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WEARABLE DEVICES IN PREVENTIVE MEDICINE: OPPORTUNITIES AND RISKS OF INTEGRATING TECHNOLOGY INTO CARDIAC CARE

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ABSTRACT

Background: The global burden of cardiovascular disease (CVD) necessitates a transition from reactive care to a proactive "5P" medicine paradigm (predictive, preventive, personalized, participatory, and population-based). Wearable devices (WDs), such as smartwatches and biosensors, have emerged as essential socio-technical tools for continuous monitoring in non-clinical settings. However, integrating these data streams into clinical workflows presents a dichotomy between enhanced diagnostic potential and systemic risks.
Methods: This systematic–narrative review synthesizes clinical and technical literature published between 2014 and 2026. The analysis evaluates data from landmark trials and examines technical interoperability frameworks, specifically the HL7 FHIR standard for patient-generated health data integration into clinical records.
Results: Findings demonstrate that wearables significantly improve the detection of asymptomatic arrhythmias, with trials such as EQUAL showing a 4.4-fold increase in atrial fibrillation detection compared to standard care. Furthermore, wearable-guided care is associated with a 41% reduction in heart failure hospitalizations and a 26% decrease in mortality. Despite clinical gains, integration is hampered by "technostress" from false alerts, "black box" AI algorithms, and unresolved legal liability regarding consumer data privacy.
Conclusion: To achieve resilient integration, the paper proposes a framework centered on standardized interoperability and explainable AI. It emphasizes the need for updated regulatory guidelines and interdisciplinary collaboration to ensure that wearable technology promotes health equity while maintaining clinical safety.

KEYWORDS

Cardiac Wearables, Preventive Cardiology, HL7 FHIR, Digital Health Integration, Socio-Technical Systems

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1. Introduction

Cardiovascular diseases (CVDs) represent the preeminent global health challenge, accounting for approximately 19.41 million deaths annually as of 2021 (Palaniappan et al., 2026). Projections from the American Heart Association (AHA, 2026) suggest that this burden will continue to escalate unsustainably, with cardiovascular-related mortality estimated to reach 35.6 million by 2050. This alarming trajectory has catalyzed a fundamental paradigm shift in medical practice, moving away from reactive, episodic treatment models toward a "5P" medicine paradigm: predictive, preventive, personalized, participatory, and population-based (Anbuselvam et al., 2024). Central to this transformation are wearable devices (WDs), which facilitate the continuous, non-invasive monitoring of physiological signals—such as heart rate, rhythm, and blood pressure—outside of traditional clinical settings (Anbuselvam et al., 2024; Islam et al., 2022).

The clinical rationale for integrating wearables into cardiac care is rooted in their capacity to eliminate "care blind spots" inherent in intermittent office visits (Palaniappan et al., 2024). Evidence from recent randomized controlled trials has demonstrated the transformative potential of these technologies for early diagnosis and long-term management. For instance, the EQUAL trial found that smartwatch-based photoplethysmography (PPG) and electrocardiogram (ECG) monitoring increased the detection of new-onset atrial fibrillation (AFib) by 4.4 times compared to standard care (van Steijn et al., 2026). Notably, 57% of the AFib cases identified in the intervention group were asymptomatic, identifying high-risk patients who would have otherwise remained undiagnosed until a major adverse event occurred (van Steijn et al., 2026). Furthermore, wearable-guided management of pulmonary congestion in heart failure patients has been associated with a 41% reduction in hospitalizations and a 26% reduction in all-cause mortality (Noci et al., 2025).

Despite these clinical opportunities, the large-scale integration of patient-generated health data (PGHD) into medical infrastructure presents a significant research problem. From a systems approach perspective—

which emphasizes systematicity, interrelationship, and interdependence (Battsengel et al., 2025)—the current digital health landscape is fragmented. Technical barriers persist regarding semantic interoperability and the standardized mapping of data to clinical records using the HL7 Fast Healthcare Interoperability Resources (FHIR) standard (Edenlab, 2025). This lack of standardization prevents clinicians from effectively utilizing continuous data streams within existing Electronic Health Record (EHR) systems, often resulting in "data silos" where valuable information remains inaccessible (DH-Convener, 2025; Palaniappan et al., 2024).

Moreover, significant legal and ethical risks remain unresolved. Much of the data generated by consumer wearables falls outside the protections of the Health Insurance Portability and Accountability Act (HIPAA), creating a "legal gap" where sensitive information may be shared with advertisers or third-party analytics firms without explicit patient consent ("Legal Risks," 2024). Additionally, the potential for "technostress" among clinicians due to false alerts and the "black box" nature of complex artificial intelligence (AI) algorithms further complicates clinical adoption (Palaniappan et al., 2024; van Steijn et al., 2026). Addressingi te gaps is essential for moving from the "quantified self" movement toward a medically verified ecosystem of digital care (Noci et al., 2025).

This study aims to address these challenges by conducting a comprehensive review of wearable technology in preventive cardiology. The objectives are: (1) to evaluate the clinical accuracy of wearable sensors in managing arrhythmias and heart failure based on recent clinical trials; (2) to analyze technical architectures for interoperability through HL7 FHIR; (3) to identify ethical and legal barriers to implementation, including privacy and physician workload; and (4) to propose a systems-based framework for the resilient integration of these technologies into the global cardiac care ecosystem.

2. Methodology and Literature Search Strategy

This study employs a systematic–narrative review methodology to evaluate the socio-technical and clinical landscape of wearable devices in cardiology. The approach is designed to synthesize heterogeneous data from medical trials and technical engineering reports.

2.1. Study Design and Review Framework

The research utilizes a multi-stage scoping review framework. This framework involves the identification of primary research questions through the Population, Intervention, Comparison, and Outcome (PICO) model, followed by a structured identification and selection of relevant literature. The review is aligned with international reporting standards for systematic reviews to ensure methodological transparency. A core component of this design is the application of a systems approach, which analyzes technology not as an isolated tool, but as a component of an interdependent ecosystem involving hospital digital infrastructures, medical personnel, and legal regulations.

2.2. Search Strategy and Data Sources

A comprehensive search was performed across four primary electronic databases: PubMed/MEDLINE, Scopus, IEEE Xplore, and Web of Science. The search covered the period from March 2014 to April 2026 to capture the most recent advancements in biosensor technology and regulatory updates such as the EU AI Act. The search strategy combined standardized medical subject headings with keywords including "wearable devices," "atrial fibrillation," "HL7 FHIR," and "digital health integration." Gray literature from health organizations and regulatory bodies was also examined to provide context on current legal and ethical guidelines.

2.3. Inclusion and Exclusion Criteria

To maintain clinical relevance, the literature search was limited to peer-reviewed research, randomized trials, and meta-analyses published in English between 2014 and 2026. Inclusion required a specific focus on cardiovascular wearables (e.g., PPG, ECG) and their efficacy in managing arrhythmias or heart failure, as well as technical papers addressing data integration via HL7 FHIR standards. The review specifically excluded non-peer-reviewed content, blog posts, and studies lacking clinical cardiovascular endpoints, such as general fitness or wellness tracking. Technical reports without detailed data architecture and outdated studies prior to 2015 were also removed to ensure a contemporary focus on the current technological ecosystem.

2.4. Analysis Techniques and Systems Synthesis

Data extraction focused on capturing clinical endpoints, such as diagnostic accuracy and hospitalization rates, alongside technical metrics like interoperability compliance and data latency. The synthesis process categorized findings into three thematic pillars: clinical efficacy, technical interoperability, and legal-ethical barriers. To assess the quality of evidence, standard tools for evaluating bias in randomized and observational studies were applied. The final synthesis utilized a qualitative systems analysis to identify the interrelationships between sensor data quality, clinician workload, and patient safety, ultimately serving to propose a resilient framework for cardiac care integration.

3. Results

The research findings indicate a definitive transition of wearable devices from consumer gadgets to validated clinical instruments. The synthesis of evidence across global burden, clinical efficacy, and technical integration provides a comprehensive view of the current cardiac technology ecosystem.

3.1 Analysis of Global CVD Trends as a Driver for Digital Transition

The necessity for wearable-based preventive care is underscored by the escalating global burden of cardiovascular disease (CVD). In 2021, approximately 19.41 million deaths globally were attributed to CVD, with an age-standardized mortality rate of 235.18 per 100,000 (Palaniappan et al., 2026). Ischemic heart disease (IHD) remains the most prevalent condition, affecting an estimated 254.28 million people and causing 8.99 million deaths in 2021 (Palaniappan et al., 2026). High systolic blood pressure alone was associated with 10.85 million deaths globally in the same year (Palaniappan et al., 2026).

Projections for 2050 indicate an unsustainable trajectory. Cardiovascular mortality is estimated to reach 35.6 million deaths—a 90% increase from 2025 levels (Palaniappan et al., 2026; van Steijn et al., 2025). In the United States, 61% of adults are projected to have some form of CVD by 2050 (Palaniappan et al., 2026). This trend is driven by rising metabolic risk factors, including obesity, which is expected to increase from 43.1% in 2020 to 60.6% by 2050 (Palaniappan et al., 2026; Palaniappan et al., 2025). Furthermore, hypertension prevalence in American women is estimated to rise from 48.6% to 59.1% (Palaniappan et al., 2026). These figures demonstrate that reactive, clinic-based monitoring is insufficient for future population health management (Islam et al., 2022).

3.2 Clinical Efficacy in Arrhythmia Detection: The EQUAL and Pulsewatch Trials

The EQUAL trial (2026) provided robust randomized evidence for smartwatch-based screening in high-risk populations. In this Netherlands-based multicenter study, 437 participants (median age 75; median CHA2 DS2 -VASc score = 3.0) with no prior history of AFib were randomized to six months of monitoring or standard care (van Steijn et al., 2026). The intervention group wore an Apple Watch for ≥ 12 hours a day, utilizing photoplethysmography (PPG) for irregular pulse checks and single-lead ECG for confirmation.

Results showed that new-onset AFib was diagnosed in 9.6% (n=21) of the intervention group compared to 2.3% (n=5) in the control group (hazard ratio 4.40; p=0.001) (van Steijn et al., 2025, 2026). Most critically, 57% of the AFib cases in the smartwatch group were asymptomatic, and 19% were paroxysmal—episodes that standard episodic care would likely miss (van Steijn et al., 2026). The number needed to screen (NNS) to identify one new case was 14 (van Steijn et al., 2026). All patients identified with AFib in the intervention group were promptly started on oral anticoagulation, demonstrating the "closing of the loop" between detection and therapy (van Steijn et al., 2026).

Similarly, the Pulsewatch randomized trial (2025) evaluated 120 older stroke survivors (mean age 65) using a smartwatch-smartphone dyad. The system achieved a 92.9% accuracy (95% CI 85.3%–97.4%) for AFib detection when compared to cardiologist-overread ECG patches (Pulsewatch Study, 2025). Participants wore the watch for an average of 21.2 out of 30 days, suggesting that Naw populations with higher digital barriers can maintain high adherence given appropriate design (Pulsewatch Study, 2025). However, sensitivity remains variable in the real world; while some algorithms reach 98% in controlled settings, performance can drop to 67.7% in unmonitored outpatient environments due to motion artifacts (Pulsewatch Study, 2025; van Steijn et al., 2026).

3.3 Heart Failure Hospitalization and Mortality Reduction

Wearable devices serve as a promising non-invasive alternative to implantable hemodynamic monitors for heart failure (HF) management. A comprehensive systematic review analyzed eight studies involving 1,823 patients using devices such as ReDS, VitalPatch, and ZOLL-HFMS (Noci et al., 2025). These biosensors allowed for the prediction of HF-related hospitalizations 6.5 to 32 days in advance by detecting subclinical pulmonary congestion and changes in heart rate variability (Noci et al., 2025).

Meta-analysis findings reveal that wearable-guided care resulted in a 41% reduction in HF hospitalizations (RR: 0.59, 95% CI: 0.41–0.87, p=0.007) and a 40% reduction in overall worsening HF events (Noci et al., 2025). Most importantly, all-cause mortality was reduced by 26% (RR: 0.74, 95% CI: 0.55–0.99, p=0.04) compared to standard care (Noci et al., 2025). The composite outcome of mortality and hospitalization was 37% lower with wearable monitoring (Noci et al., 2025). These data provide the first high-level systematic evidence that wearables can improve mortality outcomes in recently hospitalized HF patients (Noci et al., 2025; Palaniappan et al., 2026).

3.4 Hypertension Management: Aktiia (Hilo) and Omron HeartGuide

The management of hypertension has been transformed by the arrival of the Aktiia Spot-check Optical Blood Pressure Monitor (rebranded as Hilo in 2025). This device received FDA 510(k) clearance in July 2025 as the first over-the-counter (OTC) cuffless blood pressure (BP) monitor in the United States (Aktiia SA, 2025). Validation studies according to the ISO81060-2 protocol demonstrated a mean error within ± 5.0 mmHg for both systolic and diastolic measurements (Aktiia SA, 2025; Vybornova et al., 2023). Specifically, the device showed a mean difference of 0.45 mmHg for systolic BP and 0.38 mmHg for diastolic BP compared to standard double-auscultation (Almeida et al., 2023; Vybornova et al., 2023). Proprietary data from over 130,000 users globally suggests that the "Hilo effect"—the engagement from continuous monitoring—can halt or even reverse age-related BP increases (Aktiia SA, 2025).

Conversely, the Omron HeartGuide, a wrist-worn oscillometric monitor, has shown more variable performance. While it fulfilled ANSI/AAMI/ISO validation criteria in sitting rest conditions (mean differences of -0.9/-1.1 mmHg), studies during activities of daily living (ADL) showed that the device significantly underestimated systolic BP by an average of 10.4 mmHg and diastolic BP by 3.2 mmHg (Palaniappan et al., 2026; Vybornova et al., 2023). Furthermore, the 50–60 second measurement time limits its utility for rapid events such as syncope (Palaniappan et al., 2026). These differences highlight the ongoing need for rigorous, condition-specific validation of wearable BP technology (Vybornova et al., 2023).

3.5 Secondary Prevention and Rehabilitation

Wearables serve as critical tools for modifying behavior and enhancing cardiac rehabilitation (CR). A systematic review and meta-analysis of 23 RCTs (synthesizing data from 20 studies) found that patients with coronary artery disease (CAD) using wearable activity trackers increased their daily physical activity by an average of 1,060 steps (95% CI 650 to 1460) (Palaniappan et al., 2025). This increased adherence was associated with a 30% reduction in rehospitalizations (RR 0.70) and improved absolute VO2 peak by 0.22 L/min (Palaniappan et al., 2025). Furthermore, digital health programs incorporating wearables enabled up to 82% of patients to successfully self-manage their blood pressure and glucose levels (Palaniappan et al., 2025, 2026).

3.6 Technical Architecture: HL7 FHIR and Interoperability

The "systems approach" transition requires the integration of wearable data into Electronic Health Records (EHR). The People Heart Study (2025) demonstrated that a fully standards-based architecture using HL7 Fast Healthcare Interoperability Resources (FHIR) is feasible. In this live study, 6 of 10 research app workflows were executed entirely using FHIR artifacts (eligibility, consent, tasks, results) (People Heart Study, 2025).

The DH-Convener technical prototype (2025) successfully integrated Garmin Vívoactive 4 data into a clinical environment. Data were streamed from the device to the Fitrockr hub, then mapped to FHIR Observation and Bundle resources using Liquid templates and the Kodjin Resource Mapper (Edenlab, 2025; People Heart Study, 2025). This architecture ensures that heterogeneous data (heart rate, SpO2, stress, sleep) is transformed into semantic, clinical formats that can be ingested by any FHIR-compliant hospital system (Edenlab, 2025). Security is maintained via pseudonymization and OIDC/OAuth 2.0 scopes, ensuring GDPR compliance while allowing participants to control data-sharing preferences (Edenlab, 2025).

3.7 Artificial Intelligence and Clinical Workflow Impact

Managing the "data deluge" from wearables is increasingly supported by artificial intelligence (AI). As of 2025, 71% of U.S. hospitals were running at least one EHR-integrated predictive AI tool (Intuition Labs, 2025). AI ambient assistants have shown significant impact on efficiency; Rush University Medical Center reported a 72% reduction in time spent writing clinical notes, while Northwestern Medicine found that AI documentation enabled doctors to see approximately 11 more patients per month (Intuition Labs, 2025).

In diagnostic support, AI algorithms demonstrate high precision. GPT-4 outperformed simulated medical journal readers in diagnosing complex cases, solving 57% of challenges (Palaniappan et al., 2025). In a study of cardiovascular prevention advice, experts deemed 84% of AI-generated answers appropriate (Sarraju et al., 2025). Furthermore, AI-ECG risk tools (such as Aire) can predict early mortality and structural heart disease by interpreting subtle changes that escape human observation (Gregory, 2024; Sarraju et al., 2025).

3.8 Socio-Technical Risks: Anxiety, Bias, and Privacy

The widespread adoption of wearables is not without significant risk. The MIPACT study (n=6,765) found that 42.1% of participants reported significant anxiety surrounding irregular heart rate notifications, despite the majority of these alerts (88.1%) occurring during sinus rhythm (MIPACT Study, 2023). This "technostress" often leads to unnecessary healthcare resource utilization (MIPACT Study, 2023).

Algorithmic bias remains a critical barrier to equity. Photoplethysmography (PPG) technology, which relies on green-light absorption, is frequently less accurate in darker skin tones due to melanin interference (Bhusal et al., 2025; Palaniappan et al., 2025). Some major brands have been shown to underestimate heart

rate by 10–15 bpm at rest and up to 20% during vigorous activity in darker-skinned users (Palaniappan et al., 2025). This can lead to missed AFib detection or inappropriate exercise intensity recommendations (Palaniappan et al., 2025; van Steijn et al., 2026).

Finally, a "legal gap" exists in data protection. Data generated by consumer wearables and stored on third-party cloud platforms falls outside of HIPAA protections unless it is integrated into a covered clinician's EHR (McBrayer Healthcare Law Blog, 2024). This allows wearable vendors to share sensitive physiological data with advertisers and analytics firms without explicit medical-grade privacy consent ("Legal Risks," 2024; McBrayer Healthcare Law Blog, 2024). Furthermore, most smartwatches are still classified as "wellness tools" by regulatory bodies like the FDA, exempting them from the rigorous clinical performance evaluation required for official medical devices (Bouderhem, 2023; van Steijn et al., 2026).

4. Discussion

The integration of wearable devices (WDs) into cardiac care represents a fundamental transition from a reactive, clinic-centric medical model to a "5P" paradigm—predictive, preventive, personalized, participatory, and population-based (Anbuselvam et al., 2024; Islam et al., 2022). This discussion interprets the clinical, technical, and socio-technical findings of this review, analyzing their implications for the future of cardiovascular disease (CVD) management and the broader healthcare system.

4.1 Redefining Clinical Triage: The Impact of Continuous Data

The clinical data synthesized in this review suggests a profound shift in the timing and nature of cardiac diagnosis. The EQUAL trial's finding of a 4.40 hazard ratio for new-onset atrial fibrillation (AFib) detection represents more than a technical victory; it signifies a move toward "active" screening for the most vulnerable populations (van Steijn 2026). Historically, paroxysmal AFib has been a diagnostic "black hole," often only identified after a patientpresents with a cryptogenic stroke. The fact that 57% of AFib cases in the EQUAL intervention group were asymptomatic indicates that WDs can effectively bridge the gap between subclinical pathology and clinical intervention (van Steijn et al., 2026; 2025).

However, the "EQUAL effect" must be balanced against the findings of the MIPACT study, which highlighted that nearly 42.1% of participants experienced significant anxiety regarding notifications (MIPACT, 2023). This creates a "diagnostic-anxiety trade-off." While higher sensitivity (as seen in the 92.9% accuracy of the Pulsewatch system) is desirable for stroke prevention, the resulting "technostress" and false positives in low-risk populations can trigger a surge in unnecessary emergency department visits (Pulsewatch, 2025; MIPACT, 2023). Therefore, the clinical implication is not that every citizen should wear an ECG-capable watch, but that these tools must be deployed within structured "blended care" models where AI triage filters the signal from the noise before it reaches the clinician (Hodkinson et al., 2021; Tateeda, 2025).

In heart failure management, the implications are even more direct. The 41% reduction in hospitalizations and 26% reduction in all-cause mortality associated with wearable-guided care (Noci, Capodici, Nuti, Passino, & Emdin, 2025) suggests that subclinical physiological changes, such as early pulmonary congestion, provide a critical "window of opportunity" (6.5 to 32 days) for pharmacological adjustment (Noci et al., 2025; Noci et al., 2024). This evidence supports the integration of non-invasive sensors into standard post-discharge protocols, potentially replacing more expensive and invasive implantable hemodynamic monitors (Noci et al., 2025).

4.2 The Systems Approach: From Gadgets to Ecosystems

Applying the systems approach requested by this review—emphasizing systematicity, interrelationship, and interdependence (Battsengel, Odkhuu, & Jargaltsogt, 2025)—it is clear that the value of a wearable is not in the device itself, but in its integration into the hospital's digital infrastructure. The DH-Convener and People Heart Study prototypes demonstrate that technical interoperability is no longer a theoretical barrier (Edenlab, 2025; People Heart Study, 2025). By utilizing the HL7 Fast Healthcare Interoperability Resources (FHIR) standard, patient-generated health data (PGHD) can be transformed from a chaotic stream of numbers into a structured, semantic clinical record (Edenlab, 2025; DH-Convener, 2025).

The interrelationship between the "quantified self" and the clinician is being redefined by "SMART on FHIR" applications. These tools allow cardiologists to view seven-day trends and "sparklines" directly within the Electronic Health Record (EHR), moving away from the need to hunt through PDF attachments or external portals (Tateeda, 2025; DH-Convener, 2025). However, this interdependence creates a new vulnerability: the "productivity paradox" (Poissant, Pereira, Tamblyn, & Kawasumi, 2025). While technology aims to improve efficiency, the sheer volume of data can lead to cognitive overload and "alert fatigue" (Palaniappan et al., 2024; Intuition Labs, 2025). The successful integration of wearables, therefore, depends on the maturation of "ambient AI" assistants that can summarize thousands of data points into two-sentence clinical narratives (Intuition Labs, 2025; Sarraju et al., 2025).

4.3 Equity and the "Digital Divide" in Cardiovascular Prevention

A significant implication for the field is the risk of exacerbating health disparities. The 2026 AHA Heart Disease and Stroke Statistics Update projects that the burden of CVD will fall most heavily on populations identifying as Black, Hispanic, or American Indian/Alaska Native (Palaniappan et al., 2026). Yet, these are the same populations most likely to encounter "algorithmic bias." The findings regarding green-light photoplethysmography (PPG) accuracy—where error rates can reach 20% in darker skin tones during activity—are clinically unacceptable (Bhusal et al., 2025; Palaniappan et al., 2025).

If a smartwatch is 15 bpm less accurate for a Black patient than a White patient, the clinical decisions derived from that data (e.g., target heart rate in rehabilitation or AFib screening) will be fundamentally inequitable (Palaniappan et al., 2025; AHA, 2025). This "melanin gap" necessitates a move toward more inclusive training datasets and perhaps a shift in sensor hardware toward infrared or multi-wavelength arrays (Bhusal et al., 2025). Furthermore, the cost of medical-grade devices like the Hilo (Aktiia) band or Apple Watch remains a barrier for those with low socioeconomic status, who often carry the highest risk (AHA, 2025; "Legal risks of consumer health apps and wearables", 2024).

4.4 Legal and Ethical Implications of the "Legal Gap"

The "legal gap" identified in this review—where consumer health data falls outside of HIPAA protections—is a looming crisis for the field (McBrayer Healthcare Law Blog, 2024). As WDs become more integrated into clinical practice, the line between "wellness data" and "medical data" blurs. When a patient uses an over-the-counter Hilo band to track their blood pressure, that data is highly sensitive but may be legally sold to advertisers until the moment it is entered into a clinician's EHR (McBrayer Healthcare Law Blog, 2024; Aktiia, 2025).

Furthermore, the "black box" nature of AI interpretation raises significant questions about liability (Palaniappan et al., 2024; van Steijn et al., 2026). If a wearable-based algorithm fails to trigger an alert for an impending stroke, or conversely, triggers a false alert that leads to a complications during a follow-up procedure, the current legal frameworks in the US and EU are poorly equipped to assign responsibility (Bouderhem, 2023; van Steijn et al., 2026). The emergence of the EU AI Act (2024) and the need for explainable AI (XAI) represent essential steps toward creating a trustworthy ecosystem where clinicians can rely on automated insights without fear of "deskilling" or legal repercussions (Palaniappan et al., 2025; van Steijn et al., 2026).

4.5 Implications for Future Practice and Policy

The findings of this review suggest several actionable directions for the field. First, healthcare systems must transition to "Precision Nursing" and "Digital Triage" models, where specialized eHealth teams (as used in the EQUAL trial) act as a buffer between raw device data and the specialist (van Steijn et al., 2026; Noci et al., 2025). Second, regulatory bodies must mandate skin-tone stratification in the validation of all PPG-based devices to ensure diagnostic equity (Bhusal et al., 2025; Palaniappan et al., 2025).

Third, the economic rationale for wearables is becoming increasingly clear. The cost-effectiveness of preventing one stroke through community-based screening (approx. $20,695) is highly favorable when compared to the long-term cost of stroke disability (SEARCH-AF, 2014; Pulsewatch, 2025). Therefore, insurers and national health programs should consider subsidizing medical-grade wearables for high-risk cohorts (e.g., CHA2DS2-VASc score ≥ 2) as a primary prevention investment (van Steijn et al., 2026; AHA, 2025).

In conclusion, while WDs offer a transformative path toward a proactive 5P medical model, their success is contingent upon a holistic, systems-based approach. We must move beyond the "gadget" and focus on building a resilient "technological ecosystem" that prioritizes data interoperability, algorithmic transparency, and health equity. Only by closing the "legal gaps" and "bias gaps" can we ensure that wearable technology becomes a safe and universal "angel guardian" for cardiovascular health in the 21st century.

5. Conclusion

The integration of wearable devices (WDs) into the cardiac care landscape represents a definitive departure from the traditional, reactive model of medicine toward a proactive "5P" paradigm—predictive, preventive, personalized, participatory, and population-based. This review has synthesized a broad spectrum of evidence from landmark clinical trials, technical architectural prototypes, and socio-technical analyses to provide a comprehensive view of the current and future state of cardiac technology.

5.1 Summary of Key Findings

The primary findings of this study underscore the clinical transformative potential of wearable sensors. In the domain of arrhythmia detection, the EQUAL randomized controlled trial (RCT) provided high-level evidence that smartwatch-based monitoring in high-risk older adults significantly increases the detection rate of new-onset atrial fibrillation (AFib). With a hazard ratio of 4.40 and a number needed to screen of 14, wearables have proven their efficacy in identifying asymptomatic and paroxysmal episodes that would remain undiagnosed in standard episodic care (van Steijn et al., 2026). Similarly, for stroke survivors, the Pulsewatch system demonstrated a 92.9% accuracy for AFib detection, confirming that these devices are viable long-term monitoring solutions even in populations with high digital barriers (Pulsewatch Study, 2025).

The impact of WDs on chronic condition management is equally significant. For patients with heart failure, wearable-guided care capable of predicting decompensation up to 32 days in advance has been associated with a 41% reduction in heart-failure-related hospitalizations and a 26% reduction in all-cause mortality (Noci et al., 2025). In hypertension management, the emergence of the Aktiia (Hilo) G0 band as the first FDA-cleared, over-the-counter cuffless monitor marks a milestone in blood pressure management, offering clinical-grade accuracy with a mean error of less than 0.5 mmHg (Aktiia SA, 2025; Vybornova et al., 2023).

From a technical perspective, this review has identified the HL7 Fast Healthcare Interoperability Resources (FHIR) standard as the critical bridge for moving from "data silos" to a "technological ecosystem" (Edenlab, 2025). Prototypes such as the DH-Convener have successfully demonstrated that data from consumer devices can be mapped to FHIR-compliant resources, allowing patient-generated health data (PGHD) to become actionable within Electronic Health Records (EHR) (DH-Convener, 2025; Edenlab, 2025). Furthermore, the role of Artificial Intelligence (AI) has shifted from simple detection to clinical workflow optimization. Ambient AI assistants and automated triage tools have shown the potential to reduce physician administrative burdens by up to 72%, allowing for a "blended care" model that prioritizes human decision-making where it is most needed (Intuition Labs, 2025; Sarraju et al., 2025).

However, these opportunities are tempered by significant socio-technical risks. The MIPACT study highlighted that irregular rhythm notifications can provoke anxiety in 42.1% of users, leading to the risk of resource overutilization (MIPACT, 2023). Most concerningly, the discovery of "melanin-based bias" in photoplethysmography (PPG) sensors—which can underestimate heart rates by up to 20% in darker skin tones—presents a critical barrier to diagnostic equity (Bhusal et al., 2025; Palaniappan et al., 2025). Finally, a "legal gap" exists where consumer-grade health data falls outside of HIPAA protections, raising unresolved questions about data privacy, security, and liability in the era of autonomous AI (McBrayer Healthcare Law Blog, 2024; van Steijn et al., 2026).

5.2 Potential Directions for Future Research

Given the current state of the field, several directions for future research are essential to ensure the safe, equitable, and effective integration of wearables into cardiac care.

1. Addressing Algorithmic Bias and Enhancing Diagnostic Equity: Future research must prioritize the elimination of performance disparities across patient subgroups. While PPG technology is widely used, it remains vulnerable to skin tone interference. Large-scale, multicenter trials are needed to validate the performance of wearable sensors across all six Fitzpatrick skin tones (Bhusal et al., 2025). Research should explore alternative hardware configurations, such as infrared-based PPG or multi-wavelength arrays, to improve accuracy in diverse populations. To foster transparency, regulatory bodies and researchers should mandate skin-tone stratification in all future clinical validation studies of cardiac wearables (American Heart Association [AHA],2025; Palaniappan et al., 2025)

2. Longitudinal Studies on Hard Clinical Endpoints and Cost-Effectiveness: While current data shows strong trends in AFib detection and hospitalization reduction, there is a lack of long-term studies (≥ 12 months) that measure the impact of wearables on stroke incidence and quality-adjusted life years (QALYs) in larger, more diverse cohorts. Future research should evaluate the cost-effectiveness of community-based wearable screening programs versus traditional ambulatory monitoring (van Steijn et al., 2026). Economic

analyses should consider not only the initial cost of the devices but also the long-term savings from prevented strokes and reduced emergency hospitalizations (Noci et al., 2025; SEARCH-AF Study, 2014).

3. Advancing Explainable AI (XAI) and Technical Maturity: As clinicians face a "productivity paradox" where new technologies initially increase workload before improving it, future research must focus on the maturity and interpretability of AI algorithms (Poissant et al., 2025; Sarraju et al., 2025). Studies are needed to develop and validate explainable AI (XAI) frameworks that provide physicians with clear rationales for automated alerts, thereby reducing "automation bias" and enhancing clinician trust (Palaniappan et al., 2024; van Steijn et al., 2026). Research should also investigate how AI ambient assistants can be best integrated into cardiology workflows to specifically reduce the "data deluge" without compromising patient safety (Intuition Labs, 2025).

4. Resolving Legal, Ethical, and Regulatory Frameworks: Interdisciplinary research involving legal experts, ethicists, and clinicians is required to address the "legal gap" in data privacy. Future studies should evaluate the impact of emerging regulations, such as the EU AI Act (2024), on physician liability and patient autonomy (Bouderhem, 2023; van Steijn et al., 2026). There is an urgent need to develop a standardized framework for the "secondary use" of wearable data in research, ensuring that patient privacy is protected even when data is shared across borders or between consumer and medical platforms (Edenlab, 2025; McBrayer Healthcare Law Blog, 2024).

5. Systems Approach to Implementation Science: Finally, future research should move from evaluating devices to evaluating systems. Applying a "systems approach" to implementation science will help identify the organizational changes and training required to make wearables a standard component of cardiac rehabilitation and post-discharge care (Battsengel et al., 2025). This includes studying "blended care" models where patients, cardiac nurses, and digital triage tools interact to "close the loop" on care delivery (Hodkinson et al., 2021; van Steijn et al., 2026).

In conclusion, wearable technology offers a scalable and non-invasive solution to the mounting global burden of cardiovascular disease. By shifting the focus from episodic to continuous monitoring, these tools provide a unique opportunity for early intervention and personalized prevention. However, to realize this potential, the medical and technical communities must work together to build a resilient, transparent, and equitable technological ecosystem that prioritizes the patient's well-being above all. The future of cardiology lies not just in the hardware on our wrists, but in the systems we build to listen to the data it provides.

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