

Health span or life span: the role of patient reported outcomes in informing health policy

Authors

Sungwon Chang ^{1,2}

Leila Gholizadeh ²

Yenna Salamonsen²

Michelle DiGiacomo ¹

Vasiliki Betihavas ^{1,2}

Patricia M Davidson ^{1,2}

1. Centre for Cardiovascular and Chronic Care, Curtin University of Technology, Sydney, Australia.
2. University of Western Sydney, Sydney, Australia.

Corresponding author

Patricia M Davidson
Professor & Director
Centre for Cardiovascular & Chronic Care
39 Regent Street,
Chippendale. NSW. Sydney. AUSTRALIA
Phone: 61 2 8399 7831
Facsimile: 61 2 8399 7831
Email: p.davidson@curtin.edu.au

Abstract

Objectives: Population ageing and the increasing burden of chronic conditions challenge traditional metrics of assessing the efficacy of health care interventions and as a consequence policy and planning. Using chronic heart failure (CHF) as an exemplar this manuscript seeks to describe the importance of patient reported outcomes to inform policy decisions.

Methods: The method of an integrative review has been used to identify patient reported outcomes (PROs) in assessing CHF outcomes. Using the Innovative Care for Chronic Conditions the case for developing a metric to incorporate PROs in policy planning, implementation and evaluation is made.

Results: In spite of the increasing use of PROs in assessing CHF outcomes, their incorporation in the policy domain is limited.

Conclusions: Effective policy and planning of health care services is dependent on the impact on the individual and their families. Epidemiological transitions and evolving treatment paradigms challenge traditional metrics of morbidity and mortality underscoring the importance of assessing PROs.

Introduction

Aging and the increasing burden of non-communicable diseases is influencing strategic policy initiatives in both developed and developing countries. [1] These factors also challenge clinicians and policy makers to consider health and social outcomes beyond traditional concepts of morbidity and mortality. Rapidly growing disciplines, such as health economics strive to balance parameters of demands, costs, and benefits relative to patient outcomes and treatment allocation. [2, 3] Clinicians and policy makers are more aware of the complex interplay of social, economic, physiological and policy factors in determining health outcomes. [4-6] The dilemmas confronting contemporary society underscore the need to increase the links between researchers and policy makers to develop, evaluate and implement appropriate interventions. [7] As well as assessing clinical outcomes, we also need to capture the unique perspective of the individual and their social determinants of health, to effectively inform health care planning. [8] This is of particular significance in chronic and aged care conditions where psychological and social issues play an important role in etiology and prognosis. [9, 10] Balancing treatment burden in the elderly is of concern and often gains in longevity are not matched by symptom relief and quality of life. [11] The health status of a population has traditionally been measured in terms of mortality and morbidity rates. Yet, with the epidemiologic transition from infectious to chronic diseases, quantifying health in terms of death and disease rates is seen to be increasingly inadequate. [12] Moreover, the ageing of the population means that a greater proportion of the population will receive treatment for chronic disease for a longer period of time. In chronic diseases, the goal of treatment commonly changes from cure to control of symptoms through targeted interventions.

Patient reported outcomes

The increasing complexity of treatment allocation, acceptability and utility makes the views of consumers more critical in intervention development, evaluation and health service planning. [13] One way to achieve this perspective is through assessing patient-reported outcomes (PROs). This

term refers to information and measures reported directly by the individual affected by a health condition, treatment or life experience. [14] Further, PROs is an umbrella term to capture the patient's subjective perceptions of the broad spectrum of disease and treatment outcomes. Health-related quality of life (HRQoL) is one of several types of PROs. Others include subjective symptoms, functional status, psychological well being, treatment adherence, and satisfaction with treatment. For example, capturing information to bathe without assistance and participate in activities of daily living is important in determining the impact of an intervention. Further, if an individual is unable to either fill their medication prescription or open the medication container – pharmacotherapy is unlikely to be effective. Patient reported outcomes can be either generic or specific to a clinical condition or disease state. Often the term “PROs” has been used to refer to the concept being measured, the instrument used to measure that concept and the actual endpoint. There is a need to distinguish the concept and outcome one is attempting to measure and the endpoint for statistical analysis. [15] It is vital to have sufficient evidence that PRO concept is adequately measured by a PRO instrument. [16] In recent decades there has been an exponential growth in the measures and it is important to consider not only the psychometric properties but also the utility in making treatment decisions and policy development.

Despite benefits of a proposed treatment there is also the risk of intervention having deleterious effects on the individual's quality of life and capacity to undertake activities of daily living. In such a case, the cure can be worse than the disease. Likewise, extended life can mean living for a prolonged period with a disability. [17] As complexity, burden and cost of treatment escalates, it is vital that patients and their families, clinicians, policy makers and funding bodies have a realistic expectation of outcomes, not merely in relation to the physical, but from a psychological and social dimension as well. [18] Gathering the unique perspective of patients and their families is paramount. These data will be crucial in informing policy makers need to plan and implement strategic initiatives.

Therefore it is increasingly an important consideration that the unique perspective of the patient be represented in not only individual clinical encounters, including patient assessment, but also in health policy, clinical trials and health service evaluation. [19]

The Innovative Care for Chronic Conditions (ICCC) framework (Figure 1) has been developed to help reorient health care systems to manage the demands of the rising burden of chronic conditions around the world. [35] At the centre of the framework is the healthcare triad (micro level of care); the partnership between patients and families, health care teams, and community supporters. To achieve optimal outcomes this triad needs to be supported by the broader community and the integrated health care organisations (meso level of care). This in turn needs to influence the broader positive policy framework (macro level of care) and to be influenced by them. It is contingent on every member of triad (patients and families, health care teams, and community supporters) being informed, and to maintain communication and collaboration. The ICCC framework emphasizes the importance of patients and families, forming one-third of the key ‘partnership triad’ at the most basic level. Furthermore, because management of chronic conditions requires lifestyle and daily behaviour changes, emphasis needs to be placed on the patient’s central role and responsibility in health care. When we refer to the patient, we consider family members and carers as part of this unit. Inclusion of this important dimension is contingent upon developing and testing of a model to measure the patient’s unique perspective.

In order to provide a more in depth discussion of the notion of PROs and how these can inform the metric that assists policy makers in developing and implementing health policy, we have chosen heart failure (HF) as an exemplar of a chronic condition. [20] Heart failure is a disabling and progressive condition and is the end stage of most heart disease. The unpredictability and severity of physical symptoms such as dyspnea, fatigue and pedal edema has led to great deal of anxiety and

fear in patients living with heart failure. [21]. Numerous studies have also shown that HF is associated with depression, and that this association is linked with a worse prognosis. [22] In studies with comparative normative data the degree of physical, mental and social functioning impairment was greater in heart failure patients than other chronic diseases sufferers. [23, 24] In fact, many patients with advanced heart failure ascribe greater importance to quality than to duration of life which may be limited by heart failure. [25] Furthermore, HF is the leading cause of hospitalisation in industrialised countries [26] with high re-admission rates [27] and prolonged length of stay which all lead to an increasing burden on resources both personally for patients, and financially for health care services. [28] In developed countries it accounts for 1% to 2% of all healthcare expenditure. [29].

Heart failure is primarily a condition of ageing. As treatment of hypertension, acute myocardial infarction and valvular disorders has met with increasing success, the incidence and prevalence of heart failure has increased dramatically. The prevalence of HF has been shown to increase from less than 1% in the 20-39 years to over 20% in 80 years and older. [30] In addition the incidence of heart failure doubles between 65-74 years and 75-84 age bands. [31] Increasingly, ethical and treatment conundrums arise out of the need to accurately assess the wishes of patients and their families and further tailor services to meet the needs of the vulnerable elderly. [32, 33]

A diagnosis of HF presents many of the challenges associated in caring for the elderly with a chronic condition from the perspective of the individual with the condition, their family and carers, as well as health professionals and the systems to support them. [34] Namely, it is a recurrent, costly and resource intensive chronic condition with an illness trajectory punctuated by episodes of decompensation and poor prognosis. [35] In spite of extensive evidence, there is evidence of a treatment gap that necessitates researchers, clinicians, administrators and policy makers to collaborate on strategies to achieve an evidence-based approach to health care. [36] Equally, we are

aware that some treatments may impact adversely on patients' perception of quality of life in spite of improving more traditional endpoints such as mortality. It is important to remember that the definition of evidence-based health care relates not only to the best practice treatments, but the administration of these in accordance with the patient's values and preferences. [37] Although substantive literature exists in discrete categories, such as quality of life and health service evaluation, there is considerably less experience in the integration and synthesis of this information to provide an outcome measurement model that takes into consideration clinical, organizational and patient factors. [38]

As discussed above, PROs in the context of health care have become an increasingly important focus of regulatory bodies and health care administrators. [18] The potential for interventions and treatments to be assessed from the perspective of the patient through validated psychometric measures is a critical issue for clinical practice, outcome evaluation and research. At a conference to assess the contribution of the Agency for Health Care Policy and Research (AHCPR) in enhancing outcomes, it was concluded that researchers and policy makers need to build upon descriptive studies and methodological advancements with the goal of measurably improving outcomes, quality, and efficiency of care. [39] Developing this science is dependent upon collaboration between consumers, academics and clinicians from a range of disciplines as well as policy makers and administrators.

Materials and Methods

An integrative review was undertaken to summarize how PROs have been defined, measured, and used in chronic heart failure research and identify their possible implications for policy initiative. We searched the electronic databases CINAHL, Medline, Embase and the Internet were searched using key words including 'heart failure', 'instruments', 'psychometric instruments' and 'patient reported outcomes.' Furthermore the reference lists of published materials were hand searched for

additional data sources. The aim of the review was to explore PRO measures in CHF that may provide new insight in policy decisions. A range of measures contributing to the impact of the outcomes of CHF, such as medication adherence and self-management were explored. Inclusion criteria were those papers that explored PROs measures that would provide new dimension in outcomes of CHF. Exclusion criteria were papers not published in English. Abstracts were appraised that most fitted the aims of the review and met the inclusion criteria.

Examples of commonly used PROs are provided to illustrate the importance of including these issues in policy decisions. Table I provides examples of these constructs that assess the impact of CHF on an individual, ranging from limiting activities of daily living through to existential distress. Although this list is not exhaustive it provides insight into the range of measures available. Despite many potential uses of PRO measures in CHF, the primary area of application has been in randomised clinical trial investigation, particularly HRQOL. This is in line with the recognition that the changes in physiological measures may not always translate into a tangible benefits perceived by the patients. In closer inspection of these measures, outcomes important to patients are affected not only by symptoms and disease severity but also by a complex interaction of physical, social and psychological factors. By incorporating patients' perspective they account for differences, subjective as well as objective among individual patients and to cater for patient's preference. When the individual is unable to complete such measures, the use of proxies can be considered.

Importantly, PROs extend beyond traditional clinical efficacy and adverse effects and represent the patient's perspective on the impact of disease and its treatment on daily functioning and wellbeing. [40] In many situations patient report is the sole source of data on frequency and severity of symptoms and also the side effects and the impact of treatment on functioning and well being. [41] Hence they are managed and monitored almost entirely on patient reports. Indeed in conditions where there are no physical or physiological markers of disease activity, PROs become the

outcome of choice for evaluating disease activity and in providing comprehensive understanding of severity of symptoms and their impact on daily functioning and well being. Palliative and supportive care is a striking example of such a strategy. [42]

However, it is not uncommon for there to be a mismatch between the patient's perception and the clinician's assessment. [38] For example, in some instances the patient's perception of CHF and disease severity has also been overestimated when compared to physician's clinical findings. [43] This incongruence may be due to the validity of tools used to assess patient perception or, an underestimation by clinicians of patient's with HF. Therefore valid and reliable PROs can be an important communication tool. These measures provide a useful way to gather and communicate evidence about treatment risks and benefits. This information can be used to highlight particular treatment benefits or to provide a way to differentiate the patient benefits among competing treatments with similar clinical efficacy. [44] This will assist clinicians in providing patients with better information about potential effects of treatment, and thus lead to better treatment decisions. Data derived from PROs can also enable patients to increase their understanding about their illness and treatment risks and benefits. This is also a potentially useful strategy in increasing individuals' participation in their own treatment and in health care decision making. Patient adherence is a major impediment to the effectiveness of therapies. Increased patient satisfaction with a treatment has been shown to be related to adherence. [9] Accordingly, evaluating satisfaction with treatment may assist health care providers in understanding the issues influencing treatment adherence and may help identify aspects of the management plan that require improvement to enhance long term treatment outcome. [45] The Innovative Care for Chronic Conditions (ICCC) framework (Figure 1) describes the importance of community and policy aspects of improving health care for chronic conditions. [46] This model highlights the importance of considering discrete yet linked attributes at the *micro* (patient and family), *meso* (health care organisation and community), and *macro* (policy) levels, underscoring the need for a multifaceted approach to health care outcome

assessment. To date, a comprehensive model for health service evaluation including all these critical elements has not been tested.

Discussion

Patient assessments are important elements of the evaluation of treatment impact, alongside other clinical indicators. Bioethics has emphasised the importance of the patient's point of view in health care decisions through its call to respect patient autonomy. Outcome research has specified the importance of the patient's perspective on the goal of medical care in its bid to accentuate patient-centred outcome such as quality of life. [38] It is recognised that linking patient-reported health with physiological markers of disease provide not just unique information in patient care, but also help to determine the severity of disease and monitor the trajectory of illness. [32] These factors are also important in informing cogent policy decisions.

It is hard to dispute that the science of PROs is advanced, as illustrated in the vast numbers of psychometric instruments available to assess these items. Perhaps what remains is the greatest challenge is moving assessment of these constructs beyond the research setting to routine clinical practice, administrative data sets and in contexts that will inform clinical and policy makers. The relevance of the applicability of clinical trial evidence to real world populations is commonly questioned. [47] Often participants in clinical trials are commonly younger, have less comorbid conditions and commonly do not have the challenges of poor health literacy and cognitive impairment that impact on outcomes of HF. [48] This conundrum is illustrated in the adverse events related to pharmacotherapy when agents move from the clinical trial to the usual care setting.

Registry data provides a useful insight into real world situations that can provide policy makers with reliable and valid data to inform policy decisions. A number of registries have provided useful data to inform HF management in the real world setting. [49-52] Many of these registries provide

useful data – particularly relating to how factors such as socioeconomic determinants, level of insurance, and ethnicity impact on health related outcomes. [53] Data for these registries is often collected from administrative data sets that do not routinely use patient-reported outcomes.

Including valid and reliable PROs in these data sets may be useful in health service planning

As shown in the Innovative Care for Chronic Conditions Framework in Figure 1, a Positive Policy Framework is contingent upon understanding the needs of patients and their families. This can be achieved through a range of means, such as community consultations, representations of democratically-elected candidates and lobbying from particular consumer organisations. A potentially more equitable, just, reliable and valid mechanism would be to include PROs in routine clinical assessments, clinical trials and registries to allow an informed decision on how conditions, treatment and health care interventions impact on the lives of individuals and their families. For example, in Australia, the most rapidly increasing population are centenarians - many of whom will endure and die of HF. Yet, we know little of their needs and service planning requirements. [54] Further, the development of reliable and valid metrics that allow for the integration of micro, meso and macro elements of health service delivery are needed. Health care policy, often constrained by partisan politics and influence of powerful lobby groups, can struggle to keep pace with the strategies needed to administer and monitor the increasing expense and complexity of healthcare. [55] In HF, the development of innovative treatments, such as implantable cardiac defibrillators, left-ventricular assist devices have outpaced the debate and discussion of the applicability and relevance to particular groups. [56] [42] Despite benefits some patients may derive from these medical interventions, the default plan of providing these devices or procedures regardless of patient's wishes and priorities need to be reconsidered by policy makers. Furthermore, their use entails substantial financial, physiological, and psychological costs to patients, health care system and community in general. Policymakers and clinicians alike need to allocate limited resources to patients with HF to serve their interests and perspectives. Understanding the impact of these

interventions on individuals is likely to be critical in the future and require extensive debate and discussion.

Conclusions

Health care policy needs to be concerned with the financing of health care systems, access to and the outcomes of the quality of care. Contingent in this assessment is how health care services and treatments impact on the individual and their families. This article has used HF as an exemplar of a chronic condition that is costly, deadly and burdensome to individuals and communities. We need to consider the impact of CHF on the individual to inform health care policy. As the burden of chronic conditions grow and the population ages, we need to develop and refine the metrics of including the perspectives of patients on both an individual and population level to effectively evaluate the efficacy of health care intervention, treatment and planning. This in turn will lead policy makers to make decisions about service supply and health care spending that reflects the balance of extending life with improved quality. Health span or life span will become the issues that will be critical to address for both clinicians and policy makers alike.

References

1. National Public Health Partnership: **Preventing Chronic Disease: A Strategic Framework Background Paper**. In. Melbourne; 2001.
2. Meltzer MI: **Health economics and prioritising health care**. *Lancet* 2008, **372**(9639):612-613.
3. Lee WC, Chavez YE, Baker T, Luce BR: **Economic burden of heart failure: a summary of recent literature**. *Heart & Lung* 2004, **33**(6):362-371.
4. Philbin EF, Rocco TA, Jr., Lynch LJ, Rogers VA, Jenkins P: **Predictors and determinants of hospital length of stay in congestive heart failure in ten community hospitals**. *Journal of Heart & Lung Transplantation* 16(5):548-55, 1997 May.
5. Riegel B, Rich M: **Multidisciplinary disease management models of heart failure care pp 331-340**. In: *Improving Outcomes in Heart Failure: An Interdisciplinary Approach*. Edited by Moser D, Riegel B. Gaithersburg, MD: Aspen Publishing; 2001.
6. Ferrie JE, Shipley MJ, Stansfeld SA, Smith GD, Marmot M, Whitehall IIS: **Future uncertainty and socioeconomic inequalities in health: the Whitehall II study**. *Social Science & Medicine* 2003 Aug;57(4):637-46.
7. Seow H, Phillips CO, Rich MW, Spertus JA, Krumholz HM, Lynn J: **Isolation of health services research from practice and policy: the example of chronic heart failure management**. *Journal of the American Geriatrics Society* 2006, **54**(3):535-540.
8. Hebert KA, Horswell RL, Dy S, Key IJ, Jr., Butler MK, Cerise FP, Arcement LM: **Mortality benefit of a comprehensive heart failure disease management program in indigent patients**. *American Heart Journal* 2006, **151**(2):478-483.
9. Wu JR, Moser DK, Chung ML, Lennie TA: **Predictors of medication adherence using a multidimensional adherence model in patients with heart failure**. *Journal of Cardiac Failure* 2008, **14**(7):603-614.
10. Burns RB, McCarthy EP, Moskowitz MA, Ash A, Kane RL, Finch M: **Outcomes for older men and women with congestive heart failure**. *Journal of the American Geriatrics Society* 1997, **45**(3):276-280.
11. Stanton J: **The cost of living: kidney dialysis, rationing and health economics in Britain, 1965-1996**. *Social Science & Medicine* 1999, **49**(9):1169-1182.
12. Goldstein NE, Lynn J: **Trajectory of end-stage heart failure: the influence of technology and implications for policy change**. *Perspectives in Biology & Medicine* 2006, **49**(1):10-18.
13. Koeberle D, Saletti P, Borner M, Gerber D, Dietrich D, Caspar CB, Mingrone W, Beretta K, Strasser F, Ruhstaller T *et al*: **Patient-reported outcomes of patients with advanced biliary tract cancers receiving gemcitabine plus capecitabine: a multicenter, phase II trial of the Swiss Group for Clinical Cancer Research**. *Journal of Clinical Oncology* 2008, **26**(22):3702-3708.
14. Patrick D: **Patient reported outcomes: an organizing tool for concepts, measures, and applications An organizing tool for concepts, measures and applications**. *Quality of Life Newsletter* 2003, **31**:1-5.

15. Patrick DL, Burke LB, Powers JH, Scott JA, Rock EP, Dawisha S, O'Neill R, Kennedy DL: **Patient-reported outcomes to support medical product labeling claims: FDA perspective.** *Value in Health* 2007, **10**(s2):S125-S137.
16. Rothman ML, Beltran P, Cappelleri J, C., Lipscomb J, Teschendorf B: **Patient-reported outcomes: Conceptual issues.** *Value in Health* 2007, **10**(s2):S66-S75.
17. Chang CH: **Patient-reported outcomes measurement and management with innovative methodologies and technologies.** *Quality of Life Research* 2007, **16 Suppl 1**:157-166.
18. Packer M: **Proposal for a new Clinical End Point to Evaluate the Efficacy of Drugs and Devices in the Treatment of Chronic Heart Failure.** *Journal of Cardiac Failure* 2001, **7**(2):176-182.
19. Spertus J: **Assessing patients' improvement in clinical trials.[comment].** *BMJ* 2008, **336**(7656):1258-1259.
20. Li J, Holmes AM, Rosenman MB, Katz BP, Downs SM, Murray MD, Ackermann RT, Inui TS: **Indiana Chronic Disease Management Program risk stratification analysis.** *Medical Care* 2005, **43**(10):979-984.
21. English M, Mastrean MB: **Congestive heart failure: Public and private burden.** *Critical Care Nursing Quarterly* 1995, **18**(1):1-6.
22. Murberg TA, Bru E, Svebak S, Tveteras R, Aarsland T: **Depressed mood and subjective health symptoms as predictors of mortality in patients with congestive heart failure: a two-years follow-up study.** *International Journal of Psychiatry in Medicine* 1999, **29**(3):311-326.
23. Hobbs FDR, Kenkre JE, Roalfe AK, Davis RC, Hare R, Davies MK: **Impact of heart failure and left ventricular systolic dysfunction on quality of life. A cross-sectional study comparing common chronic cardiac and medical disorders and a representative adult population.** *Eur Heart J* 2002, **23**(23):1867-1876.
24. Stewart AL, Greenfield S, Hays RD, Wells K, Rogers WH, Berry SD, McGlynn EA, Ware JE, Jr.: **Functional status and well-being of patients with chronic conditions: Results from the medical outcomes study.** *JAMA* 1989, **262**(7):907-913.
25. Lewis EF, Johnson PA, Johnson W, Collins C, Griffin L, Stevenson LW: **Preferences for quality of life or survival expressed by patients with heart failure.** *The Journal of heart and lung transplantation* 2001, **20**(9):1016-1024.
26. McMurray JJ, Stewart S: **Epidemiology, aetiology, and prognosis of heart failure.** *Heart* 2000, **83**(5):56-602.
27. Cleland JGF, Swedberg K, Follath F, Komajda M, Cohen-Solal A, Aguilar JC, Dietz R, Gavazzi A, Hobbs R, Korewicki J *et al*: **The EuroHeart Failure survey programme--a survey on the quality of care among patients with heart failure in Europe: Part 1: patient characteristics and diagnosis.** *Eur Heart J* 2003, **24**(5):442-463.
28. Stewart S, Jenkins A, Buchan S, McGuire A, Capewell S, McMurray JJV: **The current cost of heart failure to the National Health Service in the UK.** *Eur J Heart Fail* 2002, **4**(3):361-371.
29. Berry C, Murdoch DR, McMurray JJV: **Economics of chronic heart failure.** *Eur J Heart Fail* 2001, **3**(3):283-291.
30. Lloyd-Jones DM, Larson MG, Leip EP, Beiser A, D'Agostino RB, Kannel WB, Murabito JM, Vasan RS, Benjamin EJ, Levy D: **Lifetime risk for developing congestive heart failure: The Framingham heart study.** *Circulation* 2002, **106**(24):3068-3072.
31. Cowie MR, Wood DA, Coats AJS, Thompson SG, Poole-Wilson PA, Suresh V, Sutton GC: **Incidence and aetiology of heart failure: A population-based study.** *Eur Heart J* 1999, **20**(6):421-428.
32. Davidson P, Inrona K, J. C, Daly J, Dunford M, Dracup K: **Synergising acute care and palliative care philosophies to optimise nursing care in cardiorespiratory disease.** *Australian Critical Care* 2002, **15**(2):64-69.

33. Davidson P, Macdonald P, Ang E, Paull G, Choucair S, Daly J, Moser D, Dracup K: **A case for consideration of cultural diversity in heart failure management- Part 1: Rationale for the DISCOVER Study.** *Contemporary Nurse* 2004, **17**(3):204-210.
34. Grady KL, Dracup K, Kennedy G, Moser DK, Piano M, Stevenson LW, Young JB: **Team management of patients with heart failure: AHA Scientific Statement.** *Circulation* 2000, **102**(19):2443-2456.
35. Stewart S, MacIntyre K, Hole D, Capewell S, McMurray J: **More 'malignant' than cancer? Five-year survival following a first admission for heart failure.** *European Journal of Heart Failure* 2001, **3**:315-322.
36. Phillips SM, Davies JM, Tofler GH: **NICS Heart Failure Forum: improving outcomes in chronic care.** *Medical Journal of Australia* 2004, **18**(6):297-299.
37. Sackett DL, Straus SE, Richardson WS, Rosenberg W, Haynes RB: **Evidence-Based Medicine. How to Practice and Teach EBM.** Edinburgh: Churchill Livingstone; 2000.
38. Davidson P, Cockburn J, Daly J, Sanson-Fisher R: **Patient-centred needs assessment: rationale for a psychometric measure for assessing needs in heart failure.** *Journal of Cardiovascular Nursing* 2004, **19**(2):162-170.
39. America Agency for Health Care Policy and Research (AHCPR). **The Outcome of Outcomes Research at the Agency for Health Care Policy and Research.** In: *SGIM Annual Scientific Meeting: Accessed April 2, 2005. 1998; Chicago; 1998.*
40. Garcia SF, Cella D, Clauser SB, Flynn KE, Lad T, Lai JS, Reeve BB, Smith AW, Stone AA, Weinfurt K: **Standardizing patient-reported outcomes assessment in cancer clinical trials: a patient-reported outcomes measurement information system initiative.[erratum appears in J Clin Oncol. 2008 Feb 20;26(6):1018 Note: Lad, Thomas [added]].** *Journal of Clinical Oncology* 2007, **25**(32):5106-5112.
41. Goss CH, Quittner AL: **Patient-reported outcomes in cystic fibrosis.** *Proceedings of the American Thoracic Society* 2007, **4**(4):378-386.
42. Davidson P: **Difficult conversations and chronic heart failure: do you talk the talk or walk the walk?** *Current Opinion in Supportive and Palliative Care* 2007, **1**:274-278.
43. Subramanian U, Weiner M, Gradus-Pizlo G, Wu J, Tu W, Murray MD: **Patient perception and provider assessment of severity of heart failure as predictors of hospitalization.** *Heart & Lung* 2005, **34**(2):89-98.
44. Willke R, Burke L, Erickson P: **Measuring treatment impact: a review of patient-reported outcomes and other efficacy endpoints in approved product labels.** *Controlled Clinical Trials* 2004, **25**(6):535-552.
45. World Health Organization: **Adherence to long-term therapies: Evidence for action.** Geneva: World Health Organization; 2003.
46. Epping-Jordan J, Pruitt S, Bengoa R, Wagner EH: **Improving the quality of health care for chronic conditions.** *Quality & Safety in Health Care* 2004, **13**:299-305.
47. Ghali J: **The Cohere Registry: Hype or Hope.** *Journal of Cardiac Failure* 2000, **6**:272-275.
48. Tsevat J, Dawson N, Wu A, al. e, Hospitalized Elderly Longitudinal Project investigators.: **Health values of hospitalized patients 80 years or older. .** *JAMA* 1998, **279**(5):371-375.
49. Steg PG, Kerner A, Van de Werf F, Lopez-Sendon J, Gore JM, Fitzgerald G, Feldman LJ, Anderson FA, Avezum A, Global Registry of Acute Coronary Events I: **Impact of in-hospital revascularization on survival in patients with non-ST-elevation acute coronary syndrome and congestive heart failure.** *Circulation* 2008, **118**(11):1163-1171.
50. Landolina M, Lunati M, Gasparini M, Santini M, Padeletti L, Achilli A, Bianchi S, Laurenzi F, Curnis A, Vincenti A *et al*: **Comparison of the effects of cardiac resynchronization therapy in patients with class II versus class III and IV heart failure (from the InSync/InSync ICD Italian Registry).** *American Journal of Cardiology* 2007, **100**(6):1007-1012.

51. Massie BM, Nelson JJ, Lukas MA, Greenberg B, Fowler MB, Gilbert EM, Abraham WT, Lottes SR, Franciosa JA, Physicians CP: **Comparison of outcomes and usefulness of carvedilol across a spectrum of left ventricular ejection fractions in patients with heart failure in clinical practice.** *American Journal of Cardiology* 2007, **99**(9):1263-1268.
52. Franciosa JA, Nelson JJ, Lukas MA, Lottes SR, Massie BM, Fowler MB, Greenberg B, Gilbert EM, Abraham WT, Physicians CP: **Heart failure in community practice: relationship to age and sex in a beta-blocker registry.** *Congestive Heart Failure* 2006, **12**(6):317-323.
53. Bernheim SM, Spertus JA, Reid KJ, Bradley EH, Desai RA, Peterson ED, Rathore SS, Normand SL, Jones PG, Rahimi A *et al*: **Socioeconomic disparities in outcomes after acute myocardial infarction.** *American Heart Journal* 2007, **153**(2):313-319.
54. Richmond R: **The changing face of the Australian population: growth in centenarians.** *Medical Journal of Australia* 2008, **188**(12):720-723.
55. Marcus A, Craven H.: **Health Care Policy in Contemporary America.** University Park: The Pennsylvania State University Press; 1997.
56. Beattie J, Connolly M, Ellershaw J.: **Deactivating implantable cardioverter defibrillators.** *Annals of Internal Medicine* 2005, **143**(9):690-691.
57. Bennett SJ, Oldridge NB, Eckert GJ, Embree JL, Browning S, Hou N, Chui M, Deer M, Murray MD: **Comparison of quality of life measures in heart failure.** *Nursing Research* 2003, **52**(4):207-216.
58. Rector TS, Cohn JN: **Assessment of patient outcome with the Minnesota Living with Heart Failure questionnaire: reliability and validity during a randomized, double-blind, placebo-controlled trial of pimobendan. Pimobendan Multicenter Research Group.** *American Heart Journal* 1992, **124**(4):1017-1025.
59. Guyatt GH, Nogradi S, Halcrow S, Singer J, Sullivan MJ, Fallen EL: **Development and testing of a new measure of health status for clinical trials in heart failure.** *Journal of General Internal Medicine* 1989, **4**(2):101-107.
60. Wiklund I, Lindvall K, Swedberg K, Zupkis R: **Self-assessment of quality of life in severe heart failure: An instrument for clinical use.** *Scandinavian Journal of Psychology*, 1987, **28**:220-225.
61. Green CP, Porter CB, Bresnahan DR, Spertus JA: **Development and evaluation of the Kansas City Cardiomyopathy Questionnaire: a new health status measure for heart failure.** *Journal of the American College of Cardiology* 2000, **35**(5):1245-1255.
62. Swenson JR: **Quality of life in patients with coronary artery disease and the impact of depression.** *Current Psychiatry Reports* 2004, **6**(6):438-445.
63. Rector TS: **A conceptual model of quality of life in relation to heart failure.** *Journal of Cardiac Failure* 2005, **11**(3):173-176.
64. Hare DL, Davis CR: **Cardiac Depression Scale: validation of a new depression scale for cardiac patients.** *Journal of Psychosomatic Research* 1996, **40**(4):379-386.
65. Jiang W, O'Connor C, Silva SG, Kuchibhatla M, Cuffe MS, Callwood DD, Zakhary B, Henke E, Arias RM, Krishnan R *et al*: **Safety and efficacy of sertraline for depression in patients with CHF (SADHART-CHF): a randomized, double-blind, placebo-controlled trial of sertraline for major depression with congestive heart failure.** *American Heart Journal* 2008, **156**(3):437-444.
66. Pelle AJ, Gidron YY, Szabo BM, Denollet J: **Psychological predictors of prognosis in chronic heart failure.** *Journal of Cardiac Failure* 2008, **14**(4):341-350.
67. Black G, Davis BA, Heathcote K, Mitchell N, Sanderson C: **The relationship between spirituality and compliance in patients with heart failure.** *Progress in Cardiovascular Nursing* 2006, **21**(3):128-133.
68. Westlake C, Dracup K: **Role of spirituality in adjustment of patients with advanced heart failure.** *Progress in Cardiovascular Nursing* 2001, **16**(3):119-125.

69. Murray SA, Kendall M, Grant E, Boyd K, Barclay S, Sheikh A: **Patterns of social, psychological, and spiritual decline toward the end of life in lung cancer and heart failure.** *Journal of Pain & Symptom Management* 2007, **34**(4):393-402.
70. Beery T, Baas L, Fowler C, Allen G: **Spirituality in persons with heart failure.** *Journal of Holistic Nursing* 2002, **20**(1):5.
71. Riegel B, Dickson VV: **A situation-specific theory of heart failure self-care.** *Journal of Cardiovascular Nursing* 2008, **23**(3):190-196.
72. Riegel B, Carlson B, Glaser D: **Development and testing of a clinical tool measuring self-management of heart failure.** *Heart & Lung* 2000, **29**(1):4-15.
73. Jaarsma T, Halfens R, Huijjer A: **Effects of education and support on self-care and resource utilization in patients with heart failure.** *European Heart Journal* 1999, **20**(9):673.
74. Perry KM: **Psychometric assessment of the Heart Failure Self-Efficacy Scale-34.** *PhD.* Chicago: University of Illinois at Chicago, Health Sciences Center; 2000.
75. Sarkar U, Ali S, Whooley M: **Self-efficacy as a marker of cardiac function and predictor of heart failure hospitalization and mortality in patients with stable coronary heart disease: Findings from the Heart and Soul Study.** *Health Psychology* 2009, **28**(2):166-173.
76. Bandura A: **Self-efficacy: the exercise of control.** New York: Freeman; 1997.
77. Lainscak M, Keber I: **Patient's view of heart failure: from the understanding to the quality of life.** *European Journal of Cardiovascular Nursing* 2003, **2**(4):275-281.
78. Stroupe KT, Hynes DM, Giobbie-Hurder A, Oddone EZ, Weinberger M, Reda DJ, Henderson WG: **Patient satisfaction and use of Veterans Affairs versus non-Veterans Affairs healthcare services by veterans.** *Medical Care* 2005, **43**(5):453-460.
79. Majani G, Pierobon A, Giardini A, Callegari S, Opasich C, Cobelli F, Tavazzi L: **Relationship between psychological profile and cardiological variables in chronic heart failure. The role of patient subjectivity.** *European Heart Journal* 1999, **20**(21):1579-1586.
80. Candlish P, Watts P, Redman S, Whyte P, Lowe J: **Elderly patients with heart failure: a study of satisfaction with care and quality of life.** *International Journal for Quality in Health Care* 1998, **10**(2):141-146.
81. Chow A, Mayer EK, Darzi AW, Athanasiou T: **Patient-reported outcome measures: The importance of patient satisfaction in surgery.** *Surgery* 2009, **146**(3):435-443.
82. Rolley J, Davidson P, Dennison C, Ong A, Everett B, Salamonson Y: **Medication adherence self-report instruments: implications for practice and research.** *Journal of Cardiovascular Nursing* 2008, **23**(6):497-505.
83. Evangelista L, Doering LV, Dracup K, Westlake C, Hamilton M, Fonarow GC: **Compliance behaviors of elderly patients with advanced heart failure.** *Journal of Cardiovascular Nursing* 2003, **18**(3):197-206; quiz 207-198.
84. Evangelista LS, Berg J, Dracup K: **Relationship between psychosocial variables and compliance in patients with heart failure [corrected] [published erratum appears in HEART LUNG J ACUTE CRIT CARE 2001 Nov-Dec; 30(6): 476].** *Heart & Lung* 2001, **30**(4):294-301.
85. Pressler SJ: **Cognitive functioning and chronic heart failure: a review of the literature (2002-July 2007).** *Journal of Cardiovascular Nursing* 2008, **23**(3):239-249.
86. Dickson VV, Deatrck JA, Riegel B: **A typology of heart failure self-care management in non-elders.** *European Journal of Cardiovascular Nursing* 2008, **7**(3):171-181.
87. McCarthy S, Wollner L, Rosenberg G, Haaland K: **Cardiogenic dementia.** *The Lancet* 1981, **318**(8256):1171.
88. Luttik ML, Jaarsma T, Moser D, Sanderman R, van Veldhuisen DJ: **The importance and impact of social support on outcomes in patients with heart failure: an overview of the literature.** *Journal of Cardiovascular Nursing* 2005, **20**(3):162-169.

89. Murberg TA: **Long-term effect of social relationships on mortality in... patients with congestive heart failure.** *International Journal of Psychiatry in Medicine* 2004, **34**(3):207-217.
90. Wilson IB, Cleary PD: **Linking clinical variables with health-related quality of life. A conceptual model of patient outcomes.** *JAMA* 1995, **273**(1):59-65.
91. Pattenden JF, Roberts H, Lewin RJP: **Living with heart failure; patient and carer perspectives.** *European Journal of Cardiovascular Nursing* 2007, **6**(4):273-279.
92. Harkness KI, Tranmer JE: **Measurement of the caregiving experience in caregivers of persons living with heart failure: a review of current instruments.** *Journal of Cardiac Failure* 2007, **13**(7):577-587.
93. Evangelista L, Dracup K, Doering L, Westlake C, Fonarow G, Hamilton M: **Emotional well-being of heart failure patients and their caregivers.** *Journal of Cardiac Failure* 2002, **8**(5):300-305.
94. Hsieh C: **A concept analysis of social capital within a health context.** *Nursing Forum* 2008, **43**(3):151-159.
95. Abel T: **Cultural capital and social inequality in health.** *Journal of Epidemiology and Community Health* 2008, **62**(7):e13.
96. Nilsson J, Rana A, Kabir Z: **Social capital and quality of life in old age: Results from a cross-sectional study in rural Bangladesh.** *Journal of Aging and Health* 2006, **18**(3):419.
97. Laporte A, Nauenberg E, Shen L: **Aging, social capital, and health care utilization in Canada.** *Health Economics, Policy and Law* 2008, **3**(04):393-411.
98. Hagglund L, Boman K, Stenlund H, Lundman B, Brulin C: **Factors related to fatigue among older patients with heart failure in primary health care.** *International Journal of Older People Nursing* 2008, **3**(2):96-103.
99. Davidson PM, Dracup K, Phillips J, Daly J, Padilla G: **Preparing for the worst while hoping for the best: the relevance of hope in the heart failure illness trajectory.** *Journal of Cardiovascular Nursing* 2007, **22**(3):159-165.
100. Asadi-Laria M, Packhamb C, Gray D: **Psychometric properties of a new health needs analysis tool designed for cardiac patients** *Public Health* 2005, **119** (7):590-598.