



Properly Incentivizing Health Care Innovation & A Case Study on the First Autonomous Artificial Intelligence

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Productivity growth in health care significantly lags that throughout the rest of the economy. To date, our health care system has poorly incorporated technological advances to improve the quality of patient care and minimize costs. Autonomous artificial intelligence (AI), which generates a medical decision without human oversight, holds the promise to improve health care productivity, largely through more accurate, timely, and affordable diagnoses as well as expanded access to care from both cheaper diagnoses and from freeing up specialists' time.

Unlike clinician diagnostic exams, autonomous AI diagnoses are standardized and highly reproducible. Additional benefits accrue from expanded access as prices decline and physicians, particularly specialists, can spend more time on consultation with patients and in their treatment. If we fail to smartly integrate such autonomous AI into our health care system, we will both harm Americans' overall well-being and we will be outcompeted by China, Europe, and the rest of the world.

New technologies and innovations in health care face greater barriers to improve the existing methods than advances in other sectors of the economy, as incentives are often misaligned. This is because of the dominance of third-party payment for medical care as well as many political factors involved with rationing health care services.

Perhaps the biggest factor involves Medicare's outsized role in determining which services and products the program will cover and what it will pay. Companies must hire consultants and lobbyists to figure out how to have their new products or devices covered. Medicare's power is amplified, since private insurance companies, as well as other public programs like Medicaid, often mimic Medicare's decisions. The status quo, which benefits many politically powerful entities, is difficult to change.

The first Food and Drug Administration (FDA)-approved autonomous AI which has been granted reimbursement by the Center for Medicare and Medicaid Services (CMS) is an AI

system that diagnoses diabetic retinopathy and diabetic macular edema. Diabetic retinopathy is a condition which can lead to severe eye damage and vision loss, including blindness. Diabetic retinopathy can also lead to diabetic macular edema, an accumulation of fluid in the macula part of the retina caused by leaking blood vessels.

The autonomous AI system is able to deliver much more accurate and much less expensive diagnoses for diabetic retinopathy than the standard of care, which is examination by an optometrist or ophthalmologist.¹ By automating the diagnosis, these providers will have more time to spend in direct patient care—consulting with patients who have eye problems or eye disease and treating them. The one remaining obstacle relates to the CMS bureaucracy appropriately compensating for this innovation. It's vital that CMS properly compensate new technology that markedly improves the value—higher quality of care at lower costs—that patients receive from the health care system.

Importance of Innovation

“Innovation is the only way to make things better and cheaper.”

Regina Herzlinger, Harvard Business School professor and author of *Who Killed Health Care?*

Innovation is responsible for driving improvements in our quality of life, as new products or services prove superior to what existed before. Cars replaced horses, trucks replaced railroads, washing machines replaced hand washing, flat screens replaced tube televisions, Facebook replaced MySpace, iPhones replaced many cameras. The new product, driven by technological improvements, offers better value to consumers than the old.

Entrepreneurs and innovators imagine what consumers value in the future and develop strategies to bring those products to market. Consumers value products of higher quality than what existed before, and consumers value cheaper products that result when entrepreneurs develop ways to minimize production costs. The key is to attract customers through lower prices and improved performance or convenience. Innovation also helps many workers. It automates certain tasks that free up workers to spend their time and creativity employed in other ways, often ways that are more enjoyable and less monotonous. Economic history clearly show that the main way workers earn higher compensation over time is becoming more productive, so innovation that increases worker productivity is crucial to raise standards of living.

Health Care Productivity Declining

The productivity of a process is a measure of the output that can be produced from a given set of inputs. Society generally advances only as much as productivity gains increase. Unfortunately, health care productivity trends over the past few decades have been depressingly small.

Three main features of the United States' health care system create an environment that leads to low productivity gains. The first is that consumers only purchase about one-tenth of health care directly. This means that consumers have only a weak ability to clearly and directly exercise

¹ <https://www.nature.com/articles/s41746-018-0040-6>

their preferences and show how much they value new technologies. The second is that the health care industry exercises enormous political power in the United States. The industry—from hospitals to insurers to doctors—tends to do very well financially and as a result may be wary of technologies that might disrupt the status quo. In fact, technologies’ disruptive effect on health care workers is limited to the extent that much of the provision of health care is, and will remain, labor-intensive.

The third and probably biggest feature that inhibits health care productivity are features of Medicare. Medicare is the world’s largest purchaser of health care, and the program determines what services and procedures are reimbursed and at what price. Since private payers, as well as state Medicaid programs, tend to adopt Medicare policy decisions, these decisions on what Medicare will pay for and how much it will pay drives, distorts, and often impedes the evolution of health care.

Atul Gawande, surgeon, writer, and public health expert, has written persuasively about the problems this creates. For example, an excessive number of cardiac centers and heart-related procedures like stenting are to a great extent the result of excessive Medicare reimbursement for these items and services.² On the other hand, there is a dearth of geriatricians since Medicare underpays for seniors’ general health care needs.³

Private insurers are heavily influenced by Medicare’s decisions, which magnifies Medicare’s role in allocating health care resources. One study found that average Medicare payments predict 89 percent of the variation in average private payments and that “private payment arrangements amplify Medicare’s capacity to steer resources across both physician specialties and geographic areas.”⁴ A second study analyzed the Resource-Based Relative Value Scale (RBRVS), which provides the basis for payment for the 13,000 service codes for which physicians submit bills.⁵ These values are derived based in large part on the time, training and intensity that the service requires of the physician. Aside from the politicization of the process that sets these values, the RBRVS method does not consider the medical value of the service. According to the study’s authors, “[t]his procurement model thus has little capacity to steer care provision towards effective—let alone cost-effective—services.”⁶

Ultimately, the CMS bureaucracy, which is heavily lobbied, makes the decisions about reimbursement. CMS, like most government bureaucracies, has internal incentives that protect the status quo. Making changes is a slow, laborious process. Studies must be conducted and consultation with the interest groups, many of which have a short-term financial stake in the current way of doing things, must occur. The process typically drags out for years. Moreover, the bureaucracy tends to be risk-averse, governed by rigid rules which impede creativity. Notably, the problem, according to health innovators, is not the Food and Drug Administration or its approval process to bring new products and devices to market, but CMS, which decides whether Medicare will cover the innovation and what the program will pay.

² Atul Gawande, *Being Mortal: Illness, Medicine and What Matters in the End*. January 1, 2015

³ *Id.*

⁴ <https://www.nber.org/papers/w19503.pdf>

⁵ <https://www.nber.org/papers/w21642.pdf>

⁶ *Id.*

Private insurers and state Medicaid programs likely rely on CMS’s decision-making for two primary reasons—their own risk aversion to be the first to reimburse new technologies and lower administrative costs if they outsource this work to the federal government. Autonomous AI may be a particularly risky proposition for CMS and private insurers because the physician is removed from the diagnostic process.

Promise of Autonomous AI in Health Care

Good health care treatment and management begins with accurate diagnosis. In addition to being as accurate as possible, the diagnosis should also be achieved as safely, quickly and cheaply as possible. According to the Institute of Medicine (IOM), “getting the right diagnosis is a key aspect of health care—it provides an explanation of a patient’s health problem and informs subsequent health care decisions.”⁷ The IOM report goes further stating that “[i]mproving the diagnostic process is not only possible, but also represents a moral, professional, and public health imperative.”⁸ One of the IOM’s goals for improving diagnosis is to “ensure that health information technologies support patients and health care professionals in the diagnostic process.”⁹

Since autonomous AI systems can make complex clinical decisions without human oversight, they seem particularly well-suited to improve health care through quicker, cheaper and, most importantly, more accurate diagnoses. As AI benefits from more observations and sophisticated algorithms around pattern recognition, there is greater precision in the new technology compared with reviews of images by human—even the best trained humans in the world. This greater precision means problems, or potential problems, are more likely identified. Moreover, overdiagnosis is also likely less prevalent and clinician bias about un-related patient characteristics is removed.

Autonomous AI will improve patient care and outcomes in additional ways. As the health system integrates autonomous AI, the cost of preventive care will decline. The marginal cost of employing autonomous AI approximates zero, so the price charged for autonomous AI will be far less than conventional treatments, particularly over time after the fixed costs have been recouped. Price declines will increase access to care. Access will increase since specialists will no longer need to make the diagnosis. Autonomous AI can be performed in a primary care setting. Better access to diabetic eye exams will almost certainly improve visual outcomes for people with diabetes.¹⁰

Eric Topol, a medical doctor who has written numerous books about the future of medicine, believes that AI and machine learning complements physician work and allows doctors more time interacting with their patients and treating them. According to Dr. Topol, “Productivity, efficiency, and workflow can all be substantially improved” by the synergy of human expertise

⁷ <https://www.nap.edu/read/21794/chapter/2#2>

⁸ Id

⁹ Id

¹⁰ <https://bmjopen.bmj.com/content/4/2/e004015>; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5429356/>

with machine learning.¹¹ Topol remarked, “We already have enough data to show that we can markedly augment the performance of physicians, so that radiologists don’t miss things. And overall, machine learning can be trained to see things that humans can’t even see.”¹² Overall, autonomous AI will improve the accuracy of diagnosis and reduce its cost, which will free up clinicians to engage in patient care. This will expand patients’ access to care and will improve patient well-being.

Properly Compensating Innovation in Health Care

In most of the economy, products derived using new technology, such as AI, are appropriately compensated. People use a portion of their income to purchase the new product because it provides them with higher value than what was previously available. The innovator is restricted in its ability to set high prices because of existing products on the market—the excess price cannot exceed the marginal value that consumers receive from the new product relative to the existing product. Many times, innovation results in lower prices from cheaper production costs.

The features of the health care market discussed above means that innovation often does not have this effect in health care. In a normal market, price equates to where marginal benefit equals marginal cost.¹³ It’s virtually impossible for CMS to divine the correct price, especially since it administers a reimbursement system that is based in large part on the value of physician labor and not the value of the actual service or treatment. A technology that provides greater value by relying less on a physician’s time and training does not square with Medicare’s payment methodology. It is consequently exceedingly difficult for CMS to set these payments in any rational way and helps explain why Medicare reimbursement is slow to adapt to new market dynamics. Innovations that significantly reduce physician labor are perversely impeded by Medicare’s payment methodology.

Given Medicare’s powerful role, health care innovators must get CMS to create a reimbursement code and set a reasonable payment for breakthrough technologies. To do this, CMS relies on the advice of an RVS Update Committee (RUC), a volunteer group of 31 physicians constituted by the American Medical Association who advise Medicare on how to value a physician's work.¹⁴ Thus, innovation in health care is subject to both status quo bias and political influence. As technology continues to improve and in the absence of fundamental reform that removes Medicare from the price-setting business, it is important for Medicare’s payment policies to update as quickly as possible.

CMS, bound by a statutory system that bases reimbursement on the value of physician labor with significant input from an advisory committee of physicians constituted by the AMA, is ill-equipped to set a market-based price. Despite the inherent flaws of Medicare’s payment-setting

¹¹ <https://www.healthcareitnews.com/news/eric-topol-ehrs-have-taken-us-astray-ai-could-fix-healthcare-meaningful-and-positive-way>

¹² Id.

¹³ Marginal benefit is the benefit the consumer receives from the product and marginal cost is the cost incurred producing the product. Under most conditions, economic well-being is maximized when marginal benefit equates with marginal cost. In a free market, price adjusts to where marginal benefit equals marginal cost.

¹⁴ <https://www.ama-assn.org/about/rvs-update-committee-ruc/rvs-update-committee-ruc>

and the need to replace this structure, it's crucial that innovation and the new health care products it allows are properly compensated. On the one hand, overpaying for innovation is problematic and will direct too many resources toward the product, even if the marginal value of the innovation is small. However, underpaying for technological advancements lessens the incentives of entrepreneurs and innovators to create improved health care products and leads to worse outcomes. Given the absence of normal market forces and market feedback loops in health care, CMS must do its best to assess how the new product compares on the margin to what it aims to replace on metrics such as quality of care and costs. CMS must try to minimize the inherent risk aversion and lobbying pressure that both protect the status quo.

Autonomous AI for Diabetic Retinopathy

The first test for how the health system will incorporate autonomous AI is an autonomous AI system for the diagnosis of diabetic retinopathy. Diabetic retinopathy is a diabetes complication that affects eyes and can cause damage to the blood vessels of the retina.¹⁵ At first, diabetic retinopathy may cause only mild symptoms, if any, but eventually it can cause severe vision loss, including blindness.¹⁶ If caught early, before they have symptoms, patients with diabetic retinopathy can receive specialty eye care that will minimize or eliminate the negative effects.

More than one-quarter of seniors have diabetes.¹⁷ Nearly half of Medicare beneficiaries who have diabetes do not receive an annual eye exam.¹⁸ According to the Centers for Disease Control and Prevention, 7.7 million Americans had diabetic retinopathy in 2010, an amount projected to increase to 14.6 million by 2050.¹⁹ In fact, CMS, has been incentivizing doctors and private payors to do more diabetic eye exams.²⁰

The current standard of care for diagnosing diabetic retinopathy is a diabetic eye exam from an optometrist or ophthalmologist. According to a Milliman client report, Medicare paid an average of \$187 for these exams in 2018, with total expenditures of nearly \$290 million.

The autonomous AI for diagnosing diabetic retinopathy was de novo authorized by the Food and Drug Administration after a preregistered clinical trial. It has become part of the American Diabetes Association Standard of Diabetes Care²¹ and has been endorsed by the National Committee for Quality Assurance.²²

¹⁵ [https://www.mayoclinic.org/diseases-conditions/diabetic-retinopathy/symptoms-causes/syc-20371611#:~:text=Diabetic%20retinopathy%20\(die%2Duh%2D,or%20only%20mild%20vision%20problems.](https://www.mayoclinic.org/diseases-conditions/diabetic-retinopathy/symptoms-causes/syc-20371611#:~:text=Diabetic%20retinopathy%20(die%2Duh%2D,or%20only%20mild%20vision%20problems.)

¹⁶ Id.

¹⁷ <https://www.diabetes.org/resources/statistics/statistics-about-diabetes#:~:text=Prevalence%20in%20seniors%3A%20The%20percentage,18%20and%20older%20had%20prediabetes.>

¹⁸ Id.

¹⁹ <https://www.cdc.gov/features/diabetic-retinopathy/index.html#:~:text=Diabetic%20retinopathy%20is%20one%20of,7.7%20million%20to%2014.6%20million.>

²⁰ https://qpp.cms.gov/docs/QPP_quality_measure_specifications/Claims-Registry-Measures/2019_Measure_117_MedicarePartBCclaims.pdf

²¹ https://care.diabetesjournals.org/content/43/Supplement_1/S135

²² https://www.ncqa.org/wp-content/uploads/2020/07/20200701_Summary_Table_of_Measures_Product_Lines_and_Changes.pdf

The autonomous AI for diabetic retinopathy is an ideal medical innovation—both improving quality of care with more accurate diagnoses and lowering the cost of care, as the autonomous examination can occur in a primary care office. Seniors are able to walk out of their diabetes care visit with the results of this eye exam in minutes, without making a separate appointment and travelling to a different medical center. This should significantly increase the likelihood that they receive timely, follow-up, specialized care. The company that developed the autonomous AI for diagnosing diabetic retinopathy is seeking a \$55 price for the test—\$34 for the AI diagnosis and \$21 to cover the camera and equipment and its operation.

For each person who receives the improved diagnostic method for diabetic retinopathy, the savings to Medicare are approximately 70 percent if payment is set at \$55. Thus, if utilization of diabetic retinopathy screenings does not increase, the savings to Medicare would be substantial. If a smaller than optimal number of patients with diabetes are being tested for diabetic retinopathy, as now seems the case, then increasing utilization is desired—as early intervention will reduce vision loss in addition to the obvious benefit of preventing blindness in more patients. While the number of diagnoses will certainly increase, the total cost of these diagnoses will likely fall, since the cost savings per diagnosis are so large. It is possible that total costs to the Medicare program increase if this leads to more patients being treated for diabetic retinopathy, although this is likely a positive overall given the large costs associated with vision loss and blindness.

In the 2021 Medicare physician fee schedule (PFS) proposed rule, CMS has proposed to reimburse physicians and other practitioners using the Current Procedural Terminology (CPT) code 9225X (imaging of retina for detection or monitoring of disease; with point-of-care automated analysis with diagnostic report; unilateral or bilateral). CMS proposed an \$11 payment with this CPT code—an amount well below what the physician or practitioner would be responsible for reimbursing the innovator. Since the physician or practitioner would lose money on utilizing the new technology, the less accurate and more costly method of clinician diagnosis of diabetic retinopathy would persist.

The bureaucratic payment structure needs to classify expenses as either direct or indirect practice expenses. A direct practice expense includes nonphysician clinical labor, disposable medical supplies, and medical equipment that are typically used to provide a service. An indirect practice expense relates to expenses such as administration, rent, and other forms of overhead that cannot be attributed to any specific service.

The RUC recommended that CMS create a direct practice expense input for the autonomous AI analysis and interpretation, which would have allowed greater payment. In the PFS proposed rule, CMS rejected this recommendation, reasoning that the fee paid by the practice for access to the imaging analysis system is a form of indirect practice expense and used that formula to arrive at an \$11 reimbursement. As such, the payment decision is being bogged down in a technocratic battle of definitions of direct and indirect expenses. This example clearly shows that the whole bureaucratic payment structure is outmoded as CMS, which may be sympathetic to this improved method for diagnosing diabetic retinopathy, is simply saying it cannot fit a round peg in a square hole. Unfortunately, the Medicare reimbursement system is constructed to ignore the clinical

value of both the innovation and the existing services. Everything must be classified as a physician RVU, practice expense (direct vs. indirect), and malpractice expense, and none of these relate to the value of the service.

In this case, it seems clear that a valuable medical service is being provided by this new diagnostic tool and classifying it as administration, rent, or overhead is inappropriate. And while it may not fit perfectly in CMS's definition of a direct practice expense, its features are more similar to the direct practice expense since the "analysis," which is the true value in this case, was the product of nonphysician labor and technological equipment aimed at a clinical outcome.

Conclusion

Given the powerful role that Medicare plays in allocating health care resources, the way CMS handles the reimbursement for autonomous AI for diabetic retinopathy will affect the future development of autonomous AI. It is vital that a new construct be designed so that new technologies that improve patient care and lower costs are appropriately compensated. In addition to improving diagnoses, autonomous AI will enable clinicians to spend more time engaged in direct patient care. Ultimately, Medicare's structure inhibits new productivity gains in health care and policymakers must develop structural reforms to the program so that the AI revolution can benefit American patients.

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