A step in the right direction: the potential role of smartwatches in supporting chronic disease prevention in health care

Smartwatches can count every step towards a predict–prevent health care system, but clinical regulation is the first leap

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Australia is struggling with the ever-increasing burden of chronic disease. Over $38 billion per year is spent on care for people with chronic diseases, such as cardiovascular disease, type 2 diabetes, and cancer.[1] The majority of this funding is dedicated to acute care, and just 9.6% of health care investment supports disease prevention.[1] Perversely, Australia's health system is rewarded for increasing acute care activity (activity-based funding) to manage disease, which perpetuates inefficient break–fix models of care.[2] The strain on acute care service provision has been accelerated by the COVID-19 pandemic[3] and Australia's ageing population, and is forecast as unsustainable.[2] Ageing increases total expenditure on hospitalisations, pathology provision, medical imaging, and cost to the Pharmaceutical Benefits Scheme.[1] This burden of chronic disease — associated with disability and premature death — is becoming less and less sensitive to further extensions in health care spending on treatment. Prevention (as defined in the Supporting Information) is urgently needed; however, dedicated funding, policies and models of preventive care for chronic diseases in communities are minimal, especially for priority populations and high risk social and environmental settings.

Digital medicine can enable efficient predict–prevent models of health care

Digital health innovations have contributed to the transformation of health care delivery over the past decade.[4] Leveraging vast amounts of data to predict risk, intervene and prevent adverse clinical outcomes is known as a predict–prevent model of health care. The predict–prevent model is proactive compared with the current reactive break–fix model.[2] To facilitate predict–prevent health care, access to real world data in the community is required. Real world data are collected outside the controlled constraints of conventional randomised controlled trials to evaluate what is happening in everyday life.[5,6] Analysis of such data can generate new knowledge to guide iterative cycles of continuous patient and population health improvement.[7]

Smartwatches generate real world data, and their popularity has exponentially increased in Australia — one in three people now own a smartwatch.[8] These devices are marketed by the health and fitness industry as a positive lifestyle choice, referencing their ability to provide health information in real time.[9,10] However, the accuracy of this information varies between metrics and manufacturers and, with very few exceptions, has not been approved for medical use by the Therapeutic Goods Administration (TGA). Smartwatch data cannot currently be used to diagnose, monitor or treat chronic disease in clinical practice. Nevertheless, there is growing evidence suggesting that patient-generated real world health data, including smartwatch-derived data, helps patients make sense of their health, enhances trust with care providers, and enables autonomy.[11]

This article explores the current role of smartwatches in chronic disease prevention, outlines regulatory frameworks for smartwatch-derived data in Australia, and proposes a roadmap for the use of smartwatches in supporting a learning health system to enable disease prevention.

The current role of smartwatches in chronic disease prevention

Smartwatches can track health metrics, such as step count, heart rate, sleep stage estimation, peripheral oxygen saturation[12] and heart rate variability,[13] with varying accuracy. The evidence behind the use of smartwatches in chronic disease prevention is limited. Most studies have adopted an observational research design and/or have small sample sizes.[14] Providing a comprehensive analysis of an individual's health in real time could enable individualised care for people with chronic disease. For instance, goal setting could be used to capture and sustain individual engagement that can include setting personalised, incremental targets, such as daily step count as a marker of physical activity. An increase in steps taken per day has recently been linked to reduced all-cause mortality in a meta-analysis of 15 international cohorts,[15] and can be accurately measured by smartwatches.

Smartwatches complement the predict–prevent model of health care in several ways. For instance, data generated can facilitate further understanding of disease physiology and may allow earlier detection of deteriorations relating to a specific chronic condition to expedite treatment. Devices can also synchronise with coexisting mobile apps to provide recommendations about positive lifestyle interventions based on the user's data. This approach fits well with the ethos of personalised care in chronic disease management.[16] In practice, however, only one study to date has found a reduction in all-cause hospital re-admission using a smartwatch-based digital intervention during recovery from acute myocardial infarction.[17]

Regulation and accuracy of smartwatch applications: current state in Australia

The TGA is mandated to regulate individual software for medical devices that fulfil a predefined purpose, namely:[18]

- providing a diagnosis or screening for a disease/condition;
- monitoring the state or progression of a disease/condition, or the parameters of a person with a disease/condition;
- specifying or recommending a treatment or intervention; or
- providing therapy through the provision of information.

Just five smartwatch-enabled applications are TGA approved to date, classified as disease-focused diagnostic support tools.[19] An example is the Apple Watch (Apple Inc.) electrocardiogram algorithm,[20] which prompts the user if an irregular heart rhythm (atrial fibrillation) is detected. The theoretical benefit of this lies in the potential to diagnose atrial fibrillation, which is associated with one in every five strokes[21] and for which initiating anticoagulation can significantly reduce risk. However, the algorithm cannot be used to diagnose atrial fibrillation independently, or to commence treatment without further investigation — Box 1 illustrates this using a fictional case example.[22] The algorithm is not recommended for use in people with pre-existing arrhythmias, or for those under the age of 22 years, and an improvement in health outcomes is yet to be observed.[20]

Smartwatches have limited scope in the health care sector as diagnostic tools, as they cannot provide validated measurements of health-related factors, including heart rate variability,[23] oxygen saturation,[12] and mood.[24] These measurements are presented to the consumer as medical information despite being recreational grade, which is not always made clear. This dissonance is confusing and creates tension as consumers are not necessarily able to distinguish between these differing grades of health information.[25]

A roadmap for integrating smartwatches into digitally enabled precision prevention models of care

We identify five challenges to overcome before routine integration of smartwatches into existing models of chronic disease prevention can occur: data accuracy, interoperability, data familiarity, equity and accessibility, and implementation (Box 2). We propose a roadmap that is aligned with the three horizons for precision prevention of chronic disease.[2] These horizons are: building digital health prevention foundations, transforming preventive care using data and analytics, and a learning system of precision prevention, which have been proposed for use in prevention of chronic disease, such as childhood obesity.[2] The roadmap has been developed to guide research and digital health investment, and highlight technical, educational and institutional barriers to integrating smartwatches into models of care for people with or at risk of chronic disease.

1 Hypothetical case example showing clinical application of the Apple Watch electrocardiogram

A 67-year-old woman with hypertension and type 2 diabetes mellitus receives an "irregular heart rhythm" notification on her Apple Watch. She presents to her general practitioner, who organises a 12-lead electrocardiogram confirming the presence of atrial fibrillation.

A subsequent transthoracic echocardiogram shows no valvular pathology. Her CHA_2DS_2-VASc score is calculated as 4, placing her annual stroke risk at 7.3%. She is commenced on a direct oral anticoagulant (apixaban), lowering her annual stroke risk to 1.9%.

Not the right time: current challenges for smartwatch integration into health care models

There are barriers preventing the transformation of smartwatches from their current lifestyle use by the "worried well" to clinical decision and disease prediction aids for at-risk populations. Variance in the accuracy of data confounds their clinical utility, alongside the manner in which accuracy is tested, which is predominantly in controlled settings with healthy volunteers. Proprietary algorithms are specific to the smartwatch manufacturer, which impacts both data familiarity and interoperability. There is a disconnect between medical regulation and level of trust placed in smartwatch applications by consumers. Taking the example of the Apple Watch electrocardiogram, a recent qualitative study found brand loyalty and marketing were a greater influence on using the app than its status as medical device software.[26]

There is no formal training or incentive for clinicians to interpret vast amounts of data generated by smartwatches. Questions also remain surrounding data ownership, storage and accessibility — data protection laws must ensure that medical data are not misused and only necessary data collected with informed consent.[27] Clinicians are currently disadvantaged by the ethical complexities arising from a lack of clarity on who actually is responsible for acting on the data, as this remains unclear. There is also a lack of routine data linkage across care settings in Australia, which limits its capacity to address health issues in real world settings.

Perhaps the greatest barrier is the digital divide created between socio-economic status (SES) groups. Smartwatches are predominantly used by and designed for people with higher SES,[28] with individuals with low SES gaining less benefit from digital health technologies.[29] There is no evidence that digital physical activity interventions are effective for those with low SES,[30] despite this group having higher rates of chronic disease and overall mortality.[31] This may be explained by lower digital health literacy, lower engagement with digital interventions, and a lack of supportive social and physical environments to facilitate increased physical activity.[30] Data protection laws must take this into account to avoid financial discrimination by health insurers. We propose that any

2 A roadmap for implementation of smartwatches in health care systems, modelled on the three horizons framework for digital health transformation towards precision prevention of chronic disease in Australia[2]

Challenge	Horizon 1: Building digital health prevention foundations	Horizon 2: Transforming preventive care using data and analytics	Horizon 3: A learning system of precision prevention
Data accuracy	• High grade disease-focused research into accuracy of data from wearables	• Using real world experience data to develop machine learning algorithms geared towards prevention of chronic disease acquisition	• Artificial intelligence use to predict risk and prevent chronic disease utilising high volumes of validated, organic data
	• Avoiding use of data in controlled settings, healthy volunteer data and/or data collected at rest to validate measurement of a particular health metric		• Continual artificial intelligence model refinement and development by collaborative teams, including clinicians, data scientists and industry partners
Interoperability	• Create interoperability between fragmented data systems across sectors and the continuum of care	• Development of interoperable software algorithms that can be used by key manufacturers	• Integration of validated data from wearables into existing electronic health records
	• Partnership between health care and industry to inform system interoperability	• Benchmarking of algorithms against interoperability standards, such as HL7 Fast Health Interoperability Resources	• Availability of real time smartwatch-generated data in patient–clinician interfaces through electronic health records, telehealth and other mobile health care apps
Data familiarity	• Greater transparency over accuracy of measurements for both consumer and clinician: distinction between medical grade and recreational grade measurements	• Inform consumers of how data will be stored and who has access (and in which format), to alleviate concerns of privacy and sharing information	• Increased access for consumers to tailored smartwatch-generated health data to guide medical and/or lifestyle interventions to reduce risk of chronic disease
	• Upskill health care professionals in digital health literacy and data familiarity	• Upskill health care professionals in wearables data interpretation through education initiatives led by digital health experts, with the provision of formal recognition and credentials	• Integration of validated disease-focused smartwatch data into existing risk prediction calculators, which are already familiar to clinicians, and generation of new risk prediction models using real world population-based data
Equity and accessibility	• Develop a multimodal, accessible digital literacy education model to reach underserved, priority areas in the community	• Develop capability to aggregate real world data from social, biomedical, environmental and behavioural determinants of health, and analyse these data with innovative analytics (clinical decision support systems, artificial intelligence) to support targeted prevention decisions and funding at community and population scale	• Ensure universal access to wearables using evidence-based digital health frameworks, to prioritise areas of greatest need based on epidemiological risk using a shared population data infrastructure
	• Increase availability of wearables to priority, at-risk populations through incentivised funding and economic analysis of effectiveness		• Strengthening existing policies to incentivise health services and communities towards a predict–prevent model of health care
Implementation	• Development of disease-focused diagnostic support tools in alignment with Therapeutic Goods Administration regulatory standards	• Use of Therapeutic Goods Administration regulated data generated from wearables to inform clinical decision support systems for a predefined chronic condition, to optimise preventive care	• Integrate evidence-based digital models of care into digital clinical practice guidelines
	• Early involvement of high level stakeholders, clinician champions and chronic disease patient advocacy groups in strategic development	• Financial support for regulatory bodies to accommodate the rate of technological advancement, through health care–industry partnerships	• Robust cost-effectiveness analyses generated by predicting avoidance of hospitalisation and adverse events using artificial intelligence

smartwatch-based health care implementation should prioritise bridging this digital health care gap.

The first steps forward: where to from here?

The ubiquity of smartwatches in society has generated a vast amount of real world health data. These data have the potential to predict risk and prevent adverse outcomes in at-risk groups. However, as outlined in our roadmap, there are challenges ahead. For consumers and clinicians today, the distinction between recreational grade and medical grade data is confusing and must be clearly communicated.

We need a concerted effort to undertake disease prevention, as our treatment efforts are failing. Smartwatches could facilitate this approach, alongside other mobile health care technologies (such as smoking cessation apps[32] and behaviour change technique apps for obesity[33]), as a user-friendly, data-rich and non-invasive intervention that may lower chronic disease morbidity. Clinical regulation of software designed for medical use is the first step. As health care professionals, we can further our understanding of smartwatch use in chronic disease through further research using real world data — with the ultimate goal of improving autonomy and health outcomes for consumers.

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1 Australian Institute of Health and Welfare. Disease expenditure in Australia 2015-16. https://www.aihw.gov.au/reports/health-welfare-expenditure/disease-expenditure-australia-2015-16 (viewed Oct 2022).

2 Canfell OJ, Littlewood R, Burton-Jones A, Sullivan C.. Digital health and precision prevention: shifting from disease-centred care to consumer-centred health. *Aust Heath Rev* 2022; 46: 279-283.

3 Myers LC, Liu VX. The COVID-19 pandemic strikes again and again and again. *JAMA Netw Open* 2022; 5: e221760.

4 Bashi N, Fatehi F, Mosadeghi-Nik M, et al. Digital health interventions for chronic diseases: a scoping review of evaluation frameworks. *BMJ Health Care Inform* 2020; 27: e100066.

5 Blonde L, Khunti K, Harris SB, et al. Interpretation and impact of real-world clinical data for the practicing clinician. *Adv Ther* 2018; 35: 1763-1774.

6 Chodankar D. Introduction to real-world evidence studies. *Perspect Clin Res* 2021; 12: 171-174.

7 Canfell OJ, Davidson K, Woods L, et al. Precision public health for non-communicable diseases: an emerging strategic roadmap and multinational use cases. *Front Public Health* 2022; 10: 854525

8 Riccio, J. Report: Rapid adoption of wearables, 2016. PwC Australia, 13 May 2016. https://www.digitalpulse.pwc.com.au/2016-wearable-statistics-report/ (viewed Oct 2022).

9 Gualtieri L, Rosenbluth S, Phillips J. Can a free wearable activity tracker change behavior? The impact of trackers on adults in a physician-led wellness group. *JMIR Res Protoc* 2016; 5: e237.

10 Jo A, Coronel BD, Coakes CE, Mainous AG 3rd. Is there a benefit to patients using wearable devices such as fitbit or health apps on mobiles? A systematic review. *Am J Med* 2019; 132: 1394-1400.e1.

11 Petersen C. Patient-generated health data: a pathway to enhanced long-term cancer survivorship. *J Am Med Inform Assoc* 2016; 23: 456-461.

12 Gupta S, Mahmoud A, Massoomi MR. A clinician's guide to smartwatch "interrogation". *Curr Cardiol Rep* 2022: 24: 995-1009.

13 Rodrigues E, Lima D, Barbosa P, et al. HRV monitoring using commercial wearable devices as a health indicator for older persons during the pandemic. *Sensors (Basel)* 2022; 22: 2001.

14 Mattison G, Canfell O, Forrester D, et al. The influence of wearables on health care outcomes in chronic disease: systematic review. *J Med Internet Res* 2022; 24: e36690.

15 Paluch AE, Bjpai S, Bassett DR, et al. Daily steps and all-cause mortality: a meta-analysis of 15 international cohorts. *Lancet Public Health* 2022; 7: e219-e228.

16 Coulter A, Entwistle VA, Eccles A, et al. Personalised care planning for adults with chronic or long-term health conditions. *Cochrane Database Syst Rev* 2015; (3): CD010523.

17 Bhardwaj V, Spaulding EM, Marvel FA, et al. Cost-effectiveness of a digital health intervention for acute myocardial infarction recovery. *Med Care* 2021; 59: 1023-1030.

18 Therapeutic Goods Administration. Regulatory changes for software based medical devices. Version 1.2, August 2021. Canberra: Commonwealth of Australia, 2021. https://www.tga.gov.au/sites/default/files/regulatory-changes-software-based-medical-devices.pdf (viewed Oct 2022).

19 Therapeutic Goods Administration. Australian Register of Therapeutic Goods. https://www.tga.gov.au/resources/artg (viewed Oct 2022).

20 Isakadze N, Martin SS. How useful is the smartwatch ECG? *Trends Cardiovasc Med* 2020; 30: 442-448.

21 Marini C, De Santis F, Sacco S, et al. Contribution of atrial fibrillation to incidence and outcome of ischemic stroke: results from a population-based study. *Stroke* 2005; 36: 1115-1159.

22 Loewen PS, Bansback N, Hicklin J, et al. Evaluating the effect of a patient decision aid for atrial fibrillation stroke prevention therapy. *Ann Pharmacother* 2019; 53: 665-674.

23 Hirten RP, Danieletto M, Tomalin L, et al. Use of physiological data from a wearable device to identify SARS-CoV-2 infection and symptoms and predict COVID-19 diagnosis: observational study. *J Med Internet Res* 2021; 23: e26107.

24 Hilty DM, Chan S, Hwang T, et al. Advances in mobile mental health: opportunities and implications for the spectrum of e-mental health *services*. *Mhealth* 2017; 3: 34.

25 Segura Anaya LH, Alsadoon A, Costadopoulos N, Prasad PWC. Ethical implications of user perceptions of wearable devices. *Sci Eng Ethics* 2018; 24: 1-28.

26 Shih P, Prokopovich K, Degeling C, et al. Direct-to-consumer detection of atrial fibrillation in a smartwatch electrocardiogram: medical overuse, medicalisation and the experience of consumers. *Soc Sci Med* 2022; 303: 114954.

27 Predel C, Steger F. Ethical challenges with smartwatch-based screening for atrial fibrillation: putting users at risk for marketing purposes? *Front Cardiovasc Med* 2021; 7: 615927.

28 Mackert M, Mabry-Flynn A, Champlin S, et al. Health literacy and health information technology adoption: the potential for a new digital divide. *J Med Internet Res* 2016; 18: e264.

29 Kontos E, Blake KD, Chou WY, Prestin A.. Predictors of eHealth usage: insights on the digital divide from the Health Information National Trends Survey 2012. *J Med Internet Res* 2014; 16: e172.

30 Western MJ, Armstrong MEG, Islam I, et al. The effectiveness of digital interventions for increasing physical activity in individuals of low socioeconomic status: a systematic review and meta-analysis. *Int J Behav Nutr Phys Act* 2021; 18: 148.

31 Dalstra JA, Kunst AE, Borrell C, et al. Socioeconomic differences in the prevalence of common chronic diseases: an overview of eight European countries. *Int J Epidemiol* 2005 34: 316-326.

32 Marler JD, Fujii CA, Utley MT, et al. Outcomes of a comprehensive mobile smoking cessation program with nicotine replacement therapy in adult smokers: pilot randomized controlled trial. *JMIR Mhealth Uhealth* 2022; 10: e41658.

33 Vlahu-Gjorgievska E, Burazor A, Win KT, Trajkovik V. mHealth apps targeting obesity and overweight in young people: app review and analysis. *JMIR Mhealth Uhealth* 2023; 11: e37716. ■

Supporting Information

Additional Supporting Information is included with the online version of this article.