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Jhund Pardeep (Orcid ID: 0000-0003-4306-5317)

Title: Implementing the evidence – the true summit of evidence based care and the false peak of guidelines

Comment on: BLITZ-HF: a nationwide initiative to evaluate and improve adherence to acute and chronic heart failure guidelines.

Authors: Pardeep S Jhund ¹

Affiliations: 1. BHF Glasgow Cardiovascular Research Centre,
School of Cardiovascular and Metabolic Health,
University of Glasgow, Glasgow, United Kingdom;

Correspondence: Pardeep S Jhund
British Heart Foundation Cardiovascular Research
Centre,
University of Glasgow,
126 University Place,
Glasgow, G12 8TA,
United Kingdom.
Tel: +44 141 330 1672
Fax: +44 141 330 6955
Email: pardeep.jhund@glasgow.ac.uk

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The synthesis of evidence through scientific study is often viewed as the pinnacle of clinical research. The robust randomised controlled trial that clearly demonstrates clinically meaningful efficacy of a new therapy for any condition, including heart failure, is usually met with appreciation from the clinicians and patients. The next hurdle that is often seen by the clinical community is the incorporation of new data into clinical guidelines and much discussion arises around where a guideline may place a new therapy and the strength of recommendation that it receives. Often the publication of the guideline generates yet more discussion, including sometimes controversy, but in general the guideline recommendation is seen as the zenith of clinical research; the findings of the trial have gained acceptance by the clinical community. However, guidelines are being increasingly becoming a false peak in the climb towards the true summit of getting the new therapy to patients (Figure).

It has been well recognised for decades that despite robust evidence the implementation of therapy for heart failure is suboptimal [1,2]. Multiple studies and registries across regions, countries, health care systems, have all produced a consistent and depressing statistic, the use of evidence-based therapy for heart failure is lower than would be expected based on contraindications or trial exclusion criteria to therapies. This is like a “Valley of Despair” that disheartened physicians and trialists reach where reality sets in after the false peak of a guideline recommendation. The scale of the task facing clinicians, the final arduous climb to the true summit of patient use of therapies, then becomes apparent. There are of course many issues behind this underuse, cost, access to healthcare, local availability of a therapy being just some of the commonly cited problems. Appreciating this gap between evidence and usage, a growing body of studies aim to address barriers to implementation of therapies in the real world and to narrow the gap between the number of eligible patients and the number of patients actually receiving guideline recommended therapy.

There are many ways to improve the use of therapies. These include interventions at an individual level, health care provider level and health care system level. The BLITZ-HF study by Gulizia *et al* [3] in this issue of the European Journal of Heart Failure is a nationwide initiative to evaluate adherence to heart failure guidelines in Italy and illustrates a program of work aimed to increase the use of evidence-based therapies in heart failure. The first phase of the study was designed to gather data on therapy usage before a targeted education program was delivered in the next phase, followed by a further data collection phase to assess the impact of the intervention. There is also a long term follow up phase that is not completed yet. The multifaceted intervention has many important aspects that deserve consideration, and which may help inform future efforts in this space. One difficulty with implementation science, and education in particular, is what the intervention should be. The BLITZ-HF investigators chose a mix of face-to-face educational meetings which discussed the guidelines but crucially also added benchmarking to the discussion following the initial collection of data. Benchmarking is a valuable aspect to any intervention strategy and is employed by other initiatives [4]. Benchmarking, comparison of results to others, may stimulate improvement and reinforce improvement especially when combined with other interventions [5]. The BLITZ-HF initiative was conducted in a network of hospitals. Having interested networks of hospitals and clinics can help roll out nationwide initiatives to improve treatment and adherence to guidelines. But hospitals that already take part in networks such as the Italian HF Network of the National Association of Hospital Cardiologists (ANMCO) (that hosted BLITZ-HF) tend to be interested and motivated hospitals and these institutions are less likely to benefit from interventions to improve guideline adherence. Conducting clinical trials in these networks leads to inclusion of high-quality sites and impressive data for randomised clinical trials, but they may not be the best setting for quality improvement initiatives. In fact, this was the main finding of BLITZ-HF, these motivated, high-quality sites were already doing very well. The adherence to guideline recommended therapies and other quality measures for heart failure such as access to echocardiography was in fact very good

prior to the intervention. Therefore, while many of the outcomes improved they did not do so by a substantial or statistically significant amount. This has been seen in other trials of other interventions where background use of therapies was high before the intervention [6]. It is difficult to improve usage rates if they are already high. For example, use of a beta blocker was 94% pre intervention and 94% after, mineralocorticoid receptor antagonist use 72% pre intervention and 71% after. Most of the remaining patients not on these therapies had known and clear clinical contraindications. However, BLITZ-HF does show us that we can still improve motivated sites and their patients can still benefit from implementation interventions. The intervention led to a doubling in the use of angiotensin receptor neprilysin inhibitors from 15% to 30%. This finding highlights the need for interventions to overcome the inertia of new therapies, even in these highly motivated sites where other quality of care markers are already high.

The BLITZ-HF study shows us how implementation science can be conducted and gives us some insights into some of the various aspects of implementation that need to be considered. The background implementation of therapies, the sites, the physicians, the intervention, data collection and analysis are all areas where decisions must be made before designing an effective and robust implementation trial or study. Recognising the nuances in implementation studies is a specialist skill that we must develop as a community. We cannot simply carry on producing more and more research documenting that therapies are underused in heart failure, we have been doing this for too long. Now is the time to embrace implementation science and seek to improve the use of guideline recommended therapies through interventions. What is clear is that no one strategy will fit all health care systems or regions of the world. We need a cadre of implementation scientists who will lead new studies in this area and provide robust evidence and recommendations for change [7]. They need to be appropriately trained in the many methods that are relevant to implementation studies. Only through implementation science will we be able to climb out of our “Valley of Despair” of underuse of evidence-based therapies and make the final ascent to the zenith of

evidence based medicine where all patients who are eligible for a guideline recommended therapy actually receive it.

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Figure: The path from clinical evidence to a patient receiving a guideline recommended therapy

