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Brief Communications

Patient-generated health data earn a seat at the table: clinical adoption during the COVID-19 transition to telemedicine

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ABSTRACT

Patient-generated health data (PGHD) have not achieved widespread clinical adoption. However, the COVID-induced shift to telemedicine may have created opportunities for PGHD as surrogates for vital signs collected in person. We assessed whether this shift was associated with greater ambulatory care PGHD use. We conducted an interrupted time series analysis of physician enrollment in, and patient-initiated vital sign transmission of non-COVID-associated PGHD through, a national PGHD platform (Validic). Ten health systems, 4695 physicians, and 51 320 patients were included. We found a significant increase in physician enrollment (slope change of 0.86/week, $P = .02$). Platform application programming interface calls continued their pre-COVID upward trend, despite large reductions in overall encounters. These findings suggest significantly greater pandemic-associated clinical demand for PGHD, and patient supply disproportionate to encounter rates. Increasing clinical use and ongoing efforts to reduce barriers, could help seize current adoption momentum to realize PGHD's potential value.

Key words: patient-generated health data, telemedicine, COVID-19, health policy

Lay Summary

Patient-generated health data (PGHD)—health-related data created and recorded by or from patients outside of the clinical setting to help address a health concern—have not yet achieved widespread adoption in routine clinical care. The COVID-19 pandemic precipitated a rapid transition of outpatient encounters to telemedicine in which healthcare providers lacked access to vital signs routinely collected during in-person visits. We conducted an analysis to determine whether the transition to telemedicine increased patient transmission of, and provider adoption of vital sign-related PGHD as surrogates for their in-person equivalents. We found that the number of healthcare providers enrolling on a national PGHD platform increased significantly following the transition to telemedicine, and that the amount of PGHD transmission continued the upward trajectory that it was already experiencing, substantially outpacing the dramatic decline in overall encounters that occurred early in the pandemic. While adoption challenges persist, including questions about accuracy of PGHD, liability, reimbursement, and the potential for exacerbating disparities, these findings suggest an increasing willingness of patients and healthcare providers to use vital sign-related PGHD to supplement telemedicine encounters. Increasing clinical use and ongoing efforts to reduce barriers, could help seize current adoption momentum to realize PGHD's potential value.

BACKGROUND AND SIGNIFICANCE

Patient-generated health data (PGHD)—defined as health-related data created and recorded by or from patients outside of the clinical setting to help address a health concern¹—have not yet achieved widespread adoption in routine clinical care.² While PGHD are commonly thought of as biometrics emanating from devices, they also consist of patient reported outcomes, symptom reporting, and metadata such as geolocation and environmental parameters that may influence health or disease. Although >85% of US adults own smartphones capable of capturing PGHD,³ barriers to PGHD use stem, in part, from clinician concerns about accuracy and liability,¹ as well as information overload, and limited reimbursement.² Patients have expressed concerns over privacy of their transmitted data, and uncertainty about the helpfulness of PGHD to their physicians.² Finally, systemic challenges persist in how to incorporate PGHD into the clinical workflow, how and where the data are stored and accessed, and by whom they ought to be reviewed and evaluated.²

The COVID-19 pandemic precipitated a breakthrough moment for telemedicine that was catalyzed by more than 31 federal regulatory changes decreasing barriers, increasing reimbursement, and relaxing restrictions.⁴ Under the telemedicine umbra, however, it remains unknown whether PGHD may have also had their own, less visible breakthrough moment. Specifically, it is possible that providing remote care could have made clinicians more open to PGHD to support clinical decision making, particularly as vital signs and weight, routinely collected in the in-person setting, became less available. We therefore assessed whether clinician initiation of PGHD receipt and patient reporting of PGHD increased following the large-scale, COVID-prompted shift to telemedicine.

MATERIALS AND METHODS

We measured changes in the number of new physicians enrolling on a national PGHD-specific platform (Impact, Validic, Inc., Durham, NC), and the number of application programming interface (API) calls containing PGHD-derived body weight, pulse, systolic and diastolic blood pressure, and temperature generated by patients on the platform. Briefly, when health systems contract to implement the platform, each physician must individually log in and complete a manual enrollment process. Once enrolled, the physician offers the opportunity to their patients to share PGHD through the platform. Patients who express interest receive an email from their healthcare provider with an electronic enrollment link that walks them through consent, program details, and how to register/sync their over-the-counter devices with the platform. Prompts to remind patients to transmit PGHD occur on an automated cadence that is agreed upon by the physician and patient in advance, depending on the condition being monitored. Email and SMS reminders may also be clinically configured to change the cadence of exchange as clinically warranted. API calls to the platform—communication or handshake events between the device and the platform at the time of data transmission—one call per measurement (eg, pulse, weight, etc.) are generated by patient action; they occur only when a patient collects PGHD from connected devices that push the data to the physician. API calls do not occur as a result of any action on the physician end. Once transmitted, the physician views data through the electronic health record, and notifications may be set for data that are out of range or clinically concerning.

Physician enrollment is a strong signal of clinical interest in PGHD receipt because the physician must manually enroll to use the

platform. Furthermore, among the health systems in our sample, there were no known financial or performance incentives that might otherwise have influenced physician enrollment. API calls are a strong signal of meaningful data transmission because in our sample, API calls were never null, and always contained a PGHD data element. Although some devices such as continuous glucose monitors may passively collect and transmit PGHD, no passively collected PGHD were considered in this analysis. Therefore, API calls in our sample reflected active, patient-initiated measurement capture events.

We hypothesized that the large-scale shift from in-person encounters to telemedicine visits, would increase both physician and patient interest in PGHD. We therefore examined the level and trend of physician enrollment, and the number of patient-initiated API calls containing PGHD-derived body weight, pulse, systolic and diastolic blood pressure, and temperature. Although reporting of other metrics such as blood glucose are supported by the platform, we chose to focus only on those such as weight and vital signs that would otherwise have been collected in clinic at the time of an in-person encounter. We assessed changes in level and trend of these measures using an interrupted time series analysis (ITSA, Stata Statistical Software: Release 16, StataCorp, 2019), with measures aggregated to the weekly level between 10/7/2019 and 9/27/2020, and using the week beginning on 3/2/2020 as the interruption week, consistent with the reported timing of the national transition to telemedicine associated with onset of the COVID pandemic in the United States.⁵ ITSA is a method that is widely used to assess for changes before and after a point in time (the interruption point) by accounting for underlying, secular trends. In this case, the linear pre-transition to telehealth trend in PGHD use is plotted. This is followed by a level or step change characterizing instantaneous effects of the intervention, and then a post-transition linear trend. The step change is assessed for significance, and the slopes pre- and post-interruption are also compared for significant changes. In addition, we conducted a sensitivity analysis using the week of 3/16/20 as an interruption week, a time point that is also commonly considered to be a transition. Inclusion criteria were physicians associated with any health system using the platform prior to and throughout the duration of the study period. We excluded health systems new to the platform during the study period, and we excluded data from the platform's COVID-specific programs to create comparable measures over time, and to describe PGHD demand independent of the expected increase for COVID-specific assessment.

RESULTS

Of the 10 health systems meeting inclusion criteria, 1 is an academic medical center, 2 are payer-provider networks, and 7 are integrated delivery networks. One health system is nationwide, while the remaining 9 are located in 11 states. Further, 9 have both urban and rural facilities, and 1 (the academic medical center) is urban only. Eight of the ten are considered safety net providers. Across these health systems, 4695 healthcare providers and 51 320 patients used the platform's non-COVID programs during the study period.

We found a significant increase in the weekly number of new providers enrolling on the platform, from a flat pre-COVID slope ($-0.35/\text{week}$; $P = .23$; CI, -0.94 to 0.23) to a positive COVID-period slope of $0.51/\text{week}$ ($P = .02$; CI, 0.09 to 0.92), representing a slope change of $0.86/\text{week}$ ($P = .02$; CI, 0.14 to 1.58 , [Figure 1](#)). There was no one-time level change to suggest any instantaneous effect. Pre-COVID, the number of API calls were increasing by $573.5/\text{week}$ ($P = .002$; CI, 228.1 to 918.8). This rate continued to increase

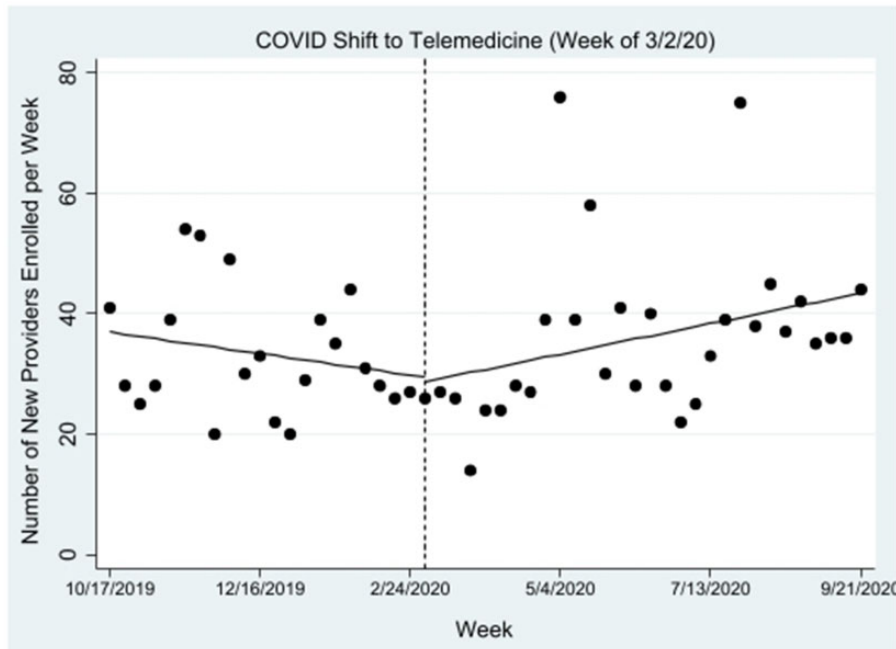


Figure 1. Weekly new provider enrollment versus time. Dots represent actual data, lines represent linear fits before and after the week of 3/2/2020 (dashed line).

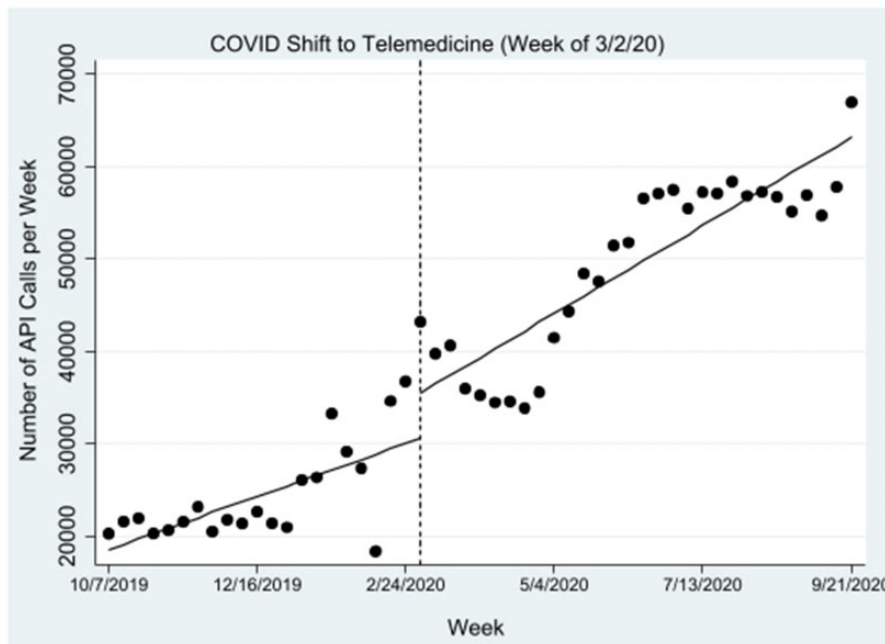


Figure 2. Weekly API calls versus time. Dots represent actual data, lines represent linear fits before and after the week of 3/2/2020 (dashed line).

in the COVID period with a slope of 953.7/week ($P < .001$; CI, 746.0 to 1161.5), representing a slope change of 380.3/week that did not reach a level of statistical significance ($P = .06$; CI, -22.7 to 783.2). As was the case for new enrolling providers, there was no significant one-time level change for API call volume (Figure 2).

A sensitivity analysis using 3/16/20 as the interruption week demonstrated consistent findings, with a slope change for the number of new providers of 0.88/week ($P = .02$; CI, 0.15 to 1.61), and a slope change for the API call volume of 254.0/week ($P = .21$; CI, -144.4 to 652.4). In addition, because Figure 1 contains two data points (weeks of 5/4/2020, and 7/27/2020) with substantially higher

physician enrollment rates than surrounding weeks, we conducted an *a posteriori* sensitivity analysis in which those two points were excluded. We found no meaningful change in the results when excluding those two points. This was confirmed for 3/2/2020 and for 3/16/2020 as the interruption points.

DISCUSSION

Our results reveal a significant increase in the number of physicians signing up to use a PGHD platform after March 2, 2020 for non-

COVID ambulatory care. This could be driven by the simultaneous shift to telemedicine and greater need for such data to support clinical assessment in the absence of analogous in-person measurement. We observed significant upward trajectories in API call volumes before and after the transition, with the change between these periods not reaching significance ($P = .06$). Nonetheless, we interpret this to mean that patient interest in PGHD reporting to their healthcare providers increased because, after the transition, national encounter data show a large drop in the overall levels of ambulatory encounters (a 36% net drop from February to April, 2020, even after including the increase in telemedicine encounters).⁵ Thus, maintaining the upward trajectory for patient-initiated reporting when fewer encounters were occurring suggests robust patient interest. Combined, these findings suggest that more clinicians may be turning to PGHD to support clinical decision making in the absence of vital signs and weight that would normally be collected by approved in-clinic devices, and that patients are interested in collecting and willing to supply these data.

While our findings are encouraging with respect to broader clinician and patient exposure to PGHD, there remain challenges for the potential future growth in their clinical adoption. Specifically, concerns over PGHD accuracy and liability, some of the same concerns that contributed to the withdrawal of PGHD from Stage 3 Meaningful Use,¹ may continue to challenge further expansion. However, as the Food and Drug Administration develops its nascent regulatory framework for Software as a Medical Device through its Digital Health Software Precertification Program,⁶ and as it promotes the adoption of unique device identifiers in both unregulated and Class I–III devices,⁷ an increasing ability to understand and identify the devices, and the accuracy of these devices used to generate PGHD, may mitigate some of these concerns.

Other adoption challenges persist, including clinical PGHD review burden and reimbursement,² as well as disparities between patient populations with respect to PGHD device and broadband access. To date, PGHD reimbursement models largely remain tied to time spent reviewing PGHD for chronic condition management and remote physiologic monitoring.⁸ However, with reimbursement opportunities under the Merit-based Incentive Payment System (MIPS),⁹ and with planned additions of new CPT codes,¹⁰ some of these barriers may begin to ebb. Device and broadband access as well as digital literacy remain obstacles to providing remote healthcare to underserved communities, and expanded use of PGHD could exacerbate current disparities. These will be important to monitor and address as the \$1.2 trillion bipartisan Infrastructure Investment and Jobs Act, signed into law on November 15, 2021, allocates \$65 billion to broadband infrastructure, subsidy, and digital equity and inclusion efforts.¹¹ Finally, it will also be important to more robustly assess the benefits of PGHD use, including from the patient perspective, and to bring greater clarity to their role in supporting care that is increasingly virtual.

This study has the following key limitations. First, the platform data do not establish PGHD use—overall or specifically within telemedicine encounters; instead, we observe PGHD trends during a period when there was a national transition to telemedicine due to the pandemic. Second, the data are at an aggregate level, and do not offer the opportunity for bias analysis or for subgroup analysis into which types of ambulatory care specialties or patient populations are driving their use. Third, there were no available data reflecting physician demand for or views of the PGHD (beyond the initial enrollment step) because the PGHD flow into, and are viewed within, the local electronic health record. Finally, this data set, with 9 health

systems across 11 states, and 1 nationwide organization is, by definition, limited. However, there is no centralized national source of PGHD transmission data, and so this dataset, coming from a single, large national vendor (over 200 clients, managing the health data of over 5 million people), offers important insights.

CONCLUSION

Our results suggest that the pandemic spurred an increase in physician interest in PGHD, and that PGHD may have filled gaps during a period of reduced in-person care. Just as the pandemic drove healthcare providers to unprecedented levels of exposure to and familiarity with encounters via telemedicine, it is possible that increasing PGHD exposure may drive greater physician and patient familiarity with and ongoing adoption of these data. When the pandemic wanes, it will be critical to continue to address barriers in order to seize current momentum and realize the potential value of PGHD.

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AUTHOR CONTRIBUTIONS

BIR takes responsibility for the integrity of the data and the accuracy of the analysis. BIR and JA-M were responsible for study concept, design, data analysis, and interpretation. BIR, JA-M, and JCK all made substantial contributions to drafting the manuscript, and revising it critically for important intellectual content.

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CONFLICT OF INTEREST STATEMENT

BIR reports holding shares in Infermedica, receiving consulting fees from the nonprofit Network of Digital Evidence, and receiving consulting fees from Yale New Haven Health for work on digital quality measures. JCK reports serving on the Advisory Board for, receiving consulting fees, and holding shares in Res App Health; holding shares in b.well; serving on the Board of Directors and holding shares in MobileHelp; advising and holding stock options in Sweetch; and advising and receiving consulting fees from Chronisense. JA-M reports serving on the Board of and holding shares in Opala Health.

DATA AVAILABILITY

The data underlying this article were provided to the authors by Validic, Inc. Data will be shared on request to the corresponding author with permission of Validic.

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