

## Review Article

## Two Decades of Research on Innovative Models of Care Delivery for Patients with Heart Failure: The End or Just the Beginning?

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### Abstract

The growing prevalence of heart failure and the cost associated with its management has become a major burden for most health care systems worldwide. We review the evidence from randomized studies of innovative models of care delivery for patients with heart failure, refer to some of the most influential non-randomized studies, and discuss the implications of the available evidence for practitioners, policy makers and researchers. Acknowledging that the relevance of evidence depends on the user's needs, we conclude that the likely impact of most models of care on health outcomes and resource utilization is likely to be modest. New approaches for design and evaluation are therefore required. Given the dynamic complexity of the health service environments in which any such models of care must be implemented, the future development of innovative models of care delivery would benefit from closer collaboration between service users, providers, policy makers and multi-disciplinary researchers, as well as more rigorous evaluation.

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A growing worldwide epidemic and the need for innovative models of care

Ageing populations with an increasing prevalence of heart failure and other chronic conditions place a growing burden on health systems across the world. With an estimated one million new cases annually, heart failure has become the most rapidly growing cardiovascular condition worldwide.<sup>1</sup> For example, in England it is estimated that 7% of the population aged 75 years or more are already affected by heart failure and this prevalence is expected to increase to 10% or more by 2025.<sup>2,3</sup> Heart failure is associated with substantial morbidity and mortality<sup>2,4,5</sup> and is one of the leading causes of admission to hospital in many high-income countries.<sup>1,5</sup> The burden of heart failure outside Europe and North America is less well established but limited evidence<sup>6-9</sup> suggests that as a consequence of ageing populations and the growing burden of coronary heart disease, heart failure has emerged as a major public health issue in these regions too. For example, in Brazil heart failure is the most common cause of admission to hospitals among those over the age of 60 years;<sup>8</sup> it is the fastest rising cardiovascular condition in terms of both incidence and prevalence in Iran with rates comparable to most European countries;<sup>10</sup> and healthcare costs attributable to heart failure are substantial in China, mainly due to prolonged hospitalization with an average admission duration of 22 days.<sup>7</sup> Moreover, this condition affects low- and middle-income country populations at a younger age than in high-income populations. For example, heart failure tends to affect people about 10 years earlier in the Arab world than in Europe and North America.<sup>9</sup>

Over the past two decades, preclinical research and clinical trials

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have provided a solid evidence-base to support the use of several drugs and devices in patients with heart failure for symptom control and prevention of premature death. However, the translation of evidence about effective and safe interventions into policy and practice remains a major challenge. In England for example, national audit data indicate wide regional disparities in both management and outcomes among people with heart failure.<sup>5</sup> In other regions of the world, it also appears that a large proportion of people with heart failure are not managed adequately and there is substantial underuse of effective and affordable therapies and overuse of expensive interventions with questionable value to individuals and populations.<sup>6,7,10</sup>

The growing burden of heart failure together with the gap between knowledge and practice and the inadequacy of our models of care delivery have resulted in increased interest in the development of alternative models of care that are better equipped to deliver essential treatment to patients with heart failure. These models have been described under a range of overlapping terminologies such as quality improvement, disease management, managed care, chronic care, coordinated care, integrated care, service re-organization, tele-health and e-health.<sup>11</sup> In this paper, we review the evidence about the effects of such models of care on major outcomes among patients with heart failure and discuss the implications for healthcare practitioners, policy makers and researchers.

The rise of disease management research in heart failure

Early investigations into the causes and precipitants of hospital admissions in patients with heart failure revealed that up to half of all admissions were potentially avoidable.<sup>12</sup> Factors contributing to avoidable admissions included incomplete investigation of treatable causes of heart failure (e.g. valve disease), underutilization of effective therapies due to prescription failures and poor adherence, adverse effects of medications, inadequate attention to comorbidities and psychosocial needs, and inadequate clinical follow-up in the community. Identification of these factors led to a series of experimental studies designed to test the hypothesis that more intensive, better-coordinated, patient-centered care with in-

tegration of acute and out-of-hospital services reduces avoidable healthcare utilization and improves clinical outcomes. One of the first trials to test this hypothesis randomized about 300 patients from a tertiary care center in the US and published its findings in 1995.<sup>13</sup> The results suggested that an intensive nurse-led multi-disciplinary management model that focused on identification of high-risk patients, treatment review, patient education and close post-discharge monitoring improved clinical outcomes. Over 90 days follow-up, the intervention was associated with a halving of the risk of re-admissions, and improved quality of life. The intervention was also found to reduce overall treatment costs (the reduced cost resulting from reduced re-admission outweighing the cost of intervention).<sup>13</sup> The promising findings from this small trial paved the way for further investigations of better systems of care delivery for patients with heart failure.

#### Evidence from early randomized comparisons

By 2006, over 35 randomized trials comprising about 8000 patients with heart failure, largely recruited from tertiary care centers, had published their findings on disease management in patients with heart failure. Despite the general agreement on the principle components of intervention in these trials (i.e. changes to service delivery and organization to facilitate evidence-based management), these trials differed in many respects. For example, the specific content, intensity and complexity of the interventions varied, as did the treatment provided in the 'usual care' comparison group. Nonetheless, several reviewers reported summary estimates of the average effects from these small-scale trials in an attempt to overcome their individually limited statistical power. Most of these meta-analyses included trials assessing the effect of comprehensive multi-disciplinary disease management programmes, which typically targeted more than one component of care delivery such as education, medication review, self-care, discharge planning, and regular remote or in-person follow-ups.<sup>14-20</sup> Other reviewers adopted a narrower focus: for example, one particular setting (e.g. hospital-based only),<sup>21</sup> one type of delivery personnel (e.g. pharmacist-led or nurse-led),<sup>22</sup> one specific facet of intervention (e.g. self-care),<sup>23</sup> or one particular outcome (e.g. quality of life).<sup>24</sup> In later years, further trials and meta-analyses of these assessed programmes utilizing innovative information and communication technologies, ranging from simple regular telephone calls between patients and care providers to more sophisticated technologies to measure, transfer and process data on physiological information.<sup>25</sup> Overall, the aim of these trials was to bridge the gap in communication between healthcare workers and patients outside the traditional health services environment.

Despite differences in focus of these meta-analyses, the trials included often overlapped and the aggregated effect estimates were largely consistent in favor of the innovative models of care delivery under investigation. Almost all reviews showed at least a trend towards reduction in death from all causes and a significant reduction in hospital admissions. On average, these analyses suggested that disease management programs reduced premature death by about one fifth and hospitalizations by about a quarter. In light of these results, international practice guidelines published in 2008 recommended routine use of disease management programmes for all recently hospitalized heart failure patients or those at 'high-risk' of adverse clinical outcomes.<sup>26</sup> Nevertheless, several questions remain to be answered. One unresolved issue is the substantial statistical heterogeneity in outcomes between the trials included. While the aggregated effects showed a clear improvement in health outcomes and resource utilization, there were

large variations between the published trials in their estimated effect sizes, ranging from an implausibly large reduction in risk<sup>27</sup> to no effect<sup>28</sup> and a significant increase in resource utilization.<sup>29</sup> Perhaps more importantly, over half of the trials included less than 200 randomized participants and the larger multi-center studies indicated no significant reductions in risk.<sup>28,29</sup> Possible explanations for this heterogeneity included differences in trial characteristics, such as quality of reporting, type of population included, content of the intervention, its recipients and the setting in which it was delivered. Indeed, some have argued that quantitative summary of such highly disparate trials should be avoided altogether.<sup>30</sup>

#### Evidence from more recent larger scale randomized trials in context

By 1999, about 200 disease management programmes were operating in the US alone with an estimated \$1bn investment in their development, implementation and evaluation.<sup>31,32</sup> The providers of such services ranged from private care providers, health insurance companies and other commercial entities who largely viewed disease management as a means of curbing the growing costs of care for people with chronic conditions. In order to secure a competitive advantage in this growing market, the providers of such services often came up with unique algorithms or variations in the components of service delivery.

Today the total number of trials on heart failure disease management exceeds 80. However, the majority of the later studies are still small and powered for unrealistically large effect sizes.<sup>33</sup> In this context, the US Congress authorized Centers for Medicare & Medicaid Services (CMS) in 2003 to launch the Medicare Health Support Pilot Program (MHSP) to test the effectiveness of disease management programmes at larger scale. Eight commercial care providers across the US were selected to provide care for a population of about 240,000 people with heart failure or diabetes who were at high risk of future resource utilization. These individuals were randomly assigned to receive disease management program or continue with usual care. However, the final results indicated no overall significant improvement in health outcomes or reduction in costs.<sup>34,35</sup>

Some critics pointed out that MHSP deviated in many respects from the previous academically-led disease management studies, which were focused on hospital-initiated programs that included well diagnosed patients into study and had close links to the other actors involved in care as opposed to the disjointed programs of providers in the MHSP.<sup>36</sup> However, a further large-scale randomized disease management trial, the Medicare Coordinated Care Demonstration (MCCD), also reported no clear effects of disease management programs despite its better integration across health systems.<sup>37</sup> The MCCD evaluated the effect of 15 diverse nurse-led, patient education and monitoring programmes for management of over 18,000 patients with heart failure, coronary heart disease or diabetes.<sup>37</sup> Each program was allowed to define, within broad boundaries of care coordination, its own target population and exclusion criteria, and designed its intervention accordingly. The authors concluded that while some processes of care were improved, these did not translate into any net reductions in hospitalizations or costs and there was no significant variation in outcomes between academic and commercial programmes.

Two further smaller, but by comparison with earlier studies still large, randomized trials investigated the effect of disease management with an emphasis on tele-health as the mode of care delivery have published findings recently.<sup>38,39</sup> The Tele-HF trial recruited about 1600 patients with a recent admission to hospital with heart failure from 33 cardiology practices across the US with partici-

pants randomized to usual care or ‘telemonitoring’.<sup>38</sup> The intervention was very simple and was based solely on an interactive voice-response system for patients designed to provide physicians with additional information about their patient’s quality of life, satisfaction with care, and use of medications. Investigators did not collect physiological data other than weight (which has a poor predictive value for worsening health status<sup>40</sup>). Formal education or self-management supports were not part of the intervention and the feedback of information to physicians was not in real-time, with delays of up to a week. Once again, this study provided no evidence that intervention was effective in improving health outcomes.<sup>38</sup>

A more complex and intensive intervention evaluated in the TIM-HF trial also failed to deliver beneficial effects. The TIM-HF trial randomized 710 patients from centers in Germany to remote ‘telemedical management’ or usual care. In the intervention group, portable devices were used to record ECG, blood pressure, and body weight which were then transmitted via mobile phones to telemedical centers.<sup>39</sup> While TIM-HF was not large enough to exclude moderate but clinically important effects on health outcomes, its non-significant findings in the context of the accumulating evidence from the larger trials certainly cast additional doubt on the reliability of reports of large benefits observed in the earlier small-scale trials and meta-analyses.

The investigators from the recent trials argued that the difference in outcomes between the earlier smaller trials and the more recent larger trials may be due, at least in part, to publication bias<sup>41</sup> (i.e. the tendency for trial results to be more likely to be published if these are strikingly positive than if they are negative or null). Publication bias can, along with other sources of bias, produce large apparent effects when treatments are actually ineffective, particularly when included studies are heterogeneous and have a limited number of events.<sup>42,43</sup> Others, however, suggested that some of the recent trials may have underestimated the true effect of such innovative models of care delivery because of poor adherence to treatment allocation and presence of treatment cross-over.<sup>38</sup> In response, the investigators have argued that considerable resources had been put in place to sustain a high level of adherence, which if anything would have increased the adherence rates above what would be achievable outside the trial context.<sup>44</sup>

#### Evidence from non-randomized comparisons

The often contradictory and frequently disappointing findings from randomized studies have been widely debated in literature. While some have argued that a modified but still rigorous framework based on medical interventions should be applied to evaluating complex interventions,<sup>45,46</sup> others have raised concerns that randomized trials are ill suited to study health care delivery and improvement research and may in fact hinder innovation.<sup>47</sup>

There are many non-randomized comparisons based on cohort or quasi-randomized studies as summarized in previous systematic reviews.<sup>48,49</sup> Although these reviews were not confined to heart failure patients, they did include several such reports. The conclusion from these reviews is that most non-randomized studies did not adequately control for secular trends or differences at baseline, casting doubt over the validity and reliability of any observed associations. Nevertheless, some of these studies have been highly influential and the models of innovation in them have been considered by some experts and think tanks as worth being adopted elsewhere.<sup>50-52</sup>

One of the largest and most influential non-randomized experiments is the RAND Chronic Illness Care Collaborative project.<sup>53</sup> The study included 51 participating sites in four collaboratives in-

volving almost 4,000 patients with diabetes, heart failure and depression.<sup>53</sup> The investigators elected a before and after design with additional selection of comparison sites to control for any secular trends. The main reason for not using a randomized trial was the ‘impracticality of randomization and the heterogeneity of organizations’.<sup>53</sup> While the core principals of the model were constant (e.g. multidisciplinary team work, iterative approach to problem solving and ongoing measurement and monitoring), the actual interventions varied from site to site depending on local needs and capacities. For example, some sites focused their effort on higher prescription rate for effective drugs, whereas others paid more attention to patient education and better diagnosis.

Although the Chronic Care Model was intentionally designed to be not disease specific, one publication reported specifically on outcomes for patients with heart failure, concluding that patients at the intervention sites were more knowledgeable, were more likely to be on recommended therapy, with an adjusted 13% reduction in hospitalizations compared to the selected control sites ( $p = 0.007$ ).<sup>54</sup> There was no difference in health-related quality of life, but with only 781 participants, statistical power was very limited. More importantly, of the 13 sites that completed the Collaborative program, only 7 agreed to be included in the evaluation. Participating organizations paid a fee to send teams to a series of collaborative meetings and the delivery of the program was reliant on dedicated heart failure nurses. The flexible approach to implementation of the specific contents of interventions has been a major achievement to test the effect of quality improvement collaboratives beyond single centers and single events. However, the positive findings on process outcomes are not reliable.

Other widely praised examples of success in healthcare delivery and innovation have been reported by the major integrated care providers in the US. The model of innovation in Geisinger’s Advanced Medical Home model has been viewed by some as an alternative to the traditional scientific assessment of medical innovations. Geisinger employs a ‘rapid-cycle innovation’ model, which is based on an iterative testing and changing of the care model to gradually improve the quality of care.<sup>47</sup> The rationale for use of such innovation and evaluation model, which is widely used in the industry, has been reported to be the long cycles of piloting and testing in randomized comparisons, which has been viewed by some as an inefficient way of service delivery innovation. Rapid cycle innovation aims to tackle some of the major limitations of the previous studies by putting emphasis on continuous change and taking account of the dynamic learning process in health services with many uncertainties. The Medical Home Model broadly entails defining a clear goal based on patients’ needs and a combination of financial incentives with the use of real-time feedback on performance. One of the latest reports from Geisinger suggests a relative reduction in acute admission rates of 28% in the Medicare population who were treated at Geisinger sites compared to those who were not. Other benefits included ‘continued downward bending of the cost curve’. Because of the relatively limited information available in the published papers, however, it is difficult to make a decision about the level of the confidence in the reported outcomes.

Another example is that of Veterans Health Administration, which has been reported to be the largest provider of tele-health worldwide. Routine analysis of data obtained for quality and performance purposes from a cohort of 17 025 patients showed a 25% reduction in numbers of bed days of care and 19% reduction in numbers of hospital admissions in those who were included in the tele-health program compared to those who were not.<sup>55</sup> However, there were significant imbalances in baseline characteristics be-

tween the two groups and as the authors discussed in their report 'the reduced utilization finding could be accountable for, in part or in total by regression to the mean. Formal research studies are needed to elucidate this further'.<sup>55</sup> Other reports from large insurance databases in other countries seem to have similar imbalances at baseline, with the intervention group starting with a much higher risk of resource utilization than the comparison group.<sup>56</sup> These results indicate that one would naturally expect that even without an intervention their risk would move towards the average over time, i.e. they regress to the mean. Thus, any causal inferences become highly unreliable.

#### The challenges of rigorous evaluation

The delivery of care for people with heart failure is complex at several levels, making the design, implementation and evaluation of care delivery programmes more challenging than standard clinical studies of drugs and devices. Heart failure is not a distinct disease but a syndrome with several potential underlying causes and precipitants, such as myocardial infarction, valve disease or non-cardiac conditions. Diagnosis often requires some physician intuition and judgment. For example, diagnosis still relies on non-specific clinical symptoms and signs such as breathlessness and fatigue. Despite advances in technologies, the actual underlying cause or causes often remain speculative. Treatment for individual patients varies depending on several factors such as the acuteness and severity of disease (including the degree of systolic dysfunction), presence of comorbidities (such as cognitive impairment and depression)<sup>57</sup> and patient preferences (e.g. trade-offs between quality and quantity of life in the predominantly elderly population). Partly due to the sometimes insidious onset of this condition many of the elderly patients believe that their worsening health status stems from inevitable consequences of ageing that may not or should not be intervened upon.<sup>58</sup> Furthermore, for many patients their medical diagnosis is not the main reason for healthcare utilization. They may be suffering from heart failure but their biggest problem is isolation, loneliness and not being able to cope at home without additional support, which in turn may lead to poorer health outcomes.<sup>59,60</sup> The multiplicity of causes of resource utilization may seem obvious but previous experience suggests that inadequate consideration of this fact has been contributing to the vastly overestimated effect sizes and inappropriately designed interventions.<sup>34</sup>

The diversity of the condition also means that any comprehensive system of care delivery needs to address two very different types of patient needs. First, improvement in quality of care requires the reduction of unnecessary variation in the use of effective interventions. Second, they need to offer sufficient flexibility for customization of diagnostic and management plans according to the severity and evolving nature of the condition and patient's priorities. This is not to suggest that statistical findings from existing population-based research are irrelevant and would have to be tailored to individual patients (in fact evidence suggests that such 'individualization' of care may reduce the quality of care<sup>61</sup>). But, there are still some management decisions that fall under the realm of intuitive medicine, for which incorporation of experts' tacit knowledge in pattern recognition remains crucial for continuous learning. However, the provision of these very different types of care by the same (costly) system has been identified as a major source of inefficiency in health care.<sup>62,63</sup>

Another challenge of combining these very different types of care into comprehensive packages is the added complexity of program evaluation. Disease management often intervenes at different levels of the system (e.g. patient, individual providers, organizations).

Some components of the intervention may have good causal links with health outcomes but others may have no rigorous evidence of effectiveness. This mixture makes evaluation of impacts more difficult, not least because of the often delayed and non-linear effects on health outcomes. Even if we assume a simple linear relationship between cause and effect, the signal to noise ratio inevitably decreases the further one moves away from patient-level outcomes, hence, increasing the risk of effect underestimation. One potential solution to this would be to focus the evaluation to process or intermediate outcomes. The challenge, however, is that for most service delivery interventions the link between patient-level outcomes and many of the process outcomes that would be more easily measurable are not established.<sup>64</sup>

Another source of complexity is the multiplicity of actors. Like many other chronic conditions, the actors who have an influence on wellbeing of heart failure patients are diverse with differing levels of knowledge, motivations, priorities and capacities. They may provide care in different settings such as hospitals, outpatient areas, community centers, and home, through face-to-face encounters or remotely.<sup>65</sup> In interventional studies, another important group of actors, namely researchers, are involved, which also adds to the complexity. While these actors often work interdependently, their activities are not necessarily coordinated and they are not passive recipients of the intervention. They may question, resist and adapt any new and external attempts to change based on their own goals and perceived needs and benefits.<sup>66</sup> Their bounded rationality, i.e. their limited information about other parts of the system, may render the system more inefficient. This also means that an intervention considered useful from one perspective may be neutral or harmful when considered from a different perspective. For example, strategies that aim to reduce the rate of admissions to hospitals may have a limited overall effect if they are targeting at in-hospital care only with no attention to outpatient or community care.

In complex systems, initial differences in contextual features, even if small, may render effect sizes unpredictable. Some of these features are more obvious than others. For example, it may be that presence of good primary care obviates the need for or at least reduces the impact of disease management programmes.<sup>67</sup> Other features, however, are less tangible and difficult to capture and measure. For example, the relationship between different actors in the system and how information is exchanged may have greater influence on outcomes than the structural elements of the system such as the number of physicians involved. Two very similar hospitals based on composition of teams, case load and technological facilities may generate very different responses to introduction of the same intervention, if in one setting the intervention is perceived as more important and well-aligned with the organization's goals than in the other.

#### Implications for practice, policy and research

What are the practical, policy and research implications from the experience and knowledge gained from these disparate studies into innovative models of care delivery for patients with heart failure? How can we make sense of their apparently contradicting findings and the wide range of interpretations? Can the evidence base help us to deliver more effective and efficient care for patients with heart failure today and in the future? Without doubt, there are no simple answers to these complex questions. But, patterns emerging from previous research and experience provide some answers.

Healthcare workers and policy makers are inherently aware of the complexity of the clinical and organizational settings. Therefore, they are not likely to be surprised to find that there is no single organizational design that could be simply transferred to their set-

ting, even if this has been shown to be unequivocally successful in another setting. As Rich, one of the forerunners of disease management in heart failure noted some years ago ‘... it should be recognized that there is no ‘one size fits all’ approach that represents the optimal disease management program; rather the most effective programs are those that are not only individually tailored to meet each patient’s needs, but which are also constructed in accordance with local practice patterns, resource availability, healthcare delivery system, and method of reimbursement.’<sup>58</sup> Indeed, poor understanding of the contexts is often the major reason for failures of medical innovations.<sup>68,69</sup> Any system-wide intervention would need to be adapted to local settings and such adaptation requires a good understanding of the needs and capacities of those individuals and organizations that are going to be affected by them. Studying other organizations’ experiences and behavior can help only up to a certain point. It will help narrow down the number of plausible options and identify some potentially transferrable principles. But it cannot replace the assessment of local needs and capacities nor can it obviate the need for ongoing testing and evaluation of interventions that are to be introduced into dynamic complex environments.

Much previous effort to synthesize the evidence so far has paradoxically focused on disentangling the effects from individual components of comprehensive intervention packages and sometimes of organizational elements. However, due to incomplete information in published reports, this is rarely possible. Even if future investigators would report study processes and contexts in more detail,<sup>31</sup> we would still not be able to reduce the effects to key elements of the intervention or organizations. Systems are more than just a simple sum of their elements. Some of their least tangible features may be the most important determinants of their behavior (and the most promising intervention points).<sup>70</sup> Changing organizations behavior is a continuous process that would need to go beyond the ‘what’ (e.g. intervention components) and must incorporate the ‘how’ (e.g. relationships and flow of information) and the ‘why’ (e.g. values and purpose of the system). This demands a participatory and interdisciplinary approach that uses a range of complementary methodologies that match the complexity of the problem.<sup>71</sup>

Another important insight from previous reports is that proportional effects of most service delivery interventions on important health outcomes (such as death) are going to be at best modest (e.g. in the range of 10% to 30% proportional reduction in risk) and any promises of cost reductions over shorter term are likely to be illusive. Changing the behavior of organizations requires time and significant resource investment. Some may be disappointed to hear that system redesign will not bring the much desired radical changes to control the surging burden of chronic diseases. However, most advances in medicine to date have had modest and incremental effects but they have cumulatively transformed the health of nations worldwide. Because heart failure is common and costly, any modest but continuous improvements in outcomes are likely to be worthwhile.

The combination of complex systems and the likely modest and delayed effects on health outcomes call for more rigorous evaluation of programmes than has been previously the case. By this we do not necessarily advocate a wider use of traditional randomized evaluations. All methods have their strengths and limitations and many of the practical challenges of health services research apply to both randomized and non-randomized comparisons. These include the limited understanding of the contexts prior to intervention, the overreliance on individuals at the expense of systems,<sup>72</sup> procedural barriers such as the perceived need for individual pa-

tient consenting<sup>73</sup> and inadequate recruitment of those at risk.<sup>74,75</sup> Overoptimistic effect size estimations, delays in information feedback, and delays in translation of effects into measurable clinical outcomes and the associated problem of outcome selection. On the other hand, many of the perceived benefits of non-randomized experiments such as flexibility of intervention designs can also be integrated into studies that assign treatments randomly.<sup>76</sup> Scientific rigor and rigid design, therefore, should not be confused. The decision about randomization or no randomization, or selection of any other non-experimental study design, should be based on the specific research question, the expected effect sizes and the desired level of certainty (in addition to technical feasibility issues).

If expected outcomes are large and can be measured during short observation periods, then simple observational designs may provide equally rigorous answers.<sup>77,78</sup> For example, if an organization is interested in using innovative models of care delivery to increase access to healthcare in rural regions, then a well-designed non-randomized comparison is usually sufficient.<sup>79</sup> However, more often than not decision makers are not satisfied with demonstrating that adding more resources increases access (without significant compromise on quality of care). They want to know whether the additional investment in health provision actually *improves* quality of care and is cost-effective or cost-saving. In such circumstances, unless decision makers are prepared to accept a study that measures effects on intermediate outcomes<sup>80</sup> or are willing to sacrifice the conventional level of confidence in scientific research,<sup>81</sup> then there is no alternative to properly designed large-scale and longer term trials that provide reliable evidence of moderate but important effects.

To advance the evidence base in healthcare delivery innovation, the tension between continuous learning and implementation must be overcome. In particular in areas such as heart failure management where certainty and uncertainty co-exist within the same setting and are not easily separable, translation of available knowledge into practice cannot be reduced to a ‘simple’ act of care standardization, which has been commonly pursued in previous randomized trials. Any promising innovative model of care delivery that aims to increase the performance of the system as a whole and over longer term will have to inevitably interact with the dynamic complex systems comprising of multiple levels, actors, linkages and feedback loops.<sup>82</sup> Inappropriate standardization is likely to make systems too rigid and would reduce their capacity to learn and self-organize through local experimentation. It can also demotivate ‘recipients’ of interventions, whose active participation is a necessary ingredient to all innovative models of care delivery. In other words, too much control stifles innovation.<sup>83</sup> On the other hand, restricting interventions to uncontrolled exploratory and experimental processes that are based on intuition and reasoning by analogy would neglect the knowledge that we have gained through sound scientific enquiry. Improvement of system’s behavior requires interventions that both facilitate standardized application of evidence-based interventions across settings *and* increase the capacity of sub-systems to learn through experimentation at the local level. The choice between one and the other is not a real choice. The challenge is to work towards the right balance.

## Conclusion

Collective evidence to date suggests that despite the intuitive appeal of new models of care delivery for management of chronic heart failure, the evidence for their effectiveness, cost-effectiveness and sustainability is mixed. Nonetheless, there is little doubt

that our traditional reactive and episodic models of care are ill equipped to address the complex needs of people with heart failure. Innovative technologies and care models are likely to play a growing role in future.<sup>84</sup> However, rigorous evaluation of such interventions is paramount to better understand their added value to patients and societies. Improvement of delivery of care for patients with heart failure is in essence an attempt to channel and enhance the learning and performance of complex systems. The complexity of our approach, therefore, needs to be matched with the complexity of the tools used to changing the system. Previous experience shows that focusing our efforts on either protocol-based models or the intuitive approach is not sufficient. We need to embrace both paradigms and use the expertise from disciplines such as statistics, cognitive psychology, organization behavior, and systems and complexity theory to improve the quality of care for patients with heart failure.<sup>85</sup> Much promising research has already taken place but the path to finding better responses to the growing heart failure epidemic is long.

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