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Wear With Care: A Call for Empirical Investigations of Adverse Outcomes of Consumer Health Wearables

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Consumer health wearables—commercially available health tracking technologies such as smartwatches, fitness trackers, and wearable sensors coupled to smartphones—have provoked a paradigm shift in how people approach their health. One fifth of Americans use a wearable on a regular basis.[1] These technologies are recognized for their promises to lower costs and save lives,[2] and research documents their efficacy for addressing a range of health promotion and management concerns.[1,3,4] However, evidence of efficacy does not mean an absence of harm. This article is motivated by the observation that the safety of wearables and the potential health risks associated with their use have gone concerningly unexamined. The ubiquity[1,2] of these health-related technologies throughout the general population is somewhat historically unique and, in and of itself, necessitates rigorous and comprehensive investigations of safety. Further, case and cohort studies[5–10] have reported preliminary evidence of negative clinical and system-level outcomes, and additional adverse outcomes of concern have been suggested in expert opinion analyses.[11,12] Yet, these have not been systematically investigated. Given the broad adoption of wearable technologies and that they are marketed directly to consumers, there is a need to investigate (a) the nature and prevalence of negative outcomes, and (b) the risk factors that confer vulnerability to negative effects.

This article calls for action by proposing a framework for investigating potential negative outcomes and their risk factors, with the current level of evidence[13] indicated for each variable (Figure). We observe that little peer-reviewed research has directly investigated the negative outcomes associated with wearables. Negative outcomes have been reported

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POTENTIAL COMPETING INTERESTS

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by a small number of case and cohort studies,[5–10] but these have not been followed by systematic investigations with rigorous designs. Furthermore, although there is review-level evidence describing technology-level risk factors such as measurement inaccuracies and privacy concerns,[14–17] characterization of individual-level risk factors (eg, psychological and medical vulnerabilities), and social-level risk factors (eg, access to health care) has thus far been largely limited to expert speculation.[11,12] Individual and social-level risks may be exacerbated when exaggerated marketing claims are made about validity and accuracy, as has been found to be the case for some popular devices.[18]

Our aim is *not* to criticize or oppose these promising technologies, and we direct readers to recent discussions of their efficacy and potential in health promotion and management.[1,3] Rather, this article aims to equip the field to empirically investigate negative outcomes and their risk factors so that a comprehensive evidence base can guide the implementation of consumer health wearable technologies.

Negative Outcomes of Wearable Use and Individual-Level Risk Factors

Adverse Psychological Symptoms and New or Exacerbated Mental Disorders.

Health tracking technologies constitute behavioral interventions, and any behavioral intervention can precipitate positive or negative health outcomes. Although few would deny that this applies to wearables, there is a lack of empirical data about the prevalence of negative health outcomes or the individual traits that confer heightened risk for negative effects. Case studies suggest that wearable-induced health anxiety warrants empirical investigation. In one case report, a patient with atrial fibrillation and no psychiatric history developed health anxiety after acquiring a smartwatch, resulting in 12 emergency department visits despite repeated outpatient reassurance.[5] A recent qualitative investigation (n=27) of experiences with wearables among chronic heart patients found that several individuals reported reductions in anxiety from wearable use, whereas 1 participant reported new health-related anxiety.[6] Two case reports constitute a weak level of evidence,[13] but together suggest that wearable use may increase health anxiety for some and decrease it for others. Further research is needed to identify prevalence rates and for whom this is a significant risk.

The exacerbation of existing mental disorders and the recurrence of disorders in remission also warrant rigorous investigation. Preliminary research has suggested that wearable technologies may have exacerbating effects on eating disorders; for example, a randomized-controlled trial that included wearable technology as part of behavioral treatment among individuals diagnosed with an eating disorder found that a subsample of participants reported that the wearable negatively affected disordered eating behaviors.[7] It is unknown whether recent developments in wearables, such as algorithms that provide nutrition recommendations, would mitigate these undesired effects.

The field lacks empirical investigations into the impact of wearables on other mental disorders, but some expert commentaries[11,12] have remarked that classes of disorders most

likely to be affected by wearable usage include depressive, sleep, and anxiety disorders. The data that wearables track may act directly on symptoms of these disorders (eg, rumination about sleep quality, reinforcement of negative beliefs about one-self). Wearables may also affect transdiagnostic processes that cut across psychiatric disorders, conferring increased risk for new or exacerbated psychological symptoms for some. For example, interoceptive awareness (the ability to identify, understand, and adaptively respond to one's bodily sensations) and its potential counterpart, interoceptive avoidance (the avoidance of certain body sensations and activities that produce them), are transdiagnostic processes implicated in several Diagnostic and Statistical Manual of Mental Disorders diagnoses. Continuous quantitative data about interoceptively detectable processes (eg, heart rate) seems likely to alter users' interoceptive awareness, but the field currently lacks data about how.

Maladaptive Health Behaviors, Mismanagement of Conditions, and Negative Physical Health Outcomes.

Data from wearables are used by individuals to guide choices that directly affect health; thus, the same data that can inspire new, adaptive health behaviors can also lead to maladaptive health behaviors. Expert opinion articles have noted that inaccurate or incomplete data from wearables can lead to behaviors that harm health,[1,4,12] a concern that is exacerbated by exaggerated marketing claims that have sometimes been identified in validation studies of popular devices.[18] Consider an individual with a diagnosed heart condition who checks their smartwatch's cardiac data during an exercise session because they are experiencing unusual shortness of breath. If the wearable inaccurately characterizes normal heart rate and rhythm (whether because of measurement error or because the smartwatch is unable to detect an arrhythmia) and the user is not aware of the device's limitations, this inaccurate reassurance could cause a medical emergency. Others have raised the possibility of maladaptive health behaviors that can result from using wearables in medically healthy individuals, such as overexercising and disordered eating,[8] or maladaptive changes to health care utilization.[5]

Individual factors such as knowledge about one's health status, knowledge of device limitations, and adherence to current treatment and preventive screenings may reduce the likelihood of unhealthy behaviors. However, research has yet to empirically characterize risk and protective factors. Such data are critically needed to inform user or patient education strategies that can mitigate these concerns and prevent adverse physical health outcomes (eg, injuries, worsened cardiovascular health, or mismanagement of a known condition) for groups of individuals at risk. For example, wearables designed for clinical research (and not consumer use) frequently restrict the data viewable by the wearer. It is possible that this approach may optimize health outcomes from consumer devices for some groups of individuals, although research is needed to identify best practices in this regard.

Beliefs, Values, and Technological Trust.-

The level of trust that people place in a wearable is closely linked to how they use and respond to the technology. Technological trust—or lack thereof—is associated with perceptions of the accuracy and usefulness of the device,[19] and its perceived compatibility

with the users' beliefs and values. Conflict with an individuals' values is highlighted as a challenge across digital health,[20] and wearables present a distinct set of concerns in this regard. Incorporating continuous biomarker monitoring into one's life is, ultimately, tied to beliefs about human-technology interactions. Although cultural variables have sometimes been included in nonrandomized usability and acceptability research,[21] they are largely absent from published efficacy trials. Investigations of technology-relevant beliefs and the role that these play in technological trust and clinical outcomes are important to include in future trials.

Negative Outcomes in Context: The Need for Social and System-Level Data

Inequities in Accuracy and Usability.

A vitally important discussion about equity in digital health has emerged in recent years. This discussion recognizes that technological innovations are implemented within societal contexts; therefore, the systems of power, structural inequities, and disparities in healthcare that are part and parcel of societal systems strongly influence the outcomes of novel technologies. Although we direct readers to comprehensive analyses of digital health equity,[20,22] in the context of the present discussion, it is essential that the individual-level risk factors described above are investigated with overarching social contexts taken into account. Individual-level vulnerabilities may either be exacerbated or buffered against by systemic contexts.

Emergent evidence of racial differences in measurement accuracy is a pressing concern for wearables. Cohort studies suggest that optical sensors of heart rate, used commonly in smartwatches, may be less accurate on darker skintones.[23] When considering the limitations to diversity and equity observed in clinical research and technology sectors, problems such as these are not surprising: when validation studies are performed on homogenous groups, confounders that would be identified with more diverse samples are overlooked. The field must bear in mind the troubling possibility that other group-level discrepancies in accuracy exist that have not yet been identified (eg, age or medical conditions). The speed with which new sensing modalities and scoring algorithms are added contributes to this challenge, as new group-level differences in accuracy can be unknowingly introduced. We urge researchers to include benchmarking of wearable-assessed metrics against data obtained using laboratory-grade equipment in research designs whenever possible, so that latent group-based discrepancies in accuracy can be swiftly identified.

Disparities in technology access and usability also warrant empirical examination. Like other areas of digital health,[24] barriers to the accessibility and usability of wearables include socioeconomic status, access to Wi-Fi, technology literacy, and individual differences (eg, persons who are blind or persons who have a physical disability). The implication of these barriers is that, in the scaling up of wearable implementation, people who are already experiencing healthcare inequities are also the most likely to be left behind. Without empirical attention, this could ultimately affect the accessibility of health care more broadly. For example, consider recent efforts to integrate wearable-assessed data (eg, step count) into workplace health insurance incentive programs.[25] Although walking is a generally salutary

behavior, some individuals may be unable to attain an incentivized step count owing to a health condition. This well-intended policy could thus have the consequence of leaving individuals who are most in need of health care to pay more for insurance than peers without a pre-existing condition.

Negative Effects on Health Care Utilization and Costs of Care.

Wearables have been touted for offering the possibility of low-cost population-level screening and early diagnosis for common conditions such as atrial fibrillation.[4] If proven effective, this would constitute a groundbreaking advance for public health. On the contrary, potential negative system-level affects must also be investigated, such as increased health costs associated with follow-up testing and health risks from complications from unnecessary procedures. With over 27 million Americans uninsured in 2022,[26] many wearable users may lack access to affordable follow-up care altogether. For those uninsured, follow-up testing for a wearable-detected false positive can have lasting financial consequences (eg, medical debt) that may affect health and future health care utilization. There is also a paucity of data about how wearable adoption affects how people use health care. There is evidence to suggest that increased personal monitoring may contribute to overutilization among individuals who develop health anxiety,[5] and it follows that wearable use may otherwise affect when and why people go to their general practitioner and what they discuss at appointments. In future controlled trials of wearables for diagnosis and screening, undesired effects on health care utilization and the cost of care should be empirically characterized.

Health Care Provider Burden.

Finally, data about the impacts on providers of the implementation of wearables into existing health care systems are needed. Concerns about wearables raised by providers in qualitative investigations[9,10] have included the feasibility of discussing data within allotted appointment time, data interpretability, and the potential for increased provider time burden. Many of the negative individual-level outcomes described here may be prevented or addressed when wearables are used in collaboration with a professional, but data are needed to characterize the actual availability and implementation potential of this kind of care. Providers' willingness and ability to discuss wearable usage with their patients may be contingent on the demands of specific practice contexts, and the burden placed on providers may also vary by use context (eg, whether use is patient-initiated or initiated at the recommendation of a provider). Given the number and heterogeneity of wearable devices and how frequently sensor technologies and scoring algorithms change, there are also clear obstacles to providers' ability to stay current on the nuances of individual devices. Moreover, many providers may lack knowledge about how to assess for and manage negative health effects associated with wearables use.

CONCLUSION

Consumer health wearables have been recognized for their promise to revolutionize how people monitor and manage their health. Indeed, a rapidly accumulating literature suggests

efficacy for the use of wearables for some health goals and conditions.[1,3] The field—and arguably the general public—also acknowledge the potential for negative effects, as evidenced by speculative mention of this barrier in recent scholarly articles[11,12] and editorial content published in general interest publications.[27] However, data about negative effects is limited to a small number of case and cohort studies, and there is a paucity of rigorous evidence for either the presence or absence of harms associated with wearable use. Given their wide adoption, systematic investigations into the nature and prevalence of undesirable outcomes must become a priority. As a call to action, we suggest a framework for investigating negative outcomes and their putative risk factors that can constitute an agenda for future research on wearables. These data are needed to identify and define the negative outcomes that are of greatest concern, to guide data-driven regulations, and to inform the development of preventive user education strategies tailored to those who may be at risk for negative effects.

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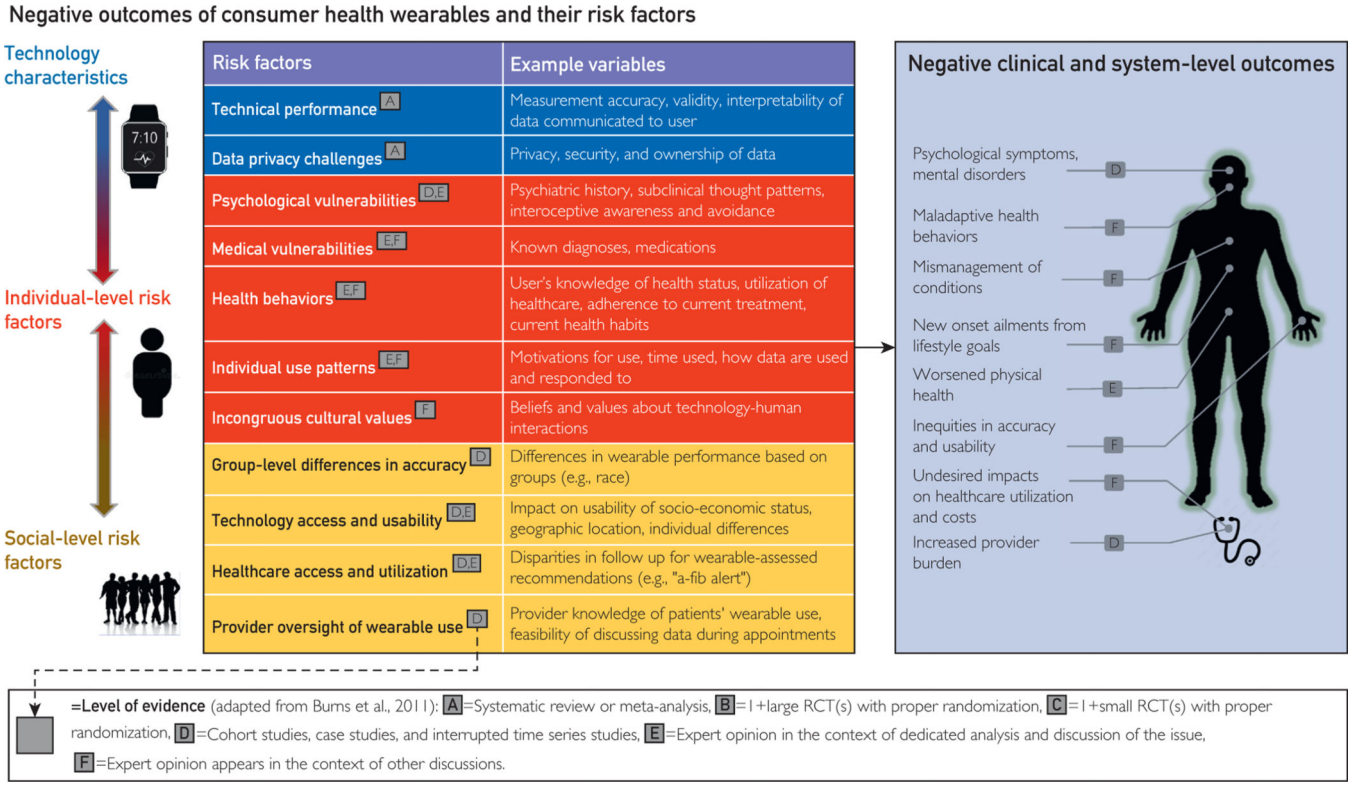

FIGURE.

Potential adverse effects of consumer health wearables span multiple levels and affect clinical and system-level outcomes but are understudied. Although potential risk factors posed by technological issues such as measurement inaccuracy and privacy concerns are characterized by a relatively high level of evidence, 2 additional categories of risk factors for negative outcomes are theoretically acknowledged but remain largely uninvestigated. At the individual level, a user's pre-existing psychological, medical, and behavioral vulnerabilities can confer a risk for negative outcomes. At the social level, characteristics of the social-structural contexts in which wearables are used (eg, access to a provider for discussion of wearable-assessed data) can exacerbate individual risk and constitute unique risk factors themselves. Finally, negative outcomes (far right) are acknowledged in theoretical discussions but largely lack rigorous empirical investigation and characterization. Negative clinical outcomes (undesired effects on specific health variables, such as a symptom or health behavior) and negative system-level outcomes (undesired effects on the systems surrounding health access and care) are shown together, given their reciprocal nature.