Remote Patient Monitoring — Overdue or Overused?

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Keizra Mecklai, B.S.,* Nicholas Smith, B.S.*, Ariel D. Stern, Ph.D., and Daniel B. Kramer, M.D., M.P.H.

*Authors contributed equally

The Covid-19 pandemic has challenged health care providers to find innovative ways to provide essential services while minimizing exposure risks for themselves and their patients. These approaches increasingly leverage remote patient monitoring (RPM), using technology platforms to support treatment for chronic conditions. As use of RPM services grows, clinicians, payers, and patients face important questions regarding the volume, value, and appropriate use of this care model.

For many years, RPM has been integrated into focused areas of disease management, such as care of patients with pacemakers or implantable cardioverter–defibrillators. RPM for these patients can reduce costs and supplement or replace in-office care, while offering convenience and heightened surveillance for clinical events. More recently, RPM technology has expanded into new areas, including chronic and acute care management for multiple common conditions. Devices used in patients' homes now capture physiological parameters such as weight, blood pressure, oxygen saturation, and blood glucose levels and transmit these data to clinicians for review. For example, wrist-worn pulse oximeters transmitting oxygen-saturation data may be used to monitor lung function in patients with chronic obstructive pulmonary disease and continuous glucose monitors with wireless transmission capabilities may provide physicians with key information about blood-sugar control in diabetic patients at different times of day and between office visits.

In 2019, the Centers for Medicare and Medicaid Services (CMS) issued a final rule[1] on changes to the Medicare Part B Physician Fee Schedule establishing three new billing codes for Chronic Care RPM. These codes allowed reimbursement for initial setup of RPM devices and associated patient education; collection and interpretation of physiological data; and RPM treatment management services. A 2020

update[2] expanded coverage for RPM services and created an add-on code for reimbursement for patients who receive an additional 20 minutes of RPM services per month, allowing providers to bill for up to 40 minutes of RPM services per Medicare patient per month.

Crucially, in response to Covid-19 and associated legislation,[3] CMS expanded RPM coverage further, specifying that it is not limited to patients with chronic conditions, but also includes those with acute conditions such as Covid-19. The interim rule also established that for the duration of the national emergency, consent for RPM services can be obtained just once a year for both new and established patients. Providers are also permitted to waive copayments for services rendered outside of an "in-person face-to-face" encounter, including telehealth and RPM. This confluence of recent technological advancement and broad assurance of reimbursement in a fee-for-service environment — particularly as health care providers lose revenue because of the pandemic — may lead to dramatic increases in RPM utilization and expenditures.

RPM has the potential to enhance the management of both acute and chronic conditions and to better personalize treatment plans with use of high-frequency health data. It is possible, although not yet demonstrated at scale, that evidence-based RPM can improve clinical outcomes for individual patients while, at the health systems level, reducing downstream health care costs, such as those associated with preventable hospital admissions. There are, however, several reasons to worry about a short-term explosion in RPM expenditures.

First, makers of RPM tools can currently pursue marketing approval (if needed) and subsequent reimbursement coverage under standards that do not require demonstration of clinical effectiveness in overall disease management. A pulse oximetry system for patients with chronic lung disease, for example, may have to meet certain engineering and manufacturing standards but does not need to be shown to improve patient outcomes to be legally marketed. For these devices in general, the Food and Drug Administration (FDA) places the burden on health care providers to "develop appropriate

processes and procedures to assess and manage the risks associated with the integration of RF wireless medical devices."[4] In the FDA's risk-based classification of devices, most involved in RPM will not be considered high-risk, and as such the statutory standard of "reasonable assurance of safety and effectiveness" generally will not require clinical trials, nor will the software running on many commercial wearables, which is expected to be regulated through the FDA's Digital Health Software Pre-Certification Program in the future.

Second, CMS has offered few stipulations to date on what specifications or standards must be met for an RPM device to be covered. Even well-studied devices in common diseases, such as hypertension, heart failure, and atrial fibrillation, have shown highly variable benefits of different products and care pathways.[5] The randomized controlled trials conducted have revealed variable effects on outcome measures such as hospital readmission, cardiovascular mortality, or all-cause mortality. Eventually, high-quality, prospective studies either designed as clinical trials or leveraging real-world data may support the clinical case for RPM systems.

Third, even without high-quality clinical data, the expansion of fee-for-service reimbursement for RPM services incentivizes rapid uptake. With more and more devices available on the market, particularly wearables, providers may enroll large numbers of patients in RPM programs with little regard as to who will see a clinically meaningful benefit. Alternative payment models such as bundled payments may shift these incentives, but traditional fee-for-service reimbursement remains a dominant feature of US health care. The costs of RPM expansion may also be borne in part by patients. RPM could increase out-of-pocket expenditures depending on co-insurance and access to devices themselves, since one of the established RPM CPT codes allows providers to bill for up to 30 minutes per patient per month without any requirement to communicate with the patient or caregiver.

Whether RPM services and associated expenditures grow rapidly remains to be seen, with few data to guide firm forecasting. However, we estimated the potential impact of RPM services on

Medicare expenditures with a simple model integrating the following variables: number of beneficiaries, chronic conditions per beneficiary, utilization of RPM, and reimbursement per RPM service (see Supplementary Appendix, available at NEJM.org). A conservative estimate would assume that RPM enrollment would be limited to patients with multiple chronic conditions, yet theoretically this could still translate into upwards of $18 billion in annual expenditures, even with just 50% uptake.

This estimate is based on the assumption that 68% of Medicare fee-for-service beneficiaries — about 25.4 million patients, as of September 2020, according to CMS — have two or more chronic conditions. The maximum annual cost per patient enrolled in an RPM program is $1,460, according to the 2020 CMS Fee Schedule. This cost comprises monthly fees for device supply and data transmission fee ($62.44, CPT code 99454) and for collection and interpretation of physiological data ($59.19, CPT code 99091). It's unrealistic to believe that 100% of eligible patients will enroll, but even with an enrollment rate of 10% among eligible beneficiaries, the annual cost to Medicare could reach $3.7 billion — just under 1% of total 2018 Medicare Part A and B expenditures (see Supplementary Appendix). Additional costs of the same order of magnitude might be accrued if Medicare Advantage and other private payers expanded similar coverage and reimbursement.

Research is urgently needed to elucidate which subgroups of patients benefit most from RPM services and which particular RPM devices and specifications provide the highest clinical value. This information will enable professional societies to publish evidence-based guidelines on which patients should enroll in RPM programs and which devices and support systems should be deployed to maximize the clinical impact of RPM and the collection of health data. Such studies would also provide needed foundational evidence to enable CMS to articulate the specifications or standards that must be met by RPM devices in order to qualify for reimbursement coverage. Furthermore, private-sector efforts to create transparency regarding the usability, validation, and data-security profiles of biosensors will support clinicians and clinical researchers in technology-adoption decisions.

At present, the recent CMS rule changes, combined with the effects of the Covid-19 pandemic, have resulted in a rapid and sweeping expansion of reimbursement for telehealth and RPM technologies and services without evidence-based coverage decisions. In the context of social-distancing mandates and the desire to enhance patient safety, RPM provides promising solutions for accessible and data-driven care while reducing exposure risks. Encouragingly, there may be opportunities to learn from other countries as RPM tools evolve. For example, Germany's 2019 Digital Healthcare Act, which provides for insurance coverage of certain digital health applications, includes provisions for evidence generation as a requirement for ongoing reimbursement. Rigorous, ongoing evaluation of RPM devices and platforms will be essential for elucidating their value and driving coverage decisions and adoption programs for the most effective solutions.

Disclosure forms provided by the authors are available at NEJM.org.

From Harvard Medical School (K.M., N.S., D.B.K.), Harvard Business School (K.M., N.S., A.D.S.), the Harvard-MIT Center for Regulatory Science (A.D.S.), and the Richard A. and Susan F. Smith Center for Outcomes Research in Cardiology, Beth Israel Deaconess Medical Center (D.B.K.) — all in Boston; and the Health Innovation Hub, German Federal Ministry of Health, Berlin (A.D.S.).

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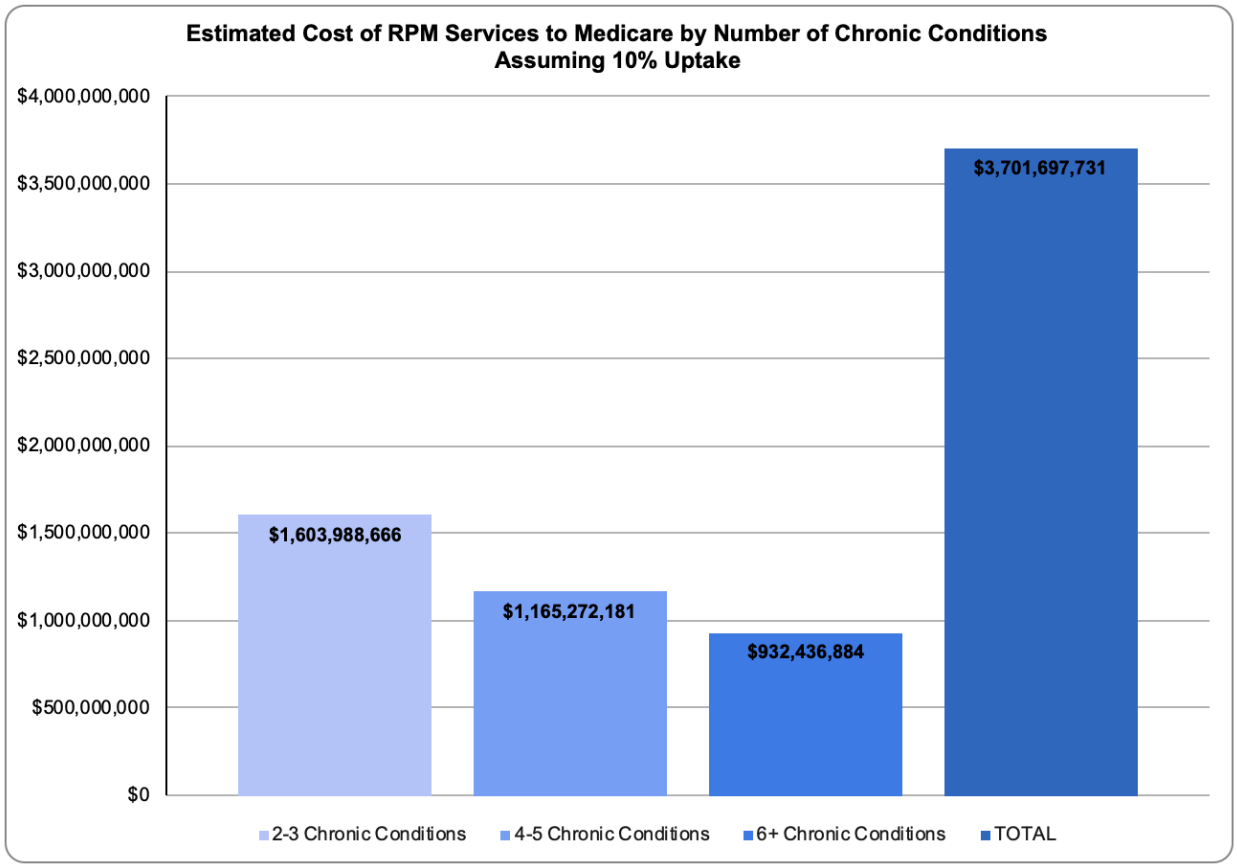
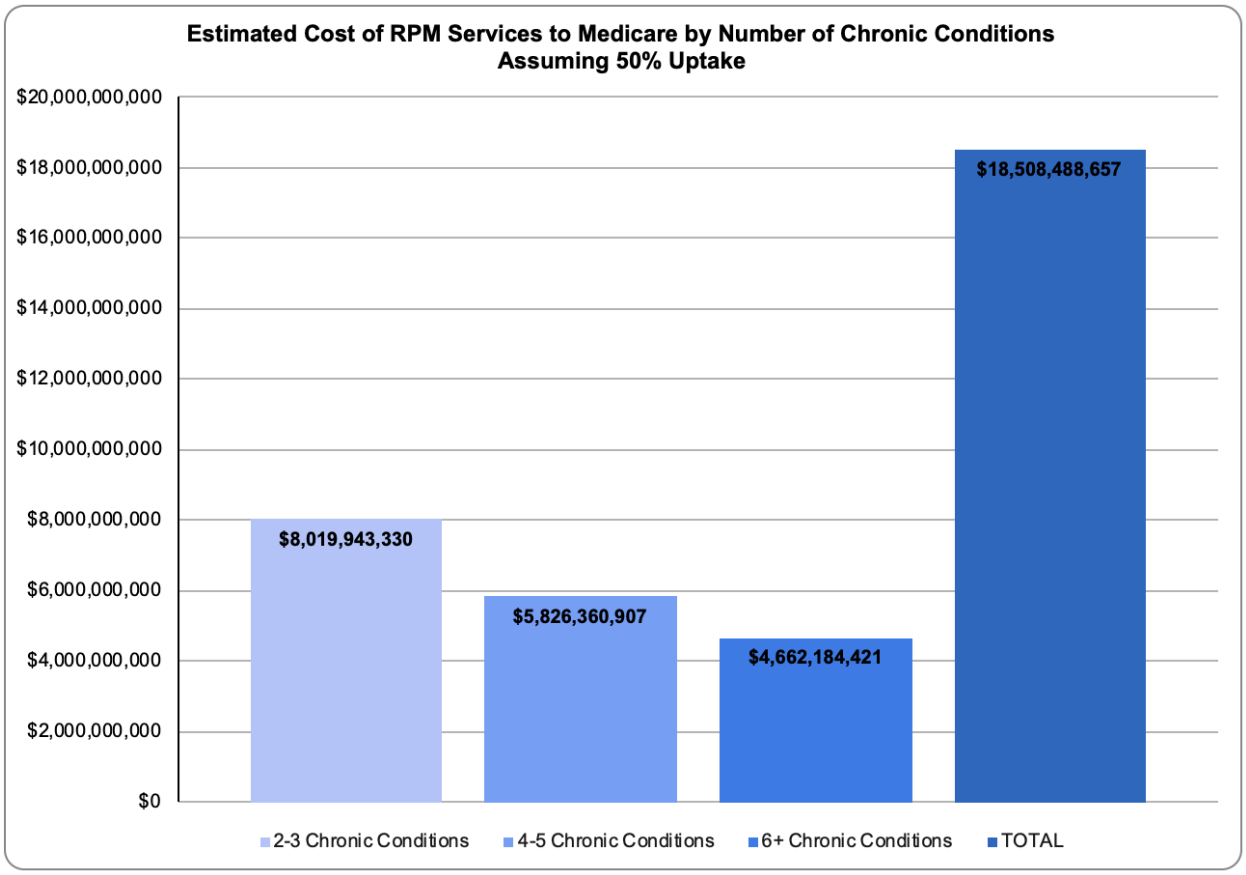

Estimated Cost of RPM Services to Medicare by Number of Chronic Conditions
Assuming 10% Uptake
$4,000,000,000
$3,500,000,000
$3,000,000,000
$2,500,000,000
$2,000,000,000
$1,500,000,000
$1,000,000,000
$500,000,000
$0
$1,603,988,666
$1,165,272,181
$932,436,884
$3,701,697,731
2-3 Chronic Conditions
4-5 Chronic Conditions
6+ Chronic Conditions
TOTAL

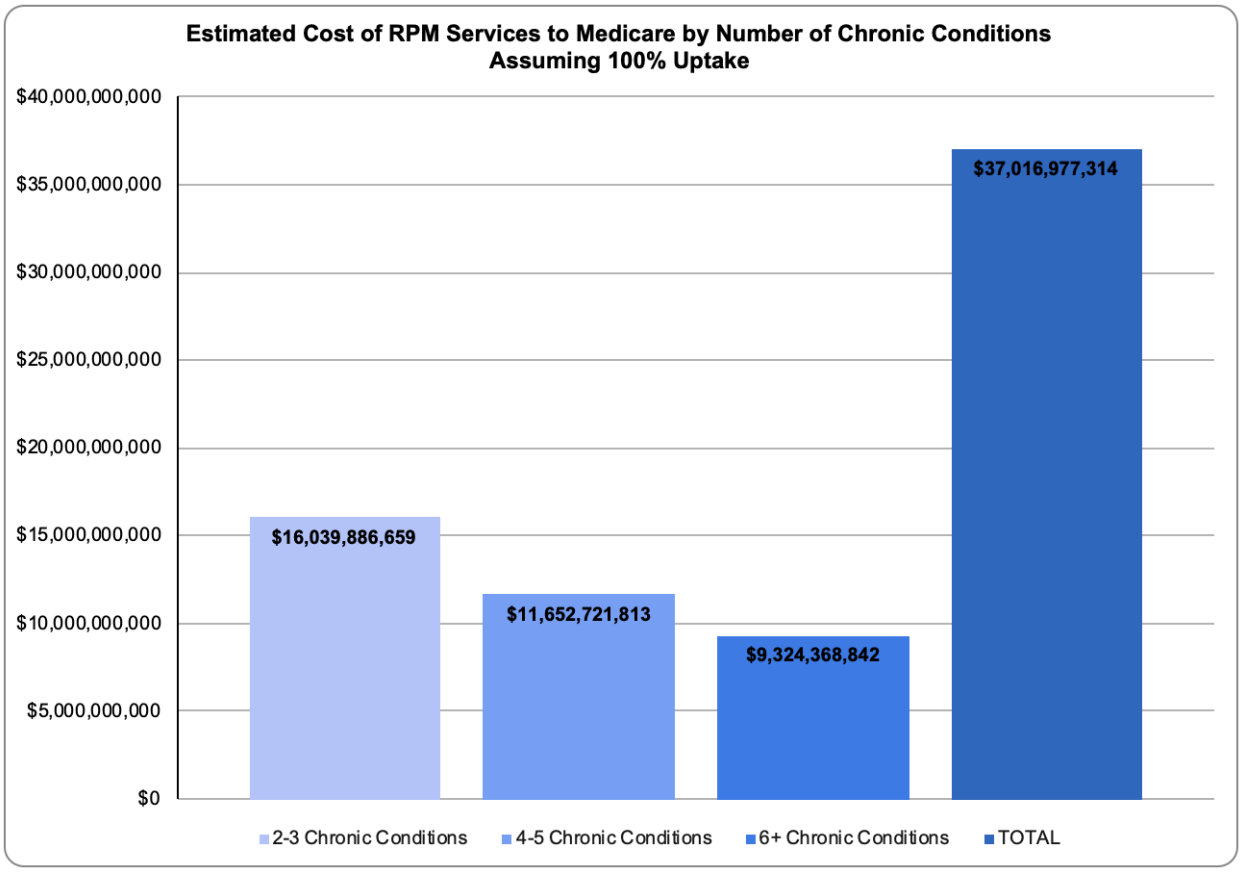
142

143


Estimated Cost of RPM Services to Medicare by Number of Chronic Conditions
Assuming 50% Uptake
$20,000,000,000
$18,000,000,000
$16,000,000,000
$14,000,000,000
$12,000,000,000
$10,000,000,000
$8,000,000,000
$6,000,000,000
$4,000,000,000
$2,000,000,000
$0
$8,019,943,330
$5,826,360,907
$4,662,184,421
$18,508,488,657
2-3 Chronic Conditions
4-5 Chronic Conditions
6+ Chronic Conditions
TOTAL

144

145


Estimated Cost of RPM Services to Medicare by Number of Chronic Conditions
Assuming 100% Uptake
$40,000,000,000
$35,000,000,000
$30,000,000,000
$25,000,000,000
$20,000,000,000
$15,000,000,000
$10,000,000,000
$5,000,000,000
$0
$16,039,886,659
$11,652,721,813
$9,324,368,842
$37,016,977,314
2-3 Chronic Conditions
4-5 Chronic Conditions
6+ Chronic Conditions
TOTAL

146