CHIRURGIE CARDIAQUE/CARDIAC SURGERY

COMPLICATIONS IN ADULT CARDIAC SURGERY - A GENERAL OVERVIEW.

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Summary

Cardiac Surgery has made significant advances over the past fifty years. Over 700,000 adult cardic operations are performed annually in the USA and more than 700,000 worldwide. Despite increasing age, complexity, and comorbidity, the results have continued to improve. This is due, in large measure, to the specific areas of improvement and experience in preoperative selection and prepar ation; operative advances, especially in monitoring, anesthesia, surgical skill, techniques and technology, cardiopulmonary bypass; and postoperative care, particularly in the intensive care environment. This review will focus on the general advances in the understanding of complications, risk assessment, quality assurance, and the emergence of evidence based medicine as a powerful tool to apply objective data to best practice medicine and prevention of mistakes, errors, near misses and complications.

Key Words: Adult Cardiac Surgery Complications-Mistakes-Errors- Quality Assurance-Risk Assessment-Evidence Based Medicine.

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Introduction
Complications/Mortality
Strategic/Organizational Initiatives
Tactical/Managerial initiatives
Pre-operatoire phase
Risk Assessment/Severity Scores
Operative phase
Postoperative phase
Long term Result
Cost
Evidence based medecine
Quality Assurance/Quality Improvement

« I keep six honest serving-me (they taught me all i knew); Their names are What and Why and Hen and How and Where and Who»

Introduction

Cardiac surgery had its for mal beginni ng in the early 20th century. Ludwig Rehn was th first to successfully suture a penetrating wound of the heart in 1896, although Ansel Cappelen first cl osed a bleeding ventricular wound in 1894 with the postoperative death probably related to coronary injury and hemorrhagic shock[1]. Interestingly, it is not uncommon for unsuccessful «firsts» not to be accor ded the usual accolades befitting their accomplishments.?+ Subsequently, closed cardiac procedures evolved in the first half of the century , notably closure of patent ductus arterious, Blalock Taussig shunt, repair of coarctation, and closed approaches to the mitral and pulmonic valve[2]. Cardiac surgery utilizing cardiopulmonary bypass (CPB) dominated the second half of the 20th century, following a brief period of remarkable clinical series utilizing systemic hypothermia[3], or cross circulation approaches[4]. Since the first successful closure of an atrial septal defect (ASD) utilizing cardiopulmonary bypass (CBP) by John Gibbon at Jefferson University in Philadelphia, in 1953[5], the number of adult operations utilizing CPB has grown to a present annual rate of over 700,0 00 cases in the USA with the majority being coronary artery bypass grafting (CABG)[6] (figure 1). Worldwide the total number of procedur es utilizing CPB including both adult and pediatric populations is estimated at 1.2-1.4 million patients per year. Another 3,000 or more cardiac surgeons in another 1,000 centers complete the gl obal picture. Kirklin in 1990[7], summarized the previous 25 years in cardiac surgery to include technical and scientific advances in support systems, hospital environment, surgical procedures, myocardial management or protection, and the devel oping systems of comparison and prediction. This has burgeoned to include cost analysis, given the escalating costs (figure 1), risk stratification and management, outcomes and quality assurance. It is this latter concern that has dominated the literature in recent years. Relman stressed this in his concept of the three recent revolutions in medical care: 1950 -1970 as the era of expansion; 1971-19 85 as the revolt of payers; and 1986 to the present as the outcome movement[8].

This outcome movement has generated a whole new vocabulary ranging from risk to quality assurance, to outcome evaluation and analy sis, and ultimately quality of life issues. Unfortunately the language of advertising, marketing, providers, clients, product lines, networking and consortiums have also brought in to healthcare the whole aspect of medicine and heal th care deliv er y as a major business enterprise with costs and profits/losses on a parwith quality of care and medical outcomes. Public awareness and a perceived need for accountability has burgeoned into a major catalyst and driving force. The emergence of internet access and web based groups has spawned a large scale oveseeing of health care activity with subsequent unregulated reporting of outcomes and results.

Figure 1

Annual Caseload Open Heart Cardiac Surger y, USA*

Coronary Artery Bypass Graft (CABG) (2002)	515,000
Valve Replacement or Repair (2002)	93,00 0
Heart Transplantation (2003)	2,057
Congenital Heart (2000) (<20yrs of age)	25,00 0
Other (1999)[6]	90,00 0
Total	**7 25,057**

Estimated Direct and Indirect Costs of Heart Diseases

Estimated direct and indirect costs (in Billion of Dollars of heart diseases (United States : 2005)	**Heart di- seases**
Direct costs	
Hospital	$77,7
Nursing home	19,1
Physicians/Other professionals	18,5
Drugs/Other	
Medical durables	19,4
Home health care	4,8
Total Expenditures	**$139,5**
Indirect costs	
Lost productivity/Morbidity	21,4
Lost productivity/Mortality	93,9
Grand total	**$254,3**

* Heart Di sease and Stroke Statistics
- -200 5 Update, American Heart Association
(HYP ERLI NK «http://www.amer i canhear t.org» http://www.americanheart .org)

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Despite this scrutiny, increased knowledge, experience, maturity, judgment, technical advances, and improved skills have made open-heart surgery safer, efficient, cost effective, and more readily available, with subsequent decreases in

** Examples: John Streider at Massachusetts General Hospital ligated a patent ductus arteriosus in 1937 one year prior to Robert Gross. Clarence Dennis closed an atrial septal defect utilizing cardiopulmonary bypass in 1951, 2 years prior to John Gibbon. Both patients died perioperatively from complications.*

** Stephenson, L.W., Ch. 1 - History of Cardiac Surgery p3-29. In Cohn, L.H., Edmunds, H. ed. Cardiac Surgery in the Adult 2nd ed. Mc Graw-Hill, New York, 2003.*

overall mortality. At the national level , the Society of Thoracic Surgery (STS) National Cardiac Database reports a raw operative mortality for cardiac surgery in the USA of less than 5% with isolated CABG mortality under 3%[9]. *(www .ctsnet. org/doc/2988)* This has been corroborated at the regional, state, Veteran's Administration (VA) and institutionall evels. Representative in stitutional experiences are summarized in (figure 2 a, b) .

Figure 2 (a) : Toronto General Hospital Experience *
Operations performed from 1993-1997

	Number	Meaning age (mean ± S.D.)	Urgent	Timing emergent	Mortality rate
Coronory Artery bypass	7371	62 10	44 %	3 %	2.3 %
Aortic valve surgery	1070	63 15	32 %	2 %	2.5 %
Mitral valve surgery	704	59 14	27 %	6 %	4.3 %
Double/triple valve surgery	381	57 16	23 %	3 %	9.0 %
Ascending aorta ± arch ± aortic valve surgery	475	57 16	26 %	16 %	6.6 %
Congenital heart surgery in adults	473	42 15	11 %	1 %	3.2 %
Miscellaneous	638	57 14	33 %	23 %	10.2 %

**Left ventricular aneurysms(254), heart transplantation (99), myectomy (94), mapping +ablation (44), post infarction rupture of the septum (37), atrial myxoma (29), others (82).*
** Adapted from Cheng DC, David TE. Peri operative care in cardiac anesthesia and surgery. Landes Bioscience Georgetown, TX 1999, p2*

Figure 2 (b) : Cleveland clinic 2002

	Mortality
CABG	1.2 %
Aortic valve surgery	< 1 % (repair) (0 % replacement)
Mitral valve surgery	0.3 %
Great vessel surgery	3.5 %

**Cleveland Clinic Department of Thoracic and Cardiovascular Surgery, 2002 Department Review (HYPERLINK «http://clevelandclinic.org/heartcenter» http://clevelandclinic.org/heartcenter)*

Figure 3 (a)[9] :

	Complications (%)	Mortality (%)
Re-operation for bleeding	2.32	13
Perioperative myocardial infarction	1.08	19
Infection – sternum – superficial	0.73	--
Infection – sternum – deep	0.63	11
Infection – Leg	1.26	--
Infection – UTI	1.52	--
Septicemia	0.9	38.6
Neurologic–CVA – permanent	1.65	28
CVA – transient	0.74	--
Delirium	2.62	--
Pulmonary–mechanical ventilation > 5 days	5.46	21
Pulmonary embolism	0.33	--
Pulmonary edema	2.12	--
ARDS	0.87	--
Pneumonia	2.45	--
Renal failure (creatinine>2.0)	3.14	30.6
With dialysis	0.87	47.6
Cardiac		
Heart block requiring pacemaker	0.81	--
Tamponade	0.39	25
Atrial fibrillation	19.37	--
Cardiac arrest	1.46	64.1
GI complication	2.45	17
Multisystem Failure	0.6	74.4

**http://www.ctsnet.org/doc/2988 (current specific complication rates after 1997 unavailable)*
+ Through 1997, 450 centers contribute patients to the STS-NCD 2.4 million patients through 1997 enrolled in STS-NCD. Data fields include 217 core fields and 255 extended fields
Data analysis and warehouse center after 1998 at Duke clinical Research Institute
+ (Shahian, D.M, Blackstone, E.H.,Edwards, FH, et al. Cardiac Surgery Risk Models: A position article. Ann Thorac Surg 2004; 78:1868-1877)
944 of 4, 856 acute care hospitals in USA perform open heart surgery (Hospital statistics - 2002 Health Forum LLL, p159)

Figure 3 (b) : Toranto General hospital Experience

Complications rates from 1993-1997				
	CABG	Valves	AA/A	CHD
Miscellaneous	1.5%	4.0%	6.5%	4.2 %
Re-exploration for bleeding (4.2 %)	1.5 %	4.0 %	6.5 %	4.2 %
Perioperative stroke 2.2%	1.4%	2.5%	6.6%	0.0%
Perioperative myocardial infarction (0.6%)	2.4 %	1.3 %	1.7 %	0.6 %
Deep sternal infection 0.2%	0.8 %	0.7 %	1.1 %	0.6 %
Superficial wound infection 1.4%	1.7 %	0.8 %	1.7 %	1.9 %
Sternal dehiscence 0.2%	0.3 %	0.1 %	0.6 %	0.0 %
Renal failure 1.6%	0.3 %	0.3 %	0.6 %	0.0 %
Mean ICU stay (days) 3.4	1.9 %	2.5 %	3.3 %	2.4 %

Abbreviations CABG = coronary artery bypass graft; AA/A = ascending aorta + / - arch; CHD = congenital heart disease
** Adapted from Cheng DC, David TE. Perioperative care in cardiac anesthesia and surgery. Landes Bioscience Georgetown, TX 1999, p2*

This has gradually increased with changing demographics (age, sex, body surface area, body mass index), complex cardiac pathology with decreased left ventricular (LV) function, and increasing associated comorbidy.
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organ fail ure, transfers to chronic health facilities, and increasing readmission rates. (Table 1)

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Table I : Risk factors associated with either increased length of stay (L) or Increased incidence of organ failure
Morbidity (M) or Both (L/M) Following coronary Revascularization.

Risk factor	Boston (10)	Albany (11)	V A (12)	Canada (13)
Demographics				
Advanced age	L		M	L
Increased ratio of age/red blood cell volume		LM		
Female gender				L
Disease specific diagnoses				
CHF or cardiomegaly	L	LM	M	
Concomitant valve disease			M	L
Reoperation			M	L
LV dysfunction (ejection fraction)				L
Surgical priority			M	L
IABP pre-op	L			
Active endocarditis			M	
Comorbid conditions				
Obesity	L			
Renal dysfunction	L	L		M
Peripheral vascular disease		L		M
Chronic obstructive lung disease		L		
Cerebrovascular disease		L/M		
Hypertension		L/M		

Abbreviations: CHF= congestive heart failure; LV = left ventricular; IABP = intraaortic balloon counterpulsation

In short, higher risk patients are surviving with attendant increases in morbidity, yet ultimate increase in survival, albeit with long term quali ty of life issues and challenges. Preoperative selection and preparation, diagnostic sophistication, improved and advanced operative approaches and technique, and advances in the intensive care unit (ICU) have contributed to this continued effort. Better knowledge of the pathophysiology of the disease process, advanced monitoring, and improved and more effective medications, especially anesthetic agents, have dramatically stabilized and improved the perioperative care of patients. Improved diagnostic support, especially at the bedside, along with increasing electronic interface, bedside computerized nursing, and more reliable point of care testing are becoming valuable components of the standartized critical pathways. ?? The application of risk analysis, best practice or evidence based medicine (EBM), along with emerging guidelines and algorythms will continue to help cardiac surgeons give better care to their patients and help avoid or decrease untowards results, i.e. complications, in this increasing group of challenging patients.

Complications

Against this background of advances in cardiac surgery with higher risk groups is the increased focus on quality assurance, outcomes and costs, along with the stress and agony of poor results or complications. Traditionally it is the cardiac surgeon who, as the head of the team, is perceived as the most culpable or responsible for untoward results. Surgeons have been most mindful of this accountability and responsibility. It has been the careful analysis of complications with emphasis on prediction, avoidance, recognition and treatment through the medium of the traditional morbidity /mortality conferences (M&M) that has advanced the quality of surgery in the USA and worldwi de through the years. The report of the Institute of Medicine, «To Error is Human», focused national attention on the potentially harmful effects of human error in medicine, noting 44,000 to 98,000 deaths occurring annually due to medical errors[14]. The incidence of iatrogenic deaths and society cost from all causes may be even higher (Table 2).

Table 2 : Iatrogenic Deaths in the United States*

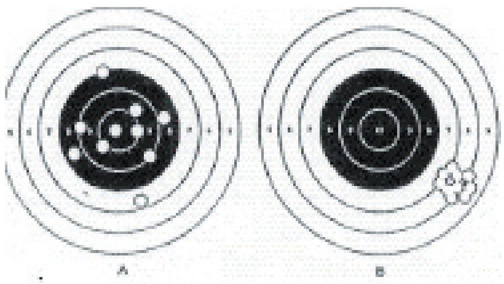
Iatrogenic Deaths in The United States (Deaths induced inadvertently by a physician or surgeon or by medical treatment or diagnostic procedures)		
Condition Deaths	**Deaths**	**Costs**
Adverse Drug Reactions	106,000	$12 billion
Medical error	98,000	$2 billion
Bedsores	115,000	$55 billion
Infection	88,000	$5 billion
Malnutrition	108,800	------
Outpatients	199,000	$77 billion
Unnecessary Procedures	37,136	$122 billion
Surgery-Related	32,000	$9 billion
TOTAL	7 83, 93	$ 282 billlion
* *(http://www.ourciviliztion.com/medicine/usamed/deaths.htm)*		

The public and press, especially with the burgeoning internet access have demanded increased knowledge and information re. outcomes and results (Table 3, 4). The bottom line is the perception, or, in fact, the reality that safety and quality are of major concern to the general public. A detailed analysis of complications is thus warranted to help us better predict, prevent, recognize, and treat complications.

Three aspects of untoward results or complications need

"Critical pathways, also known as critical paths, clinical pathways, or care paths, are management plans that display goals for patients and pro -
vide the sequence and timing of actions necessary to achieve these goals with optimal efficiency."
Every, N.R., Hochman, J., Becker, R., Kopecky, S. Cannon, C.P.
AHA Scientific statement ; Critical pathways - A review circulation 2000;101:461-470

to be examined : human factors, errors and complications. Carthey et al[15] have summarized nicely the aspects of the human factor in cardiac surgery. They utilized the concepts of institutional and individual differences in surgical performance. This is based on the organizational accident causation theor ies of Reason[16]. These theories distinguish between active failures and latent conditions. Active failures are made at the scene, e.g. during surgery, whereas latent conditions are poor or inaccurate decisions made at higher levels, e.g., the manufacturers of product. In a detailed study of human factors in a multicenter study of 243 arterial switch operations for transposition of the great vessels, de Leval et al[17] highlighted the role of human factors in negative surgical outcomes. The negative outcome is accentuated by the patients' risk factors. Human compensation, i.e. recovery or rescue methods, are utilized to address both the error and risk factor. Human errors are normal in the sense that they occur . These errors result from inadequate, flawed, or illogical knowledge or behavior patterns. Reason[16] subsequently distinguishes variable and constant errors (Figure 4).



Target patterns of ten shots fired by two riflemen. As pattern exhibits no constant error, but rather large variable errors. B's pattern shows a large constant error, but small variable errors[17].

Clearly target B is constant and more easily corrected with a change in the rifle sight. This has dramatic application in the clinical setting where correcting an individuals performance is much easier than analysis and correction of a systems failure. Reason[16] nicely defines errors, mistakes, slips, and lapses.

« Error will be taken as a generic term to encompass all those occasions in which a planned sequence of mental or physical activities fails to achieve its intended outcome, and when these failures cannot be attributed to the intervention of some chance agency.»

« Mistakes may be defined as deficiencies or failures in the judgmental and/or inferential processes involved in the selection of an objective or in the specifications of the means to achieve it, irrespective of whether or not the actions directed by this decision-scheme run according to plan.» Slip is failure in execution of an intended action sequence[18]. Lapse is failure in the storage or memory phase of an action sequence[18].

Complications are thus the result of one of more of the four. Slips and lapses are active errors, whereas, mistakes are latent errors. A complication is thus a deviation or departure from the expected or anticipated outcome of a surgical procedure. Morbidity is a diseased condition or state that results from complications. This is a more generic term that includes the entire panorama or complications associated with cardiac surgery. Complications can be anticipated/ unanticipated, expected/unexpected, predicted/unpredicted, avoidable/unavoidable, or recognized/unrecognized. They can be temporally classified as preoperative, operative, or postoperative complications. Post-operative complications are further divided into early (<30 days) or late (>30 days) with chronic complications, residua, or deciduas being temporary (eg. phrenic nerve paraparesis) or fixed (e.g. CVA). Mortality is defined by The Society of Thoracic Surgery and The American Association for Thoracic Surgery as :

« Thirty-day mortality (sometimes termed operative mortality) is death within 30 days of operation. Hospital mortality is death within any time interval after operation if the patient is not discharged from the hospital. Hospital to hospital transfer is not considered discharge; transfer to a nursing home or rehabilitation unit is considered hospital discharge unless the patient subsequently dies of complications of the operation[19]».

Strategic/organizational Iniatives

Historically, postoperati e complications have been well addressed by the surgical community. In the early 1900's Ernest A. Codman classified complications as errors due to lack of technical knowledge or skill, surgical judgment, care, equipment or diagnostic skill[20]. It was also Codman who first championed the need for outcomes assessment[21]. Even earlier, Florence Nightingale, a devoted English nurse, noted disparity in outcomes in many London hospitals of the mid 1800's. She highlighted the concept of severity of di sease and risk adjustment[21]. She emphasized the concept that the hospital should do the sick no harm (*primum non nocere*).

The cornerstone of the approach to complications or adverse outcomes has been with the development of the American surgical training programs. The time honored surgical morbidity and mortality conferences (M&M's) are the origin and main stay of present day peer review and outcomes analysis. This all evolved with the departure of the American Halstedian surgical training programs from the European model of total proctored training. This American model of surgical resident included planning the operation, performing it, and providing the postoperative care, all in a structured, supervised way, with graduating degrees of super vision and autonomy[22]. Analysis of problems or complications was an integral component of this processed learning.

This program became the model for subsequent specialty programs (American Board of Specialties), and the ultimate establishment of the American Board of Thoracic Surgery in 1948[23]. This Halstedian tradition has been maintained with the structured system of progressive training, phased transfer or delegation of responsibility, and evaluation of surgical results and outcomes. Frank Spencer, a disciple of the Halsted/Blalock School, stated that 75% of the important events in an operation are related to making decisions, and 25% to dexterity (Figures 5a, b)[24].

Figure 5 (a)[24] : Characteristics o f surgical decisions

1. Decisions are a combination of planning, observation, and deduction.
2. Two components
   - A. A precise plan
   - B. Modify the plan with unexpected events
3. Emotional considerations
   - A. Decisions under stress, within limited time "Balan cing probabilities" (Dunphy)
   - B. Few things in an operating room are neutral : either help or harm the operation

C. A calm, serious atmosphere with intense concentration (a conductor and a symphony orchestra)

Figure 5 (b)[24] : Four basic concepts about dexterity

1. Teaching is badly neglected
   - a. Importance minimized
     - i. "Teach a monkey to operate"
     - ii. "Will automatically learn"
   - b. Don't know how
   - c. Time consuming
2. A significant percentage of surgical complications are "error in technique"
3. Residents vary widely in natural ability, often those with little dexterity are taught "least".
4. Learning how to operate is a process that should continue for decades. The residency should teach one how to learn on his own.

Here again, the emphasis was placed on the individual surgeon, and not the system.

Both Frank Spencer and John Kirklin focused on the operating room environment. The atmosphere in the OR was serious, professional, calm, organized, and methodical. There was no wasted moves/motions or conversations (idle palaver). Concentration on the task at hand was the order of the day. Recent technology has added objective to subjective validation of these concepts. Tried and true aphorisms from our mentors still hold true - *«Cut well, tie well, get well»; « Modify, simplify, apply»; «Keep it simple»* - Denton A Cooley.

Unfortunately, the morbidity/mortality conference, as traditionally described, primarily addresses factual data, and offers limit ed insight into all aspects of complications. The discussi on oftentimes failed to balance punitive with constructive criticism. (Figure 6)

Figure 6 : Problems with Morbidity/Mortality Conference

- Presentation of chronological difficult cases, complications, deaths without tracking trends.
- Anecdotal without national statistical norms
- Narrow focus; ignores systems analysis
- Required by hospital or program; Hesitancy to be judgmental or punitive.

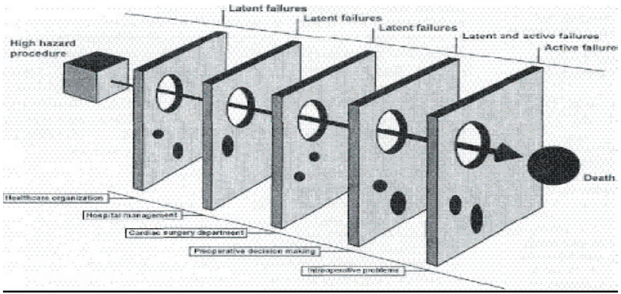
At a higher level discussion of trends and sentinel efforts affords deeper insight in to team function, product lines, critical care pathways, and systems analysis. Again the theories of Reason[16], as promulgated by de Leval and others[17], continue to stress the human failures or active errors and system or latent failure concepts. The broader concept of surgical failure also includes the notions of omission a nd commission. This implies things done or not done. Not to do an operation (omission), when indicated, can create a complication that is avoidable. In contrast, an operation done without absolute or relative indications (commission), can also cause complications that are unavoidable. De Laval continues to drive home the message of the Bristol affair. In his address «Beyond Flatland» he describes Flatland, a race of two dimensional people who are unable to appreciate the full reality of the Spaceland, or three dimensional universe[25]. Now we are in Complexland, a new wave of thinking resulting from the 1944 discovery of nonequilibrium thermodynamics. This implies self organization, whereby space and time patterns emerge at random without external influence. Again he is striving to emphasize methods to analyze complex problems. A note of caution here is not to add complex solutions to complex problems. Seek simplicity, then distrust, may be an appropriate approach. De Leval[17], in a simplified organized fashion analyzes medical outcomes resulting from the interaction of three sets of complex variables patients, treatment, and care providers. It is the care providers that constitute the human factor. Emphasis on error prevention, detection, and recovery ar e the logical areas of concentration in the detection and analysis of errors, or near misses. Error recovery is a crucial area, since it requires fairness and tolerance. Errors will occur and many are unpreventable. The ability to recover a serious unavoidable error or complication is the hall mark of a successful strategy for patient safety. Four isolated or combined factors will cause an airplane crash – weather, mechanical failure, human error, or a violent human action i.e. terrorism. All of these factors have been addressed in the airline industry, thus achieving the 2nd safest form of travel, after «escalators».

The Law of Parsimony may apply here, as fashioned from William of Occam's Razor theory, which is to look for simple solutions within a complex mileu. Humans are parsimony machines: they select the shortest and thus most efficient path to the production of true theorems, given a set of facts (observations) and theories *(HYPERLINK «http://www. knowledge-finder.c om/philosophy/parsimony-fourth-substance.html «www.knowledge-finder.com/philosophy/* parsimony-fourth - substance.html).

Blackstone[26] carries this further by nicely offering his statistical expertise to help us better utilize statistical data mechanisms in this analysis and assessment of outcomes. Employing a Newtonian concept, one should abandon traditional methods of logic, deduction, expert opinion (ie. «in my experience»), consensus, and let actual data speak for themselves. This type of approach is called inductive logic, where analysis of the data infers information regarding the problem, or question, or hypothesis being considered. Blackstone[27] in a well reasoned editorial again emphasizes the Reason methodology in commenting on a series of articles devoted to monitoring of clinical performance[28,29,30].

The common cause variation in outcome analysis focuses on the «blunt end» i e. systems failure, whereas special cause variation is «sharp end» variation i.e. extrinsic influ ence (eg surgical skill or judgment).

Sundt, et al [31] has beautifully built on the Reason, de Leval and Blackstone approach. He utilizes the tools and methods described herein to focus on patient safety, ie. avoidance of problems through the understanding of the systems involv ed. This is adequately summarized in (Figure 7).



In Reason's[17] «Swiss cheese» model of accident causation, adverse events occur when active failures at the operational level align with gaps or weaknesses in the systems, or latent failures at the organizational level permitting an error or accident sequence to go untrapped and uncompensated. Efforts must be made to reduce the gaps as well as reduce the errors. The defense systems can fail either because of or organizational failure or because of performance failures of the operators. (Adapted from Carthley J, et al. The human factor in cardiac surgery: errors and near misses in a high technology medical domain. Ann Thorac Surg 2001; 72:300-5.)(16)

The concept of systems is an important one. Systems analysis is a common practice in the non-medical world. Systems analysis or improvement is synonymous with continuous quality improvement (CQI) or total quality management (TQM). W. Edwards Deming and J. M. Juran are the architects of this movement[32]. Following World War they dramatically helped re-establish and re-form Japan's manufacturing base. Deming established 14 points of management (Figure 8).

within a system of profound knowledge :

- knowledge of a system
- Knowledge of variation
- Knowledge of psychology
- Theory of knowledge

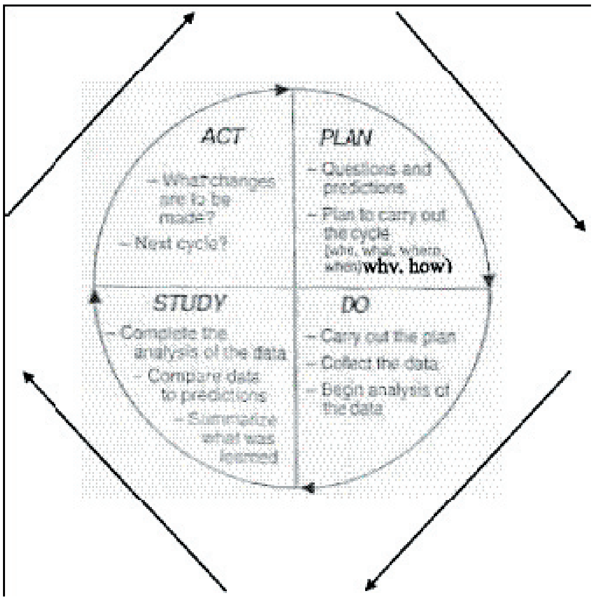
Noland[33] combiend this Deming improvement knowledge and professional health care nowledge into a PDSA (Plan-Do-Study-Act) cycle (figure 9)

Figure 8 : Demin's 14 Points for Management*

1. Create constancy of purpose for improvement of product and service.
2. Adopt the new philosophy.
3. Cease dependence on mass inspection.
4. End the practice of awarding business on the basis of price tag alone.
5. Improve constantly and forever the system of production
6. Institute training.
7. Adopt and institute leadership.
8. Drive out fear.
9. Break down barriers among staff areas.
10. Eliminate slogans, exhortations, and targets for the work force.
11. Eliminate numerical quotas for the work force and numerical goals for people in management.
12. Remove barriers that rob people of pride of workmanship.
13. Encourage education and self-improvement for everyone.
14. Take action to accomplish the transformation.

(32) Adapted from Scherkenbach WW: The Deming Route to Quality and Productivity. Milwaukee, ASQC Quality Press, 1986

figure 9 : The PDSA cycle for learning and improvement[33]



A practical example of system anal ysis is the failure made effect analysis (FMEA) process developed by the military . The objective of FMEA is to identify failures or improvements in a product or process, as well as individual operator mistakes or errors. An example of its application is the evaluation of extracorporeal perfusion circuits[34]. A rating scale was developed to evaluate the degree of failure, the occurrence or incidence of failure, and the means of detection of failure. This highlights the concept that once recognized, failure of process or device can be corrected, improved, or replaced, thus avoiding adverse results.

There are very few classification systems available for recording or documenting complications. Most texts and reviews list the major and minor complications associated with various procedures and operations. A generic classification system has been adapted from Rutherford[35] and Clavien[36]. (Figure 10)

Figure 10 : Surgical Complications

Classification schemes Types of complication	
Anticipated/Unanticipated Expected/Unexpected Predicted/Unpredicted Avoidable/Unavoidable Recognized/Unrecognized Preventable/Unpreventable	- Fatal/Nonfatal (mortality/morbidity) - Early/Late (<30 days/>30 days)? - Major/Minor - Permanent/Temporary - Disabling/Nondisabling - Specific/Nonspecific - Single/Multiple - Systemic/Local - Cardiac/Noncardiac
Categor y	
- Comorbidity factors – patient related - Systems failure - Directly attributable to operation (commission) – Human Factor - Directly attributable to delayed or premature operation or management, omission of operation, or failure to recognize error/complication - Unrelated to operation/procedure - Sequela*	
Outcome	
- Complete recovery/resolution from complication - Partial recovery - No recovery - Fatal	
Grading	
Grade I - Minor - resolved spontaneously without care, or patient care, or minimal medical care Grade II - Potentially - life threatening requiring intervention Grade III - Residual or lasting disability Grade IV - Death directly related to complication	

**Sequela (ae) accepted negative consequence of an operation or procedure eg surgical scar, decreased pulmonary function following lung resection, or decreased mobility following lower leg amputation.*
(35) Rutherford, R.B. Suggested Standards for reporting complications in Vascular Surgery p1-10. Complications in Vascular Surgery Bernhard, VM, Towne, JB ed Quality Med. Pub, St. Louis, 1991
(36) Clavien, PA, Sanabria, JR, Strasberg, SM. Proposed classification of complications of surgery with examples of utility in cholecystectomy Surgery 1992; 111:518-526.
**Early - One-time events - occuring within 30 days of surgery or before hospital discharge, whichever is sooner.*
Late - time-related events - after 30 days.
**Grunkemeier, G, Jin, R. Ch7-Surgical Treatment of Outcome Data p225-231. In Cohn, L.H., Edmunds, L.H., ed. Cardiac Surgery in the Adult 2nd edition, MC Graw Hill, New York, 2003.*

Tactical/Managerial/Initiatives

Given this broad based background of complications that attempts to give structure to the surgical process, let us now focus on specific efforts and initiatives to both understand and improve the process. Interestingly, cardiac surgeons perform operations and care for patients. Yet, all of this revolves around problem solving (Figure 11).

Figure 11 :

Problem solving equation	
OBJECTIVE Knowledge Skill Technique	
Problem (Challenge) → Solution (Management/Resolution)	
SUBJECTIVE Judgment Maturity Experience	
«Doing Right Things Right»	
Accepted Indications Relative/Absolute Accepted Contraindications	Proper Time of Operation Suitable operation for patient Technically correct

The subjective and objective elements involve a lifelong career of study and reflection beyond the formative training years. This is the role for the continuing medical education (CME) process. This includes conferences, meetings, seminars, workshops, symposia and personal interaction with colleagues. The internet has become a powerful tool in this endeavor *(www.ctsnet.org)*. A word of caution regarding experience. When tested and challenged with thoughtful study and reflection and appropriate changes and modifications experience is a most powerful tool. However, when not used properly and effectively, it can be extremely harmful. To quote Oscar Wilde «Experience is the name everyone gives to their mistakes». An experience with 100 operations could be one operation done wrong or improperly 100 times.

The establishment of standard guidelines, algorithms, local practice and clinical care pathways, are extremely useful and informative. Examples include practice guidelines developed by the Society of Thoracic Surgery[37] (Figure 12)

Figure 12 : Example of Surgical Practice Guidelines

ISCHEMIC HEART DISEASE: III[37]		
Diagnosis:	414.10	Left ventricular aneurysm
Procedure: ventricular aneurysm	33542	Resection or application
Indication:	1 2 3 4	Congestive heart failure Systemic emboli Angina pectoris Ventricular arrhythmias
Confirmation of Indication:		Cardiac imaging study with contrast, echocardiography, or radionuclide technique showing dyskinesia
Relative Contraindications		Asymptomatic true aneurysm
Actions Prior to Procedure:	1 2	Coronary arteriography Left ventriculography often indicated
Actions During Procedure:	1. 2	Remove mural thrombus In presence of ventricular tachycardia, map endocardium and ablate sites of early repolarization
Actions Following Procedure:	1 2	Cardiorespiratory support Treat arrhythmias
Outcome:	1 2	Mortality of 3% to 30% determined by patient age, general status, associated disease, and extent of myocardium involved. Discharge in 7 to 21 days
depending on preoperative status		
	3	Diminution or relief of symptoms

References
Komeda M, David TE, Malik A, Invanov J, Sun Z. Operative Risk and Long Term Results of Operation for Left Ventricular Aneurysm. Ann Thorac Surg 1992; 53:22-29.
Mills NL, Everson CT, Hockmuth DR. Technical Advances in the Treatment of Left Ventricular Aneurysm. Ann Thorac Surg 1993;55:792-800.
Baciewicz PA, Weintraub WS, Jones EL, et al. Late Follow-up after Repair of Left Ventricular Aneurysm and (usually) associated Coronary Bypass Grafting. Am J Cardiol 1991:68:193-200.

as well as the American Heart Association/American College of Cardiology (AHA/ACC) recommendations or guidelines, series (*www.acc.org/clinical/statements.htm*). However, they do not replace the time honored individualized approach to patient care. The paradigm shift to focus on the total patient in a holistic fashion as the basis of care has dominated the current scene[38]. The Cardiothoracic surgeon may delegate responsibility of care of his patient to appropriate consultants or services (e.g. Intensivists) but he/she remains totally involved in the short and long term care.

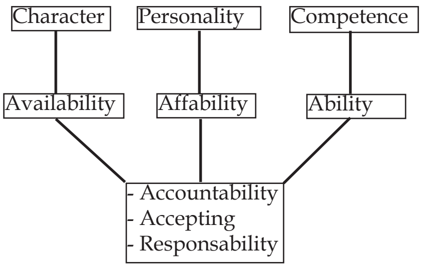
Familiarity with proper diagnosis and coding are extremely important. It is these codes that form the basis for data retrieval and billing. Improper documentation can become the source of inaccurate database information and billing submissions, especially in an unaudited atmosphere. The International Classification of Disease, Ninth Revision, and Clinical Modification (ICD-9- CM) classifies morbidity and mortality information for statistical purposes, as well as indexing of hospital records by disease and operations [39]. It is important to distinguish complications of care from preexisting co-morbidities. The coding is also limited by the inability to document the temporal relationships of preoperative and postoperative conditions or complication. The Current Procedural Terminology (CPT) is a listing of descriptive terms and identify ing codes for medical services and procedures performed by physicians[40]. Most of the data utilized by overseeing groups, like Leapfrog, and Medicare eminate from these sources. The Society of Thoracic Surgery and the American Association of Thoracic Surgery have been very proactive in educational aspects of CPT and I CD- 9- CM codi ng. (HYPERLINK *« http://www.ctsnet. org/doc/319» http://www. ctsnet. org/doc/319*).

The residency training period has undergone recent modification both in length, operative requirements, and quality. The American Cardiothoracic Residency program is evolving in to a six year program with 3 years basic surgery, and 3 years specialty training. Competence has become a focal point for all graduate medical education programs. The Accreditation Council for Graduate Medical Education (ACGME) has endorsed six areas of general competencies to be incorporated in to the GME programs. Ultimately, the successful surgeon must have 3 attributes : Character, Personality and Competence (figure 13)

Figure 12 : Areas of general ACGME competency

Category	ACGME competency
Patient care	Residents must be able to provide patient care that is compassionate, appropiate, and effective for the treatment of health problems and promotion of health
Medical knowledge	Residents must demonstrate knowledge about established and evolvir biomedical, clinical, and cognate (eg, epidemiological and socio-behavioral) sciences and the application of the knowledge to patient
Practice-based learning and improvment	Residents must be able to investigate and evaluate their patient care apraise and assimilate scientific evidence, and improve their patient pratices
Interpersonal ans communications skills	Residents must be able to demonstrate interpersonal and communicative skills that result in effective information exchange and teaming with patients, patients' families, and profesional associates
Profesionalism	Residents must be demonstrate a commitment to carrying out profesional responsabilities, adherence to ethical principles, and sensitivity to a patient population
System-based practice	Residents must demonstrate an awarness of and responsiveness to the contxt and system of health care and the to call on system to provide care that is of optimal value

Figure 13[41] : Competence Personality



Kwasnik[42] has added a fourth "A"- Accountability (figure 14). This also includes accepting responsibility. This incorporates the other A's since it requires autonomy or ability to do the job; assumption or willingness to do the job; and assignment or ability to work with others and delegate responsibility.

Beyond this structural education and training period, resulting in state licensure and board certification, the remainder of the cardiac surgeon's career revolves around state license renewal, renewing hospital privileges and credentialing, board re-certification (every 10 years for CT Surgery), and continuing medical education (CME). The initial hospital privilege credentialing process may also involve a fixed period of proctoring and/or temporary privileges prior to full unrestricted privileges.

Beyond this, mandated surgical morbidity/mortality conferences, peer review and mandatory reporting in many states of sentinel adverse events or outcomes have become the mainstay of both voluntary and involuntary reporting and tracking of complications, as well as evaluating obvious cases of professional in competence.

This proctoring process is required by many medical staffs[43]. The goal is to assess a physician's technical skill prior to granting full medical staff privileges. This peer review system has become the cornerstone of ensuring quality medical care[44]. The Health Care Quality Improvement Act (HCQIA) of 1986 created the National Practitioner's Data Bank (NPDA). This outlines the whole process of peer review, in terms of how reviews are conducted and physicians protected. Implemented in 1995 the NPDA authorized the Secretary of Health and Human Services (HHS) to establish a registry that restricts the ability of unethical or incompetent doctors to move within the states with out documentation of previous damaging or incompetent performance[45]. Basic to this whole concept of compli cations and accountability is the development of an attitude of maturity and sensibility. This requires both personal and group professionalism and collegiality . Professionalism carries with it three elements[1,46]. Knowledge implies acquisition of a predetermined period of training and education, and a life-time of continuing application of this knowledge with constant relearning and acquisition of new and evolving information and shills[2]. Altruism is the commitment to patients and society and adherence to a code of ethics (Hippocratic Oath)[3]. Self - regulation revolves around accepted standards and regulations for education, training, performance, and competency. This all translates into the expectancy that physicians act with integrity and skill in their relationships with peers, staff, patients and families. Patient confidentiality enters the equation at this point. Discussions at the bedside, as well as discussions of other health care professionals regarding physicians, care, recommendations, and opinions must be tempered with professionalism and caution. Loose lips do sink ships. Human behavior in this area is hard to modify and temper. The Health Insurance Portability and accountability act of 1996 (HI PAA) *(http://www.hhs.gov/ocr/hipaa/privacy.html*) has created standards for the privacy of individually identifiable health information. This law also protects the patients rights to health coverage during certain situations. (*http://cms.hhs.gov/hipaa/onlin e/default.asp)*

Medical malpractice is the legal process through which the patient or family seeks financial retribution for all eged negligence or incompetence resulting in an adverse outcome. There is a crisis in medicine today related to the increasing malpractice suits, large settlement and increasing malpractice premium costs. Tort reform at the state and federal level has become a major priority given the increasing direct and indirect financial impact on the overall healthcare system.

Once again it is important to stress that the largest contributor to errors or complications is system failure[47]. Surprisingly, there has been a decrease in overall medical adverse events from 1972 to 1992. The current rate is below 3%. It is also noted that cardiothoracic surgery accounts for about 3% of malpractice claims noted in the Physicians Insurers Association of America (PIAA) database[48]. The components of a malpractice lawsuit are illustrated in (Figure15)[49]

Figure 15 : Anatomy af a suit[49]

Plaintiff's complaint	Summons-complaint and venue Verification (Bill of particulars)
Defendant's answera Dyscovera	Interrogatories Requests for production Documents Name of witness Depositions Plaintiff Defendant Motionsa Trial (judge or jury) Appeals (not always)

[a] These steps do not always occur in this order

One area not noted is settlements. The important point to stress regarding a settlement is that it is reported as a lost malpractice suit, which is subsequently recorded in the National Data Bank[49]. Prevention of malpractice is nicely summarized in (Figure 16)[48] .

+ Two risk calculators-simple additive standard Euro Score (Roques. F. NashefSA, Michel. p. et al. Risk Factors and Outcome in European Cardiac Surgery : Analysis of the Euro Score multinational database of 19,030 patients. Eur J Cardiothoracic Surg 1999; 8:16-22) and thefulliogistic Euro Score (Roques. F. Michel. p. Goldstone. AR. Nashef, SA Logistic Euro Score. Eur Heart J 2003; 24:882-883). The later gives more accurate risk predictions for higher risk patients.

Figure 16[48] : Prevention of malpractice

1. Listen patiently.
2. Respect the patient's dignity and privacy.
3. Return phone calls promptly.
4. Be polite.
5. Be on time.
6. Have the patient join in decision-making. Allow time for reflection.
7. Keep patient's expectations in line with reality (prepare them for all eventualitie s).
8. Be honest about a mis adventure (never cover up or try to blame other s).
9. Avoid high-ri sk situati ons such as cases you are not fully
10- Treat the patient as you would to be treatred

Clearly, trusting and caring physicians who are honest, sincere and have performed everything in the best interest of the patient, will avoid the majority of lawsuits. Yet we cannot ignore the medical malpractice crisis in the USA (especially in 19 states)[50]. This translates into decreased access for patients because of an inflated cost of medical liability premiums. The adage of crisis precipitates change is long over due. A recent survey of 4 Florida counties revealed 94% of CT surgeons have been sued with an average of 3.62 lawsuits each thus far in their surgical careers[50]. Combining the elements of practice guidelines and malpractice prevention into a useful checklist for the operating surgeon is summarized in (Figure17).

Figure 17 : Surgical consideration

Preoperative Counselling :
Patient; family; relative; appropriate others; referring primary and specialist
HIPAA Compliance
Operative :
Indications: relative/absolute
Contraindications: relative/absolute
Timing: when/where to operate (level of facility capability)
Techniques available : Various methods; aggressive; conservative; palliative; curative
Technique employed : knowledge, familiarity
Complications :
(major/minor)
Preoperative risks; comorbidity
Operative – predicted; unpredicted
Early postoperative < 30 days
Late postoperative > 30 days
Chronic/residua/sequela

Post-operative :
Disclosure – too much; too little information re. complications/outcome*

**Mavroudis, C., Mavroudis C.D., Naunheim, K.S., Sade, R.M. Ethics in Cardiothoracic Surgery-Should Surgical Errors Always be disclosed to the patient? Ann. Thorac. Surg 2005; 80:399-408*
- A debate regarding a surgical error that allowed the operating surgeon the opportunity to hide or conceal the information from family members following the patient's death.

Pre-operative counseling is a crucial phase. It is there that the risks and benefits are discussed. Risks include complications. Whether these complications should be broadly discussed or detailed, including written information is a matter of debate. In any event, complications related to the patient's problem, related comorbidity, and the extent of surgery should be openly presented and discussed. The disclosure of complications perioperatively is also a debated issue. Certainly disclosure to patient, family , and discussion at morbidity/mortality conference, or peer review is the usual procedure. A useful phrase for consideration is to admit your mistakes, errors, or shortcomings, but don't «advertise». The evaluation and discussions that follow commission, e.g. performance of operations or procedures, again do not include omission, e.g. operations/procedures turned down or rejected. How dramatic was the change in mortality noted in New York state when high risk cases were turned down, and referred out of state! However, when death, complications, or other adverse outcomes occur a useful mnemonic is help ful to follow (Figure 18).

Figure 18 : The ABCDE Mnemomc for Breaking Bad News

Advance preparation
Arrange for adequate time, privacy and no interruption (tom pager off or to silent mode).
Review relevant clinical information.
Menta1ly rehearse, identify words or phrases to use and avoid.
Prepare yourself emotionally.
Build a therapeutic environment/relationship
- Determine what and how much the patient wants to know.
- Have family or support persons present.
- Introduce yourself to everyone.
- Warn the patient that bad news is coming.
- Use touch when appropriate.
- Schedule follow-up appointments.
Communicate well
- Ask what the patient or family already knows.
- Be frank but compassionate; avoid euphemisms and medical jargon.
- Allow for silence and tears; proceed at the patient's pace.
- Have the patient describe bis or ber understanding of the news; repeat this information at subsequent visits.
- Allow time to answer questions; write things down and provide written information.
- Conc1ude cach visit with a surnmary and follow-up plan.
Deal with patient and famlly reactions
- Assess and respond to the patient and the family's emotional reaction; repeat at cath visit.
- Be empathetic.
- Do not argue with or criticize colleagues.
Encourage and validate emotions
- Explore what the news means to the patient.
- Offer rcalistic hope according to the patieut's goals.
- Use interdisciplinary resources.
- Take rare of our own needs; be attuned to the needs of involved house staff and office or hospital personnel.

* *Adapted from Rabow MW, McPhee SJ Beyond Brequipped to+*

Pre-operative Phase

RISK ASSESSMENT/SEVERITY SCORES

Let us now look at complications in a temporal setting. As mentioned,open-heart surgery has become increasingly important in terms of access, cost, and results, particularly in the setting of a sophisticated public awareness which desires more information regarding both surgeon specifie and institutional outcomes. This information is now readily available on the internet (Table 2, 3, 4).

Table 2 : Iatrogenic Deaths in the United States*

Iatrogemc Deaths in The United States (Deaths induced inadvertently by a physician or surgeon or by medical treatment or diagnostic procedures)		
Condition	**Deaths**	**TOTAL**
Adverse Drug Reactions	106,000	$12 billion
Medical error	98,000	$2 billion
Bedsores	115,000	$55 billion
Infection	88,000	$5 billion
Malnutrition	108,800	....
Outpatients	199,000	$77 billion
Unnecessary Procedure	37,136	$122 billion
Surgery-Related	32,000	$9 billion
TOTAL	**783,936**	**$282 billion**

* *(http://www.ourciviliztion.com/medicinelusamed/deaths.htm)*

Source	Targeted audience	Communication media	Information available
American college of Cardiology/ American Heart	Patients needing CABG (nationwide)	Internet (http://www.acc.org/clinical/guidelines/bypass/bypass7.htm Internet (http://www.ahcpr.gov/)	Literature-based indications for CABG
Association Agency for Health Care quality	Broed base of Broed base of health care consumers and providers	Intemct (http://www.ahcpr.gov/)	Large knowledge base focusing on empowering consumers to judge health care quality. In hospital CABG mortality data from 1998
Calofornia Office of statewide health Planning and Development Canadian Health Care System	Patients who purchase healthcare insurance in California provide consumers witrh hospital outcomes for various procedures that might indicate quality at a given hospital all interested consumers	Internet (http://www.ospd.cahnet.gov/hpp/ccmsp/ccmrp summary.pdf) Internet (http://www.hcscgc.ca/ohihbsi/available/conference/presentation/guerrieree.pdf	Risk-adjusted hospital mortality rates for Canadian hospitals
Cochrane Collaboration	All interested consumers	*(http://www.cochrane-consumer.com)*	ummarized available published evidence about a wide variety of health care interventions including cardiac surgery.
Darmouth University	Use large health-care databases to inform the public of nationwide trends in health care delivery	Internet *(http://www.dartmouthatlas.org/99US/chap* 5 sec 12.php	CABG mortality rates across the U.S. based primarily on claims databases
Health Care Choices	New York not-for-profit corpration dedicated to educating the public about the nation'shealth care system	Internet *(http:www.healthcarechoices.org/cardiacsurgeryv.htm)*	Select state CABG mortality rates, primitive attempt to collate data about physicians. Not nearly complete enough but evolving
Health finder	NIH government sponsored information web about a wide variety of medical problems	*http://www.healthfinder.gov/healthcare*	Geneal information in fairly specific detail about cardiac procedures (with drawing and diagrams)
Healthoutcomes.com	Patients requiring operation or catheter based intervention nationwide	*Internet (http://www.healthoucomes.com*	In hospital outcome for medicare patients having selected procedures (e.g.CABG)
The Leapfrog group (consortium of fortune 500 companies and health care insurers	Provide concumers with list of hospitals that employ leapfrog defined quality measures	*Internet (http://www.leapfroggroup.org/index.html*	List of hospital that use quality measures. Hospitals that use quality measures will be financially rewarded ly Leapfrog group
Medscape Inc.	Consumers information source for all types of medical conditions and for preventive medicine	*Internet (http://www.medscape.com)*	Comprehensive, searchable website with multiple links to external sites capable of finding comprehensive information about details of cardiac surgery.
The National Quality Forum	Provides to the public a standardized set of measures and framework for improving the quality of cardiac surgery	*Internet (http://www.qualityforum.org)*	The set includes 21 hospital level measures that facilite efforts to achieve higher levels of patient safety and better outcomes for patients.
New Jersey State Department of Health	Patients having cardiac procedures in New york tate	*Internet (http://www.health_state_ny.us)*	Surgeon specific and hospital in hospital mortality rates for CABG
Pennsylvania Care Cost Containment Council Rand Corporation	Patients who require CABG in the state of Pennsylvania	*Internet (http://phcl.org)*	Hospital and surgeon specific CABG mortality rates
Rand Corporation	Provide the public with results of cardiac surgery	*Internet (http://www.rand.org/publications)*	Summary of publicly available CABG mortality rates with critical appraiseal of methods and some estimation of appropiates of care

Society of Thoracic Surgeons	Provide the public with results of cardiac surgery over as broad of a population as possible (including VA, Northern New England Consortium, and Great Britain	*Internet (http://www.ctsnet.org/section/oucomes/)*	Mortality and other outcomes data for thoracic procedures. Some of the data is presented as raw mortality data without data risk adjustment. One of the only databases that includes non cardiac surgery
Sohncient Corp. Inc. (Top 100 Heart Hospital)	Provide the public with rather arbitrary rating of overall quality of cardiac care	*Internet (http:www.100tophospitals.com)*	Rates all hospitals in the U.S. that do cardiac surgery and lists the tgop 100 heart hospitals
Washington Post Meical website	Provider of medical information reports to consumers in Noth America	*Internet (http://www.medifocus.com)*	General information about cardiac disease
Webmd Inc.	Provide information to consumers and physicians about a broad spectrum of health care issues	*Internet (http://www.web*	Information about CABG and expected outcomes
Women's Heart Foundation	Provide health related	*Internet (http:www.womensheartfoundation.org)*	Links to internet available report cards on cardiac surgery

They are essential tools for risk assessment, cost analysis and over all assessment of patient benefit.

The major determinants of perioperative morbidity and mortality remain age, sex, body surface area, acuity of the operation (elective, urgent, emergency), associated co-morbiditi s (especially smoking, diabetes, obesity, renal dysfunction, hypertension, stroke, chronic obstructive pulmonary disease, and peripheral vascular disease); and the degree of cardiac dysfunction.

Univariate analysis is used to correlate a particular risk factor with a specific outcome, which is the methodology utilize d in the Society of Thoracic Surgeons (STS) database (Figure 19).

Figure 19 : particular risk factor

Demographics	Age, Gender
Acuity/Priority	Elective/urgent/emergent Comorbidities Smoking Diabetes Morbid obesity Renal failure Hypertension Stroke COPD Peripheral vascular disease Cerebrovascular disease
Cardiac disease	Recent MI Type of angina Cardiogenic shock Preoperative arrhythmias Preoperative meds (diuretics, inotropes, antiarrhythmics, NTG)

**Current Core STS data elements and definitions available at HYPERLINK «http://www.sts.org/doc/4502» http://www.sts.org/doc/4502*
? Bojar RM. Manual of Perioperative Care in Cardiac Surgery. Third Edition Malden, MA, Blackwell Science, 1999, p80

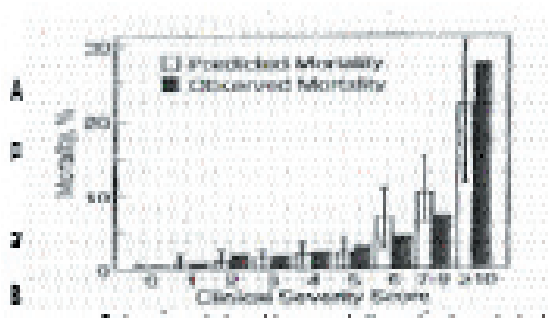
This calculation is difficult to assess when multiple factors are involved. In multivariate regress ion analysis, only those variables found significant in univariate analysis are used to assess the independent association of these variables with specific outcome or results.

Several multivariate risk modes allow for bedside calculation of operative risk, including the Parsonnet scoring system which is one of the earliest[65]. The Cleveland Clinic (CCF in Table 3) severity scoring system is practical in that the score is directly correlated with predicted mortality (Figure 20a,b)[59]

Figure 20 (a) : Cleveland Clinic Clinical Preoperative Severity Scoring System*[59]

Preoperative Factor	Factor
Emergency case	6
Creatinine > 1.6-1.8	1
Creatinine > 1.9 4	4
Severe LV dysfunction	3
Reoperation	3
Mitral regurgitation	3
Age 65-74	1
Age > 75	2
Prior vascular surgery	2
COPD	2
Hematocrit < 34%	2
Aortic stenosis	1
Weight < 65kg	1
Diabetes	1
Cerebrovascular disease	1
Maximum Score	31
Relevant range	0-13+
COPD - chronic obstructive pulmonary disease LV - left ventricular	

** The correlation of the clinical severity scoring system with mortality at the Cleveland Clinic (Source : higgiens TL, Estafanous FG, Loop FD, et al. Stratification of morbidity and mortality outcome by preoperative risk factors in coronary artery bypass patients. JAMA 1992;265:234-238[59]*



Determine what and how much the patient wants to know. Have family or support persons present. Introduce yourself to everyone. Warn the patient that bad news is coming

The Northern England risk includes CABG and valve surgery risk (Figure 21[66])

Figure 21[66]:Risk algorithm Northern New England

Preoperative estimation of risk of CABG or aotic valve mortality			
Patient or disease characteristic	CABG mortality score	Aprtic valve mortality score	Mitral valve mortality scoe
Age 60-69	2.5	1.5	1.5
Age 70-79	4.0	2.0	3.0
Age > 80	11.0	3.0	3.0
Female sex	2.0		1.5
EF < 40 %	1.5	1.0	
NYHA 1b		1.5	1.0
NYHA 1c			2.0
LVHDP 30			1.5
Urgent surgery	2.0	1.5	2.0
Emergency surgery	9.0	5.5	6.0
Prior CVA			1.5
Prior CABG	3.0	1.5	
FVD	1.5		
CHF		2.0	1.5
Atrial fibrillation		1.5	1.4
CAD	1.5		1.5
Disheets			1.5
Dialysis or creatinine 2	2.5		1.5
BSA < 1.70	2.0	1.5	
BSA 1.70-1.99		1.5	
Mitral replacement		1.0	
Concomittant CABG			2.0
Total score		1.5	

Preoperative risk			
Total score	**Mortality (%)**	**Aortic (%)**	**Mitral (%)**
< 3	< 0.4	< 1.8	< 0.6
3	0.4	1.8	0.6
4	0.6	2.2	0.9
5	0.8	3.1	1.1
6	1.2	3.6	1.5
7	1.5	5.1	2.0
8	2.1	6.6	2.7
9	2.8	8.5	4.0
10	3.7	11.9	4.8
11	4.6	15.1	7.1
12	6.6	17.2	9.2
13	5.2	23.7	11.6
14	9.9	31.4	17.0
15	7.3	36.9	19.6
16	9.6	43.0	26.6
17	12.0	> 43.0	34.0
18	15.8		41.2
19	31.6		48.0
20	< 31.7		> 60.0

The Euro Score is an additional risk source which is available for on.line calculation. *www»euroscore.org+*

Specifically, the risk of advanced age has become important and relevant in terms of access to care, cost and outcome. At present, three percent of Americans are octogenarians, and by 2010 there is projected to be an increase to 4.3%, representing 12 million people[67]. Between 1987 and 1990 there was a 67% increase in cardiac surgery in this age group[68]. Mortality and quality of life are the prime indicators of success in this age group. Operative mortalities between 7.9% and 13.5% have been reported in octogenarians, with one study reporting a 5-year median survival of 55%, compared to 69% in age group 70-79 years, and 81% for age group 60-69 years[68]. Utilizing Standard Form 36 Health questionnaire (SF-36 form) and the Seattle Angina Questionnaire, 83.7% of the octogenarian surgical patients were living at home with 74.8% enjoying good or excellent health[69] (Figure 22).

Figure 22 : Seattle Angina Questionnaire

Short form 36 (SF 36)	Seattle angina questionnaire	Michigan Health profile
Physical functionning Social functionning Role limitations physical Emotional Mental health Energy/Vitality Pain General heealth perceptions	Extional capacity Angina stability Treatment frequency Treatment satisfaction Disease perception	Mobility Pain Energy Sleep Emotional perception Social isolation

Females remain at higher risk for myocardial revascularization. Iwo basic studies show a two-to-three fold increase in mortality for women versus men[70,71]. Waiting lists for emergency, urgent, or elective cardiac surgery has ceased to be a problem in the United States, with the exception of heart, and heart-lung transplantation. Unfortunately, cost effectiveness and efficiency can be problematic in some cases where preoperative counselling and more complete evaluation of the disease process or comorbidity are not approached. In other countries waiting lists pose a problem or challenge. Rexius et al[72] from Sweden noted a median waiting time for CABG of 55 days. There was a 1.3% mortality in the 5,864 patients waiting for elective surgery. Cesena et al[73] from Brazil noted a median waiting time of 126 days. There was a 2.5% mortality in a group of 516 patients. Impaired LV function was a major risk factor for death in both groups.

Interestingly none of the risk scores for myocardial revascularization include either hospital or surgeon specific volumes as specific risks for mortality or adverse outcome. At least nine large studies have addressed the notion that hospitals performing small numbers of CABG operations have higher operative mortality[74-82]. Six of these nine studies found increased operative mortality in low volume providers[74-79]. In three other studies there was no correlation[77-79]. The Institute of Medicine summarized the relationship between higher-volume and better outcome «*(www.nap.edu/catalog/IOO5.html)*» and concluded that procedure or patient volume is an imprecise indicator of quality even though a majority of the studies reviewed showed some association of higher volume and better outcome[83]. The observations on operator volume and outcome have prompted some to suggest «regionalization» i.e. to refer non emergent CABG patients to large volume centers[79,84]. The role for «selective regionalization» was advocated by Nallamothu et al[82] when they found that low risk patients did equally well in high volume or low volume hospitals. They suggested regional referral for elective high risk patients to high volume institutions. Crawford et al[85] pointed out that a policy of regionalized referrals for CABG may have adverse effects on healthcare, including increased cost, decreased patient satisfaction, and reduced availability of surgical services in remote or rural locations. Birkmeyer et al[86] again point out the emphasis on hospital volume by both the Institute of Medicine and the Leapfrog group. Again using Medicare Claims data and the Nationwide Inpatient sample they examined 6 cardiovascular procedures between 1994 and 1999 and noted a 2-5% change in adjusted mortality for valve surgery, and <2% change in adjusted mortality for CABG Surgery. Clearly this debate will continue[87].

A sensitive area of discussion revolves around modalities to adjust risks and outcomes. Referral of high risks patients to high volume centers or out of state shifts the risk, decreases the cost for the referring facility, and lets the surgeon «off the hook». Whether the motive is patient driven, facility driven, or surgeon driven is a matter of speculation. Shahian et al(88) have openly discussed «gaming». This includes upcoding of comorbidities, change of operative class, transfer of postoperative patients to extended care facilities, and avoidance ofhigh risk patients. Inappropriate or excessive coding of risk factors increases the expected mortality rate. Adding mitral valve repair to CABG changes the class from isolated CABG. Finally transfer of patients from acute to chronic care facilities changes the database of deaths occurring where the operation was performed.

Carey et al[89] studied the Califomia statewide discharge database ever a 3 year period. When corrected for transfer to chronic facilities the aggregated 3 year in-hospital mortality rose for CABG (2.98% to 3.45%); CABG plus (9.25% to 10.67%); and valve only (4.85% to 5.45%). Once again, as painted out earlier the SIS defmition of hospital mortality includes patients transferred to chronic health facilities, whose death was attributable to the operation[19].

Operative Phase

A difficult area to gather objective data and document ontoward events is the data dense environment of the operating room or theater. Notable attention has been given to preoperative and postoper ative aspects in the literature, but there is a dearth of objective information re intraoperative events. We assume the infrastructure and design of the operating room is safe and functional. Basic knowledge of OR design and function should be familiar to the cardiac surgeon and the operating team room team. A knowledge of the basic equipment, monitors, and supplies necessary for specific operations is fundamental.

Anesthesia controls IV access, airway, anesthesia, monitoring, and overall patient support during the operation. Recent attention has been given to general and specific anesthesia related complications. Anesthesia complications are not discussed.

Nursing issues in the OR include chart control, patient identification, positioning, prepping, and draping. The OR documentation paperwork is maintained by nursing. Instruments and supplies are usually prepared from physician and procedure specific pereference lists. The recently implemented «time out» routine insures that the right patient is receiving the right operation on the right anatomical part of the body. Positioning is important insofar as pressure necrosis and peripheral nerve injury are concerned events. Cautery burns are documented. A summary of operating room data and events is maintained in the operative nursing record.

The attending primary cardiac surgeon must have a mental checkl ist to assure that the appropriate instruments, suture, and product needed for a specific operation is available, ready, and operational (eg – the surgical sternal saw must be checked and functional prior to use). It is wise and prudent to review and reheare the sequence of the operation with the operating room team prior to the incision. Any specifics or deviation from the routine are better received and discussed prior to the skin incision. Notification of the family or relatives of the progress of the operation at various times during the procedure is considered routine in most programs. Certainly, notification of an intraoperative complication or catastrophe is appropriate. A designated spokes person or protocol is standard in most centers.

Surgeon specific data or the human factor is difficult to quantify and document. The three fundamental requirements for the surgeon include character, personality, and competence. Attempts at objective measurement of the surgical personality offer some insight in to character as well. Mc Greevy et al[90] used the US Air force NEO PIR psychological testing to measure personality traits in surgical residents. Data on the five major personality traits (Neuroticism, Extraversion, Openness,Agreeableness, and Conscientiousness) were analyzed. The Conscientiousness facet analysis was the most revealing.

The traits of conscientiousness include competence, order, dutifulness, achievements triving, self-discipline, and deliberation. All residents, both male and female scored higher in this facet than the general population.

The NEO PI-R is a stable testing modality across the adult lif e span, and consistent in retesting.

Technical proficiency is a basic required surgical trait. Validation of this proficiency historically has been the qualitive assessment by mentor observation. This modality will remain the basis of apprentice-based teaching or transfer of skills. These In-Training Evaluation Reports (ITERs) are composed of global rating scales of technical proficiency evaluated, assessed, and completed at various phases of the surgical residency training period. True validity and reliability remain a major concern[91]. Objective testing and evaluation of technical proficiency and dexterity is gaining more attention.

Guerlain et al[9]2 have employed a multitrack, synchronized, digital audio-visual recording system (RATE tool) to monitorint raoperative performance. This RATE tool allows analysis of technical judgment, technique, team performance, and communication patterns. Hance et al [93] have adopted an objective system to evaluate technical proficiency and dexterity. It consists of a « bench model» skills assessment for cardiac surgery. The goal is to establish construct validity, which is a means to differentiate varying skill levels. Four skills are assessed - aortic root cannulation, femoral triangle dissection, aorta to vein graft anastomosis, and vein graft to Left Anterior Descending Artery anastomosis. Cadaveric porcine models were utilized. Assessment was performed by senior surgeons utilizing a standard validated evaluation system. This type of assessment protocol will gradually be integrated into many training programs. The perfusionist is a critical component of the operative team. Complications related to cardiopulmonary bypass are beyond the scope of this review . However, all programs are encouraged and often required to formulate perfusion protocols that include routine cases, special cases, and recognition and correction of operative complications i.e. «troubl e-shooting». The cardiac surgeon must maintain a basic knowledge of cardiopulmonary bypass physiology and techniques.
A coordinated communicative network between Anesthesia, Surgeon, Perfusionist, and Nursing is crucial to operative success and avoidance of preventable complications. Probably, the most valuable component of the operative phase, is a regularly scheduled meeting of the operating room team, including the ICU staff, to discuss routine protocols, problems, concers, suggestions, and other items that all contribute to a «smooth running service» . This is a notable example of the Hawthorne effect.

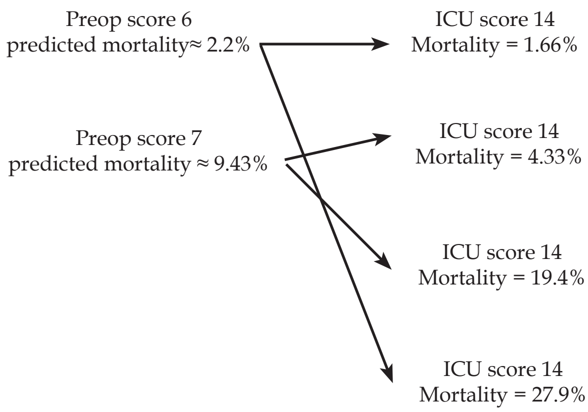
Post-operative Phase

RISKS AFTER ARRIVAL IN THE INTENSIVE CARE UNIT (ICU)
In general, risk is stratified for the overall cardiac surgery experience, including early outcomes for the operative procedure based on preoperative risk factors. The APACHE III score (Acute Physiologic And Chronic Health Evalu ation), however, is used only for non-cardiac surgery risk based on clinical presentation upon arrival in the ICU[94]. Since application of the APACHE III to cardiac surgery is difficult (with many variables changing rapidly due to the manipulation that occurs early), a refined APACHE III was developed for patients undergoing CABG[94] . Independent predictors of survival were acute physiology score, age, emergency operation, reoperation, number of grafts performed and gender .
Higgns et al[95], from the Clevel and Clinic, developed an ICU admission score for predicting morbidity and mortality (Figure 23)

Figure 23 : ICU admission score for predicting morbidity and mortality

Variable	Value
Preoperative factors	
Small body size (BSA<1.7m²	1
Prior hear operation	
One	1
Two or more	2
History of operation or angioplasty for peripheral vascular disease	3
Age ≥ 70 years	3
Preoperative creatinine ≥ 1.9mg/dl	4
Preoperative albumin < 3.5 mg/dl	5
Intraoperative factors	
CPB time ≥ 160 minutes	3
Use of IABI after CPB	7
ICU admission physiologie	
A-a O_2 gradient ≥ 250 mmhg	2
Heart rate ≥ 100 beats/min	3
Cardiac index < 2.1 L. $min^{-1}.m^2$	3
CVP ≥ 17 mmHg	4
Arterial bicarbonate < 21 mmol/L	4

A-a = Alveolar-arteriol BSA=body surfaces area; CPB= Cardiopulmonary bypass CVP = Central veinous pressure IABP intraaortic balloon pump; ICU= intensive care unit



This allowed sequential assessment of prognosis, and improved This allowed sequential assessment of prognosis, and improved stratification because of a continliously updated data. For example, the use of intra-aortic balloon counter pulsation (IABP) signified a worsening prognosis likely due to a significant intracardiac event related to degree of pathology, myocardial protection, technical events or extended cardiopulmonary bypass times. Knaus[96] gives a nice historical review of APACHE, noting that over 2000 peer review articles utilize APACHE as a key component for the methods and results section. Assessments have been made for risks after the fust ICU day. Kubn et al[97], utilizing APACHE, noted a mortality of 500/0 for patients

with APACHE score of 28 after the first ICU day. Another consideration is readmission to the ICU.
This is a significant event. Bardel et al[98] noted a 3.6% readmission rate with pre-operative renal failure and initial mechanical ventilation for >24 hour following CABG as risk factors for readmission. Again, prolonged ICU-WS is an independent variable for complications and poor outcomes. Williams et al[99] noted that in a group of 49 patients (3.8% of total over a one year period) remaining in ICU > 14 days had a 28.5% in hospital mortality; compared with 5.3% ofthose in ICU <14 days. At 2 years there were 22 of 35 discharged patients alive (81% survival); or 45% of the original 49 patients. The older Ontario score system (Figure 24) is still useful in correlating overall mortality, ICU-LOS, and Postop-LOS[13].

Figure 24 : Ontario Score : Risk Index for mortality, ICU LOS and PostOp LOS[13]

Risk Factor	Risk Score
Age, Y	
< 65	0
65-74	2
≥ 75	3
Sex	
Male	0
Female	1
Left ventricular function	
Grade 1	0
Grade 2	1
Grade 3	2
Grade 4	3
Type of surgery	
CABG only	0
Single valve	2
Complex	3
Urgence of surgery	
Elective	0
Urgent	1
Emergency	4
Repeat operation	
No	0
Yes	2
Range of scores	

	Observed Mortality Rates, ICU, LOS and Postop LOS by Risk Score in-hospital			
Risk score	Patients %	Mortality Rates %	Mean ICU LOS,d	Mean PostOp LOS,d
0	11,81	0,25	2,27	8,04
1	14,73	0,79	2,39	8,43
2	17,84	1,30	2,81	9,25
3	17,07	2,89	2,89	10,35
4	14,23	4,59	3,16	10,97
5	10,72	5,69	3,31	11,44
6	6,43	8,13	3,68	12,80
7	3,88	11,61	4,33	13,14
≥ 8	3,30	13,22	5,87	14,51

The ICU is a complex environment. Nast et al[100] report a contemporary experience in an ICU setting. The goal was to evaluate voluntary patient safety events. Physicians, nurses, and allied health personal participated. Of 157 events reported 85.54% caused no harm, 48% were human factor related, and 34% organizational or system related. The data highlights the value of voluntary, confidential, non-punitive approaches, used in a constructive manner to identify errors, near misses, and other causative factors.

Long Term Results

Outcomes after hospitalization have become increasingly important in terms of quality of life. Basically, quality of life (QOL) indicators are objective and subjective. Objective health status and function can be assessed directly with patient contact by health care professionals. Subjective assessment is the patients perception of how they feel or are doing. QOL can be generic (eg SF-36; Seattle Questionnaire; Notti gham Health Profil e), functional status, disease specific, or symptom severity. As mentioned, SF-36 form is a short questionnaire with eight multi-item variables (Figure 22)[101]. Falcoz et al[102] found the SF- 36 more suitable for cardiac surgery compared to the Nottingham Health Profile (Figure 22); especially with regards to the assessment of angina and dyspnea. Lindsay et al[103] reported 214 patients undergoing CABG in whom the SF-36 form was used before and after operation. At a mean of 16.4 months postoperatively, the SF-36 score showed that high levels of social support were associated with improved health status and quality of life. Simchen et al[10]4 in a study from Israel, reported on 1270 patient one year following CABG. One-third reported their quality of life as not good, particularly females and those of lower socioeconomic status. Rehabilitation programs were targeted as the reason for improvement. QOL measures are becoming increasingly utilized as predictors of health related quality of life (HRQL) outcomes. Preoperative SF 36 studies were performed before, and at 6 mos, and 1 year post-operatively. A VA study[105] evaluated 1,973 patients undergoing coronary artery bypass (CABG) surgery before and six months postoperatively. Multivariable analysis targeted current smoking and psychiatric disease as targets for improvement. A French study[106] evaluated CABG and valve patients pre-operatively and one year postoperatively. Functional status was better for valve patients with NYHA functional class or and angina class or as predictors of impairment at one year. These quality of life measures following CABG will undoubtedly become more important as the population ages. More importantly, six month and twelve month outcomes in terms of mortality may be better indicators for quality assurance than the traditional 30 day or hospital mortality reporting.

COST

The number of Medicare patients has risen to over 40 million, with the number of uninsured rising to an almost equal number. Access to care and rising costs continue to challenge healthcare providers. The Health Care Financing Administration [HCFA: now called Centers for Medical and

Medicaid Services (CMS)] budget has risen from 21.5 billion in 1977 to 214.6 billion in 1997[107], with treatment for coronary artery disease accounting for more than 80 billion of that cost, and CAD continuing to be the leading cause of death and morbidity in the USA. The total cost of cardiovascular disease and stroke in the USA in 2005 is estimated at $393.5 billion. (Figure 1) This includes the direct costs of $241.9 billion and the indirect costs of $151.6 billion (lost productivity morbidity and mortality).

This all translates in to approximately 16% of GNP spent on healthcare. At the same time, expensive medical technology continues to grow and develop. With the escalating costs of cardiac surgery, attempts have been made to find effective ways to reduce these costs while maintaining good outcomes. Beginning in the last decade, individual cardiac surgeon and institutional results in New York State were made available to the media and public, causing outcries both within the medical establishment and the general public[108]. CMS has mandated progressively lowering reimbursements, utilizing DRG's for cardiac surgical procedures, in a further attempt to control the continuing growth of operations and cost.

Initiated in 1983, Diagnosis- related-groups or DRD's are reimbursed fixed fees for each patient admission, regardless of the provider's actual incurred costs. These prospective payments shifted financial risk from payers to hospitals. Adopted by other third party payers, variations of payment have evolved, including «capitation» or lump sum payment for all in patient care. The reimbursement for cardiac surgery from Medicare decreased 9.3% from 1991 to 1997[102]. With a rising population at risk and the in flux of the baby boomers into this patient mix , financial issues will become even more critical and relevant.

The specific cost of CABG has been studied extensively, with particular attention given to preoperative risk factors and complications, both of which increase length of stay (LOS). Taylor[109] prospectively studied 500 patients undergoing CABG, and found a charge of $11,900+12,700. No preoperative clinical features were significant predictors of cost, whereas postoperative sternal wound infection, respiratory failure and LV failure were. Ferraris et al[110] studied hospital charges in 938 patients undergoing CABG. They found that risk factors for postoperative morbidity are different than those for postoperative mortality. Their findings suggested that older patients with preoperative anemia and low blood volume who also have other comorbidities (CHF, stroke, COPD or hypertension) are at increased risk for postoperative complications and increased hospital costs. The most costly outcome in their study was perioperative death. Cohen et al[111], analyzed hospital cost, (not charges) for 89 elective CABG patients with an average postoperative LOS of 9.3 days and found the total costs were from $17,420, $19,153 and $21,828 for the 25th, 50th and 75th percentiles, respectively. Williams et al[112], found increased cost to be correlated with high aver age risk (utilizing the Parsonnet equation) and increas ed LOS in 2,589 CABG patients. Shahian et al[113], however showed no correlation between hospital size, volume of surgery and cost.

Strategies to decrease cost include operating on lower risk patients, more expedient surgery (i.e. on the same admission as diagnostic catheterization, same day admissions, decreasing ICU and restrictive hospital stay, improved home care, and greater use of chronic care facilities and rehabilitation centers). Shorter LOS in the acute car e hospital, however, has led to increased readmission rates, and more frequent discharges to chronic facilities, along with increasing utilization of home health services. Lazar et al[114], demonstrated a distinct change from 1990 to 1998, with discharge-tohome-with-services increasing from 14.75% to 46.5%, and transfer to rehabilitation units increasing from 2.9% to 13.7%. Readmission rates fol lowing cardiac surgery range from 5.3% to 20.9%[114-118]. Preoperative risk factors associated with increased readmission rates include female sex, diabetes, chronic lung disease and preoperative atrial fibrillation[117-118]. The most common readmission diagnoses have included atrial fibrillation, angina, congestive heart failure, ventricular tachycardia, wound problems, pneumonia and gastrointestinal complaints[115].

Evidence-Based Medecine (EBM)

EBM provides a basis for the evaluation of treatment and application to a specific clinical problem or situation. Meakins[119] nicely summarizes the five steps in EBM : define the question or problem; search for the evidence; critically evaluate the literature; apply the results; and audit the outcome. A number of resources have emerged as a source EBM information i.e. (*www.clinical evidence.org) (www.ebmny.org), (www.cochrane.org*).

Familiarity with the precepts and principals of EBM will help facilitate the organization of a large amount of information and enable the practitioner to answer clinical questions at the point of care in real time. It is important to note the historical contribution of Archie Cochrane to the EBM concept[21,120,121]. A quote summarized hisrtionale: «I had considerable freedom of clinical choice of therapy: my trouble was that I did not know which to use and when. I would gladly have sacrificed my freedom for a little knowledge[21]». Thirty years later we are a lot closer to that knowledge.

Simply put evidence is the link between what we know and what we do in medicine. EBM is designed to achieve optimal management of clinical problems or challenges. From this, practice management guidelines, paradigms and algorithms can be developed. The ultimate focus of risk stratification and outcome assessment is to account for differences in patient risk factors so that patient outcomes can be used as an indicator of quality of care. A major problem arises in attaining this goal because uniform definitions of quality of care are not available. A grading or standardized classifications system has emerged that recognizes the difficulties in defining «best practices» for a given illness or problem. Professional organizations have opted to promote practice guidelines or «suggested therapy» for given disease[122,123] (Figure 25, 26).

Figure 25 : grading of Recommandations and Levels of Evidence*

GRADE A	
Level 1a	Evidence from large randomized clinical trials (RCTs) or systematic reviews (including meta-analyses) of multiple randomized trials which collectively has at least as much data as one single well-defined trial.
Level 1b	Evidence from at least on "All or None" high quality cohort study; in which ALL patients died/failed with conventional therapy and some sur vived/succeeded with the new therapy (e.g. chemotherapy for tuberculo sis, meningitis, or defibrillation for ventricular fibrillation); or in which many died/failed with conventional therapy (e.g. penicillin for pneumo coccal infections).
Level 1c	Evidence from at least one moderate sized RCT or a metaanalysis of small trials which collectively only has a moderate number of patients.
GRADE B	Level 1d Evidence from at least one RCT.
Level 2	Evidence from at least one high quality study of non-randomized cohorts who did and did not receive the new therapy.
Level 3	Evidence from at least one high quality case control study.
Level 4	Evidence from at least one high quality case series.
GRADE C	
Level 5	Opinions from experts without reference or access to any of the foregoing (e.g. argument from physiology, bench research or first principles).

**Adapted from (122) Yusuf S, Cairns JA, Camm AJ, Fallen EL, Gersh BJ. Evidence based Cardiology. 1998 BMJ Books, London p2*

Figure 26 : ACC/AHA Classification for Guidelines Series[123]

The ACC/AHA classifications I, II and III are used to summarize indications as follows:

Class I	Conditions for which there is evidence and/or general agreement that a given procedure or treatment is usefulClass
ClassII	Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/or efficacy of a procedure.
Class IIa	Weight of evidence/opinion is in favor of usefulness/efficacy.
Class IIb	Usefulness/efficacy is less well established by evidence/opinion.
Class III	Class III: Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful

These guidelines or recommendations represent a compilation of available published evidence, including randomized trials and risk adjusted observational studies, as well as consensus among panel of experts proficient at treating the given disease[115]. For example, the practice guideline for coronary artery bypass grafting is available on the internet *(www.acc.org/clinical/guidelines/bypass/ExecIndex.htm)* for both practitioners and the lay public. (Figure 27)

Figure 27 : 1999 AHA/ACC Guidelines for CABG in ST-segment elevation (Q-wave) MI[123]

Indication and clinical condition	Definition of level of evidence
Class I None	Class I : Conditions for which there is evidence and/or general agreement that a given procedure or treatment is useful and effective.
Class IIa 1. On going ischemia/infarction not responsive to maximal therapy. Class IIb : 1. Progressive LV pump failure with coronary stenosis compromising the initial infarct area. 2. Primary reperfusion in the early hours (<6 to 12 hours) of an evolving ST-segment elevation MI.	Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness or efficacy of a procedure. Class IIa: Weight of evidence/1. opinion is in favor of usefulness/efficacy. Class IIb: Usefulness/efficacy is less well established by evidence/opinion.
Class III : 1. Primary reperfusion late is (>12 hours) in evolving ST-segment elevation MI without ongoing ischemia	Class III: Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful

Figure 27 illustrates the 1999 AHA/ACC Guidelines for coronary artery bypass grafting in patients with acute (Q-wave) myocardial infarction. These guidelines were developed using a summation of available randomized controlled trials, risk adjusted observational studies, and expert consensus. They are meant to provide clinicians with accepted standards of care that most would agree upon, with an ultimate goal of limiting deviations from accepted standards. Guideline development continues to represent a work in progress. The methodology for developing guidelines for disease treatment is evolving. Many published guidelines do not adhere to accepted standards for developing guidelines[124]. The area where greatest improvement is needed is in the identification, evaluation and synthesis of the scientific evidence.

An implicit part of assessing outcome is the development of a best standard of care for a given illness or disease process. Once the most efficacious treatment is known then comparisons with, or deviations from, the standard can be assessed - a process called «benchmarking». As mentioned above, the «best standard» is not always known. Meta-analysis is a quantitative approach for systemically assessing the result s of multiple previous studies to determine the best outcome. The overall goal of meta-analysis is to combine the results of previous students to arrive at a consensus conclusion about the bet outcome. Stated in a different way, meta-analysis is a tool used to summarize efficacy studies (usually RCT's) of an intervention in a defined population with disease in order to determine which intervention is likely to be effective in a large population with similar disorder.

Meta-analysis is a tool that can relate efficacy studies to effectiveness of an intervention by summarizing available medical evidence. To date EBM recommendations are slowly evolving regarding the perioperative care of the cardiac surgery patient. In addition to EBM indications for coronary acting bypass grafting, similar guidelines are available for valve surgery *(www.acc.org/clinical/guidelines/valvular /dir index.htm) .*

Teaching and incorporationg EBM into Clinical training programs has developed[125]. The American College of Surgeons has established the Office of Evidence- Based Surgery (OEBS)[126]. They have utilized the four steps as developed by Sackett et al[127] :

(1) Formulate a question based on a clinical situation encourtered in daily practice.

(2) Do a focused search of the relevant literature.

(3) Critically appraise the literature obtained to find the best evidence.

(4) In tegrate the information and act in accordance with the best available evidence.

So who is involved in these 4 steps. The individual surgeon can accomplish (step 1 and 4). A librarian or independent Pub Med search can identify the available literature (step 2). Critical appraisal is the difficult area. Interpretation of the literature and statistical knowledge can be a formidable challenge (step 3). Research coordinators and unbiased committees within the concerned societies are in the best position to generate overall recommendations. Yet the individual surgeon must have a basic understanding of statistics. Critical analysis of the literature is crucial to the process of understanding and making any necessary changes or adjustments in one's clinical practice[128]. Since approximately 30% of journal articles may contain errors a basic knowledge of statistics and research design is useful[128].

Formulating the question (step 1) is basic to the EBM process. The clinical question is formulated as PICO[129]:

P - Patient/problem
I - Intervention
C - Comparison
O - Outcome(s) of interest

A clinical example is given :

What is the value of laser transmyocardial myocardial revascularyation (TMR) with no option angina.

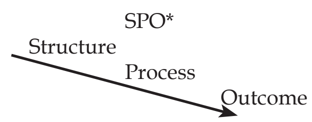
P - Patient with unstable angina or bypassable lesions
I - TMR
C - No TMR
O - Early, mid, or long term results.

Dunning et al[129] have nicely organized a best evidence series in cardiac surgery. A structured protocal has been constructed to answer the patient problem (p) : Introduction; Clinical scenario; 3 Part question (eg - No option angina; TMR; angina relief or survival) ; search strategy; search outcome[130,131]. Outcome analysis has become the ultimate test of all of our efforts. This has been clearly echoed by Donabedian: «Outcomes are much more easily used… only as cues that prompt and motivate the assessment of process and structure in a search for causes that can be remedied[132,133].» Further, Donabedian views quality as the ultimate goal. It depends on 2 interdependent variables : technical and interpersonal. Technical is basically our craft or what we do; interpersonal is interaction with our patients, balancing their needs and wants.

Quality Assurance/Quality Improvement

The ultimate goal is to make the surgical operation safer and minimize on toward results or complications. The search for the Holy Grail of perfection will continue, or, in economic terms, for high quality providers or valuebased purchasing. The experts agree that humans cannot perform flawles sly and the expectation of perfection is unattainable. Reason[17] and Sundt[31] have emphasized structure or systems with human components as a part. This structure or system starts or continues a pr ocess or function. Finally the outcomes or results are analyzed, evaluated, recorded, and subsequently reported. Birkmeyer et al[134] has beautifully outlined the structure, process, and outcome process (Figure 28).

Figure 28 : Summation



Structure

- Surgeon - Character/Personality/Competence - Human Factor- Staff - Support - Team - Product Line - Clinical Care Pathways - Hospital - infrastructure/volume/resources - Systems - Patient - Risk assessment

Process

- Effective - EBM (evidence-based-medicine)
- Safe - Surgeon/System related
- Timely - waits/delays
- Efficient - Cost control/Personal waste
- Patient centered - Individual Focus
- Equitable – Quality to all served

Outcome

- Surgeon participation
- Evaluation/Database
- Methods of analysis
- Results/Critiques/"Report Card"
- PDSA cycle (Plan/Do/Study/Act) (see Figure 9)

** Modified from (134) Birkmeyer, JD, Dimick, JB. Birkmeyer, NJ Measuring the quality of medical care; Structure, Process, or Outcomes? J Am Coll Surg 2004;198:626-632*

Surgical competence and proficie ncy r emains a key component of the structure, process, and outcome (SPO) cascade. Satava et al[135] have summarized the ACGME six components of competence (Figure 13) and add proficiency as the level of performance in each area of competence. To maintain proficiency requires evidence of professional standing, lifelong learning and quality improvement, cognitive expertise, and practice performance. Unless the surgeon and surgical community engage in maintaining competence/proficiency, as well as buying in or investing in the total SPO effort, the entire effort will be compromised.
A useful and practical device that br idges the statistical and tactical aspects is the critical paths or pathways. Utilizing clinical guidelines as a basis these pathways are designed to reduce vari ation in care, decrease resource utilization, costs and, hopefully, improve quality[136]. One potential weakness in this approach is application to the complicated or «less ideal» patient.
Outcome analysis has received the most attention in this quality assurance effort. Certain lessons have been learned: Crude mortality is not enough; differences related to chance and casemix do make a difference; disclosure of results to the general public can encourage potentially harmful consequences; and data collection requires organized and experienced individuals and teams.
On a practical note, the available database record should be initiated early in the process, usually at the time of surgery. Computer entry following the operation by an unbiased, designated database person is recommended, and cruci al to the process. Subsequent perioperative events are recorded at the time of discharge. Partiality re. what events took place or what constitutes complication remain a sensitive and controversial area. Again, the discharge coding (ICD-9) is crucial to subsequent chart reviews[39]. The computer tool s and systems utilized to collate, analyze, and validate the data and make subsequent conclusions and recommendations continue to evolve.
There are 3 risk-adjustment database systems presently being used by many centers and groups: National Surgical Quality Improvement Program (NSQIP); DXCG; and Charlson Comorbidity Index (CCI)[137]. The NSQIP utilizes medical record abstraction, whereas the other 2 use secondary data produced by hospitals for accounting/billing purposes. These last two utilize ICD-9 Codes. Blackstone, Rogers, Spiegelhalter, and Treasure have nicely summarized the outcome analysis process and debate, with particular attention to CUSUM or cumulative sum charts[27-30]. This charting system is designed to identify deviation from a performance standard. Its forte is that it provides early warning signs for subtle changes or problems in a system. Whereas the CUSUM methods examine overall surgical outcomes, it does not compensate for variable case mix . VLAD charts (Variable Life Adjusted Display) address this situation[138] That probably sums up the whole purpose of report cards – recognize problems early and offer solutions, rather then affixing blame. Herein lies the strength of the Northern New England study group. *(www.nnecdsg.org/)*
A focused regional group of centers have combined in a proactive way to share data, analyze it in a constructive way, and offer suggestions and recommendations for change or improvement.
There is a word of caution regarding mandatory databases. Shahian et al[139] have nicely documented the evolution and initiation of a mandatory reporting system in Massachusetts. The major progressive element in this program is the statewide adoption of the Society of Thoracic Surgeons (STS) National Cardiac Database (NCD). Grun kemeier, et al[140] in commenting on the Massachusetts argue that the model entails both continuous quality improvement (CQI) which is proactive and progressive, and cardiac report cards which can be negative, and at times punitive. They applaud the well received Northern New England Cardiovascular Disease Study group model which is voluntary, and the participants controlling the data[141].
In summary, quality assur ance is shifting from quality improvement to performance or value improvement.
This becomes a pro-active movement that is less punitive and accusatory and more constructive. The joint commission on the accreditation of Healthcare Organizations (JCAHO), as well as the American College of Surgeons in collaboration with the National Surgical Quality Improvement Program have been notable examples of this improvement effort. It is interesting to compare a macro approach, i.e. JCAHO, and the micro approach, i.e. a clinical cardiathoracic surgery working in the trenches (Figure 29).

Figure 29 : Components of Quality Assurance/Performance

JCAHO[142]	V. A. Gaudiani[143]
- Accessibility of Care - Appropriateness of Care - Continuity of Care - Effectiveness of Care - Efficacy of Care - Efficiency of Care - Patient Perspective Issues - Safety of Care Environment - Timeliness of Care	- Patient Satisfaction - Institutional process - Outcomes - Appropriateness of care - Efficiency of resource management

The strategic/tactical top/down and the strategic bottom/up approaches are sur prisingly similar[142,143]. The strategic and tactical goals have thus been set. The basic tools are now available, and continue to evolve and improve. Application is the ongoing process, with the ultimate goal of making surgery and surgic al decisions safe and beneficial for the patients we treat and serve.

References
1- Shumaker HB. The Evolution of Cardiac Surgery. Indiana Univ er si ty Pre ss, Bloomington, 1992 Ch 2 p. 11-17 .
2- Harken DE. The emergence of cardiac surgery I. Personal Recollections of the 1940's an1950's. J Thorac Cardiovasc Surg 1989; 98:805- 813.
3- Swan, H. Zeavin I. Blount, SG, Virtue RW. Surgery by direct vision in the open heart during hypothermia JAMA 1953; 153:1081-
4- Lillehei CW, Varco RL, Cohen M, Warden H E, Patton C, Moller JH. The first open heart repairs of Ventricular Septal Defect, and Atrioventricular Communis and Tetraology of Fallot using Extracorporeal circulation by cross-circulation: A 20-year follow-up . Ann Thorac Surg 1986; 41:4-2 1.
5- G ibbon JH. Application of a mechanical heart and lung apparatus. Minnesota Medicine 1954; 37:171-185.
6- Popovic JR, Hall MJ. 1999 National Hospital Discharge Survey, Advance Data number 319, Center for Disease Control and Prevention. Apri124, 2001, p.1-20.
7- Kirklin JW. Technical and scientific advances in Cardiac Surgery over the past 25 years. Ann Thorac Surg 1990; 49:26-31.
8- Relman AS. Assessment and accountability-The third revolution in medical care. New Engl J Med 1988; 319:1220-1222.
9- Grover, F.L., Cleveland, JC, Shroyer, LW. Quality Improvement in Cardiac care Arch Surg 2002; 137:28-36. Afr. Ann. Thorac. Cardiovasc. Surg. 2007; 1(3)
10- Lahey SJ, et al. Preoperative risk factors that predict hospital length of stay in coronary artery bypass patients > 60 years old. Circulation, 1992; 8:111 81-85.
11- Ferraris VA, Ferraris SP. Risk factors for postoperative morbidity. Journal of Thoracic and Cardiovascular Surgery, 1996; II:731-738; discussion 738-741.
12- Hammermeister KE, et al. Identification ofpatients at greatest risk for developing major complications at cardiac surgery. Circulation, 1990; 82:IV 380-389.
13- Tu JV, Jaglal SB, Naylor CD. Multicenter validation of a risk index for mortality, intensive care unit stay and overall hospital length of stay after cardiac surgery. Steering Committee of the Provincial Adult Cardiac Care Network of Ontario. Circulation, 1995; 91:677-684.
14- Institute of Medicine. Kohn LT, Corrigan JM, Donaldson MS, eds. To Err is Hum an. Washington, DC, National Academy Press, 1999.
15- Carthey J, de Levai MR, Reason JT. The human factor in Cardiac Surgery: Errors and near misses in a High Technology Medical domain. Ann Thoracic Surg. 2001; 72:300-305.
16- Reason J. Human Error Cambridge University Press New York, 1990, Chapter I, 3.
17- de Levai MR, Carthey J, Wright DJ, Farewell VT, Reason JT. Human factors and Cardiac Surgery: A Multicenter Study. J Thorac Cardiovasc Surg. 2000; 119:661-672.
18- Kouchoukos, NT, Blackstone, EH, Doty, D8, Hanley, FL, Karp, R.B. ed. Kirklin/Barratt-Boyes Cardiac Surgery, 3rd ed. Churchill, Livingstone Philadelphia, 2003. p 256-262.
19- Edmunds LH, Clark RE, Cohn LH, Grunkemeier GL, Miller DC, Weisel RD. Guidelines for reporting morbidity and mortality after cardiac valvular operations. J Thorac Cardiovasc Surg. 1996; 112:708-711.
20- Passaro EA, Organ CH. Ernest A. Codman: The Improper Bostonian. Bulletin of Am ColI of Surgeons 1999; 84: 16-22.
21- Ferraris, VA, Ferraris, SP. Ch6 -Risk Stratification and Comorbidity. ln. Cohn, LH, Edmunds, CH, ed. Cardiac Surgery in the Adult, 2nd ed. New York, Mc Graw-Hill, 2003 pI87-224.
22- Griswold ML George J, Heuer MD. A critical analysis of the role that he played in introducing the residency system of training. Surgery 1975; 78:349-362.
23- Sloan H, Kirsh MM, Orringer MD. Thoracic Surgery training at the University of Michigan Chest Surgery Clinics of N America 2000; 10:210-211.
24- Spencer FC. Observations on the teaching of Operative Technique. Bulletin Am ColI of Surg March 1983;3-6.
25- De Levai, M.R. Beyond Flatland J. Thorac Cardiovasc. Surgery2003; 125:12-19.
26- Blackstone, E.H. Let the data Speak for themselves. Pediatric Cardiac Surgery Annual of the Seminars in Thorac and Cardiovasc. Surgery 2004; 7:192-198.
27- Blackstone, E.H. Monitoring Surgical Performance J. Thorac Cardiovasc. Surg 2004; 128:807-810.
28- Rogers, CA, Reeves, B.C., Caputo, M, Ganesh, JS, Bonser, R.S., Angelino, G.D. Control chart methods for monitoring cardiac surgical perfonnance and their interpretation. J. Thorac Cardiovase Surg2004; 128:811-819.
29- Spiegelhalter, D.J. Monitoring Clinical Perfonnance: A Commentary J. Thorac Cardiovase Surg 2004; 128:820-822.
30- Treasure, T, Gallivan, S., Sherlaw-Johnson, C. Monitoring Cardiac surgery perfonnance: A Commentary. J. Thorac Cardiovasc Surg 2004; 128:823-825.
31- Sundt, T.M., Brown, J.P., Uhlig, PN. STS Workforce on Patient Advocacy, Communications, and Safety. Ann. Thoracic Srugery 2005; 79:11-15.
32- Scherkenbach, WW: The Deming Route to Quality and Productivity Milwaukee, ASQC Quality Press, 1986.
33- Noland, TW. System Changes to improve patient safety BMJ 2000; 320:771-773.
34- Wehrli-Viet, M, Riley, JB, Austin, J.W. A Failure made effect analysis on Extracorporeal Circuits for cardiopulmonary bypass. JECT 2004; 36:351-357.
35- Rutherford, RB. Suggested standards for reporting complications in Vascular Surgery pl-10. Complications in Vascular Surgery, Bernhard, VM, Towne, rn, ed. Quality Med. Pub; St. Louis, 1991
36- Clavien, PA, Sanabria, JR, Strasberg, SM. Proposed Classification of Complications of Surgery with examples of utility in cholecystectomy Surgery, 1992; 111:518-526
37- Practice Guidelines in Cardiothoracic Surgery. Ann Thorac Surg 1995;(suppl) S-l
38- Replogle RL. Responsibility, Honor and Integrity (or, How Do We Write the Perfect Practice Guidelines?) Ann Thorac Surg 1997; 63:7-8.
39- ICD-9 [Expert] for Physicians -Volumes 1&2. 2003 -6th ed. Ingenix St. Anthony Publishing/Medicode Salt Lake City, UT.
40- Current Procedural Tenninology CPT 2003 Standard Edition (4th ed) American Medical Association, Chicago plll-130.
41- Leach, DC. The ACGME Competencies: Substance or Fonn J. Am ColI Surg 2001;192:396-398.
42- Kwasnik, E.M. Accountability -the Fourth «A» J .Am ColI Surg 2004; 199:732-733.
43- Livingston EH, Harwell JD. The medicolegal aspects of proctoring. Am J Surg 2002; 184:26-30.
44- Livingston EH, Harwell JD. Peer Review. Am J Surg 2001; 182:103-109.
45- Satiani, B. The National Practitioner Data Bank: Structure and Function. JAm ColI Surg. 2004; 199:981-986.
46- Acsell, J.R. Professionalism as a Perfusion Problem JECT 2005; 37:136-147.
47- Lang NP. Professionalism liability, patient safety and first do no harm. Am J Surg 2001; 182:537-541.

48. Wells WJ. And Justice for Whom? J Thorac Cardiovasc Surg 1999; 177:211-219.
49- Pate JW, Cutting JA. ln defense ofmalpractice charges: A survey of the legal process. Ann Thorac Surg 1994; 58:1356-1361.
50- Palmisano, D. J. The Hidden Cost of Medical Liability Litigation. AnD Thorac Surg 2004; 79:9-13.
51- Grunkemeier GL., Zerr KJ., Jin R. Cardiac Surgery Report Cards: Making the Grade. Ann Thoracic Surgery, 2001; 72:1845-1848.
52- Hannan EL, et al. lmproving the outcomes of coronary artery bypass surgery in New York State. JAMA, 1994; 71:761-76.
53- Ghali WA, Quan H, Brant R. Coronary artery bypass grafting in Canada: national and provincial mortality trends. 1992-1995 CMAJ, 1998; 59:25-31.
54- Ghali WA, et al. Statewide quality improvement initiatives and mortality after cardiac surgery. JAMA, 1997; 227:379-382.
55- Weintrub WS, et al. Changing clinical characteristics of coronary surgery patients. Differences between men and women. Circulation, 1993; 88:1179-86.
56- Grover FL, et al. Factors predictive of operative mortality among coronary artery bypass subsets. Annals ofThoracic Surgery, 1993; 56:1296-1309; discussion 1306-7.
57. Iyer VS, et al. Mortality and myocardial infarction after coronary artery surgery. A Review of 12,300 patients. Medical Journal ofAustralia, 1993; 159:166-170.
58- Ivanov J, Ru JV, Naylor CD. Ready-made, recalibrated or remodeled? Issues in the use of risk indexes for assessing mortality after coronary artery bypass graft surgery. Circulation, 1999; 99:2098-2104.
59- Higgins TL, Estafanous, FG, Loop, FD, et al. Stratification of morbidity and mortality outcome by preoperative risk factors in coronary artery bypass patients. JAMA 1992; 265: 234-238.
60- Mozes B, et al. A national study of postoperative mortality associated with coronary artery bypass grafting in Israel. ISCAB Consortium. Israel Coronary Artery Bypass Study. Annals of Thoracic Surgery, 1998; 66:1254-1262; discussion 1263.
61- DeLong ER, et al. Comparing risk -adjustment methods for provider profiling. Statistics in Medicine. 1997; 16:2654-2664.
62- O'Connor GR, et al. Multivariate prediction ofin-hospital mortality associated with coronary artery bypass graft surgery. Northem New England Cardiovascular Disease Study Group. Circulation, 1992; 85:2110-2118.
63- Reich DL, et al. Intraoperative hemodynamics predictors of mortality, stroke and myocardial infarction after coronary artery bypass surgery. Anesthesia and Analgesia. 1999; 89:814-822.
64- Bernstein AD and Parsonnet V. Beside estimation ofrisk as an aid for decision-making in cardiac surgery. Annals of Thoracic Surgery. 2000; 69:823-828.
65- Parsonnet V, Dean D, Bernstein AD. A Method of Uniform Stratification ofRisk for Evaluating the Results of Surgery in Acquired Adult Heart Disease. Circulation. 1989; 79(suppl): 1-3-1-12.
66- Northern New England Risk Calculator. *http ://www.nnecdsg. org/supercard04 .pdf*
67- Pifarre R. Open Heart Operations in the Elderly: Changing Risk Parameters. Ann Thorac Surg 1993; 56:S71-73.
68- Craver JM, Paskas JD, Weintraub WW, et al. 601 Octogenarians Undergoing Cardiac Surgery: Outcome and Comparison with Younger Age Groups. Ann Thorac Surg 1999; 67:1104-1110.
69- Fruitman DS, MacDougalI CE, Ross DB. Cardiac Surgery in Octogenarians: Can Elderly Patients Benefit? Quality of Life After Cardiac Surgery. Ann Thorac Surg 1999; 68:2129-2135.
70- Abramov D, ramariz MG, Sever JY, Christakis Gr, et al. The Influence of Oender on the Outcome of Coronary Artery Bypass Surgery. Ann Thorac Surg 2000; 70:800-806.
71- O'Rourke DJ, Malenka DJ, Olmstead EM, et al. Improved In-Hospital Mortality in Women Undergoing Coronary Artery Bypass Orafting. Mn Thorac Surg 2001; 71:507-511.
72- Rexius, R, Brandrup -Wognsen, O, Oden, A, Jeppsson, A. Mortality on the waiting list for coronary artery bypass grafting: Incidence and risk factors. Ann Thorac Surg 2004; 77:769- 775.
73- Cesena FR, Favarato D, Cesar LA, de Oliveira SA, da Luz PL. Cardiac complications during waiting for elective coronary artery bypass graft surgery: incidence, temporal distribution and predictive factors. Eur. J Cardiothorac Surg 2004; 25:196-202.
74- Riley O, Lubitz J. Outcomes of surgery amount the Medicare aged: Surgical volume and mortality. Health Care Financing Review. 1985;71:37-47. ,
75- Showstack JA, et al. Association of volume with outcome of coronary artery bypass graft surgery. Scheduled vs. nonscheduled operations. JAMA, 1987; 257:785-789.
76- Rannan EL, et al. Investigation of the relationship between volume and mortality for surgical procedures performed in New York State hospitals. JAMA 1989; 262:503-510.
77. Rannan EL, et al. Coronary Artery Bypass Surgery -The relationship between in-hospital mortality rate and surgi cal volume after controlling for clinic risk factors. Medical Care 1991; 29: 1094-1107.
78. Farley DE, Ozminkowski RJ. Volume outcome relationships and in-hospital mortality: The effect of changes in volume over time. Medical Care 1992; 30-77-9.
79- Grumbach K, et al. Regionalization of coronary surgery in the United States and Canada -Oeographic access, choice and OUtcomes. JAMAJourn of the Am MedAssoc 1995; 274:1282-1288.
80- Shroyer ALW, et al. No continuous relationship between Veterans Affairs Hospital coronary artery bypass grafting surgical volume and operative mortality. Ann ofThorac Surg 1996; 61:17-20.
81- Sollano JA, et al. Volume outcome relationships in cardiovascular operations: New York State, 1990-1995. Journal ofThoracic and Cardiovascular Surgery 1999; 117:419-430.
82- Nallamothu BK, et al. The role of hospital volume in coronary artery bypass grafting: Is more always better? Journal of the American College ofCardiology, 2001; 38:1923-1930.
83- Rewitt M, and f.t. C.o.Q.o.o.H.C.I.A.a.t.N.C.P. Board, Interpreting the Volume-Outcome Relationship in the Context of Health Care Quality: workshop Summary. 2000, Washington, D.C.: Institute of Medicine. I-vii, 1-128.
84- Tu JV, Naylor CD. Coronary artery bypass mortality rates in Ontario. A Canadian approach to quality assurance in cardiac surgery. Steering Committee of the Provincial Adult Cardiac Care Network of Ontario. Circulation, 1996; 94:2429-2433.
85- Crawford FA, et al. Volume requirements for cardiac surgery credentialing: a critical examination. The Ad Hoc Committee on Cardiac Surgery Credentialing of the Society ofThoracic Surgeons. Annals of Thoracic Surgery. 1996; 61:12-16.
86- Birkmeyer J.D., Siewers AE, Finlayson EV. Hospital volume and surgical mortality in the United States. N. Engl J. Med 2002; 346:1128-1137.
87- Nallamothu BK, Eagle KA Ferraris VA, Sade R.M. Ethics in cardiothoracic Surgery: Should Coronary Artery Bypass Grafting be Regionalized. Ann Thorac Surg 2005; 80:1572-1581
88- Shahian D.M, Norman SL, Torchiana DF et al. Cardiac Surgery Report Cards: Comprehensive Review and Statistical Critique. AnD Thorac Surg 2001; 72:2155-2168.
89- Carey JS, Parker JP, Robertson JM, Misbach GA, Fisher A.L. Hospital Discharge to Other Healthcare facilities: Impact on In-Hospital Mortality. J Am ColI Surg 2003; 197: 806-812.

90- Mc Greevy J., Wiebe D. A preliminary measurement of the surgical personality. Am. J. Surg 2002; 184:121-125.
91- Wanzel KR, Ward M, ReznickRK. Teaching the surgical craft: from selection to certification. Curr Prob Surg 2002; 39:573-660.
92- Guerlain S, Adams R.B., Turrentine FB, et al. Assessing team performance in the operating room; development and use of a «black-box» recorder and other tools for the intraoperative environment. J. Am. ColI Surg 2005; 200:29-37.
93- Hance J., Aggarwal R., Stanbridge R. et al. Objective assessment oftechnical skills in cardiac surgery. Eur. J. Cardiothorac Surg 2005; 28:157-162.
94. Higgins TL. Quantifying risk and assessing outcome in cardiac surgery. J Cardiovasc Vasc Anes 1998; 12:330-340.
95- Higgins TL, Estatanous FG, Loop FD, et al. ICU admission score for predicting morbidity and mortality risk after coronary artery bypass grafting. AnD Thorac Surg 1997; 64:1050-1058.
96- Knaus WA, APACHE 1978-2001: The development ofa quality assurance system based on prognosis. Arch Surg 2002; 137:37-41.
97- Kuhn C, Muller-Werdan U, Schmitt DV et al Improved out-corne of APACHE ? score-defined escalating systemic inflammatory response syndrome in patients post cardiac surgery in 1996 compared to 1988-1990: the ESSICS-study pilot project Eur. J. Cardiothorac Surg. 2000; 17:30-37.
98- Bardell T., Legare JF, Buth KJ, Hirsch GM, Ali I.S. ICU readmission after cardiac surgery Eur. J Cardiothorac Surg 2003; 23:354-359.
99- Williams M.R., Wellner R.B., Hartnett EA et al. Long-term Survival and Quality ofLife in Cardiac Surgery Patients with prolon ged intensive care unit length of stay Ann Thorac Surg 2002; 73:1472-1478.
100- Nast PA, Avidan M, Harris CB. Reporting and classification of patient safety events in a cardiothoracic intensive care unit and cardiothoracic postoperative care unit. J. Thorac Cardiovasc Surg 2005; 130:1137-1143.
101- Jenkinson C, Coulter A, Wright L. Short form 36 (SF 36) health survey questionnaire: normative data for adults of working age. British Med J 1993; 306:1437-1440.
102-. Falcoz PE, Chocron S, Mercier M, Puyraveau M, Etievent JP. Comparison of the Nottingham Health Profile and the 36-item Health Survey Questionnaires in Cardiac Surgery Ann Thorac Surg 2002; 73:1222-1228.
103- Lindsay GM, Harlon P, Smith LN, Wheatley DJ. Assessment of changes in general health status using the short form 36 questionnaire 1 year following coronary artery bypass grafting. European J Cardio-thorac Surg 2000; 18:557-564.
104. Simchen E, Galai N, Braun O, Zitser-Gurevich Y, Shabtai E, Naveh I. Sociodemographic and clinical factors associated with low quality of life one year after coronary bypass operations: The Israeli Coronary Artery Bypass Study (ISCAB). J Thorac Cardiovasc Surg 2001; 121:909.919.
105- Rumsfeld, JS, Ho, PM, Magid, DJ et al. Predictors of Health .related quality of life after coronary artery bypass surgery. Ann Thorac Surg 2004; 77:1508-1513.
106. Falcoz PE, Chocron S., Stoica L. et al. Open Heart Surgery: One year Self-Assessment of Quality of Life and Functional Outcome. Ann Thorac Surg 2003; 76:1598-1604.
107- Iglehart JK. The American Hea1th Care System. Medicare. NEJM 1999; 340:327-332.
108- Harlan BJ. Statewide reporting of coronary artery surgery results: A view from Califomia. J Thorac Cardiovasc Surg 2001; 121:409.417.
109- Taylor GJ, Mikell FL, Moses HW, et al. Determinant of hospital charges for coronary artery bypass surgery: The economic consequences of postoperative complications. Am J Cardiol 1990; 65:309-313.
110- Ferraris VA, Ferraris SP, Singh A. Operative outcome and hospital cost. Joumal ofThoracic and Cardiovascular Surgery 1998; 115:593-602; discussion 602-603.
111- Cohen DJ, Breall JA, Ho KKL, et al. Economic of elective coronary revascularization. Comparison of costs and charges for conventional angioplasty, directional atherectomy, stenting and bypass surgery. J Am ColI Cardio11993; 22:1052-1059.
112- Williams JrTE, Fanning WJ, Benton WC, et al. What is the marginal cost for marginal risk cardiac surgery? Ann Thorac Surg 1998; 66:1969-1971.
113- Shahian DM, Heatley GJ, Westcott GA. Relationship of hospital size, case volume, and cost for coronary artery bypass surgery: Ana1ysis of 12,77 4 patients operated on in Massachusetts during fiscal years 1195 and 1996. J Thorac Cardiovasc Surg 2001; 122:53-64.
114- Lazar HL, Fitzgerald CA, Ahmad T, et al. Early discharge after coronary artery bypass graft surgery: Are patients really going home earlier? J Thorac Cardiovasc Surg 2001; 121 :943-950.
115- Lahey SJ, Campos CT, Jennings B, Pawlow P, Stokes T, Levisky S. Hospital readmission after cardiac surgery. Does «Fast Track» cardiac surgery result in cost saving or cost shifting? Circulation. 1998; 98:1I-35-1I-40.
116- D'Agostino RS, Jacobson J, Clarkson M, Svensson LG, Williamson C, Shahian DM. Readmission after cardiac operations: Prevalence, patterns, and predisposing factors. J Thorac Cardiovasc Surg 1999; 118:823-832.
117- Stewart RD, Campos CT, Jennings B, Lollis SS, Levitsky S, Lahey SJ. Predictors of30-day hospital readmission after coronary artery bypass. Ann Thorac Surg 2000; 70:169-174.
118- Ferraris VA, Ferraris SP, Harmon RC, Evans BD. Risk factors for early hospital readmission after cardiac operations. J Thorac Cardiovasc Surg 2001; 122:278-286.
119- Meakins JL. Innovation in surgery: The rules of evidence Am J Surgergy 2002; 183:399-405.
120- Editorial-Cochrane's Legacy. Lancet 1992; 340:1131-1132.
121- Cochrane AL. Effectiveness and efficiency -random reflection on health services. London: Nuffield Provincial Hospitals Trust, 1972.
122- Yusuf S, Cairns JA, Camm AJ, Fallen EL, Gersh BJ. Evidence based cardiology. 1998 BMJ Books, London p. 3-23.
123- Eagle KA, et al. ACC/AHA Guidelines for coronary artery bypass graft surgery: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to revise the 1991 guidelines for coronary artery bypass graft surgery). American College of Cardiology/American Heath Association. Journal of the American College of Cardiology 1999; 34:1262-1347.
124- Shaneyfelt TM, Mayo-Smith MF, Rothwangl J. Are guideli nes following guidelines? The methodological quality of clinical practice guidelines in the peer-reviewed medicalliterature. JAMA 1999;281:1990-1905.
125- Haines, S.J. Nicholas, J.S. Teaching Evidence-Based medicine to surgical subspecialty residents J. Am. ColI. Surg 2003; 197:285-289.
126- Troedter L.J., Thompson LL, Rohatgi C. Training Surgeons to do Evidence-based Surgery: A Collaberative Approach. J. Am. ColI Surg 2004;199:293-299
127- SackettDL, Straus SE, Richardson WS, et al. Evidence-based medicine. How to practice and teach EBM. 2nd ed Edinburgh, Churchill Livingstone; 2000
128- Ferraris VA, Ferraris SP. Assessing the medicalliterature: Let the buyer beware. Ann Thorac Surg 2003; 76:4-11.

129- Dunning J., Prendergast B., Mackway-Jones K. Towards evidence-based medicine in cardiothoracic surgery: Best BETS. Interactive Cardiovascular and Thoracic Surgery 2003; 2:405-409.
130- Sanni A., Dunning J. Best evidence Topic -Cardiac general-Is transmyocardial revascularization of benefit to people with no option' angina? Interactive Cardiovasculor and Thoracic Surgery 2004; 3:586-592
131- Sanni A., Dunning J. Best evidence topic -Cardiac General-Is transmyocardial revascularization of benefit in addition to coronary artery bypass grafting for patients with diffuse coronary disease. Interactive Cardiovasculor and Thoracic Surgery 2004; 3:581-585
132- Greene P.S., Baumgartner W.A. Ch.35 Cardiac Surgery p497-507 ln: Gordon, TA, Cameron, J.L., ed. Evidence Based Surgery Ist Ed London, BC Decker Inc; 2000.
133- Donabedian A. Evaluating the quality of medical care. Milbank 1996; 44:166-203
134- Birkmeyer JD, Dimick JB, Birkmeyer NJ. Measuring the quality of surgical care: Structure, Process, or Outcomes? J. Am Coll Surg 2004; 198:626-632.
135- Satava R.M., Gallagher A.G., Pellegrini CA. Surgical Competence and Surgical Proficiency: Definitions, Taxonomy, and Metrics. J. Am ColI Surg 2003; 196:933-948.
136- Every NR, Hochman J., Becker R., Kopecky S, Cannon CP. Critical Pathways: A Review Circulation 2000; 101:461-470.
137- Atherly A., Fink A.S, Campbell DC et al. Eva1uating alternative risk-adjustment strategies for surgery. Am. J. Surg 2004; 188:566-570.
138- Sherlaw -Johnson C., Gallivan S., Treasure T, Nashef S.A.M. Computer Tools to assist the monitoring of outcomes in surgery , Eur J Cardiothorac Surg 2004; 26: 1032-1036.
139- Shahian D.M., Torchiana D.F., Normand ST. lmplementation of a Cardiac Surgery Report Card: Lessons Leamed from the Massachusetts Experience. Ann Thorac Surg 2005; 80: 1146-1150
140- Grunkemeier G.L., Furnary A.P. Mandatory Database Participation: Risky Business. Ann Thorac Surg 2005; 80:799-801
141-. O'Connor GT, Plume SK, Olmstead EM et al. A regional prospective study of in-hospital mortality associated with coronary artery bypass surgery. Northem New England Cardiovascular Study Group. JAMA 1991; 266:803-809.
142- Dodson BA. Ch 79 Qua1ity Assurance/Qua1ity Improvement p2597-2612 Miller, RD ed. Anesthesia 5th ed. Harcourt, Asia Churchill Livingstone, Singapore 2000.
143- Gaudiani, VA. Comprehensive Quality for Cardiac Surgery *(http :/ /www .ctsn et. org/secti ons/n ewsandviews/inmyopini on/ articles/article-5.html)*

Bibliography

I. Complications in Cardiothoracic Surgery. Waldhausen, I.A., Orringer, MB. Mosby Year Book, St. Louis 1991
2. Cardiac and Noncardiac Complications of Open Heart Surgery Prevention, Diagnosis, Treatment. Kotler, MN, Alfieri, A Futura Pub. Co Inc. Mount Kisko, NY 1992
3. Complications -A Surgeon's Notes on an Imperfect Science. Atul Gawande. Henry Holt Co, New York 2002
4. Complications in Cardiothoracic Surgery -Avoidance and Treatment. Little, AG. Blackwell, Futura Elmsford, New York 2004
5. Carr, I.M, Krempin, I, Weintraub, RM -Ch 67- Clinical Quality and Cardiac Surgery pII03-1113. ln: Sellke, FW, del Nido, PI, wason, S.I. Sabiston and Spencer Surgery of the Chest 7th ed. Elsevier Saunders, Phila, 2005.
6. Bojar, R.M. Manual of Perioperative Care in Adult Cardiac Surgery 4th ed. Blackwell Publishing, Malden, MA, 2005
7. Cohn, LH, Edmunds, LH, ed. Cardiac Surgery in the adult 2nd ed. Mc Graw Hill, New York 2003
-Ferraris, VA, Ferraris, SP Ch 6 Risk stratification and comorbidity
-Grunkemeier, G, Jin, R. Ch 7 Surgical Treatment of Outcome Data
-Vijay, V, Gold, JP. Ch 18 Late Complications of Cardiac Surgery.