU, EM, DP</p>	<p>Will consumers/patients be able to opt-out of CGD use for a specific context (e.g., marketing)?</p> <p>For health providers, is it implied that consent is a condition for receiving medical treatment? (Consent should not be a condition for receiving medical treatment).</p>	<p>Strategic Planning & Governance</p>	<p>DT</p>
<p>For consumer segmentation, consumers/patients should have an opportunity to review the data segment/category of which they are members, that was informed by their CGD.</p> <p>S, P, AU, EM, DP</p>	<p>Will your organization maintain descriptions for each data segment/category?</p> <p>Will consumers/patients have a means to access their categorization(s)?</p> <p>Will consumers/patients have a means to contest their categorization(s)?</p>	<p>Strategic Planning & Governance</p>	<p>DT</p>
<p>The organization should ensure consumers/patients or their advocates have the opportunity (to the extent feasible) to access a full file disclosure, and/or file description, which contains details about how the organization is using their CGD.</p> <p>S, P, AU, EM, DP</p>	<p>Will your organization make a file disclosure, or description, available to consumers containing their personal information?</p> <p>Will your organization make an aggregate file disclosure, or description, available to advocates for purposes of analysis or audit?</p> <p>What will be your organization's process for updating the file description based on CGD application deployment?</p> <p>What will be the standardized process for consumers/ patients or their advocates to obtain their full file disclosure or file description?</p>	<p>Strategic Planning & Governance</p>	<p>DT</p>

Table 1. Guidelines for Organizations, Senior Leaders, Managers, and/or Policymakers (continued)

Guidelines	Questions/Considerations	Area(s) of Focus	Aligned Decision Maker
<p>If CGD is acquired from a third party, the organization should review the third party's notice and consent standards for data collection.</p> <p>P, T, DP, DS</p>		Strategic Planning & Governance	
<p>If CGD is acquired from a third party, the organization should adhere to the conditions, under which the third-party acquired the data, and restrictions imposed by the third-party.</p> <p>P, T, DP, DS</p>	Will compliance be automated, if possible?	Strategic Planning & Governance	
<p>If data-intensive, CGD-based services are performed by a third party, the organization should complete the following activities to assure they are consistent with organizational standards:</p> <p>Request and review third-party data collection/ acquisition, access, retention, storage, and disposal policies and standards;</p> <p>Request and review data quality standards;</p> <p>Request and review vendor ethics, integrity, and internal oversight governance.</p> <p>P, T, DP, DS</p>	<p>Did you assess the potential impact/liability involved in the contractual arrangement under two scenarios: (1) the third party meets all contractual obligations with regards to CGD use; and (2) they do not?</p> <p>Did you assess the potential impact/liability in the event the third-party will not, or does not provide sufficient information for review?</p> <p>Did you consider liability risk in the context of error tolerance for the intended CGD use (e.g., marketing vs resource allocation)?</p> <p>How will your liability assessment inform the acquisition of services?</p>	Strategic Planning & Governance	
<p>The organization should ensure that CGD storage and data security adhere to standard data protection requirements and best practices recognized by industry, based on the sensitivity of the data, consistent with the existing statutory and regulatory framework.</p> <p>P, T, DP, DS</p>		Strategic Planning & Governance	
<p>The organization should ensure that governance structures are in place to provide oversight regarding adherence to CGD (and other data) process and documentation requirements or standards.</p> <p>P, T, AC, TR, DS</p>	<p>Does the organization's current governance structure achieve its intended aims and provide value?</p> <ul style="list-style-type: none"> • Consider what benefits the current data governance structure provides to data scientists, developers, and implementers. • Consider what additional supports/changes are needed to provide value. 	Strategic Planning & Governance	DT

Table 1. Guidelines for Organizations, Senior Leaders, Managers, and/or Policymakers (continued)

Guidelines	Questions/Considerations	Area(s) of Focus	Aligned Decision Maker
<p>The organization should identify and be aware of where CGD is used in the organization and promote use of appropriate controls on each usage.</p> <p>P, T, AC, TR, DS</p>	<p>What enabling controls are needed?</p> <p>What enforcement or accountability controls are needed?</p> <p>Are controls implemented and executed?</p>	<p>Strategic Planning & Governance</p>	<p>DT</p>
<p>The organization should identify the department(s) and/or person(s) directly responsible for CGD-based analytics, including predictive modeling, machine learning, and other AI within the organization.</p> <p>T, AC, TR</p>	<p>How will the department(s) or person(s) promote good practices to ALL groups that need them?</p> <p>How will the department(s) or person(s) promote transparency?</p> <p>What mechanisms need to be in place to hold the department(s) or person(s) accountable?</p>	<p>Strategic Planning & Governance</p>	<p>DT</p>
<p>The organization should foster a culture of data ethics.</p> <p>T, AC, TR</p>	<p>What cultural changes are needed to foster a culture of ethics?</p> <ul style="list-style-type: none"> • Consider data ethics and integrity training. • Consider regular data ethics roundtables (or grand rounds) to address issues surrounding CGD (or other data use), machine learning implemented within the organization, and/or vulnerabilities of decision making surrounding application of outputs. 	<p>Strategic Planning & Governance</p>	<p>DT</p>
<p>The organization should ensure ethics expertise is available within the organization, to provide support to staff in aligning their technical choices with ethical decisions, for issues surrounding CGD-based analytics, machine learning, and other AI.</p> <p>T, AC, TR</p>	<p>What ethics expertise is available within the organization?</p> <ul style="list-style-type: none"> • Consider contracting with external experts if expertise is not available within the organization. This may include collaboration with ethics consensus groups, centers, or organizations. 	<p>Strategic Planning & Governance</p>	
<p>The organization should establish an organizational resource for patients/ consumers and their advocates, or relevant stakeholders, to ask questions about CGD-based analytics, machine learning applications, and other AI, so that end users are not tasked with explaining technical nuances.</p> <p>S, T, EM, AC, TR</p>		<p>Strategic Planning & Governance</p>	<p>EU</p>

Table 1. Guidelines for Organizations, Senior Leaders, Managers, and/or Policymakers (continued)

Guidelines	Questions/Considerations	Area(s) of Focus	Aligned Decision Maker
<p>The organization should ensure there is a formal process for patients/ consumers and/or their advocates to report concerns and/or seek redress for harms resulting from CGD data use, machine learning, or other AI applications.</p> <p>S, T, EM, AC, TR</p>	<p>What will be your process for monitoring/identifying problems?</p> <p>How will you respond to problem reports and implement changes, as appropriate?</p> <p>Will you allow an external party to audit your use of CGD, machine learning, and/or AI applications?</p>	<p>Strategic Planning & Governance</p>	
<p>The organization should ensure that all end users of CGD-based analytic and machine learning applications understand how to interpret and apply their outputs, including general limitations, errors and biases, for important decisions or allocation of resources.</p> <p>T, AC, TR</p>	<p>What will be your process for assessing end users understanding, application, and/or knowledge?</p> <ul style="list-style-type: none"> • Consider training, human-computer interaction assessment, or knowledge checks. <p>How will the organization re-evaluate the application of machine learning and AI as they become more advanced and are able to outperform humans in certain contexts?</p>	<p>Strategic Planning & Governance</p>	<p>EU</p>
<p>When designing CGD-based applications, especially machine learning applications, the organization should ensure that diverse viewpoints are heard, both across the organization and from patients/ consumers.</p> <p>T, AC</p>	<p>To ensure representation of diverse viewpoints, both across the organization and from patients/ consumers, did you pursue the following, as appropriate?:</p> <ul style="list-style-type: none"> • Use modern development processes (e.g., agile development) that seek early and frequent feedback from users, patient/consumer groups, or their advocates • Seek feedback from diverse groups of patient/consumers, as appropriate, based on sociocultural and demographic factors such, as age, race, gender, sexual orientation, income literacy, cognitive ability, technophobia, language proficiency, etc. (Ensure that vulnerable and/or disadvantaged groups are represented) • Assess third-party vendor processes for ensuring that diverse viewpoints are heard • Increase the recruitment and retention of diverse staff who can provide technical expertise • Establish a team of additional domain experts from other areas within the organization to provide strategic advice and guidance to data teams and increase diversity of thought (e.g., legal, public relations, clinical, etc.) 	<p>Strategic Planning & Governance</p>	<p>DT</p>

Table 1. Guidelines for Organizations, Senior Leaders, Managers, and/or Policymakers (concluded)

Guidelines	Questions/Considerations	Area(s) of Focus	Aligned Decision Maker
<p>The organization should consider the sensitivity and importance of the intended CGD-based application output to individuals and populations.</p> <p>S, AU, EM</p>	<p>Will you engage stakeholders in assessing the sensitivity and importance of the intended application output?</p> <p>For the most sensitive and important uses, how will you increase efforts to obtain diverse viewpoints?</p>	<p>Strategic Planning & Governance</p>	
<p>The organization should ensure that a mechanism exists for data teams and end users to provide feedback and report ethics concerns and safety events resulting from the design, development, and application of machine learning models and/or other AI. The process should ensure there is no threat of retaliatory action.</p> <p>T, AC, TR</p>	<p>What is your plan and standardized process to meaningfully respond to data team and end user concerns?</p> <p>Do the individuals responsible for the review of ethics or safety concerns involving CGD-based analytics, machine learning, or other AI have the appropriate health domain and technical expertise? If no, how will you obtain this expertise?</p>	<p>Strategic Planning & Governance</p>	<p>DT, EU</p>

Table 2. Guidelines for Data Teams

Guidelines	Questions/Considerations	Area(s) of Focus	Aligned Decision Maker
<p>Data teams should ensure CGD storage and data security adhere to standard data protection and security requirements and best practices recognized by industry, based on the sensitivity of the data, consistent with the existing statutory and regulatory framework.</p> <p>P, T, DP, DS</p>	<p>What is the sensitivity of the CGD?</p> <p>Will CGD be identified/de-identified?</p> <p>How will you balance individual privacy concerns with the need to link data across sources, to derive a complete picture of the patient/consumer?</p> <p>How will you balance individual privacy concerns with the need for individual demographic data to avoid harmful biases?</p>	<p>Strategic Planning & Governance</p>	<p>SL</p>
<p>Data teams in collaboration with organizational leadership, should assess what type(s) of CGD (e.g., social media data, internet browsing history, etc.) should be used for each specified purpose.</p> <p>J, H, S, P, FA, IP, AU</p>	<p>Are there certain types of CGD that should not be used for specified purposes? Specifically, are you aware of your organization's "hard stops" with regards to CGD use?</p> <p>What is the sensitivity and/or importance of the specific CGD to consumer/patients and populations?</p> <p>Is CGD really necessary, e.g., makes a significant difference?</p>	<p>Analysis, Design & Development</p>	<p>SL</p>
<p>Data teams in collaboration with organizational leadership, should assess and document how they will use (e.g., analyze, apply, examine) CGD for each specified purpose (i.e. the conditions of use).</p> <p>J, H, S, P, FA, IP, AU</p>	<p>Will the data be:</p> <ul style="list-style-type: none"> • Used at the individual level? • Used at the population level? • Integrated with clinical data? • Used for adults or minors? 	<p>Analysis, Design & Development</p>	<p>SL</p>
<p>Data teams should identify data quality metrics and rules consistent with industry standards and best practices for the specified purposes, context, and intended application when assessing and describing the quality of CGD.</p> <p>P, T, AC</p>	<p>At a minimum, what is the accuracy, validity, completeness, consistency, timeliness, and uniqueness of the CGD?</p>	<p>Analysis, Design & Development</p>	
<p>Data teams should establish a formal strategy and process for identifying and addressing biases within CGD (and other data), especially in the results from the use the data.</p> <p>J, T, FA, AC, TR</p>		<p>Analysis, Design & Development</p>	

Table 2. Guidelines for Data Teams (continued)

Guidelines	Questions/Considerations	Area(s) of Focus	Aligned Decision Maker
<p>Data teams should document the following for each data set used in machine learning:</p> <ol style="list-style-type: none"> 1. Data quality 2. Biases observed in the data and the results 3. The strategy/steps to address those biases 4. Processing assumptions, inclusions, and exclusions <p>J, T, FA, AC, TR</p>		Analysis, Design & Development	
<p>Data teams should try to understand the qualities of training data and algorithms used for machine learning models and compare these with the robustness requirements of the application. The data team should at minimum complete the following activities:</p> <ol style="list-style-type: none"> 1. Test rigorously, consistent with industry best practices and standards, based on the intended use and impact 2. Identify and document performance metrics for monitoring and evaluation, informed by organization risk tolerance 3. Develop a plan or rules to address the discovery of secondary findings and insights that may result from model application/ implementation <p>H, P, T, FA, IP, AC, TR</p>		Analysis, Design & Development	
<p>Data teams, in collaboration with organizational leadership, should develop a strategy and plan to monitor and track outcomes for each specified machine learning application.</p> <p>H, P, T, FA, IP, AC, TR</p>	<p>What is your process for lifecycle performance review for each specified machine learning application?</p> <p>Does the scheduled frequency of lifecycle performance review align with the sensitivity of the outcome and/or importance of the outcome to individuals and populations?</p> <p>How will you monitor machine learning applications for accuracy and consistency in accordance with the definitions of fairness?</p> <p>What is your process to alert appropriate parties if there are serious problems?</p>	Analysis, Design & Development	SL

Table 2. Guidelines for Data Teams (continued)

Guidelines	Questions/Considerations	Area(s) of Focus	Aligned Decision Maker
<p>Data teams, in collaboration with organizational leadership, should define fairness for the specific CGD-based application, especially for outputs of machine learning or other AI.</p> <p>J, H, FA, IP</p>	<p>Is your definition of fairness informed only by mathematical definitions or does it also consider the following?:</p> <ul style="list-style-type: none"> • What data is fair to use, and what capabilities are fair to invest in • Alignment with core ethical values, specifically distributive justice • Expectation for use of the specified application, including sensitivity and impact • Trade-offs, including advantages and disadvantages • Stakeholder assessment, engagement, and impact • Guidance from domain experts and/or the existing evidence • Existing statutory and regulatory framework • Allocative as well as representative harms in the system 	<p>Analysis, Design & Development</p>	<p>SL</p>
<p>Data teams, in collaboration with organizational leadership, should consider fairness implications throughout model development.</p> <p>J, H, FA, IP</p>	<p>What changes in the workflow are needed to incorporate fairness considerations throughout development?</p> <p>What is the representativeness of your data set(s)?</p> <p>Are there opportunities for a more representative data set(s)?</p> <p>Should this data be used based on the representativeness of the data set?</p> <p>Are there opportunities to work with the data collector to improve future data collection for use?</p> <p>In designing the test set, what fairness issues should the design team be aware of?</p> <p>What subpopulations should be considered based on the problem definition and intended application?</p> <p>Is individual demographic data needed or available?</p> <p>What steps should be taken if individual identified demographic data is not available?</p>	<p>Analysis, Design & Development</p> <p>Monitoring & Evaluation</p>	<p>SL</p>
<p>Over the course of the lifecycle, data teams, in collaboration with organizational leadership, should monitor all machine learning and AI applications to ensure they achieve what they purport to do. The frequency of evaluation should be determined based on the sensitivity of the outcome.</p> <p>J, H, T FA, IP, AC</p>	<p>What is the performance on threshold/confidence metrics?</p> <p>Is there reproducibility and consistent application by end users?</p> <p>What harm(s), if any, result from implementation?</p> <p>Are additional risk mitigation controls (e.g., outlier detection, automated alerting) needed?</p>	<p>Monitoring & Evaluation</p>	

Table 2. Guidelines for Data Teams (concluded)

Guidelines	Questions/Considerations	Area(s) of Focus	Aligned Decision Maker
<p>Over the course of the lifecycle, data teams should monitor all CGD-based algorithms, machine learning models, and other AI for differential impact based on definitions of fairness.</p> <p>J, H, FA, IP</p>	<p>Does the definition of fairness need to change based on observed outcomes post-implementation?</p> <p>What is the impact of observed outcomes on health disparities and health equity?</p>	<p>Monitoring & Evaluation</p>	
<p>Data teams should maintain a description, searchable and browsable by all relevant staff, of all machine learning and AI applications, with lifecycle documentation for those impacting important decisions.</p> <p>T, AC, TR</p>	<p>Will each model have a full description, with pertinent lifecycle and application information, rather than simply a label?</p> <p>Will your lifecycle documentation description include the following?:</p> <ul style="list-style-type: none"> • Purpose of the machine learning or other AI application • Date of introduction • Date(s) of update • Data sets • Data sources • Evaluation metrics • Evaluation date(s) • Biases • Monitoring and risk mitigations that are in place • Observed outcomes from implementation and improvements • Algorithms and/or training data descriptions 	<p>Monitoring & Evaluation</p>	<p>SL</p>

Table 3. Guidelines for End Users

Guidelines	Questions/Considerations	Area(s) of Focus	Aligned Decision Maker
<p>End users, in collaboration with organizational leadership, should specifically address autonomy and the use of professional judgment to make decisions when applying analytic outputs (especially machine learning outputs) in their specific context.</p> <p>H, S, IP, AU, AC</p>	<p>In what situations is it appropriate for end users to override recommendations from application outputs?</p> <p>How will adherence or non-adherence to recommended decisions or actions from applications affect organizational performance evaluation of end users?</p>	Implementation	SL
<p>End users should be able to provide feedback and report ethics concerns and safety events resulting from the application and use of analytic outputs without the threat of retaliatory action.</p> <p>T, AC</p>		Implementation	SL

APPENDIX A

REPRESENTATIVE PREVAILING
ELEMENTS OF EXISTING ETHICAL
FRAMEWORKS IN MEDICAL ETHICS,
PUBLIC HEALTH ETHICS, DATA ETHICS,
AI, AND ORGANIZATIONAL ETHICS

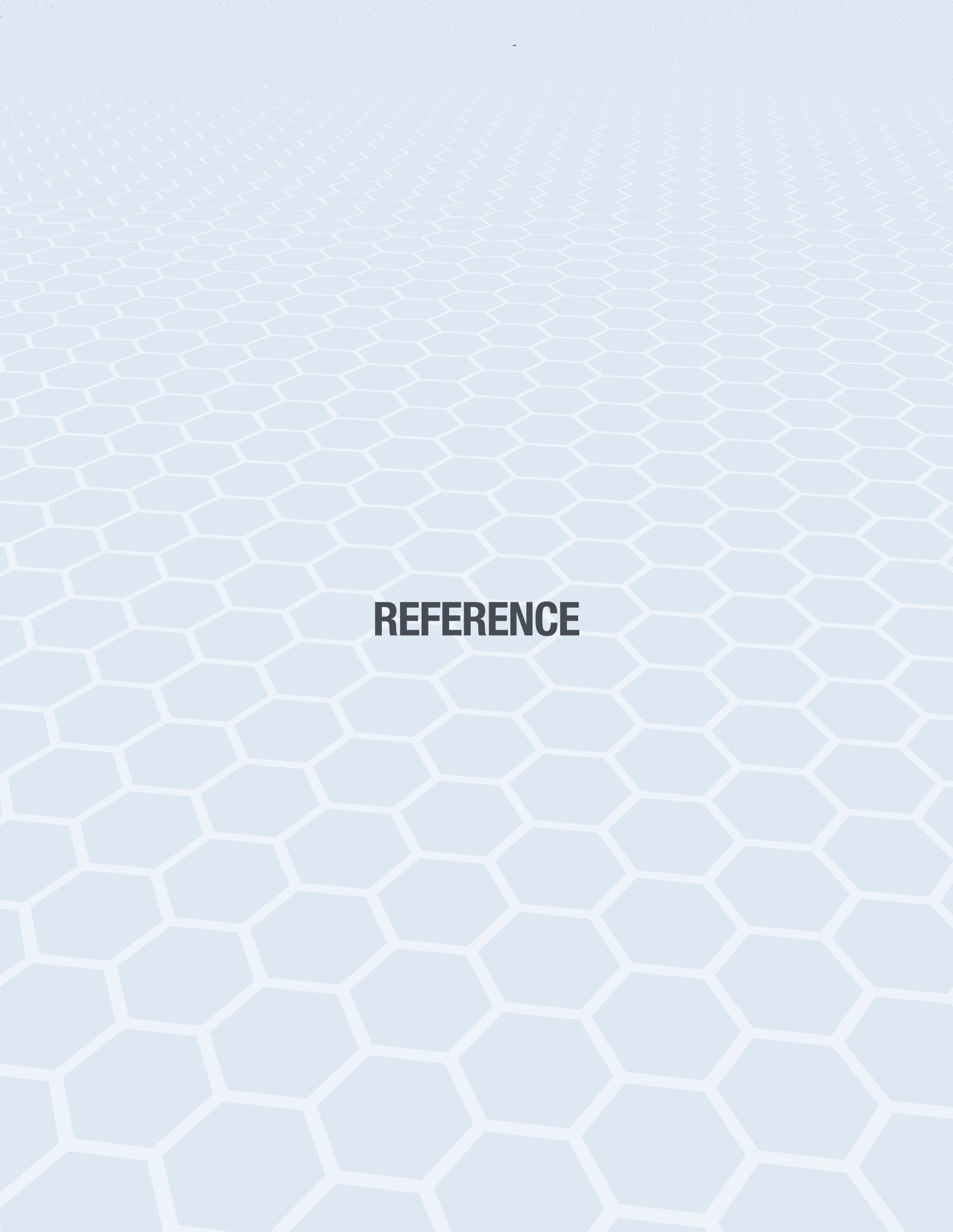


APPENDIX A

Representative Prevailing Elements of Existing Ethical Frameworks in Medical Ethics, Public Health Ethics, Data Ethics, AI, and Organizational Ethics

Daniels ⁵⁸	Kass ⁵⁹	Childress ⁶⁰	Public Health Leadership Society ⁶¹	Singer ⁶²
<ol style="list-style-type: none"> 1. Accountability 2. Inclusiveness 3. Openness and transparency 4. Reasonableness 5. Responsiveness 	<ol style="list-style-type: none"> 1. Well-being 2. Privacy and confidentiality 3. Liberty and self-determination 4. Distributive justice 5. Procedural justice 	<ol style="list-style-type: none"> 1. Well-being 2. Utility 3. Distributive justice and fairness 4. Procedural justice and participation 5. Liberty and autonomy 6. Privacy and confidentiality 7. Trustworthiness 8. Transparency and openness 	<ol style="list-style-type: none"> 1. Well-being 2. Individual rights 3. Participation 4. Empowerment 5. Equality 6. Evidence based 7. Transparency 8. Effectiveness 9. Consent 10. Swiftswness 11. Cultural value pluralism 12. Respect for environment 13. Confidentiality and privacy 14. Professionalism 15. Trustworthiness 	<ol style="list-style-type: none"> 1. Individual liberty 2. Protection of the public from harm 3. Proportionality 4. Reciprocity 5. Transparency 6. Privacy 7. Protection of communities from undue stigmatization 8. Duty to provide care 9. Equity 10. Solidarity
Nuffield ⁶³	Tannahill ⁶⁴	Carter ⁶⁵		EuroPHEN ⁶⁶
<ol style="list-style-type: none"> 1. Well-being 2. Care of the vulnerable 3. Empowerment 4. Autonomy 5. Fairness and equality 6. Liberty and self-determination 7. Openness 8. Privacy 	<ol style="list-style-type: none"> 1. Well-being 2. Equity 3. Respect 4. Empowerment 5. Sustainability 6. Social responsibility 7. Participation 8. Openness. 9. Accountability 	<ol style="list-style-type: none"> 1. Recognize that health promotion thinking must be responsive to particular situations—it cannot be universal. 2. Formally recognize and implement two iterative systems of reasoning, an evidence-based system and an ethical system, each containing explicit values. 3. Clearly specify the evidential and ethical concepts that are valued or devalued in each situation, and the dimensions along which these vary. Use both existing theory and detailed empirical study of the practice of health promotion in the situation. 4. Be specific about trade-offs occurring along the identified dimensions—consider how valued or devalued concepts interact. 5. Prioritize procedural transparency: be certain that processes used for reasoning, defining, and trading off can be explained clearly. 		<ol style="list-style-type: none"> 1. Well-being 2. Empowerment 3. Individual rights 4. Liberty and autonomy 5. Personal responsibility and duties 6. Communitarianism 7. Participation 8. Transparency 9. Accountability 10. Trust 11. Confidentiality and privacy 12. Swiftswness

US ACM⁶⁷	International Accountability Foundation⁶⁸	Fairness, Accountability and Transparency in Machine Learning (FAT/ML)⁶⁹	ASILOMAR⁷⁰	IEEE Ethically Aligned Design, Version 1 and 2⁷¹
<ol style="list-style-type: none"> 1. Awareness 2. Access and redress 3. Accountability 4. Explanation 5. Validation and testing 6. Data provenance 7. Auditability 	<ol style="list-style-type: none"> 1. Beneficial 2. Progressive 3. Sustainable 4. Respectful 5. Fair 	<ol style="list-style-type: none"> 1. Responsibility 2. Explainability 3. Accuracy 4. Auditability 5. Fairness 	<ol style="list-style-type: none"> 1. Safety 2. Failure transparency 3. Judicial transparency 4. Responsibility 5. Value alignment 6. Human values 7. Personal privacy 8. Liberty and privacy 9. Shared benefit 10. Shared prosperity 11. Human control 12. Non-subversion 13. AI arms race 	<ol style="list-style-type: none"> 1. Human benefit (Human rights) 2. Responsibility (Accountability) 3. Transparency 4. Education and awareness 5. Personal data: Individual access and control 6. Well-being
Other general Principles found across the computing and literature		Organizational Ethics in Healthcare Priorities⁷²		
<ol style="list-style-type: none"> 1. Autonomy 2. Privacy 3. Identity 4. Transparency 5. Fairness 6. Trust 7. Accountability 8. Auditability 9. Accuracy 10. Safety 11. Explainability 12. Privacy 13. Personal data control 		<ol style="list-style-type: none"> 1. Patient's health care services 2. Health professionals' expertise 3. Public health 4. Unmet health care needs 5. Advocacy for social policy reform 6. Relationships with clinical staff, management, employees, and affiliated professionals 7. Organizational solvency/ survival 8. Benefit to the community 		



REFERENCE

GLOSSARY

Agent or decision maker

Individuals who are able to act according to reason (deliberate and make decisions) and can be held morally responsible for their actions. For purposes of our Framework, agents include all individuals involved in the use of CGD, including its use in the design, development, implementation, and application of machine learning models for health care purposes. Organizational leadership, data scientists and developers, and clinical end users are considered types of agents or decision makers.

Allocative harms

Harms that occur when a system withholds an economic (or other) opportunity or resource from a person or persons.⁴⁸

Bias

A deviation from a standard, which is inclusive of different types of biases (statistical, emotional, moral, legal etc.), and allows for the same thing to be biased according to one standard (e.g., moral), but not according to another (e.g., legal).⁴⁹

Data broker

A company that collects or buys consumers' personal information and resells or shares that information with others without direct interaction with the consumer.⁵⁰

Data subject

Any individual whose personal data is collected, stored, processed, analyzed, and/or disseminated.

Data user

Any entity that controls, processes, and/or stores personal data.

Decision regret

A complex emotional and cognitive remorseful reaction either to how a decision was made or to the outcomes of a decision.

Essential public health services

Services that advance the public's health including the following: (1) monitoring health status to identify and solve health problems; (2) diagnosing and investigating health problems and health hazards; (3) informing, educating, and empowering people about health issues; (4) mobilizing community partnerships and action to identify and solve health problems; (5) developing policies and plans that support individual and community health efforts; (6) enforcing laws and regulations that protect health and ensure safety; (7) linking people to needed personal health services and assure the provision of health care when otherwise unavailable; (8) assuring a competent public and personal health care workforce; (9) evaluating effectiveness, accessibility, and quality of personal and population-based health services; and (10) researching new insights and innovative solutions to health problems.⁵¹

Ethical theories

Attempt to identify and justify "norms" of moral behavior and provide structure by which to guide and evaluate conduct based on those norms. Distinguishing features of ethical theories include: 1) universalizability; 2) comprehensiveness; and 3) consistency.⁵²

Health care purposes

Refers to diagnosis, prevention, treatment, payment, care operations, health monitoring, population management, and/or the delivery of essential public health services as defined above.

Health equity

All individuals have a fair and just opportunity to be as healthy as possible, which requires removing obstacles to health and reducing or eliminating disparities in health and its determinants that adversely affect excluded or marginalized groups.⁵³

Health literacy

The degree to which individuals have the capacity to obtain, communicate, process, and understand basic health information and services needed to make appropriate health decisions.

Organization

A provider, payer, or health system, and their population management partners, as well as other industry organizations (e.g., technology, social media, or e-commerce companies) engaging in the health care space by providing products or services for health care purposes.

Personal data

Any data relating to an individual for which there is a reasonable basis to believe it can be associated with the individual either directly or indirectly. This includes discovered data and inferences as a result of data aggregation and analysis.

Policymaker(s)

Individuals/groups internal or external to an organization that may work with organizations to create internal organizational policies but may not have the authority of senior leaders or managers within the organization to ensure implementation.

Representative harms

Harms with diffuse long-term effects that occur when a system reinforces the subordination of a group.⁵⁴

Social determinants of health

Conditions in the environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risk. Some of these conditions include availability of resources to meet daily needs (e.g., safe housing and local food markets); access to educational, economic, and job opportunities; access to health care services; quality of education and job training; availability of community-based resources in support of community living and opportunities for recreational and leisure-time activities; transportation options; public safety; social support; social norms and attitudes; exposure to crime, violence, and social disorder; socioeconomic conditions; residential segregation; language/literacy; access to mass media and emerging technologies; and culture.⁵⁵

Structural factors

Include all social and political mechanisms (e.g., institutions, processes) that generate and maintain social hierarchies within society, which influence one's socioeconomic position, and in turn social determinants of health.⁵⁶

Third party

An entity, other than the data subject, which operates under authority of the data user (e.g., service vendors).

Vlog

A video blog, which is a video record of an individual's thoughts, opinions, or experiences that is published on the internet.⁵⁷

FOOTNOTES

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