World Journal of Methodology

Submit a Manuscript: http://www.wjgnet.com/esps/
Help Desk: http://www.wjgnet.com/esps/helpdesk.aspx
DOI: 10.5662/wjm.v5.i4.179

World J Methodol 2015 December 26; 5(4): 179-184
ISSN 2222-0682 (online)

EDITORIAL

Toward phase 4 trials in heart failure: A social and corporate responsibility of the medical profession

Pupalan Iyngkaran, Glen S Beneby

Pupalan Iyngkaran, NT Medical School, Research Fellow and Senior Lecturer Flinders University, Darwin NT 0815, Australia

Glen S Beneby, Commonwealth of the Bahamas, 3rd and West Centerville, Nassau 999154, Bahamas

Author contributions: Iyngkaran P wrote the manuscript; Beneby GS edited and added in additional relevant points.

Conflict-of-interest statement: All co-authors have won independent and governmental research funding. Several members provide counsel to pharmaceuticals. None pose a conflict of interest for this short paper.

Correspondence to: Dr. Pupalan Iyngkaran, MBBS, FRACP, Consultant Cardiologist, NT Medical School, Research Fellow and Senior Lecturer Flinders University, PO Box 41326, Casuarina, Darwin NT 0815, Australia. gbeneby@batelnet.bs
Telephone: +61-88-9467488
Fax: +61-88-9467599

Received: December 10, 2014
Peer-review started: December 12, 2014
First decision: January 8, 2015
Revised: October 20, 2015
Accepted: October 23, 2015
Article in press: October 27, 2015
Published online: December 26, 2015

Abstract

Congestive heart failure (CHF) is a chronic condition, requiring polypharmacy, allied health supports and regular monitoring. All these factors are needed to ensure compliance and to deliver the positive outcomes demonstrated from randomized controlled trials. Unfortunately many centers around the world are unable to match trial level support. The outcomes for many communities are thus unclear. Research design factors in post-marketing surveillance to address this issue. Phase 4 studies is the name given to trials designed to obtain such community level data and thus address issues of external validity. CHF phase 4 studies are relatively underutilized. We feel the onus for this research lies with the health profession. In this commentary we provide arguments as to why phase 4 studies should be viewed as a social and corporate responsibility of health professional that care for clients with CHF.

Key words: Clinical trial; Corporate responsibility; Health system; Congestive heart failure; Phase 4

Core tip: This commentary brings needed and timely attention to phase 4 or postmarketing surveillance. Only a handful of congestive heart failure (CHF) therapies have actually been studied in the community after the randomized controlled trial. In this millennium it is important we not only innovate and support trials of new therapies, but also ensure the therapies we are already using are effective for all patients. As drug discovery and randomised controlled trial evidence is often done by private sector pharmaceuticals, we thus feel the need to bring attention on treating health care teams to regularly generate efficacy and effectiveness data for the CHF treatments they prescribe.

Iyngkaran P, Beneby GS. Toward phase 4 trials in heart failure: A social and corporate responsibility of the medical profession. *World J Methodol* 2015; 5(4): 179-184 Available from: URL: http://www.wjgnet.com/2222-0682/full/v5/i4/179.htm DOI:

http://dx.doi.org/10.5662/wjm.v5.i4.179

INTRODUCTION

"…'medical Profession' consists of the sum of the identities of its membership … if the 'profession' is held responsible for something, each of its members is responsible, in some way, for it". -French PA

It is the collective responsibility of the medical profession to seek and administer processes to account for past practices and improve future health practices. The practice of medicine, today, is a complex process that has to factor many considerations. An important consideration is the evidence based practice. This evolution initially saw prescribing that was based on uncontrolled observations of physiology in individuals, to controlled observations on groups. The pursuit of this new goal has become quite complex and corporatized, such that we often forget some of the basics that has safely steered the profession. All systems also have to factor the social and ethical contracts between governments, and its citizens, demanding equitable health services, or risk community wrath at the ballot box. The prescription of pharmaceuticals is one arm of this complex process. Many pharmaceutical manufacturers operate from the private sector. A financial investment is made in developing a drug, where there is always the risk that it may not provide the necessary benefits, hence unmarketable. To standardize this competition with accountability, the randomised controlled trial (RCT) has been used to generate the evidence base. Should there be positive findings, the company that has made that investment now has the legitimacy to market the product. There are however limitations with this process. In this editorial we discuss the importance of continuing governance once the drug is approved for community use. In this, all health professionals have to ask the hard questions and truly understand the entirety of their responsibilities not only in the delivery but the governance of clinical as well as the corporate issues. Let us look at examples for this from several vantage points that are timeless.

ETHICS

Whenever a doctor cannot do good, he must be kept from doing harm. -Hippocrates

Safety, the pillar of medical practice, ingrained at the start of training and reminded at graduation with the "Hippocratic Oath", is a social contract we as health care workers (HCW) have with our clients. Before a HCW does anything we should firstly do no harm. As soon as a HCW starts their duties whether it is consulting, diagnosing, prescribing, dispensing, delivering, promoting or preventing, they run the risk of doing harm. There is no way to determine risk-benefits ratios of any intervention without adequate checks and balances. Medication errors are the eighth leading cause of death in the United States. Cardiovascular medications account for a large proportion of these errors, predominately as inpatients in the emergency department and acute hospital settings. Errors include omissions, incorrect dosage, under prescribing, and failure to consider adverse interactions. Errors are more likely to occur when clinical workload is heavy; there is language, communication, cultural barriers; although, generally the majority of these errors occur from a lack of intention[1]. Geographical distances and unavailability of services are not factored much in guidelines to achieve simplicity of the therapeutic regime. Universal and standardized reporting of errors and adverse side effects has been in play from many health bodies and centralised to government bodies to ensure accountability. Standardization of knowledge and training at undergraduate and continuity thereafter are also important measures to reduce this risk[2,3]. System wide the monitoring of this, however, remains inadequate.

STANDARDS

"…The art of medicine was to be properly learned only from its practice and its exercise…" -Thomas Sydenham

Health regulators have ensured that delivery of health care has a minimum basic standard through law and enforcement by regulatory bodies. Such examples include the medical universities, training colleges, therapeutic goods admirations, medical councils and overseas trained doctor regulators. At the core of this is the curriculum. As health information and technologies are evolving so must HCW and systems. Continuous medical education (CME) is now required by medical bodies to maintain up-to-date knowledge, although barriers remain. Among a small number of general practitioners, barriers were identified in many dimension of care[4]. With system wide barriers it will be difficult for regulators to introduce standards for improvement at the level of the health clusters. In addition there are silos between the administrators, HCW and clients. This often makes it difficult for HCW to practice in-sync with advancements, while using their local experience. This in fact is a translational block that occurs far too often. In-fact these local experiences in the practice of medicine are not given any emphasis. No doubt HCW may use this in their practice, perhaps unregulated, without the knowledge of how it is translating. As an example, Joynt *et al*[5] highlighted the differences in mortality outcomes between physicians managing a high *vs* low volume of congestive heart failure (CHF) cases. These benefits were noted regardless of age, sex, race and comorbidities. Such care was also more intense, and with greater use of skilled nurse and rehabilitation. However, readmission rates were higher[5]. Identifying priorities is one reason. The experience of HCW also appears vital for improved outcomes. In the real world

there remain many clusters that never achieve this high volume status, and where admitting patients more frequently are not possible. How we learn from these positive examples, how we disseminate that knowledge and how we use technology to share workloads to achieve the adequate standards and outcomes are issues health systems must address. To truly factor in experiences, guidelines need to achieve consensus and standardize sections in it that reflects on the benefits of regional variations in practice. Creating options of how such variations can be created, while ensuring all these deviations are audited is an important standard to set in shaping CHF guidelines of the future. Another issue of concern when dealing with fixed guidelines is its generalizability.

GENERALIZABILITY

"We should be concerned not only about the health of individual patients, but also the health of our entire society". -Benjamin Carson

It is important we pay attention to the generalizability of standards and guidelines. Rothwell, highlighted two vital questions when evidence is gathered through RCTs: firstly, are the results valid for patients other than from the trials; and are the results generalizable to similar patients but in a different treatment setting[6]. Due to the way trials are set up, it will be impossible to test every conceivable permutation (scenario) while controlling biases. Cultural sensitivities, an example of one such, are important areas to negotiate. Often HCW exercise judgement which on occasion could flirt the boundaries of such guidelines or the skills they are thought[7]. This art of medicine touches greatly on subjectivity and relies on the HCW intuition or perhaps experience. In a study of general practitioners if was found that prescribing closely of HF guidelines varied inversely with age[7]. While the younger group could relate to familiarity with guidelines, the importance of age and experience, perhaps related more to on the ground realities in different communities, and may have influenced these differences. There are unfortunately no universal ways to standardize this, but we can still account for this. As highlighted earlier experience can be a factor that affects outcomes. From this HCW may start being creative in their administration of health services. It is not only important that there be accountability but also sharing of this experience to reflect in the published literature.

EXPERIENCE

"It is much more important to know what sort of a patient has a disease than what sort of a disease a patient has". -William Osler

No two health care workers will be identical in the way they practice medicine. Experiences of both client and physicians are important as they tailor their individual views on health and illness. The undisputed common outcome is perhaps the ability to "…live a long, productive and quality life…". Again studies have shown that the higher the volume of HF clients seen by physicians, outcomes tended to be better, suggesting the importance of clinical experience[5]. While we allow doctors to practice in this fashion, we find it difficult to find guidelines that describe medical care in this fashion. Similarly client experiences are important. The clients view on how they are treated in the medical system will reinforce their attitudes to health. These views will have cultural and socioeconomic slants, factors that are not often factored into RCT or guidelines. It may not be as simple in all cases to tell a patient that the medicine you are giving them is the best and they ought to comply regardless of how they feel about it[8,9]. In this sense two powerful qualities are relationships which is vital to develop a good understanding, and choice, which is needed to provide for a holistic HCW-patient experience.

RELATIONSHIPS

"The good physician treats the disease; the great physician treats the patient who has the disease". -William Osler

It is universally accepted that most clients and systems rate HCWs who provide a holistic approach to medical care. There is a spectrum of what is considered holistic including partnerships and seeking of expertise when unavailable. It is also imperative that HCW look out for and form partnerships with other specialists in their own right. Knowledge is not the right of one person and no one group has all the knowledge. To provide a comprehensive client experience all HCW at some point must seek the assistance of their colleague. This area becomes more complex when skills are outside the health cluster. Forming relationships with centres of excellence will help. Technology can be used to bridge such gaps. Translational blocks for these are administrative, requiring a new mind set from all parties. Similarly health services with a greater density of HF specialist were associated with improved outcomes[10,11]. These are other reasons for such partnerships. Good client HCW relationship is an independent marker of positive outcomes[12]. The National institute of health which advocates for improved evidence translation discusses the continuation of "Bench to Bedside" research. In the second arm, "Bedside to Bench", clinical and basic research are equally important in the delivery. It is the obligation of the HCW to seek these out, to improve translation of evidence or to generate greater evidence should it be required. Healthy clinical and scientist HCW relationships are an obligation in pursuit of the optimal client services, where there is also adequate choice.

CHOICE

"Never go to a doctor whose office plants have died". -Erma Bombeck

HCW and clients alike need choices, and the freedom to make informed choices. This includes the

choice of doctor, therapies and the manner in which all aspects of their care are delivered. Guideline based care and the Western paradigm of ambulatory chronic condition care has subverted this process, subtlety such that both HCW and clients deliberate from a small basket of choices[12,13]. We are acknowledged that "a one shoe fits all" approach does not work. Having choices is not an easy process as it requires extension of evidence beyond a Bench to Bedside approach. In the vast majority of cases a guideline based approach is sufficient. In perhaps one in ten cases there is a need for a more creative approach. This may involve using a medication with improved activity for a comorbidity, that is easier to use, that has potentially less side effects. Drug companies that develop the evidence will often stop after the RCT is concluded. In the conclusion of the presented findings it is often written to imply a wide generalizability when in actual fact the results apply to the chosen population treated. It is often left to the HCW to generate this evidence. This involves a competitive process from formulation of the research question to grant funding applications for investigator initiated research. Again this process could be simplified where regulatory authorities directly approve the investigator initiated research and provide the formulary medication. Clearly health economics is a factor and this needs to be discussed. A new approach is also encouraged. Understanding how clients and HCW interact within clusters could be important in reducing this block.

COST

"A hospital bed is a parked taxi with the meter running". -Groucho Marx

"There are no free lunches", "the age of entitlement is over", are choruses that can be heard loudly at political rallies. Escalating health care costs are a concern. The increase in pharmaceuticals prescribed will see funds diverted from other essential services. The easiest way to save cost is to keep the client healthy, prevent future illnesses and reduce tertiary hospital utilization. CHF alone utilizes close to 2% of health care costs, in the United States estimated at close to $35 billion dollars. Among 1054 CHF clients, when this cost is broken down, after a mean follow-up of 4.6 years 73% had died. The estimated lifetime costs were close to $110000 where more than three fourths the costs are accumulated from hospitalizations. The majority of HF patients will suffer at least one other chronic comorbidity[14,15]. As there are overlaps with care within the chronic ambulatory care model ways can be found to minimize this overlap and reduce duplication. This is one simple way. Other options include preventing the treatment of one illness affecting the outcome of another. In these cases we have previously discussed how extra-class effects of drugs, their variable pharmacological properties could be better suited some clients. It is important we generate this evidence at the community level.

MORAL RESPONSIBILITY

"Modern medicine is a negation of health. It isn't organized to serve human health, but only itself, as an institution. It makes more people sick than it heals". -Ivan Illich

Do medical professionals have responsibility beyond the description of their respective professions? There have been in our time physicians who have stood out more than others. Many of these, some included in the above quotes, point to an unwritten, subjective obligation that comes closer to the spiritual than the scientific domain. Regardless of our view points on this we have to accept that the practice of medicine is an inexact science. We are there for obligated to keep an open mind and to continuously strive for improvement in our clients welfare. This can be defined as common sense by pragmatist; of interest by health systems focused on cost and a moral imperative by others. CME is one arm of this where HCW increase their armament for service delivery. Prospective clinical audits are another arm where the focus is on the health system. They should be run by centralised committees within local health clusters controlling the key performance indicators. Six domains from preadmission, emergency, admission, discharge, community and the dimensions of care in each of these domains should be negotiated. An agreed framework for data mining will allow for better and quicker access to information. Health systems in the future should work on standardising the entry, sharing of data and allow for easier access to prospective health data so that local situations can be addressed quicker. We must always find way to provide a frame for the picture to the painted. The barriers here are often administrative and jurisdiction. It is a moral imperative we balance our views on this, prevent silos and look for commonalities. From this picture we can execute our social responsibility as citizens. Thus HCW have responsibilities "…Beyond their call for Duty…".

SOCIAL AND CORPORATE RESPONSIBILITY

"The physician's highest calling, his only calling, is to make sick people healthy-to heal, as it is termed". -Samuel Hahnemann

It is important that systems ask socially responsible questions, *e.g.*, should we provide health services to a community for a decade what is the expected outcome at the end of that time? Is there anything we should do differently? Do we have the adequate skills? Phase 4 studies are a continuation of research once evidence is generated from a RCT. They seek to advance the translational factors such as access, organizational and client factors that could hinder delivery of best practice. Such research could understand both clinical and economic

issues relevant to health clusters and health systems. It provides both information and hypotheses generating questions and should be part of continuous quality improvement[16-18]. It is our collective responsibility to ask these post marketing questions such as: What are the strains on the health systems? What can I or we as a group do to help? When and where to seek assistance? When and where to draw attention? It is thus a social and corporate responsibility for HCW to continue to audit their work to look for better and cheaper ways to provide health services moving into the future.

In summary, to provide medical services and reinforce the RCT findings is a complex process with many factors at play. Health systems have to factor all these. It may seem difficult as such it may be easy to merely do the same. In fact with very simple measures we could achieve an improved standard of medical care. We feel that this standard involves a dedicated emphasis by HCW and systems for post marketing surveillance to address issues within health clusters[19-25]. There are technological advancements now to ensure that this process need not be as laborious as it previously was. Data storage, data mining and standardization of key performance indicators in HF suggest that a subtle shift in thinking and an investment in technology could prove useful. The future must encompass a dedication to regular audits to inform a dynamic CME education curriculum, by breaking down of silos, and embracing technology[26-30]. More powers be given and greater accountability requested from heath clusters by preventing translational blocks. Phase 4 trials should not be viewed as a rigorous process, a vindictive process where some are rewarded and other punished. It should be viewed as a process to generate evidence, improve service delivery, understands subtle local variations, inform the health cluster and add to the global pool of knowledge. Doing so will not only reduce costs but uphold the social contract between providers and recipients of health care.

REFERENCES

1 **Michaels AD**, Spinler SA, Leeper B, Ohman EM, Alexander KP, Newby LK, Ay H, Gibler WB. Medication errors in acute cardiovascular and stroke patients: a scientific statement from the American Heart Association. *Circulation* 2010; **121**: 1664-1682 [PMID: 20308619 DOI: 10.1161/CIR.0b013e3181d4b43e]

2 **Yancy CW**, Jessup M, Bozkurt B, Butler J, Casey DE, Drazner MH, Fonarow GC, Geraci SA, Horwich T, Januzzi JL, Johnson MR, Kasper EK, Levy WC, Masoudi FA, McBride PE, McMurray JJ, Mitchell JE, Peterson PN, Riegel B, Sam F, Stevenson LW, Tang WH, Tsai EJ, Wilkoff BL. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on practice guidelines. *Circulation* 2013; **128**: e240-e327 [PMID: 23741058 DOI: 10.1016/j.jacc.2013.05.019]

3 **Heart Foundation of Australia**. Living well with chronic heart failure. Available from: URL: http://www.heartfoundation.org.au/SiteCollectionDocuments/Living-well-with-chronic-heart-failure.pdf

4 **Peters-Klimm F**, Natanzon I, Müller-Tasch T, Ludt S, Nikendei C, Lossnitzer N, Szecsenyi J, Herzog W, Jünger J. Barriers to guideline implementation and educational needs of general practitioners regarding heart failure: a qualitative study. *GMS Z Med Ausbild* 2012; **29**: Doc46 [PMID: 22737201 DOI: 10.3205/zma000816]

5 **Joynt KE**, Orav EJ, Jha AK. Physician volume, specialty, and outcomes of care for patients with heart failure. *Circ Heart Fail* 2013; **6**: 890-897 [PMID: 23926203 DOI: 10.1161/CIRCHEARTFAILURE.112.000064]

6 **Rothwell PM**. Commentary: External validity of results of randomized trials: disentangling a complex concept. *Int J Epidemiol* 2010; **39**: 94-96 [PMID: 19776246 DOI: 10.1093/ije/dyp305]

7 **Parnicka A**, Wizner B, Fedyk-Łukasik M, Windak A, Grodzicki T. Knowledge about heart failure in primary care: need for strengthening of continuing medical education. *Cardiol J* 2013; **20**: 356-363 [PMID: 23913453 DOI: 10.5603/CJ.2013.0093]

8 **Sacco SJ**, Park CL, Suresh DP, Bliss D. Living with heart failure: psychosocial resources, meaning, gratitude and well-being. *Heart Lung* 2014; **43**: 213-218 [PMID: 24661743 DOI: 10.1016/j.hrtlng.2014.01.012]

9 **Browne S**, Macdonald S, May CR, Macleod U, Mair FS. Patient, carer and professional perspectives on barriers and facilitators to quality care in advanced heart failure. *PLoS One* 2014; **9**: e93288 [PMID: 24676421 DOI: 10.1371/journal.pone.0093288]

10 **Kulkarni VT**, Ross JS, Wang Y, Nallamothu BK, Spertus JA, Normand SL, Masoudi FA, Krumholz HM. Regional density of cardiologists and rates of mortality for acute myocardial infarction and heart failure. *Circ Cardiovasc Qual Outcomes* 2013; **6**: 352-359 [PMID: 23680965 DOI: 10.1161/CIRCOUTCOMES.113.000214]

11 **Goodrich K**, Krumholz HM, Conway PH, Lindenauer P, Auerbach AD. Hospitalist utilization and hospital performance on 6 publicly reported patient outcomes. *J Hosp Med* 2012; **7**: 482-488 [PMID: 22689448 DOI: 10.1002/jhm.1943]

12 **Olshansky B**. Placebo and nocebo in cardiovascular health: implications for healthcare, research, and the doctor-patient relationship. *J Am Coll Cardiol* 2007; **49**: 415-421 [PMID: 17258086 DOI: 10.1016/j.jacc.2006.09.036]

13 **Sanders T**, Harrison S, Checkland K. Evidence-based medicine and patient choice: the case of heart failure care. *J Health Serv Res Policy* 2008; **13**: 103-108 [PMID: 18416916 DOI: 10.1258/jhsrp.2008.007130]

14 **Dunlay SM**, Shah ND, Shi Q, Morlan B, VanHouten H, Long KH, Roger VL. Lifetime costs of medical care after heart failure diagnosis. *Circ Cardiovasc Qual Outcomes* 2011; **4**: 68-75 [PMID: 21139091 DOI: 10.1161/CIRCOUTCOMES.110.957225]

15 **Smith DH**, Johnson ES, Blough DK, Thorp ML, Yang X, Petrik AF, Crispell KA. Predicting costs of care in heart failure patients. *BMC Health Serv Res* 2012; **12**: 434 [PMID: 23194470 DOI: 10.1186/1472-6963-12-434]

16 **Strachan PH**, Joy C, Costigan J, Carter N. Development of a practice tool for community-based nurses: the Heart Failure Palliative Approach to Care (HeFPAC). *Eur J Cardiovasc Nurs* 2014; **13**: 134-141 [PMID: 24434049 DOI: 10.1177/1474515113519522]

17 **Ralph AP**, Fittock M, Schultz R, Thompson D, Dowden M, Clemens T, Parnaby MG, Clark M, McDonald MI, Edwards KN, Carapetis JR, Bailie RS. Improvement in rheumatic fever and rheumatic heart disease management and prevention using a health centre-based continuous quality improvement approach. *BMC Health Serv Res* 2013; **13**: 525 [PMID: 24350582 DOI: 10.1186/1472-6963-13-525]

18 **Brush JE**, Balakrishnan SA, Brough J, Hartman C, Hines G, Liverman DP, Parker JP, Rich J, Tindall N. Implementation of a continuous quality improvement program for percutaneous coronary intervention and cardiac surgery at a large community hospital. *Am Heart J* 2006; **152**: 379-385 [PMID: 16875926 DOI: 10.1016/j.ahj.2005.12.014]

19 **Bergman SM**, Vernillo AT. The ethics of corporate social responsibility. *J Am Coll Dent* 2014; **81**: 41-45 [PMID: 25080670]

20 **Sass HM**. The clinic as a good corporate neighbor. *Croat Med J*

2013; **54**: 78-82 [PMID: 23444251 DOI: 10.3325/cmj.2013.54.78]
21 **Bassett S**, Westmore K. How nurse leaders can foster a climate of good governance. *Nurs Manag* (Harrow) 2012; **19**: 22-24 [PMID: 23008901]
22 **Brandão C**, Rego G, Duarte I, Nunes R. Social responsibility: a new paradigm of hospital governance? *Health Care Anal* 2013; **21**: 390-402 [PMID: 22481565 DOI: 10.1007/s10728-012-0206-3]
23 **Haddad AM**. The nurse's role and responsibility in corporate-level planning. *Nurs Adm Q* 1981; **5**: 1-6 [PMID: 6907745 DOI: 10.1097/00006216-198100520-00003]
24 **French PA**. Collective responsibility and the practice of medicine. *J Med Philos* 1982; **7**: 65-85 [PMID: 7086316 DOI: 10.1093/jmp/7.1.65]
25 **Foreman S**. Social responsibility and the academic medical center: building community-based systems for the nation's health. *Acad Med* 1994; **69**: 97-102 [PMID: 8311894 DOI: 10.1097/00001888-199402000-00002]
26 **Krumholz HM**, Currie PM, Riegel B, Phillips CO, Peterson ED, Smith R, Yancy CW, Faxon DP. A taxonomy for disease management: a scientific statement from the American Heart Association Disease Management Taxonomy Writing Group. *Circulation* 2006; **114**: 1432-1445 [PMID: 16952985 DOI: 10.1161/CIRCULATIONAHA.106.177322]
27 **Bonow RO**, Bennett S, Casey DE, Ganiats TG, Hlatky MA, Konstam MA, Lambrew CT, Normand SL, Pina IL, Radford MJ, Smith AL, Stevenson LW, Burke G, Eagle KA, Krumholz HM, Linderbaum J, Masoudi FA, Ritchie JL, Rumsfeld JS, Spertus JA. ACC/AHA Clinical Performance Measures for Adults with Chronic Heart Failure: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures (Writing Committee to Develop Heart Failure Clinical Performance Measures): endorsed by the Heart Failure Society of America. *Circulation* 2005; **112**: 1853-1887 [PMID: 16160201 DOI: 10.1161/CIRCULATIONAHA.105.170072]
28 **Spertus JA**, Bonow RO, Chan P, Diamond GA, Drozda JP, Kaul S, Krumholz HM, Masoudi FA, Normand SL, Peterson ED, Radford MJ, Rumsfeld JS. ACCF/AHA new insights into the methodology of performance measurement: a report of the American College of Cardiology Foundation/American Heart Association Task Force on performance measures. *Circulation* 2010; **122**: 2091-2106 [PMID: 21060078 DOI: 10.1161/CIR.0b013e3181f7d78c]
29 **Riegel B**, Lee CS, Sochalski J. Developing an instrument to measure heart failure disease management program intensity and complexity. *Circ Cardiovasc Qual Outcomes* 2010; **3**: 324-330 [PMID: 20484202 DOI: 10.1161/CIRCOUTCOMES.109.877324]
30 **Iyngkaran P**, Tinsley J, Smith D, Haste M, Nadarajan K, Ilton M, Battersby M, Stewart S, Brown A. Northern Territory Heart Failure Initiative-Clinical Audit (NTHFI-CA)-a prospective database on the quality of care and outcomes for acute decompensated heart failure admission in the Northern Territory: study design and rationale. *BMJ Open* 2014; **4**: e004137 [PMID: 24477314 DOI: 10.1136/bmjopen-2013-004137]

P- Reviewer: Chawla M, Sugawara A, Simkhovich BZ
S- Editor: Gong XM **L- Editor**: A **E- Editor**: Lu YJ

Published by **Baishideng Publishing Group Inc**
8226 Regency Drive, Pleasanton, CA 94588, USA
Telephone: +1-925-223-8242
Fax: +1-925-223-8243
E-mail: bpgoffice@wjgnet.com
Help Desk: http://www.wjgnet.com/esps/helpdesk.aspx
http://www.wjgnet.com