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Review Article

Valvular heart disease: Patient needs and practice guidelines

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INTRODUCTION

Major advances in the evaluation and management of valvular heart disease, occurring principally over the past four decades, have resulted in marked improvement in the outcomes of patients with these conditions throughout the world. These advances have developed on several fronts, including development of imaging modalities (most notable ultrasound) that have provided essential data on natural history and predictors of outcome after operative intervention. This information provides cardiologists with the necessary clinical data, along with symptomatic status, to make informed decisions regarding frequency of repeat evaluations and ultimately timing of surgery. At that same time, the steady significant advances in cardiac surgery, including improved prosthetic valve design, evolution of valve repair and valve-sparing techniques, and enhanced methods for intraoperative myocardial preservation, have expanded operative windows to include surgery on both older patients and younger patients, and even patients who are asymptomatic. Rather than waiting to operate on patients when they are severely symptomatic and have impaired left ventricular function, which was the paradigm 50 years ago, the current clinical strategies are now moving toward earlier intervention before the onset of severe symptoms, left ventricular dysfunction and other adverse endpoints such as atrial fibrillation and pulmonary hypertension.

This remarkable evolution in patient evaluation and treatment has been highlighted by the development of practice guidelines that codify the collective wisdom and expert consensus regarding the use of diagnostic testing and the timing of operative intervention. First published in 1998, the American College of Cardiology / American Heart Association (ACC/AHA) guidelines for the management of valvular heart disease have been updated in 2006 and 2008 [1]. The guidelines of the European Society of Cardiology (ESC) were published in 2007 [2]. The knowledge base embodied in the guidelines is channeled into a large number of specific recommendations supported by the literature to assist clinicians in their care of patients across the wide spectrum of valvular heart disease.

Although the practice guidelines of the ACC/AHA and ESC represent a major step forward in improving and standardizing quality of care, there are two important aspects of these guidelines that are worthy of further discussion. There are weaknesses in the foundations of the guidelines and also in their translation to the community. My perspective is that of a cardiologist in the United States and may differ from many in other regions of the world.

Firstly, unlike the vast majority of other practice guidelines emanating from the ACC/AHA and ESC, in which there is an evidence base supported by randomized clinical trials (and in some cases multiple confirmatory clinical trials), the evidence base in valvular heart disease is noteworthy for its lack of an underpinning of randomized clinical trials. Thus, virtually all of the recommendations in both sets of guidelines are based on expert consensus (level of evidence "C") of the existing literature, which is mostly comprised of retrospective single-center studies rather than prospective multicenter randomized trials (level of evidence "A"). In fact, in the ACC/AHA valvular heart disease guidelines, only 1 of 320 recommendations (0.3%) was based on level of evidence A data [3]. Despite the lack of an evidence base in valve disease akin to those in many other areas of cardiovascular disease, such as acute coronary syndromes and heart failure, the consensus-driven recommendations in the ACC/AHA and ESC valve guidelines are remarkably similar. This underscores

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the collective wisdom that has accumulated over the past several decades. Nonetheless, implementation of prospective randomized trials is necessary to move the field forward. Several proposed areas in which clinical trials would be very useful in future recommendations for patient management are listed in Table 1. This is only a partial list, as there are undoubtedly other topics in which evidence is needed.

A second shortcoming of the current practice relative to the guidelines is the growing evidence that they are not implemented effectively in many areas of the United States, and presumably this holds true for much of the international community as well. Several examples of inconsistent adherence to guidelines recommendations and variations in care delivery are discussed subsequently.

Finally, it is uncertain how the current ACC/AHA and ESC guidelines, derived from cardiologists and surgeons in the Western developed countries, can be translated to the developing world, in which resources in terms of equipment, facilities and skilled personnel are less abundant. These guidelines need to be modified at the local level to match need and available resources as much as possible. The guidelines do provide some limited insights into treatment of rheumatic fever and evaluation and treatment of rheumatic heart disease in the mitral stenosis recommendations, but the majority of the recommendations in the documents are devoted to the degenerative forms of valve disease that affect the vast majority of patients in Western countries.

GLOBAL BURDEN OF VALVULAR HEART DISEASE

Rheumatic heart disease

Any discussion of valvular heart disease in terms of its impact on international cardiovascular health would be incomplete without a dialogue on rheumatic heart disease, and it is appropriate to begin a discussion of patient needs versus practice guidelines with this subject. To deal effectively with the totality of valvular heart disease at the global level, greater attention to the burden of rheumatic heart disease and the need for research in this disease is required from funding agencies. Although no longer a public health threat in developed countries, rheumatic heart disease still has epidemic proportions in many of the developing countries, accounting for 15 million existing cases, over 250,000 new cases each year and over 225,000 deaths each year [4,5]. These figures are felt to be underestimates. The economic impact of rheumatic heart disease, in terms of disability-adjusted life-years (DALYs) and lost manpower is equivalent to, or greater than, other infectious diseases such as tuberculosis, HIV/AIDS and malaria in Southeast Asia and South Asia and it rivals these conditions in Sub-Saharan Africa [6]. It is apparent that echocardiographic surveillance is more effective than clinical evaluation (more than 10-fold) in detecting young individuals with underlying rheumatic valvular disease and selecting them for secondary prophylaxis [7]. Pilot projects are underway in several African countries to determine the efficacy of echocardiographic screening programs [8]. It is hoped that data emanating from these programs might inform subsequent regional guidelines development.

Degenerative forms of valvular heart disease

Although rheumatic heart disease remains a major cause of cardiovascular morbidity and mortality in developing countries, degenerative valve disease presents important public health issues to developing and developed countries alike. With aging of the population and evolving cardiovascular risk factors, degenerative valve disease contributes and will continue to contribute importantly to the global burden of cardiovascular disease. In addition, up to 2% of the population has underlying bicuspid aortic valves that degenerate with advancing age and this adds to the burden of valve disease in middle age and older individuals. Valvular heart disease represents an growing reason for hospitalization in the United States [9,10]; at a time when overall hospitalization rates are declining, hospitalization for valve disease is increasing. It is estimated that 5% to 10% of the otherwise healthy population over the age of 75 has significant mitral (usually regurgitation) or aortic valve (usually stenosis) disease [10–13], and secondary forms of mitral regurgitation related to previous myocardial infarction or heart failure are increasingly common [14–16]. Women are affected equally to men, and cardiovascular and all-cause mortality rates are significantly worse than in those without valve disease [13]. The epidemiology of valvular heart diseases clearly delineates their impact on human lives and health care resources and the potential need for quality improvement. It is for this reason that the guidelines working groups of the ACC/AHA and ESC established committees to formulate the valvular heart disease guidelines. Despite guidelines being in place for over 12 years with periodic updates, there is evidence of lack of adherence. There is also evidence of disparities in delivery of quality of care that have emerged since their publication.

QUALITY OF CARE CONCERNS

Disparities in care among surgical programs

Aortic valve replacement mortality

There are several pieces of evidence that point to disparate outcomes in the United States and Europe for patients with heart valve disease. In the Society of Thoracic Surgeons (STS) Database, in which the majority of hospitals in the US and Canada provide data on patient characteristics and in-hospital outcomes, the average in-hospital mortality for aortic valve replacement (AVR) has fallen from 3.4% in 1997 to 2.6% in 2006 [17]. This extensive study of over 100,000 patients during at 10 year observation period is reassuring, but it is uncertain if this is a uniform experience in North American Hospitals or whether there is a wide variation in outcomes. Analysis of US Medicare data, which provides information on virtually all US citizens 65 years of age or older, provides a less comforting look at short-term outcomes following AVR. Goodney et al. reported 30-day mortality data in Medicare for 684 hospitals performing AVR in over 142,000 patients from 1994 to 1999 [18]. The overall in-hospital mortality was 8.8%. The striking finding of this study was the wide variability of short-term mortality related to hospital volume. In hospitals with the lowest number of AVR procedures per year, in-hospital mortality (13%) was more than twice that of the highest volume centers (6%), as shown in Fig. 1. When hospitals were subdivided into deciles according to hospital volume, a nearly linear relationship was observed between hospital volume and in-hospital mortality (Fig. 1). Thus, using hospital volume as a simple (and perhaps overly simple) measure of quality provides evidence of disparity in patient outcomes.

Mitral valve surgery mortality

Similar data are evident in short-term outcomes following mitral valve surgery for mitral regurgitation (MR). In the STS database, the in-hospital mortality for mitral valve surgery averages 2.12% (excluding patients with mitral stenosis, previous cardiac surgery, cardiogenic shock, recent infarction, and those undergoing any concomitant surgery except procedures on the tricuspid

Table 1. Candidate Topics for Prospective Randomized Trials in Valvular Heart Disease.

- Aortic valve replacement versus watchful waiting in elderly patients with aortic stenosis
- Mitral valve repair versus medical therapy in patients with left ventricular dysfunction and functional mitral regurgitation
- Vasodilator therapy in patients with severe aortic regurgitation
- Beta blocker therapy in patients with severe mitral regurgitation
- Statin therapy in patients with mild aortic stenosis or in patients with bicuspid aortic valves with no stenosis or regurgitation presently
- Statin therapy in patients with bioprosthetic valves
- Transcatheter valve therapies versus surgical valve replacement/repair

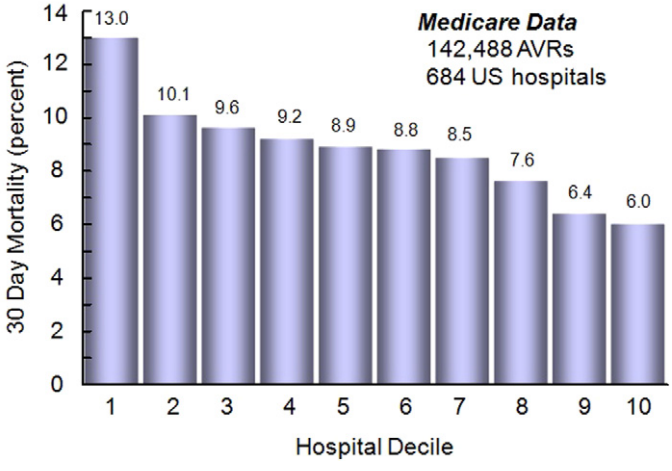

Figure. 1 Relationship between hospital volume and in-hospital mortality for aortic valve replacement (AVR) in patients 65 years or older in the US Medicare system. There is nearly a linear relationship between hospital volume (expressed in deciles) and in-hospital mortality. Data are taken from Goodney et al. [18], with permission.

valve) [19]. Even with this low in-hospital mortality, an effect of hospital volume was noted, with an in-hospital mortality rate of 3.08% in hospitals in the lowest volume quartile and 1.11% ($p < 0.0001$) in those in the highest volume quartile. However, in the Medicare study of Goodney et al. noted above [18], an even greater effect of hospital volume on mortality following mitral valve replacement (MVR) was noted (Fig. 2). Among 61,252 patients undergoing MVR, those operated upon in hospitals in the lowest volume decile had twice the in-hospital mortality (20.5%) compared to those undergoing MVR in the highest volume hospitals (10.1%).

Mitral valve replacement versus repair

In the developed countries, the leading causes of MR are degenerative (myxomatous disease or fibroelastic deficiency) or functional (secondary to left ventricular dysfunction from ischemic or dilated cardiomyopathy). Unlike MR stemming from severely deformed valves in patients with rheumatic MR, the majority of patients in developed countries have valves that are reparable. Numerous studies suggest that the short- and long-term outcomes of patients undergoing successful mitral valve repair are superior to those undergoing MVR [20]. It should be noted, as previously discussed, that there is no randomized study comparing the two modes of mitral valve surgery, and comparisons between the two using propensity matching or other statistical methods are fraught with difficulty. Despite these concerns, the ACC/AHA guidelines have given a class I indication that whenever possible, patients with MR should undergo mitral valve repair instead of MVR, and that patients should therefore be referred to centers and surgeons experiences in mitral valve repair [1].

The frequency of mitral valve repair among patients who are candidates for this procedure has been steadily increasing in the US with a corresponding decrease in MVR over the past decade. The STS database demonstrates, among patients with degenerative forms of MR (excluding those with mitral stenosis, previous cardiac surgery and those undergoing forms of surgery other than procedures on the tricuspid valve), the percentage undergoing mitral valve repair has increased from roughly 50% in 2000 to nearly 70% in 2007 (Fig. 3). Nonetheless, over 30% of patients eligible for mitral valve repair are receiving MVR instead. Is this related to patient characteristics that predict this outcome and are these rates consistent among hospitals, or is there evidence of disparity of care regarding who receives mitral valve repair surgery? Unfortunately, several lines of evidence indicate that disparities exist.

Gammie et al. [19], as noted previously, subsetted hospitals in the STS Database according to quartiles of volume of MR surgery. Hospitals in the highest quartile of MR surgical volume not only had 50% lower in-hospital mortality than the lowest volume quartile, as discussed above, but also had a significantly higher percentage of mitral valve repair procedures instead of MVR, compared to the lower volume centers (Fig. 4). This analysis was extended recently by Bolling et al. [21] who examined the relationship between the volume of MR surgery performed by individual surgeons and

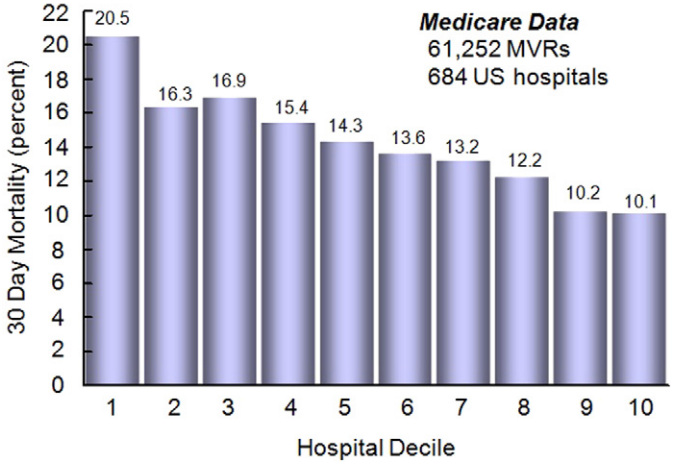

Figure. 2 Relationship between hospital volume and in-hospital mortality for mitral valve replacement (MVR) in patients 65 years or older in the US Medicare system. As with aortic valve replacement (Fig. 1), there is a nearly linear relationship between hospital volume (expressed in deciles) and in-hospital mortality. Data are taken from Goodney et al. [18], with permission.

the likelihood of mitral valve repair. This novel study of 1,008 surgeons in 639 North American hospitals provides several important insights into the state of MR surgery in developed countries. First, among surgeons performing MR surgery, the mean rate of mitral valve repair was only 41% (range 0 to 100%). The median number of mitral valve operations per surgeon was only 5 (range 1 to 166). Only 16 surgeons performed more than 50 MR operations per year, and only 3 performed more than 100 per year. The likelihood of a patient receiving mitral valve repair versus MVR was highly related to the volume of the individual surgeon (Fig. 5). Thus, at both the hospital and the provider level, there is evidence of disparity in surgical treatment. The majority of patients undergo surgery by low volume operators with a high likelihood of receiving MVR instead of repair. Whether these trends in individual surgeons' outcomes translate in to disparate outcomes (as they have been shown to do at the hospital level) will require further study.

Use of bioprosthetic valves in the elderly

Current guidelines recommend bioprosthetic valves in patients over the age of 65 [1,2], because of excellent longevity of current generation bioprostheses in this age group and the risks of

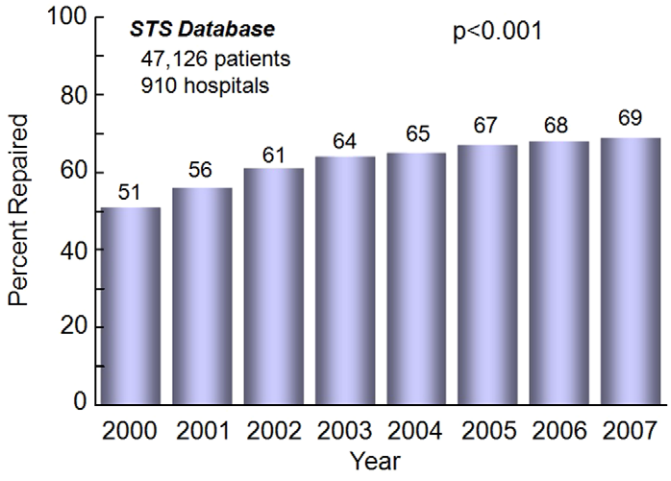

Figure. 3 Percent of patients in the Society of Thoracic Surgeons (STS) Database undergoing mitral valve repair for primary mitral regurgitation. Patients with mitral stenosis are excluded. The percent undergoing mitral valve repair has increased steadily. Reproduced from Gammie et al. [20] with permission.

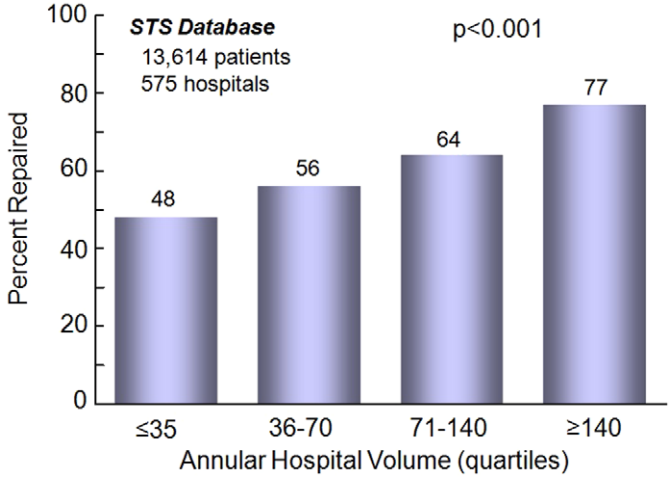

Figure. 4 Rates of mitral valve repair for primary mitral regurgitation in the Society of Thoracic Surgeons (STS) Database related to hospital volume of mitral valve surgery. Patients undergoing surgery for MR at higher volume centers were significantly more likely to receive mitral valve repair rather than mitral valve replacement, compared to those undergoing surgery at lower volume centers. Reproduced from Gammie et al. [19] with permission.

anticoagulant therapy with advancing age. Data from the US Medicare system has demonstrated disparities of care related to this measure of quality [22]. Among 1,045 US hospitals performing a total of over 80,000 AVRs in individuals 65 years of age or older, there was a strong relationship between hospital volume of AVRs and the likelihood that a patient would receive a bioprosthetic valve rather than a mechanical prosthesis (Fig. 6). Hospital volume or the volume of an individual surgeon is only a rough surrogate for quality. However, the data available for both process measures such as this, or outcome measures such as the mortality data previously discussed for AVR and MVR consistently point toward higher volume operators and higher volume centers demonstrating better adherence to guideline recommendations and better patient outcomes.

DISPARITIES IN CARE AMONG CARDIOLOGISTS

The findings of disparities in care in valvular heart disease are not limited to surgeons or hospital surgical programs. There is also evidence of disparities among cardiologists who treat patients with these conditions and are responsible for referring them for surgery in a timely manner when indicated.

Echocardiography

Echocardiography is the mainstay of cardiology evaluation of valve disease, both for baseline assessment for serial follow-examinations. Both the ACC/AHA and ESC guidelines recommend that the severity of stenotic and regurgitant conditions be assessed using quantitative principles and not merely qualitatively. However, a large number of echocardiography laboratories do not follow these principles. The result is a large variability in the quality of echocardiograms, both in terms of technical skills and in interpretative skills. Patient outcomes are put at risk, as a misdiagnosis or failure to accurately determine rate and magnitude of changes with time can lead to improper referrals to surgery—either too early or too late.

Referral of symptomatic patients for surgery

There is also variation in quality of referral of patients who fulfill definite class I guidelines recommendations for valve surgery. One obvious indication for AVR for aortic stenosis, for example, is the development of symptoms [1,2]. Numerous studies have confirmed that symptomatic patients are at high risk of death over a 2–3 year period and that AVR improves symptoms, improves left ventricular function and improves survival. However a number of studies in Europe [23,24] and the US [25,26] have pointed out that large numbers (up to 30%–40%) of patients with symptomatic aortic stenosis are not referred for surgery, even those deemed to be at low surgical risk [26]. These studies also confirm the predictably high mortality rate without surgery in these symptomatic patients [23,25,26].

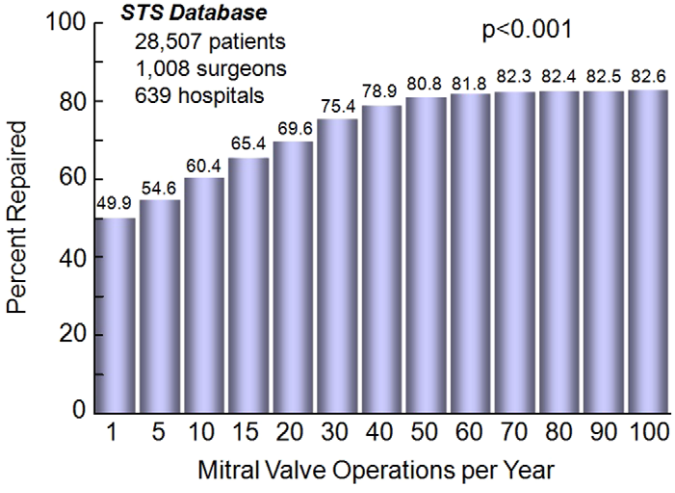

Figure. 5 Rates of mitral valve repair for primary mitral regurgitation in the Society of Thoracic Surgeons (STS) Database related to individual surgeon volume of mitral. Surgeons performing a greater volume of mitral valve procedures are significantly more likely to perform mitral valve repair than mitral valve replacement, compared to those performing fewer procedures. Reproduced from Bolling et al. [21] with permission.

Similar data have evolved regarding the large number of patients with symptomatic MR who are not referred for surgical correction [27–29]. This lack of referral on the part of many cardiologists is inexplicable in view of the class I recommendations for surgery [1,2] and the poor outcome of patients when surgery is delayed until there are severe symptoms or declining left ventricular function [30,31].

IMPROVING QUALITY OF CARE IN VALVULAR HEART DISEASE

It is clear from the previous discussion that measurable variations exist in the quality of care for valvular heart disease. When such variations represent a gap in care, as is the case in this instance, an important step in quality improvement is to develop clinical performance measures to serve as quality metrics to improve performance [32]. Such measures have been developed previously by the STS for other forms of cardiac surgery and by the ACC/AHA for other cardiovascular conditions. The development of quality indicators and performance measures are two steps in the cycle of quality improvement [33] that ties healthcare quality initiatives to outcomes research, which in turn informs the next round of clinical investigation (Fig. 7).

Such processes are worthy of development in valvular heart disease. Clinical practice will become much more complex in the near future with the advent of novel transcatheter methods for prosthetic valve implantation and valve repair, and creating the infrastructure now to measure and improve quality will be an important foundation for future developments. Centers of excellence should be defined, based on multidisciplinary teams of surgeons, cardiologists, anesthesiologists, and nurses, as proposed by Bridgewater et al. [34], that can track volume, assure adequate training, establish internal quality control systems, and audit results.

Recommendations for improving quality of care

The following are recommendations for developed countries to improve quality and outcomes for patients with valvular heart disease. Clinical research networks should be developed to design,

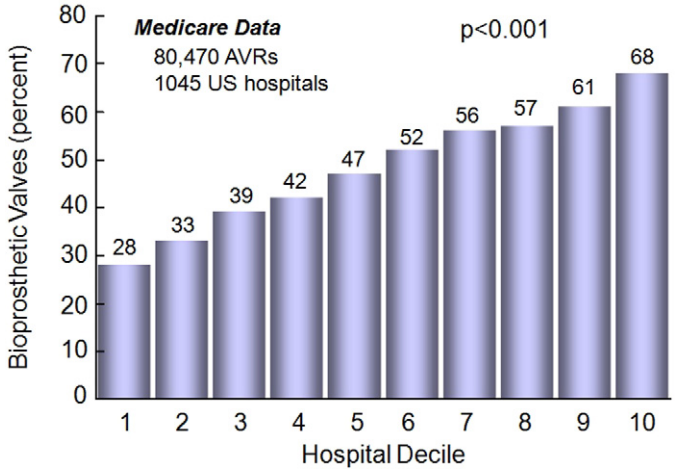

Figure. 6 Rates of aortic valve replacement (AVR) with bioprosthetic valves in patients 65 years and older in the US Medicare system. Patients undergoing AVR higher volume centers were significantly more likely to receive a bioprosthesis than a mechanical prosthesis, compared to those undergoing surgery at lower volume centers. Reproduced from Shelbert et al. [22] with permission.

Figure. 7 Cycle of clinical research and quality improvement. Reproduced from Califf et al. [33] with permission.

implement and interpret clinical trials in valve disease. Ideally, these should be international in composition. A more robust evidence base will allow future guidelines to be based on stronger, randomized data rather than expert consensus alone. Centers of excellence in heart valve disease should be established based on principles defined by quality indicators and clinical performance measures. The cardiology and cardiac surgery professional societies have a responsibility to oversee the development of the quality metrics and their use in measuring performance and reporting the results.

For developing countries, there are a number of additional fundamental objectives. Any success in research and implementation in developed countries needs to be translated and customized to meet the needs at the local level. In addition, research in partnership between developed and developing nations is necessary at the basic and translational levels that can lead to prevention and cures for rheumatic fever and rheumatic heart disease. Research in genetics and epidemiology at the regional level is also necessary to identify the unique aspects of the manifestations of valvular heart disease in relation to emerging chronic diseases in the region. Resources from international funding agencies are necessary to develop equipment and facilities to create laboratories and clinical and surgical centers. Most importantly, creating and training a sustainable workforce, both in science and clinical care, are necessary to meet the current and future needs of the population.

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