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IMPLEMENTATION (L E ROHDE, SECTION EDITOR)

# Have Traditional Heart Failure Management Programs Reached Their "Use by" Date? Time to Apply More Nuanced Care

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## Abstract

**Purpose of Review** To determine the current evidence supporting the otherwise proven heart failure management programs (HFMPs) in the setting of an increasingly older and more complex patient population.

**Recent Findings** Attempts to replace proven face-to-face, multidisciplinary management of HF with remote management techniques (including telemedicine and implantable remote monitoring devices) have yielded mixed results. This may well reflect the *clinical cascade effect* of greater surveillance paradoxically leading to worse health outcomes as well as a narrow focus on HF alone in patients with clinically significant multimorbidity. Concurrently, there is preliminary evidence that the increasing phenomenon of HF and multimorbidity in older patients is undermining the otherwise positive impact of "traditional" HFMPs.

**Summary** A more nuanced approach to determining who would benefit from what form of HF management, including the integration of remote surveillance techniques, is required.

**Keywords** Heart failure · Disease management · Nurse-led intervention · Multidisciplinary · Morbidity · Mortality · Health outcomes

## Introduction

By any measure, the long-feared [1] juggernaut of heart failure (HF) within our ageing populations is progressively reaching its full potential to overwhelm health care systems around the globe. For example, in the USA alone, with HF already affecting ~ 6.5 million people, within the next decade, this figure is predicted to rise to ~ 8.0 million people [2]. Concurrently, the proportion of affected individuals aged ≥ 65 years will steadily rise (from ~ 60 to ~ 70%) [3]. Accordingly, the cost-burden of this syndrome, predominantly driven by costly hospital admissions continues to sky-rocket [4]. This is particularly true in the USA where total direct medical costs are predicted to rise by a staggering $US32 billion per annum during the period 2012 to 2030 (to a total of $US53 billion) [2].

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## The Cost-Dynamics of Shifting Away from Hospital Care in Heart Failure

Given the evolving burden of HF and a major role for recurrent periods of clinical instability to drive health care expenditure via costly hospital admissions [4], it should come as no surprise that any strategy demonstrating an ability to reduce hospitalisation in HF is likely to be cost-effective. A critical but often overlooked facet of the HF burden (and any specific responses therein) is the fact that HF is not routinely the primary cause of subsequent morbidity and mortality. Indeed, as recently suggested [5] and then demonstrated [6], it is the pattern of multimorbidity that largely determines health outcomes in older individuals with HF. These individuals, of course, have and will become increasingly predominant within the HF population [7]. As an example of the likely benefits of replacing hospital care with outpatient/community-based care, combined with the pitfalls of focussing on acute HF events only, it is worth considering a recently reported analysis conducted in the USA of 151,908 Medicare beneficiaries with HF. In this analysis, Fitch and colleagues estimated that the annual cost of treating worsening HF in the hospital setting ranged from $US9.3–17.0 billion per annum (2.4–4.3% of total Medicare expenditure) [8]. Unsurprisingly, strategies

such as rapid-access IV-diuretic clinics to treat associated congestion, that could successfully target 10% of HF admissions and then shift 60% (6% success rate overall) to outpatient care, were predicted to save $US667.5 million (or 0.17% of total Medicare expenditure) per annum [8]. However, as explicitly acknowledged by the authors, a worsening HF accounts for a relatively small proportion of the overall hospital expenditure attributable to HF in the USA [9]. Moreover, there is no guarantee that short-term cost shifting will not lead to poorer health outcomes in the longer term [9].

## An Established Role for Heart Failure Management Programs

Given the need for a more holistic approach to HF management to cater for the broad range of health issues and multiple points at which the syndrome will prove costly to the individual and health care system, predominantly nurse-led, multidisciplinary management has become part of the a gold-standard management of HF in many parts of the world [10]. However, it is salient to note that unlike the clear pathway for approving and then rapidly applying (backed by commercial interests) pharmacological agents and monitoring devices, there was a long gap and numerous trials completed before this occurred. As subsequently proven by meta-analysis [11], seminal trials undertaken in the mid-to-late 1990s in the USA [12], Australia [13], and Europe [14] demonstrated the ability of HF management programs (HFMPs—in multiple forms) to reduce the risk of rehospitalisation and prolong survival relative to standard care. Critically, given the cost-dynamics of HF [4] and supporting the findings of the recent analysis of HF within the Medicare population in the USA [8], the evidence-base supporting HFMPs are founded on "all-cause" as well as HF-specific outcomes; noting the likely indifference of any patient with HF if told they were being managed with a strategy that reduced their risk of a primary HF event but not the high probability of them being hospitalised or dying from something closely related to their syndrome.

**The Role of Remote Management** An important sidebar to the evolution of HFMPs has been the focus on essentially replacing in-person teams applying a now well-developed platform of strategies (including clinical monitoring, applying flexible treatment regimen, promoting self-care [15], and, more latterly, using natriuretic peptide monitoring for the early detection of decompensation [16]) with either remote contact (e.g. structured telephone support), more sophisticated telemedicine techniques or implanted haemodynamic monitoring devices. Reflecting the enormous cost-burden and, therefore, potential cost-savings in HF, nearly all of these initiatives are commercially driven and very expensive in their own right. As noted by the authors of an essentially "rolling" Cochrane review of person-driven, remote care strategies [17], the number of trials of varying modes of management in this category continues to grow (at their last count 41 trials). Overall, their meta-analysis suggests that both telemedicine and structured telephone support result in reduced risk of mortality (RR 0.80, 95% 0.68–0.94 and RR 0.87, 0.77–0.98) and HF hospitalisation (RR 0.71, 95% 0.60–0.83 and RR 0.85, 0.77–0.93), respectively [17]. However, as undoubtedly noted by the authors of the European Society of Cardiology guidelines [10], it is difficult to ignore the indifferent outcomes of large, very well-conducted trials such as Tele-HF [18], TIM-HF [19] and TEHAF [20]; their conclusions were that these trials have failed to demonstrate the clinical efficacy of this broad strategy [10]. Whether they can complement more consistently positive, face-to-face strategies is yet to be fully determined (see below).

As for the third component of remote management (implantable monitoring devices), one might argue that the same issues around inconsistency of results and the limitations of addressing only one small piece of the puzzle in HF have applied [21]. For example, the COMPASS-HF Trial [22] evaluated a device monitoring right ventricular pressures relative to standard care without reducing the primary endpoint of HF hospitalisation. Alternatively, the HOMEOSTASIS trial showed that mortality and HF hospitalizations could be reduced if left atrial pressures were monitored and pharmacotherapy adjusted [23]. Likewise, the CHAMPIONS trial showed a 28% reduction of HF hospitalisation in 6 months and 37% in 15 months (notably without increasing other causes of hospitalisation) [24] by monitoring and adjusting pulmonary artery pressures. Other positive trials, including the REDUCE-LAP HF trial [25•] have triggered a relative explosion in the number of more sophisticated devices (not always successful!) being developed and tested in largely younger individuals in whom HF is the predominant driver of morbidity/mortality.

If one were to consider the evidence focusing on remote management in its current entirety, therefore, one might come to the unforgiving conclusion that much effort to date has been made to prove that these (often costly and commercially driven) strategies are effective in isolation from proven forms of integrated HF management, often with mixed results.

## Are Traditional Forms of Heart Failure Past Their "use by" Date?

The relative lack of trials seeking to fully integrate face-to-face care with potentially useful remote/implantable surveillance strategies has coincided with a time where traditional HFMPs are being overwhelmed by increasingly older patient population with multimorbidity [26]. This should not come as any surprise given that the appropriate application of

evidence-based secondary prevention and then HF management will inevitably produce this otherwise paradoxical phenomenon. To appreciate the acceleration in clinical complexity within the HF patient population, consider the contrasting profile of the original WHICH? trial of two forms of HF management [27] and the equivalent WHICH? II trial conducted almost a decade later (both trials being conducted in Australia) [28•]. In the original trial, the mean age was 71 years and the median Charlson Index of Comorbidity Score was 6 [27]. In the subsequent trial, these values had increased to 74 years and 7, respectively [28•]. More importantly perhaps, when applying a very detailed scoring system of risk (combining clinical stability, socio-economic factors and clinical management [29]) to both trials, within a decade the proportion of very high-risk patients, correlating to recurrent hospitalisation and premature mortality had more than doubled [28•].

As described in the primary report of this trial [28•], when compared with gold-standard HF management, a more intensive program of intervention (integrating advanced risk profiling using the traffic-light GARDIAN tool [29], structured telephone support and brain natriuretic peptide monitoring) tested in a multicentre trial involving 787 patients, did not, as hypothesised, result in fewer health care costs associated with greater reductions in hospital stay during 12-month follow-up. Indeed, recurrent hospital stay was slightly elevated in the study intervention group ($18.6 \pm 26.5$ versus $16.6 \pm 24.8$ days; $p = 0.199$) and mortality only slightly reduced (17.7% versus 18.4%; $p = 0.848$) [28•].

A post-mortem of the WHICH? II trial quickly revealed that the number of high-risk patients was much higher than anticipated (almost 50%). Moreover, when adding incremental surveillance (via structured telephone support) to the interventional group, as shown in Fig. 1, despite the ability to differentiate between lower- (green bars), moderate- (amber bars) and higher-risk (red bars) patients overall, using the GARDIAN tool, nearly every (98%) experienced clinical instability. That meant difficultly avoiding the dreaded "clinical cascade" [30]: a term that explains how the phenomenon of the "more you look the more you find" can drive increased consumer expectations for more proactive care whilst negatively altering the normal threshold for (re-)hospitalisation [30]. Further analyses demonstrated that the increasing age and complexity of the HF population has resulted in the emergence of "malignant phenotypes of multimorbidity" [6, 31] typically characterised by comorbid respiratory disease and renal dysfunction that contribute to stubbornly high levels of morbidity and mortality, even among those individuals exposed to the best of care.

## Time for a More Nuanced Approach to HF Management

Whilst it might be argued that the neutral results of the WHICH? II [28•] (broadly reflecting those of the earlier COACH trial conducted in Europe [32]) does not mean that "standard" HFMPs are ineffective/redundant, two recently reported studies provide a clear warning that current programs are simply not keeping pace with the needs of a changing HF population. At the risk of committing *heresy* within the HF community, it should be noted there is emerging evidence that HFMPs may even cause harm in certain individuals. In a combined analysis of the impact of our model of home-based intervention that forms the basis for many HF programs around the world, across the spectrum of heart disease in 1226 patients, we found a U-shaped pattern of benefit according to the age and complexity of patients [33]. As such, although our model of care was highly effective overall in reducing

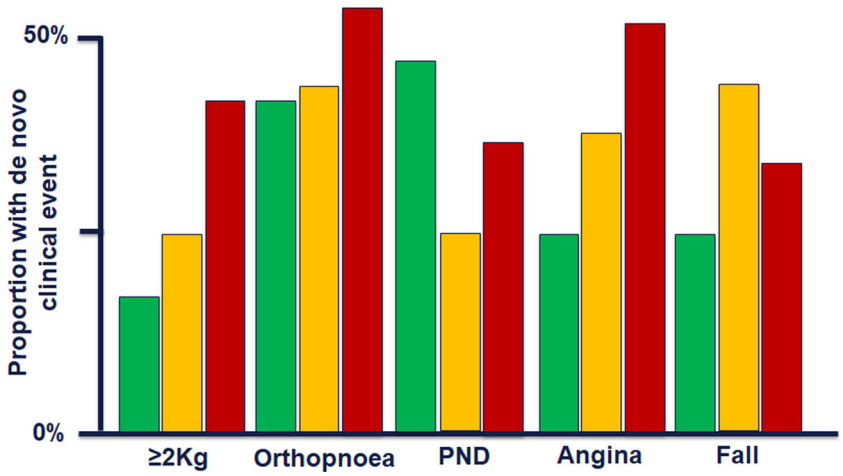


**Fig. 1** Pattern of clinical instability detected by structured telephone support within the WHICH? trial [28•]. The proportion of 303 individuals exposed to more intensive HF management (including structured telephone support) during a 12-month follow-up who experienced a significant clinical event according to their GARDIAN at risk status—green (low-risk), amber (intermediate risk) and red (high-risk). ≥ 2 kg, significant (dry-) weight gain in past week. PND, paroxysmal nocturnal dyspnoea

readmissions and prolonging survival, efficacy was largely confined to two thirds of patients. Accordingly, those typically older patients with the greatest clinical complexity (i.e. the contemporary profile of HF patients) had a worse outcome, as reflected in days-alive and out-of-hospital, when exposed to our model of care [33].

Recently reported data from the USA clearly suggest that these findings are not an isolated or random occurrence. In their analysis of 8.3 million hospitalisations for HF, acute myocardial infarction and pneumonia among Medicare beneficiaries (mean age 79.6 ± 6.7 years and 53.4% female), Wadhera and colleagues found a clear signal of *increased mortality* within 30 days among patients with HF and pneumonia following the introduction of a hospital readmission-reduction policy [34••]. Critically, these data expose the clinical tension and competing risks of attempting to monitor patients more closely, discharging them earlier, reducing their risk (as least in the short term) of re-hospitalisation whilst potentially causing harm (and even death) in vulnerable individuals.

Unfortunately, the science of understanding the unintended consequences of applying more intensive surveillance and then more aggressive management of vulnerable patients remains in its infancy. This perhaps reflects a misguided notion that monitoring devices and HFMPs are highly unlikely to do any harm. We do know, for example, that highly prevalent cognitive impairment is an important modulator of the success of disease management in both HF [35] and chronic atrial fibrillation [36]. We also know that there is an increasing proportion of patients in whom a more pragmatic palliative care and/or end-of-life approach is indicated; a formal study of the same in Scotland reporting that 27% of hospitalised patients meet the criteria for palliation with very few accessing such specialist care [37]. As indicated, however, this and many other facets of potentially more effective HF management remain under-researched.

## Conclusions

Although HFMPs have become critical to improving health outcomes in patients hospitalised with the syndrome [10], their routine application may well be misguided in the setting of patient population that is becoming increasingly older and more complex [26]. Attempts to introduce technological advances in HF monitoring, whilst probably effective in relatively younger (predominantly males) individuals with HF with reduced ejection fraction associated with an acute coronary event and minimal comorbidity, are likely to fail in older more complex cases with less definitive (and yet more frequent) clinical episodes. Likewise, current HFMPs applying face-to-face management, whilst still effective in most cases, are faced with the distinct possibility that they are counter-productive in older patients with multimorbidity. In this increasingly likely scenario, it might be argued that a more nuanced and pragmatic "less is more" approach to management might prove to be most effective. However, we have no research or clinical evidence to guide clinical practice. On this basis, there is an urgent need to undertake more sophisticated observational and interventional trials of HF management to determine if we can cost-effectively manage the evolving HF patient population who will likely unravel the benefits of HFMPs we have observed to date.

## Compliance with Ethical Standards

**Conflict of Interest** The author declares that he has no conflicts of interest.

**Human and Animal Rights and Informed Consent** This article does not contain any studies with human or animal subjects performed by any of the authors.

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