The hope is that the focus on moving to more value-based payment models will begin to bring in more measures of the effects this has on patient outcomes, which are the most important measure of the effects of changes in the use of health care services. That, along with the focus on comparative effectiveness analysis, attempts to provide information on the differential clinical effects of using various interventions and treatment agents on different types of patients, should improve the ability to treat patients in a more clinically and cost-effective manner.

To say that much remains in the path to accomplishing the objectives associated with value-based payment models is an understatement. However, this analysis suggests that the move to reduce overvalued payments can have differentiated effects, reducing the use of a procedure by physicians and other health care professionals who are not trained to use it while maintaining similar levels of its use by those who are trained in the use of the procedure. The CMS should consider using this strategy for other potentially overvalued services, particularly those that have a high cost, such as the use of proton beam therapy, which is a very expensive intervention with little clinical evidence supporting its use.4

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Conflict of Interest Disclosures: None reported.


Validation of the Instant Blood Pressure Smartphone App

Mobile health (mHealth) technologies include unregulated consumer smartphone apps.1 The Instant Blood Pressure app (IBP; AuraLife) estimates blood pressure (BP) using a technique in which the top edge of the smartphone is placed on the left side of the chest while the individual places his or her right index finger over the smartphone’s camera. Between its release on June 5, 2014, and removal on July 30, 2015 (421 days), the IBP app spent 156 days as one of the top 50 best-selling iPhone apps; at least 950 copies of this $4.99 app were sold on each of those days.2 Validation of this popular app or any of the similar iPhone apps still available (eg, Blood Pressure Pocket, Quick Blood Pressure Measure and Monitor), have not been performed. Using a protocol based on national guidelines,3 we investigated the accuracy and precision of IBP.

Methods | A Johns Hopkins University School of Medicine institutional review board approved this study. In August and September 2015, we enrolled patients and staff who were at least 18 years old from 5 ambulatory Johns Hopkins sites (1 clinic each in general internal medicine, nephrology, and the Pro-Health clinical research unit, and 2 in cardiology clinics). Clinicians referred patients with or without hypertension or a baseline hypertensive reading for enrollment. After prescreening 105 individuals, written informed consent was obtained from 101 participants. Participants were given $5 gift cards for their time. Per prespecified dropping rules, data from 16 individuals were discarded because of unavailable cuff sizes (n = 1), standard device errors (n = 2), and excessive variation in sequential standard BP measurements, greater than 12 mm Hg for systolic BP or greater than 8 mm Hg for diastolic BP (n = 13).3

For IBP measurements, research staff were trained to measure BP according to manufacturer guidelines using the IBP app, version 1.2.3, on a smartphone (iPhone 5s and 6; iOS version 8.3; Apple Inc); IBP required entry of date of birth, sex, height, and weight for each measurement. For standard BP measurements, research staff were trained to follow a standard protocol using calibrated, validated automated sphygmomanometers (Omron 907 and 907 XL).4 Measurement order (IBP and standard) was random. Following 5 minutes of quiet sitting, 2 sequential BPs were taken by each device, separated by 60 seconds. The standard BP measurement was an average of the 2 BP measurements by sphygmomanometry. Sensitivity and specificity for detection of hypertensive BP were calculated using systolic BP of at least 140 mm Hg or diastolic BP of at least 90 mm Hg.

Calculation of the mean of the absolute value of the difference and data visualization were examined using Stata statistical software (version 13.1; StataCorp).

Results | Of 85 participants, 44 (52%) were women. Their mean (SD) age was 56.6 (16.3) years, and their body mass index, calculated as weight in kilograms divided by height in meters squared, was 27.8 (5.8); 45 (53%) self-reported hypertension, and 91% of these (41) reported taking antihypertensive medications.

The mean (SD) of the absolute values of the difference between IBP and standard were 12.4 (10.5) mm Hg for systolic BP and 10.1 (8.1) mm Hg for diastolic BP. IBP underestimated higher BPs and overestimated lower BPs (Figure). IBP systolic BP readings were within 5, 10, and 15 mm Hg of the standard BP measurement 24%, 44%, and 59% of the time, respectively, whereas respective proportions for diastolic BP were 26%, 48%, and 70%, correlating with the lowest possible accuracy grade in all categories by British Hypertensive Society scoring.5 Spearman ρ was 0.44 (P < .001) for systolic BP and 0.41 (P < .001) for diastolic BP. Sensitivity and specificity of IBP for hypertensive BPs were 0.22 and 0.92, respectively.

Discussion | The BP measurements from an mHealth app with more than 148 000 units sold were highly inaccurate. The low sensitivity for hypertensive measurements means that approximately four-fifths (77.5%) of individuals with hypertensive BP levels will be falsely reassured that their BP is in the nonhypertensive range.
Our study has both clinical and public health relevance. While IBP recently became unavailable for unclear reasons, it is installed on a vast number of iPhones; furthermore, several “me-too” apps are still available. Hence, we remain concerned that individuals may use these apps to assess their BP and titrate therapy. From a public health perspective, our study supports partnership of app developers, distributors, and regulatory bodies to set and follow standards for safe, validated mHealth technologies.

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Conflict of Interest Disclosures: Dr Martin reports grants from the P J Schafer Cardiovascular Research Fund, during the conduct of the study; and grants from American Heart Association and Aetna Foundation and personal fees from

Figure. Standard Blood Pressure (BP) vs Instant Blood Pressure (IBP) App Measurements

A Systolic BP

B Diastolic BP

C Systolic BP

D Diastolic BP

Spearman ρ, 0.44 (P < .001)

Spearman ρ, 0.41 (P < .001)

IBP underestimates BP

IBP overestimates BP

IBP underestimates BP

IBP overestimates BP

Elevated systolic BP false-positive findings

Elevated diastolic BP false-positive findings

Elevated systolic BP false-negative findings

Elevated diastolic BP false-negative findings

IBP Minus Standard BP Measurement, mm Hg

Average of IBP and Standard BP Measurements, mm Hg

IBP Minus Standard BP Measurement, mm Hg

Average of IBP and Standard BP Measurements, mm Hg
Accuracy of Wearable Devices for Estimating Total Energy Expenditure: Comparison With Metabolic Chamber and Doubly Labeled Water Method

Accurate estimation of energy expenditure is a key element in determining the relationships between aspects of human behavior, physical activity, and overall health.1,2 Although wearable devices for estimating energy expenditure are becoming increasingly popular, there is little evidence regarding their validity.3,4 This study was performed to examine the validity of total energy expenditure estimates made by several wearable devices compared with gold standard measurements for a standardized day (metabolic chamber method) and free-living days (doubly labeled water [DLW] method).

Methods | All protocols were reviewed and approved by the ethics review board of the National Institute of Health and Nutrition, Tokyo, Japan. Written informed consent was obtained from all participants, who were compensated for their participation. Participants were 19 healthy adults (9 men and 10 women) aged 21 to 50 years who were not obese and had no problems performing regular daily activities. Total energy expenditure was measured using 12 wearable devices. Eight were consumer devices selected because the manufacturers claim that they measure total energy expenditure and they are popular according to Japanese sales rankings (JAWBONE UP24, Fitbit Flex, Misfit Shine, EPSON PULSENCE PS-100, Garmin Vivofit, TANITA AM-160, OMRON CaloriScan HJA-403C, and Withings Pulse O2). The remaining 4 devices are validated for use in research (OMRON Active style Pro HJA-350IT, Panasonic Actimarker EW4800, SUZUKEN Lifecorder EX, and ActiGraph GT3X). All 12 devices were worn simultaneously at randomly assigned positions on the wrist, chest, or waist as appropriate to minimize possible bias owing to placement (Figure 1).

Detailed procedures for total energy expenditure measurement using the metabolic chamber and DLW methods have been described.5,6 For the metabolic chamber experiment, participants visited the laboratory at 7:30 AM after an overnight

---

**Table 1. Differences in Total Energy Expenditure in 19 Patients**

<table>
<thead>
<tr>
<th>Device Name (Wearing Position)</th>
<th>Standard Day (Measured by Metabolic Chamber: 2093.0 ([310.4] kcal/day))</th>
<th>Free-living Days (Measured by DLW Method: 2314.4 ([312.6] kcal/day))</th>
<th>Spearman Rank Correlation Coefficienta</th>
<th>Spearman Rank Correlation Coefficienta</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Difference in TEE Between Each Device and Metabolic Chamber (kcal/day), Mean (SD)</td>
<td>Estimated TEE by Each Device, Mean (SD)</td>
<td>Difference in TEE Between Each Device and DLW (kcal/day), Mean (SD)</td>
<td>Estimated TEE by Each Device, Mean (SD)</td>
</tr>
<tr>
<td>Withings Pulse O2 (wrist)</td>
<td>1814.8 (230.3)³</td>
<td>0.88</td>
<td>1796.6 (246.5)³</td>
<td>0.82</td>
</tr>
<tr>
<td>Jawbone (UP24) (wrist)</td>
<td>1815.8 (206.8)³</td>
<td>0.89</td>
<td>1724.2 (229.7)³</td>
<td>0.81</td>
</tr>
<tr>
<td>Garmin Vivosmart (wrist)</td>
<td>1844.1 (268.3)</td>
<td>0.90</td>
<td>1811.6 (274.8)³</td>
<td>0.85</td>
</tr>
<tr>
<td>ActiGraph GT3X (waist)²</td>
<td>1919.8 (343.0)</td>
<td>0.88</td>
<td>1789.5 (314.2)³</td>
<td>0.80</td>
</tr>
<tr>
<td>Suzuken Lifecorder EX (waist)</td>
<td>2051.8 (277.7)</td>
<td>0.93</td>
<td>2034.4 (298.3)</td>
<td>0.83</td>
</tr>
<tr>
<td>Panasonic Actimarker (waist)</td>
<td>2081.5 (329.9)</td>
<td>0.92</td>
<td>2069.8 (320.3)</td>
<td>0.85</td>
</tr>
<tr>
<td>Epson Pulsense (wrist)</td>
<td>2128.9 (206.2)</td>
<td>0.71</td>
<td>2097.4 (292.9)</td>
<td>0.82</td>
</tr>
<tr>
<td>Tanita AM-160 (pocket)</td>
<td>2138.0 (363.1)</td>
<td>0.92</td>
<td>2094.4 (402.3)</td>
<td>0.85</td>
</tr>
<tr>
<td>Fitbit Flex (wrist)</td>
<td>2219.3 (327.5)</td>
<td>0.90</td>
<td>2142.5 (354.4)</td>
<td>0.84</td>
</tr>
<tr>
<td>Misfit Shine (wrist)</td>
<td>2221.5 (312.4)</td>
<td>0.84</td>
<td>2084.1 (330.8)</td>
<td>0.85</td>
</tr>
<tr>
<td>OMRON Active Style Pro (waist)</td>
<td>2268.3 (367.2)</td>
<td>0.92</td>
<td>2245.2 (359.5)</td>
<td>0.88</td>
</tr>
<tr>
<td>OMRON CaloriScan (pocket)</td>
<td>2297.5 (345.5)</td>
<td>0.93</td>
<td>2221.3 (384.5)</td>
<td>0.88</td>
</tr>
</tbody>
</table>

Spearman rank correlation coefficients were obtained by interparticipant analysis. DLW indicates doubly labelled water; TEE, total energy expenditure.

³ Significant difference from TEE obtained by the metabolic chamber or DLW method.

⁴ Significant correlation for Spearman test between standard TEE and TEE estimated by each device.

⁵ TEE was calculated by adding resting metabolic ratio to physical activity energy expenditure provided by Actigraph.
fast. After setting and applying all devices, participants entered the metabolic chamber from 9:00 AM to 9:00 AM the following day. They completed 24-hour indirect calorimetry under a standardized protocol simulating normal daily life, which included 3 meals, desk work, watching TV, housework, treadmill walking, and sleeping.

For the DLW experiment, DLW dosing was performed in the laboratory after collection of baseline urine samples. Each participant collected urine in air tight containers on 8 days spread over a 15-day free-living period. Concurrently, the participants wore all 12 devices while awake except when bathing, special activities in which wearing the devices would be difficult, or when charging the battery. The 5 wearable devices worn on the wrist were worn while sleeping. After 15 days, urine samples and all wearable devices were recovered to analyze mean daily total energy expenditure during 15 free-living days.

Results | Total mean (SD) energy expenditure measured by the metabolic chamber (2093 [304] kcal/d) was significantly lower than that measured by the DLW method (2314 [313] kcal/d; P < .05). For both gold standard measures, Spearman rank correlation coefficients for most devices were greater than 0.8. Measurements from the 12 devices for a standardized day ranged from 278 kcal/d lower to 204 kcal/d higher than the metabolic chamber. Compared with the DLW measure for free-living days, estimates from the 12 devices ranged from 590 kcal/d lower to 69 kcal/d lower (Figure 2).

Discussion | The wearable devices that we tested were able to rank daily total energy expenditure between individuals, but absolute values differed widely among devices and varied significantly from the gold standard measures. Furthermore, all wearable devices underestimated total energy expenditure under free-living conditions. The large variance may be associated with epoch lengths and posture detection (sitting or standing), and underestimation might be due to periods of not wearing the devices during bathing and battery charge. Our study was limited by the small sample size and including only nonobese, healthy participants. Although further studies are required, the findings presented herein suggest that most wearable devices do not produce a valid measure of total energy expenditure.

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Administrative, technical, or material support: Kawakami, Nakae, Ishikawa-Takata, Tanaka, Miyachi.
Study supervision: Nakae, Nakata, Tanaka, Miyachi.

Conflict of Interest Disclosures: The authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr Tanaka reported receiving research funding from Omron Health Care Inc. No other disclosures were reported.

Funding/Support: This research was supported by the Practical Research Project for Lifestyle-related Diseases including Cardiovascular Diseases and Diabetes Mellitus from the Japan Agency for Medical Research and Development (AMED).

Role of the Funder/Sponsor: AMED had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Invited Commentary
The Challenges of Mobile Health Regulation

The field of mobile health (mHealth), involving the use of smartphones, tablets, and other wireless devices to collect, aggregate, or disseminate health information, has been heralded as a health care revolution. Applications (apps) and sensors—many included in consumer-focused wearables, and others more specifically targeting diseases or therapeutics—present an array of potential tools and opportunities for people, patients, and physicians to monitor and improve health. For example, apps have the potential to help patients and physicians remotely diagnose acute conditions, like bacterial pharyngitis or otitis media. Remote sensor devices may assist in monitoring chronic conditions, like the blood glucose levels of patients with diabetes, or blood pressure in patients with hypertension. Smartphone-delivered messages and interventions may improve adherence to medication, exercise, or diet. However, in this issue of *JAMA Internal Medicine*, 2 articles describe core challenges to the development of reliable mHealth apps. Plante et al.\(^1\) find that, while on the market, one of the most popular smartphone apps for measuring blood pressure was inaccurate. Murakami et al.\(^2\) provide a similarly sobering look at the variation in accuracy among wearable devices designed to measure energy expenditure.

These studies\(^1,2\) demonstrate that even the most popular apps and mHealth devices may be inaccurate or highly variable. When used to monitor heart rhythm in patients with atrial fibrillation, or fluid status in patients with heart failure, and especially when used by clinicians for medical decision making, lack of validity and accuracy may put patients at substantial risk. Minimizing this risk while supporting the development of convenient wearable monitors and remote interventions presents a number of major challenges, especially when one considers the range of diseases and patient populations involved. Chief among these challenges are the volume and growth in the number of mHealth apps. Major app stores now include more than 165,000 health-related apps.\(^3\)

Use of health-related apps may pose little risk in healthy persons if the information collected is not used for medical decision-making, but these apps should still undergo basic testing for accuracy. For mHealth apps that are designed to play a role in medical care, documenting the validity and accuracy of measurements is crucial. But beyond accuracy, like other medical devices, mHealth devices designed to be used in diagnosis and management of disease need to be tested for efficacy—that is, does use of these devices improve health outcomes?

Currently, health-related apps and devices are regulated by the US Food and Drug Administration (FDA) under the Food, Drug, and Cosmetic Act. mHealth apps, like medical devices, are categorized as class 1 (low risk), class 2 (moderate risk), and class 3 (high risk). Although class 3 apps, like medical devices, would usually require collecting premarket clinical data, the class 2 devices can be approved under a much more streamlined process of approval, and class 1 devices do not need FDA approval. To date, most medical apps have fallen in the class 1 or 2 category and are therefore subject to minimal premarket clinical testing.\(^4\)

The FDA recently drafted new guidance on mobile health.\(^4\) The FDA explains that it will focus on regulating a subset of mobile apps “whose functionality could pose a risk to a patient’s safety if the mobile app were not to function as intended.”\(^5\) The proposal makes clear that the FDA will not regulate the mobile devices themselves and that it will focus on functionality and risk of the data collected from these devices, the interpretation of these data, and any guidance the device or app provides to users. Examples of platforms that might fall under FDA purview include apps that link to sensors and produce electrocardiograms, electroencephalograms, or measure blood oxygen or glucose.\(^5\)

As the mHealth world continues to evolve, we see a number of potential solutions that could improve the utility and effectiveness of mHealth interventions.

App and sensor companies should be clear about the intended use of their devices and clearly delineate when “wellness” support becomes “disease management” that requires supervision by a health care professional. Low-risk apps and devices designed to improve health behaviors should be tested for accuracy, and the design and results of such tests should be made public to allow consumers to select apps on the basis of accuracy as well as consumer reviews.

The FDA should play an important role in approving apps and devices intended to support medical decision-making. The FDA will require additional funding to screen the many mHealth interventions being pushed to market.

The FDA should determine the risk categories for mobile health devices and apps. A key first step will be to develop criteria that distinguish between apps that provide patient education or motivational support, which should not require FDA approval, and those that support medical decision-making. For apps that will be used to guide medical decisions, the FDA should require testing for validity, accuracy, and efficacy for these products to be allowed on the market.

Finally, we support greater commitment to partnerships that provide empirical data to support the health impacts of apps and sensors and how these platforms affect population health. This association will allow for increased scientific testing of mHealth apps prior to market release. The recent partnership between the American Heart Association and Google Life Sciences to improve cardiac health is a step in the right direction.\(^6\)

mHealth technologies have the potential to help improve outcomes, reduce costs, and broadly engage patients in their health. However, mHealth companies can only achieve these goals if their apps are safe, accurate, and reliable.

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Multidrug-Resistant Organisms on Patients’ Hands: A Missed Opportunity

Multidrug-resistant organisms (MDROs) are increasingly prevalent in post–acute care (PAC) facilities. Increased contact between health care workers, the environment, and patients in PAC facilities can increase the risk of MDRO cross-transmission because PAC patients may need assistance with activities of daily living and are encouraged to be mobile outside of their room for rehabilitation, dining, and other recreational activities. Much more than other anatomic sites, patients’ hands are more likely to come in contact with environmental surfaces, health care workers’ hands, and other patients in PAC facilities. Our objective was to evaluate baseline, new acquisition, and duration of MDRO hand carriage among patients newly admitted to PAC facilities from acute care hospitals.

Methods | This prospective observational cohort study in 6 PAC facilities in metropolitan Detroit and Southeast Michigan was approved by the institutional review board of the University of Michigan. After obtaining written informed consent, the dominant hands of newly admitted PAC patients were sampled. We swabbed the palm, fingers, and around nails of patients’ hands. Samples were collected at baseline (day of enrollment), day 14, and monthly for up to 180 days or until discharge from the facility. Methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant Enterococcus (VRE), and resistant gram-negative bacilli (RGNB) were identified using standard microbiological methods. Gram-negative bacilli resistant to either ceftazidime, ciprofloxacin, or imipenem were defined as RGNB.

Results | Of 826 consecutive eligible PAC patients approached for the study, 357 (43.2%) agreed to participate and were followed for 806 visits (mean, 2.3 visits; range, 1-8 visits). Most participants were female (54.9%), with a mean age of 75.8 years. Nearly one-quarter (86 of 357 [24.1%]) had at least 1 MDRO on their hands on discharge from an acute care hospital and admission to the PAC facility (Table). Baseline hand carriage rates of VRE, MRSA, and RGNB were 13.7%, 10.9%, and 2.8%, respectively. During follow-up (Figure), 34.2% of patients’ hands (122 of 357) were colonized with an MDRO, with 10.1% of patients (36 of 357) newly acquiring 1 or more MDROs. Specifically, 7.1% (22 of 308 at risk), 6.3% (20 of 318 at risk), and 2.8% (8 of 284 at risk), respectively.

Table. Baseline Patient Hand Carriage of MDROs in 6 Post–Acute Care Facilities

<table>
<thead>
<tr>
<th>Facility (Patients, No.)</th>
<th>Organisms, No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MRSA</td>
</tr>
<tr>
<td>Total (357)</td>
<td>39(10.9)</td>
</tr>
<tr>
<td>1 (81)</td>
<td>8(9.9)</td>
</tr>
<tr>
<td>2 (47)</td>
<td>6(12.8)</td>
</tr>
<tr>
<td>3 (85)</td>
<td>9(10.6)</td>
</tr>
<tr>
<td>4 (81)</td>
<td>8(9.9)</td>
</tr>
<tr>
<td>5 (26)</td>
<td>3(11.5)</td>
</tr>
<tr>
<td>6 (37)</td>
<td>5(13.5)</td>
</tr>
</tbody>
</table>

Abbreviations: MDRO, multidrug resistant organism; MRSA, methicillin-resistant Staphylococcus aureus; RGNB, resistant-gram negative bacilli; and VRE, vancomycin-resistant Enterococcus. At least 1 MDRO.