

Introduction

Algorithm, a word that was mainly used in math class, is now frequently dropped in casual conversation. Often associated with social media feeds, we wonder how "the algorithm" gets us – or doesn't. We know algorithms use data, like search history, internet activity and connections, but the details that follow may be fuzzy. In addition, algorithms often operate in the background of an app or system, which contributes to the mystery of their work.

For algorithms used for social media, the stakes are low – we may or may not buy something based on the results. But what happens when algorithms are incorporated into health care? The stakes are considerably higher, and there is both promise and risk.

Algorithm Use in Health Care

How are algorithms used in health care? Algorithms have a variety of uses in health care. For instance, they have assisted with clinical decision support for decades.¹ Algorithms incorporated into electronic health records (EHRs) also support clinicians by enabling voice-to-text notetaking. In addition, algorithms are used to power apps that provide patients with mental health support, and they can help diagnose and predict the risk of disease.

What are the benefits of using algorithms in health care? Algorithms can save clinicians time, provide a more holistic picture of a patient's health and increase access to care. Risk calculators, a type of algorithm, input data from disease risk factors (such as genetics, environmental exposures or behaviors) to determine if a patient should be tracked more closely for a disease, such as with earlier or more frequent screenings. Actress Olivia Munn benefitted from one of these tools,² which flagged her as a high risk for breast cancer. Additional screenings detected cancer before she had symptoms, enabling quick treatment.

How is data incorporated into an algorithm? Data sets the "rules" of the algorithm, enabling it to deliver general insights, decisions and predictions. For example, health care research has shown certain genes are associated with an increased risk of disease. When developing an algorithm for breast cancer risk, for instance, it makes sense to include information (data)



- What is an algorithm? An algorithm is a process or rule used to solve problems.
- How are algorithms related to artificial intelligence (AI)? Algorithms are foundational to Al systems, helping to structure the logic and data processing of the AI system.
- How are algorithms developed? After identifying a problem to solve, algorithm developers break the problem down into specific steps and use logic and data to solve it.

Assistant Secretary for Technology Policy, Getting the Best out of Algorithms in Health Care. https://www.healthit.gov/buzzblog/electronic-health-and-medical-records/getting-the-best-out-of-algorithms-in-health-care. Last accessed November 21, 2024.

CNN Health, This risk assessment tool helped Olivia Munn discover her breast cancer. https://www.cnn.com/2024/03/13/ health/breast-cancer-risk-assessment-tool/index.html. Last accessed November 21, 2024.

about a patient who has the BRCA gene, as we know it increases the risk of breast cancer. Data helps test and validate the developed algorithm to ensure consistent results.

Where does the foundational data used to build algorithms come from? Depending on what the algorithm is for and who is creating it, the data can come from various places. Large data sets are typically best to increase accuracy and reliability. Examples of large data sets in health care may be those from a clinical trial or from health care vendors (such as EHR vendors or health insurance plans).

How can we be sure the algorithms are correct? In simple terms, algorithms are typically tested repeatedly under different scenarios to ensure they produce the expected outcome – and are considered "validated." However, the depth of that testing can vary due to available data and time. And algorithms sometimes come with caveats for their use. For example, they may be valid only for patients in specific health settings such as patients in hospitals but not nursing homes - or people with certain characteristics. The Gail model³ to assess breast cancer risk, for instance, warns that it cannot accurately assess people with the BRCA gene.

Understanding the details of the algorithm is important, as all are not created equal. For example, a recent Agency for Healthcare Quality and Research (AHRQ) Evidence-Based Practice Center (EPC) review⁴ on the impact of algorithms on racial and ethnic disparities in health care have shown they can have both a positive and negative impact on health.

Although we highlighted the benefits of algorithms to health care, the negative consequences can be severe.

These consequences have been most apparent in the use of common algorithms for measuring the glomerular filtration rate (GFR) to diagnose and treat chronic kidney disease (CKD). Because measuring GFR is "expensive and lengthy," creatinine levels are used to estimate GFR with algorithms CKD-EPI and Modification of Diet in Renal Disease.⁵

These equations incorporate race to estimate GFR and have been shown to be based on "small and flawed studies published between the 1970s and 1990s," where Black men and women showed a higher creatinine excretion rate than White people.6

Incorporating race into these equations has contributed to disparities in the care of kidney disease. Black patients with end-stage renal disease (ESRD), for example, are less likely to be referred for a kidney transplant (the optimal treatment for ESRD) and even when they are on the transplant list, they wait longer than White patients.7

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Adding to this inequity, non-Hispanic Black adults make up 20% of those with kidney disease (White adults represent 12%) and are four times more likely to have kidney failure than White adults.8 CKD is a major public health issue in the United States - it is the eighth leading cause of death and affects about 35.5 million adults.9

National Cancer Institute, Breast Cancer Risk Assessment Tool: Online Calculator (The Gail Model). https://bcrisktool.cancer. gov/. Last accessed November 21, 2024.

Agency for Healthcare Research and Quality, Comparative Effectiveness Review, No. 268: Impact of Healthcare Algorithms on Racial and Ethnic Disparities in Health and Healthcare. https://effectivehealthcare.ahrq.gov/sites/default/files/related_files/cer-268racial-disparities-health-healthcare-addendum.pdf. Last accessed November 21, 2024.

Uppal P, et al. The case against race-based GFR. Delaware Journal of Public Health 2022 Aug 31; 8(3): 86-89. https://pmc. ncbi.nlm.nih.gov/articles/PMC9495470/. Last accessed November 21, 2024.

See Footnote 5.

⁷ See Footnote 5.

National Kidney Foundation, Kidney Disease: Fact Sheet. https://www.kidney.org/about/kidney-disease-fact-sheet. Last accessed November 21, 2024.

See Footnote 8.



What are some considerations when using algorithms in health care? Understanding how an algorithm was developed, how it was tested and what data was used greatly influences its accuracy and usefulness. The authors of the AHRQ EPC review¹⁰ found that original source data was available for "many but not all of the algorithms" studied. Further, a 2023 journal article found that for clinical predictive algorithms, the generalizability of algorithms "often goes untested."11 Academic and federal researchers who develop algorithms often publish articles describing validation methods and data sources for their tools, while for-profit companies may be less transparent about their process to validate proprietary algorithms to protect their work.

What is on the horizon for improving the safety of using algorithms in health care? Thankfully, knowledge of these issues is pushing the U.S. health care system to improve algorithm transparency and quality. For example, many health care organizations and insurers

are removing adjustments for race from algorithms and pushing these changes enterprise wide.

And at the beginning of 2025 a federal "HTI-1 rule"12 took effect to establish the "first of its kind transparency requirements" related to predictive algorithms and AI used in certified health IT products.¹³ This rule will enable clinical users to access a "consistent, baseline set of information about the algorithms they use to support their decision making" and to review algorithms for issues including "fairness, appropriateness, validity, effectiveness and safety."14

While these are significant changes to improve the quality of care, more will need to be done to reverse the negative effects of poorly designed algorithms and ensure equitable treatment of patients. Ensuring patients and physicians are aware of algorithm use and the validity of the algorithm for the patient's individual situation is paramount.

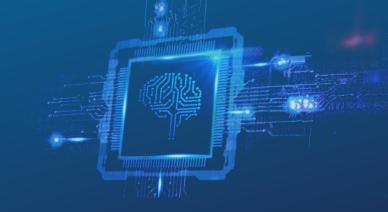
¹⁰ See Footnote 4.

¹¹ De Hond, A., et al. Perspectives on validation of clinical predictive algorithms. NPJ Digit Med 2023 May 6; 6:86. https://pmc. ncbi.nlm.nih.gov/articles/PMC10163568. Last accessed November 21, 2024.

¹² Code of Federal Regulations (CFR) 45 CFR Part 170.402(b)(4). https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/ part-170#p-170.402(b)(4). Last accessed November 21, 2024.

¹³ ASTP. Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule. https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperabilitycertification-program. Last accessed November 21, 2024.

See Footnote 13.



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