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## Device-based measurement of physical activity in cardiovascular healthcare – potential and challenges

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Low physical activity<sup>1</sup> and slow walking pace<sup>2</sup> have a two-way relationship with cardiovascular disease (CVD). Low physical activity increases future risk of CVD, while when CVD develops it often impairs activity. This means that wearable or smartphone-based measurement of physical activity may provide clinically useful “digital biomarkers”. Clinicians predict future risk, diagnose disease, and recommend appropriate treatment, and for any biomarker to be used in healthcare, its measurement must influence these decisions to improve patient outcomes. Here we consider how this may be achieved.

### Risk Prediction

Despite the clear relationship between activity and future CVD, risk prediction tools such as QRISK3 and SCORE do not include physical activity. This is despite the evidence that inclusion of *self-reported* walking pace improves prediction of CVD<sup>3</sup> while a fitness algorithm incorporating self-reported activity improved CVD risk classification<sup>4</sup>. The American Diabetes Association 60 second risk score for type 2 diabetes does include binary self-reported activity. This suggests that device-based measurement, which more accurately and completely captures a comprehensive array of activity characteristics than self-report (including walking pace, total volume or intermittent vigorous activity) may further improve risk prediction. Importantly, unlike unmodifiable factors such as age, incorporating activity provides a non-pharmacological approach to reduce calculated future risk.

### Diagnosis

Diagnosis of CVDs that impact activity (such as heart failure and symptomatic valvular heart disease) relies on self-recognised and self-reported symptoms. Patients must recognize such impacts (which are often insidious), seek medical attention, and accurately describe current levels of activity and how this has changed over time to the physician. This disadvantages

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3 people with cognitive impairment or difficulty communicating. Objective assessment of exercise  
4 capacity such as a six-minute walk test<sup>5</sup> is rarely used and relates poorly to what patients do in  
5 everyday life. Device-based measures that objectively quantify activity (especially if compared  
6 with a previous “baseline” to identify onset and rate of decline) would provide individualised  
7 assessments to guide decisions on diagnosis, investigation or specialist referral.  
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### 10 **Treatment selection**

11 Though rarely measured in clinical practice, physicians’ inferences about patients’ activity affect  
12 critical treatment decisions. Subjectively rated “frailty” influences whether a patient is offered  
13 surgery, ventilated for pneumonia, or resuscitated after cardiac arrest. Patients with heart failure  
14 are classified by the 4-point New York Heart Association (NYHA) score (1 = no limitation of  
15 activity, 4 = limitation even at rest). Many decisions, such as medication prescription, or  
16 implantation of devices such as defibrillators, are based on the NYHA class. Subjective  
17 assessment may deprive appropriate treatment to some, while subjecting others to unnecessary  
18 treatment.  
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### 22 **Barriers**

23 Although clinical decisions about risk, diagnosis, and treatment selection could be enhanced by  
24 considering device-based measures of activity, many barriers prevent incorporation into routine  
25 clinical practice. Despite the millions of consumer devices used in daily use, few if any are  
26 approved medical devices for activity measurement. Incentives for manufacturers to obtain such  
27 approvals are small compared with direct sales as “wellbeing” tools. The accuracy and range of  
28 measures provided varies considerably across different devices, with all using different  
29 proprietary, and often updated algorithms to process raw accelerometry into features such as  
30 “steps”. Wearables capture continuous indoor and outdoor activity data, while mobile phones  
31 are carried intermittently, particularly indoors. This makes smartphone-based measures of  
32 activity less suitable for people who rarely leave home, such as the elderly or ill. Conversely,  
33 only 18% of UK adults have a smartwatch, while 93% use smartphones which are also more  
34 equally distributed across income groups<sup>6</sup>. If better healthcare requires wearable ownership this  
35 would lead to health inequalities. Decision-support algorithms trained on non-representative  
36 data from wearable-owning populations would further entrench inequity<sup>7</sup>. Unlike research data,  
37 data used in healthcare must be available at the point of decision-making. This requires an IT  
38 infrastructure able to regularly ingest activity data into the patient’s medical record in an  
39 interpretable format for clinicians, while being secure from external threats and protecting  
40 privacy and data security.  
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### 47 **Recommendations**

48 To address these barriers we propose the following steps. Although intuitively useful, evidence  
49 to justify introduction of device-based measures of activity in healthcare is limited. Randomised  
50 controlled trials are needed that examine the effect of adding information on device-measured  
51 physical activity to standard of care, versus standard of care alone, on endpoints including  
52 patient satisfaction, clinician confidence, healthcare usage and other outcomes. Should these  
53 show benefit, we propose regulators approve devices that successfully fulfil Verification,  
54 Analytic Validation, and Clinical Validation assessments<sup>8</sup> for augmentation of clinical decision  
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making, where such decisions are also informed by self-report and clinical assessment. The cost of devices is reducing and may be offset by improved patient outcomes, requiring cost-effectiveness assessment alongside clinical effectiveness studies. Should these prove device-based measurement of activity improves prediction, diagnosis and treatment selection, healthcare systems will have both a responsibility and an incentive to provide devices to those without them.

### Conflicts of Interest:

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