

Psychosocial Evaluation of Adult Cardiothoracic Transplant Candidates and Candidates for Long-term Mechanical Circulatory Support

by

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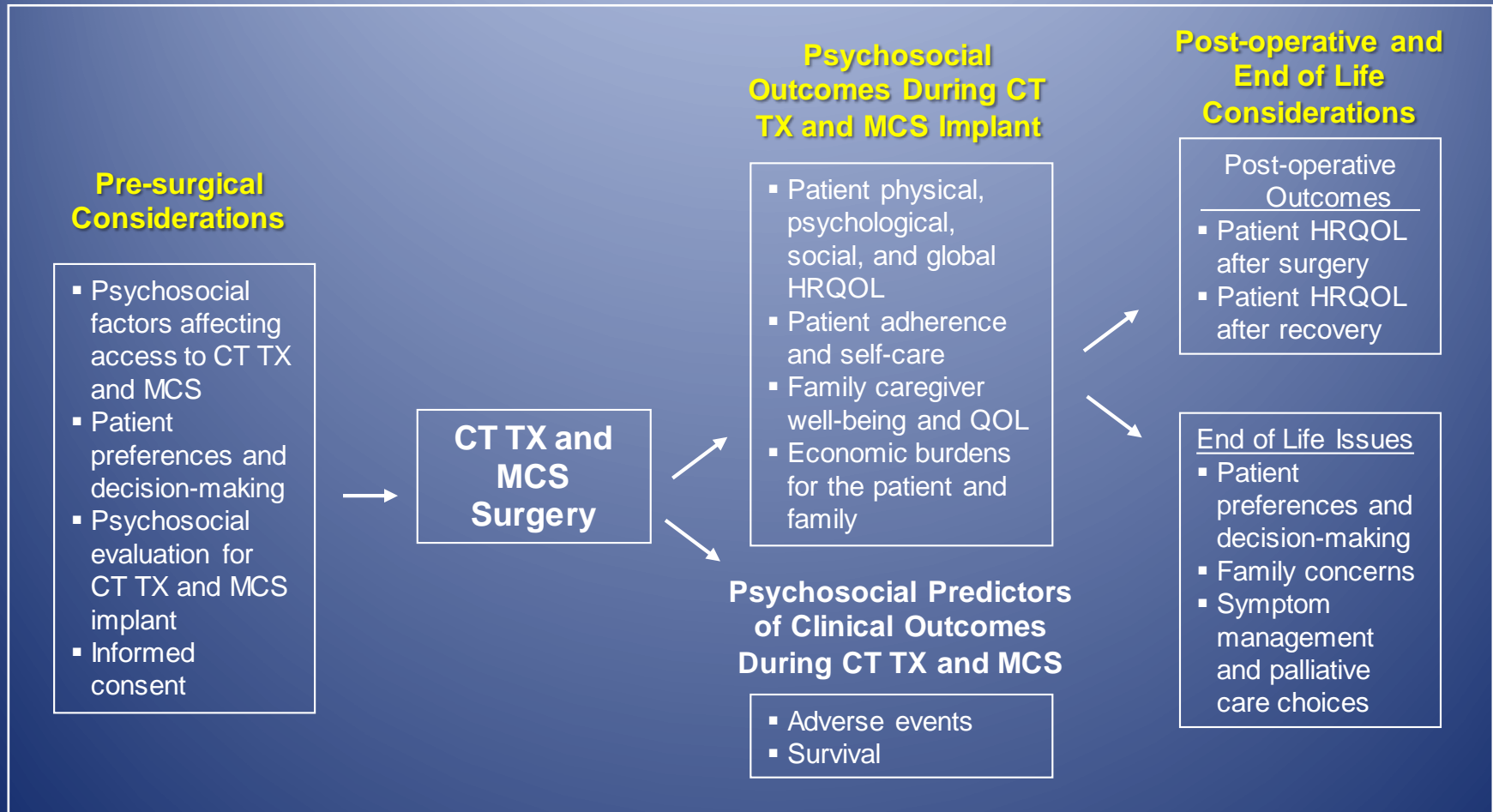
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Exceptional care in the heart of Chicago

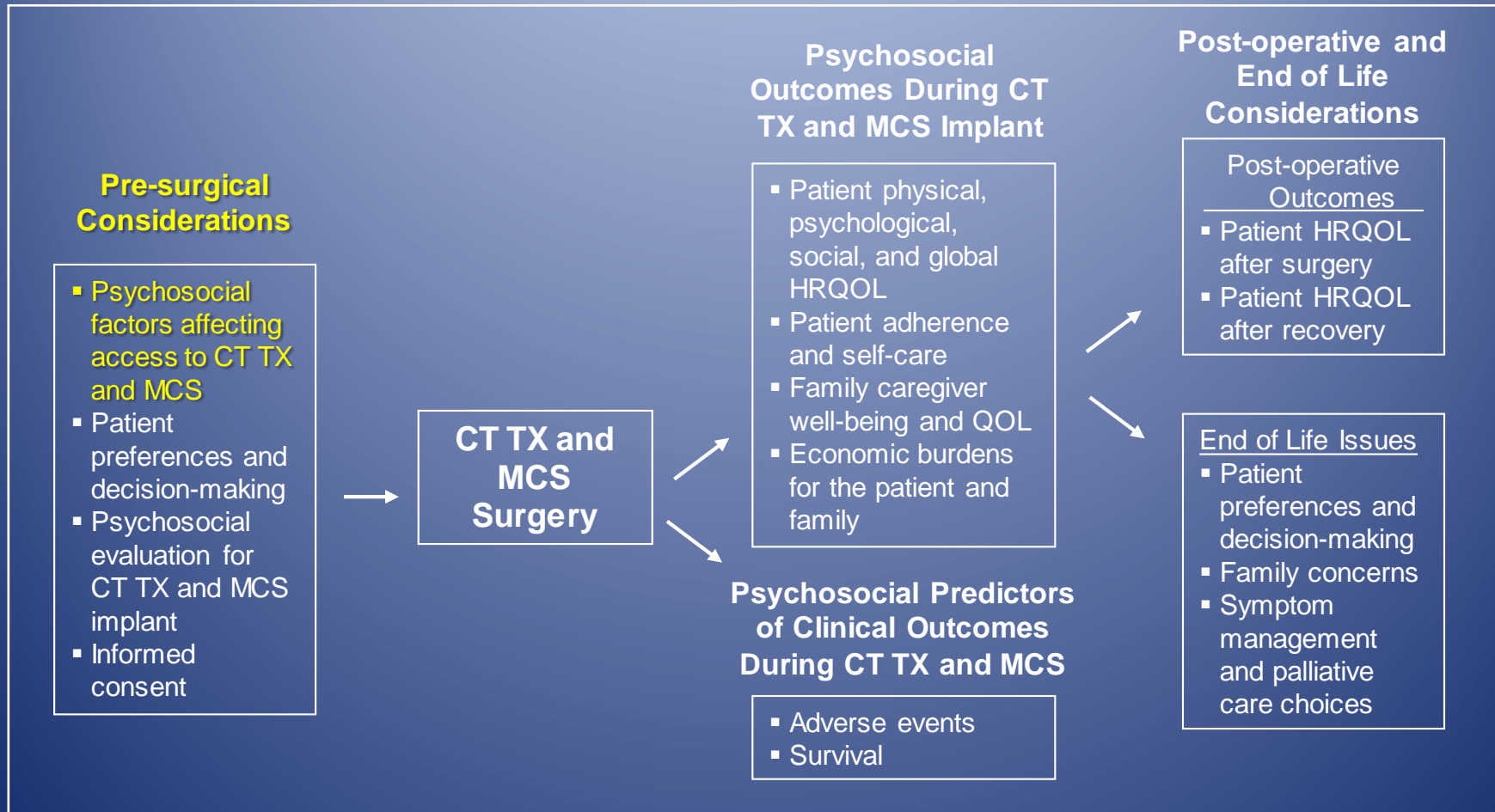
I have no disclosures relevant to this lecture to report.

Psychosocial factors at each stage of the transplant & mechanical circulatory support process



CT = cardiothoracic; TX= transplant; MCS = mechanical circulatory support; HRQOL = health-related quality of life

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Access to Care

- Race and sex disparities in receipt of CT TX and MCS stem from multiple factors
 - referral practices and biases
 - uneven application of evidence-based guidelines for care
 - patient preferences for care
- There is growing evidence that interventions that facilitate care provider adherence to clinical practice guidelines can reduce disparities in treatments offered to patients

HT in Women with Dilated Cardiomyopathy

- Single-center German study
(n=698 DCM pts referred to HT center [15.5% female])
- Women vs men more frequently:
 - NYHA III-IV
 - ↓ exercise tolerance
 - worse pulmonary and kidney function
- Referral for HT:
 - Women=16%
 - Men=84%
- Listing for HT:
 - Women=43%
 - Men=41%
- HT among listed patients:
 - Women=61% / 24% died
 - Men=55% / 33% died

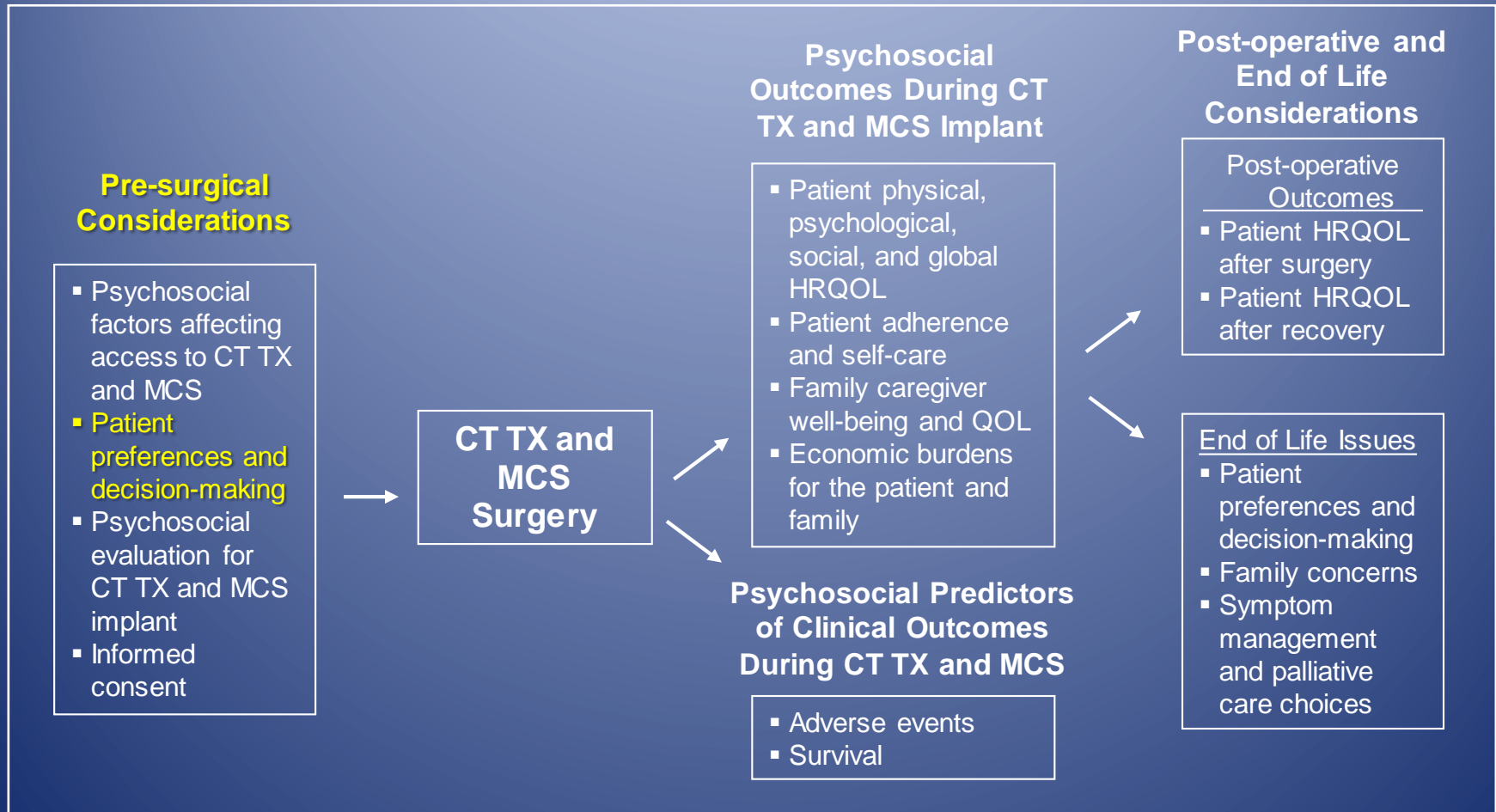
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Why were Female Referral Rates Lower?

- Single center U.S. study (*Aaronson KD, 1995*)
 - n=386 pts referred for management of mod-severe HF and/or HT evaluation
- Female gender was associated with not being accepted for HT (odds ratio, 2.57, p=0.01)
- Reason for not being accepted:
 - mostly self-refusal: women (29%) vs men (9%)
- Other reasons for non acceptance:
 - lower patient income (*Aaronson KD et al*)
 - lower social support in women than men (*Regitz-Zagrosek V et al.*)

Psychosocial factors at each stage of the transplant & mechanical circulatory support process



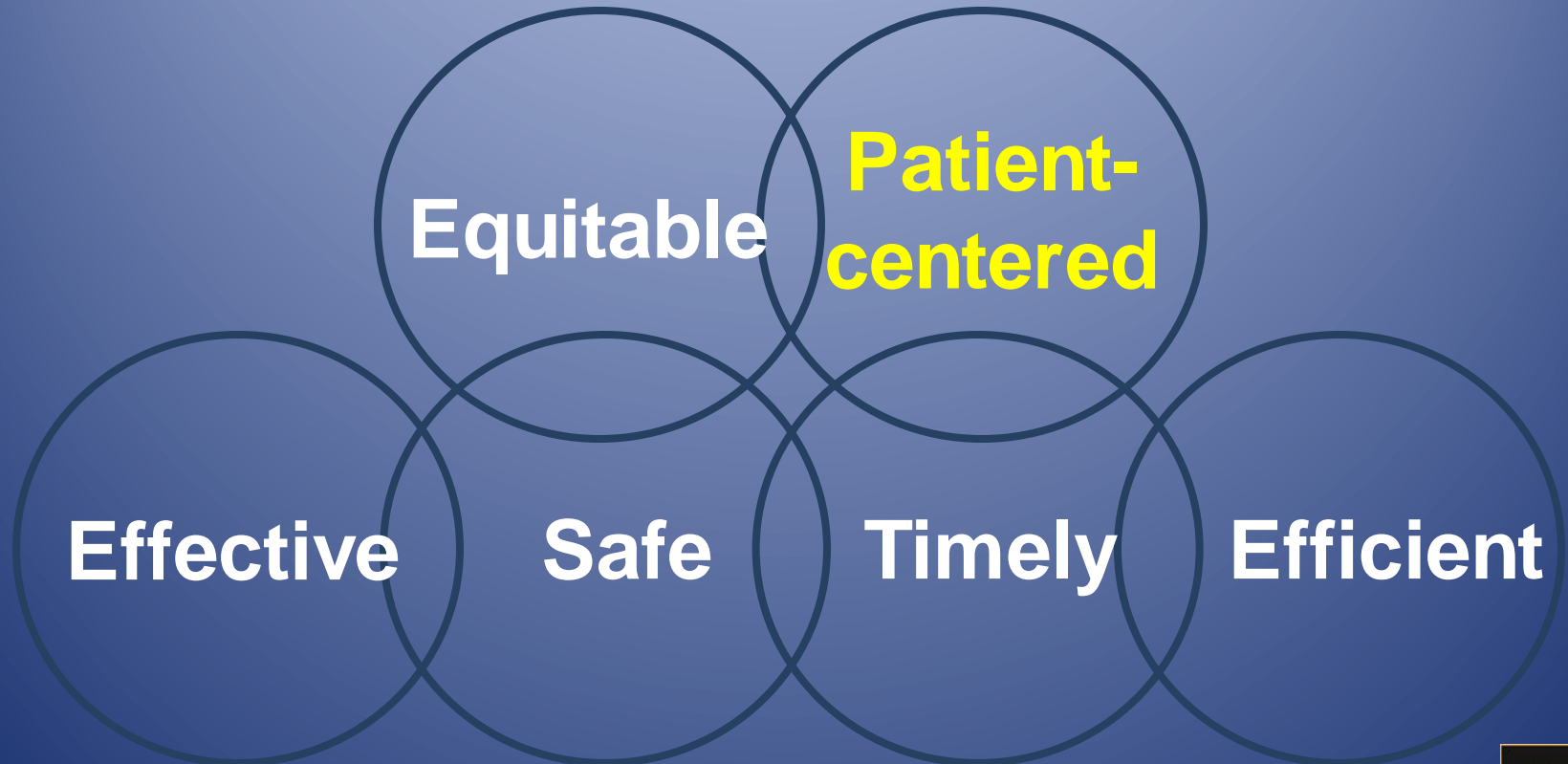
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Decision Making

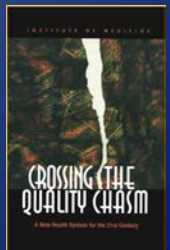
- Risks and benefits are presented when clinicians and patients together consider treatment options



Shared Decision Making Incorporates Patient-centered Care



Institute of Medicine. Crossing the Quality Chasm: A New Healthcare System for the 21st Century National Academy Press



Shared Decision Making Incorporates Patient-centered Care

- Respectful of and responsive to individual patient preferences, needs, values, and goals which guide all clinical decisions.
- Consistent with current professional knowledge AND includes a discussion of desired patient health outcomes.



Institute of Medicine. Crossing the Quality Chasm: A New Healthcare System for the 21st Century

Allen LA et al. Circ Cardiovascular Quality Outcomes. 2011.

Shared decision making and mechanical circulatory support implantation

- **Interviewer:** “Do you have any expectations regarding the VAD”?
- **Interviewee:** “... I will feel better and the main thing is it will help keep me alive, so that is also an incentive”.
- **Interviewer:** “What are your expectations in terms of getting the VAD”?
- **Interviewee:** “Really for me it is kind of simple things like I can walk, I can go to basketball games and football games climb a couple of bleachers; just do some things with my wife. I like to go shopping with her and we pretty much do a lot of things together anyway but when I go now she shops and I find a place to sit”.

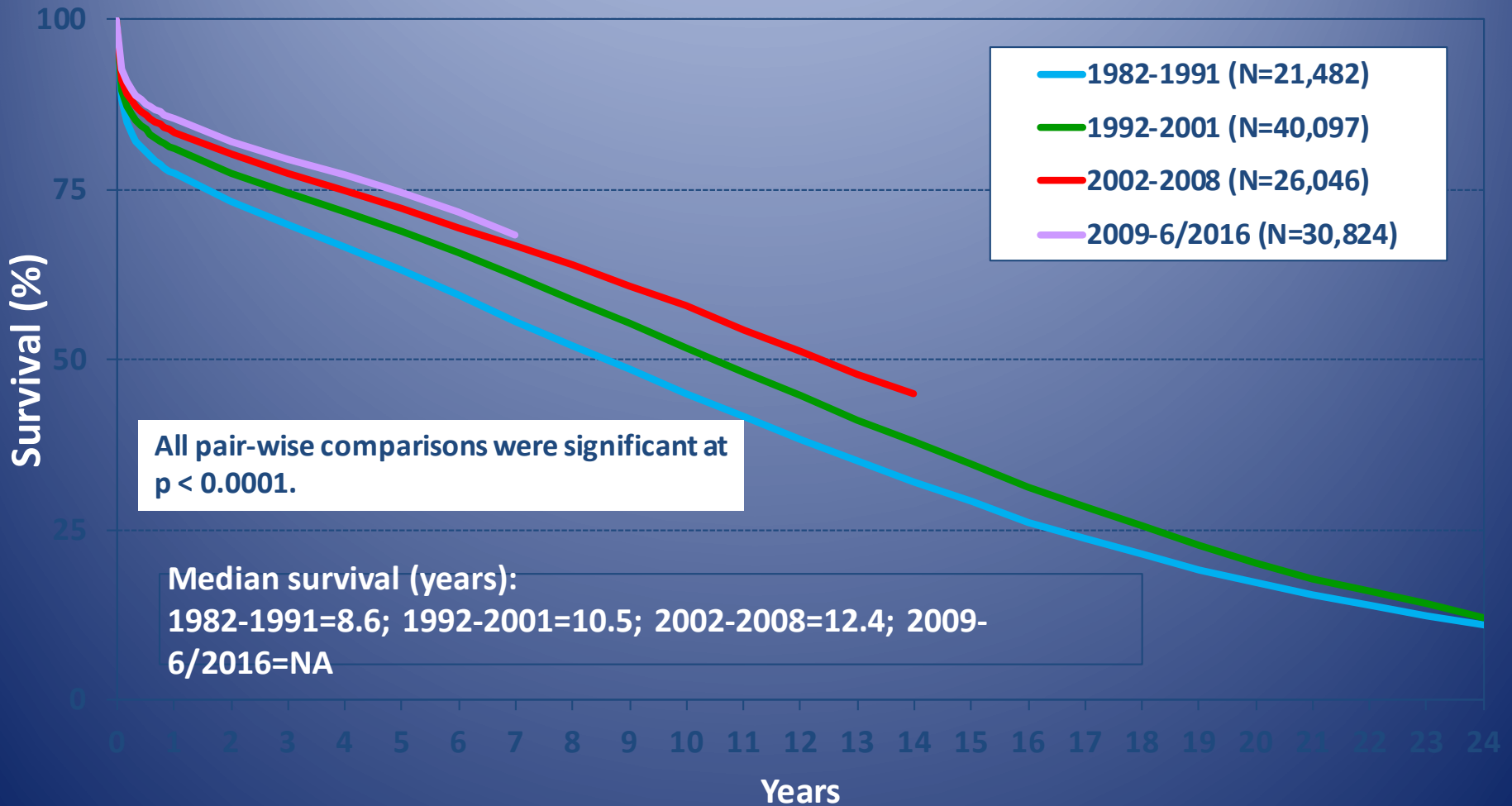
What Outcomes do Patients Care About?



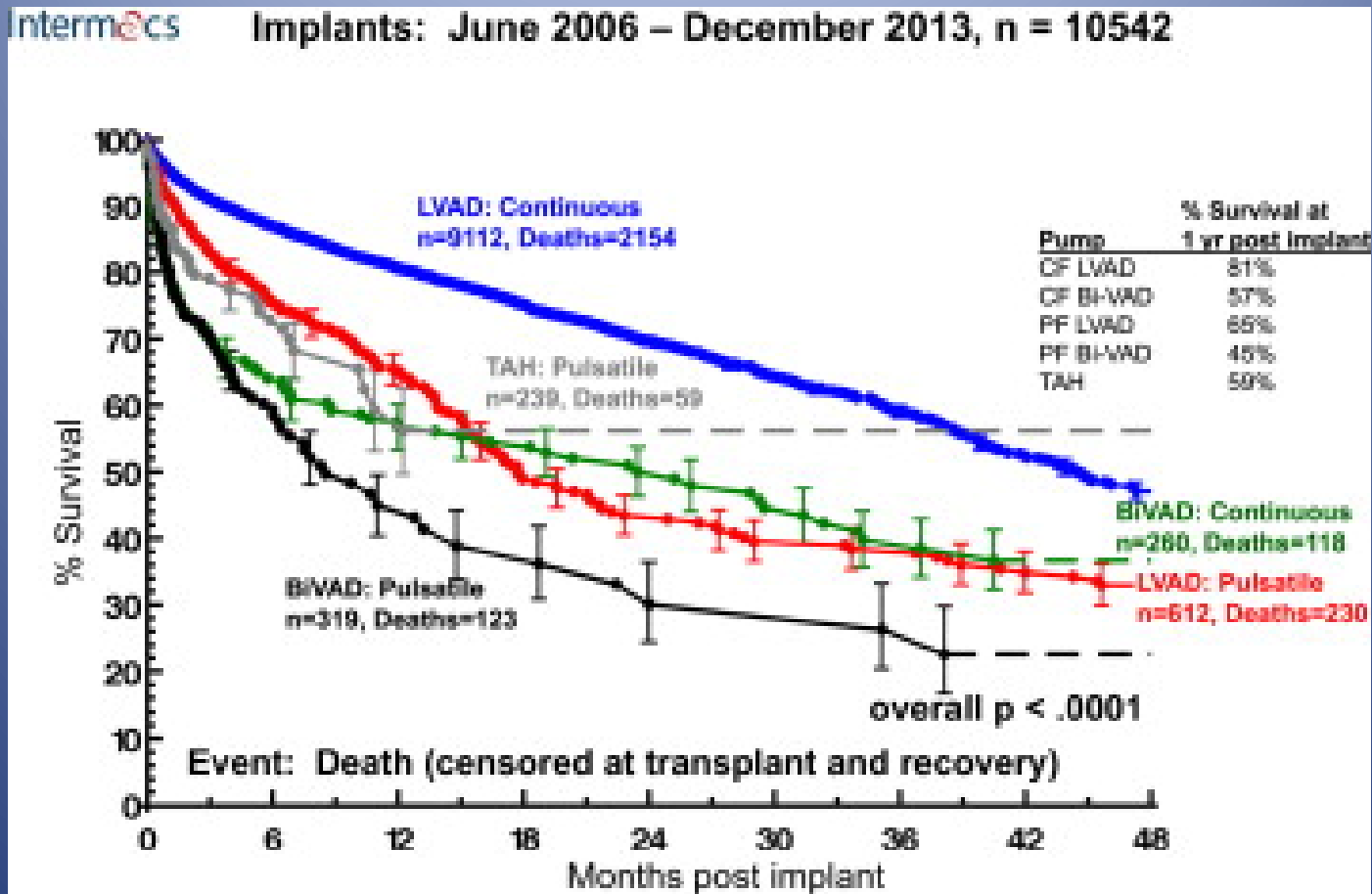
Adult Heart Transplants

Kaplan-Meier Survival by Era

(Transplants: January 1982 – June 2016)

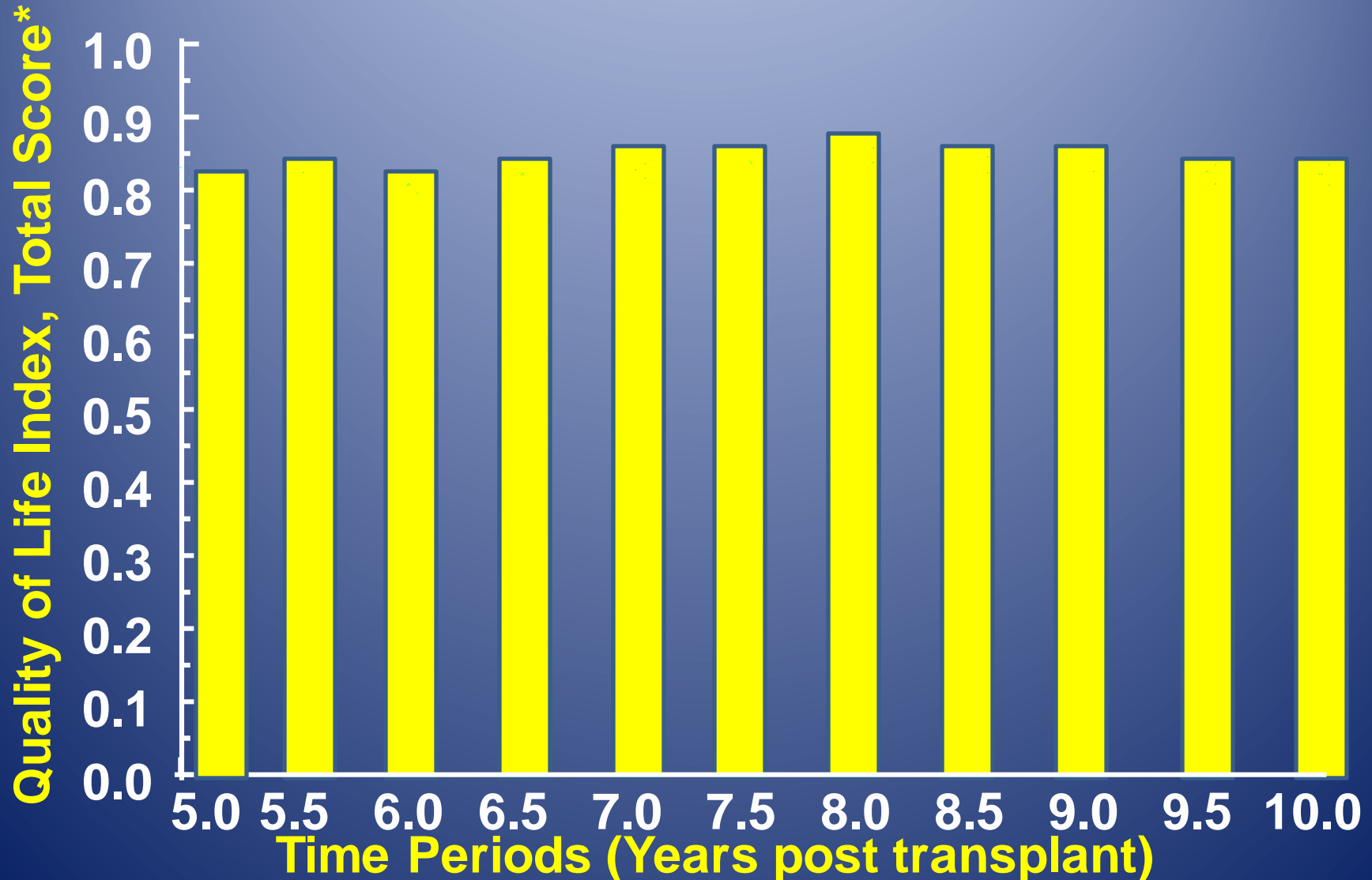


Improvement in Survival after LVAD Implant



Actuarial survival for primary device implant, stratified by device type. Error bars indicate ± 1 SE. Patients are censored at transplant and recovery. CF, continuous flow; LVAD, left ventricular assist device; PF, pulsatile flow; TAH, total artificial heart

Satisfaction with Quality of Life at 5- 10 Years after Heart Transplantation



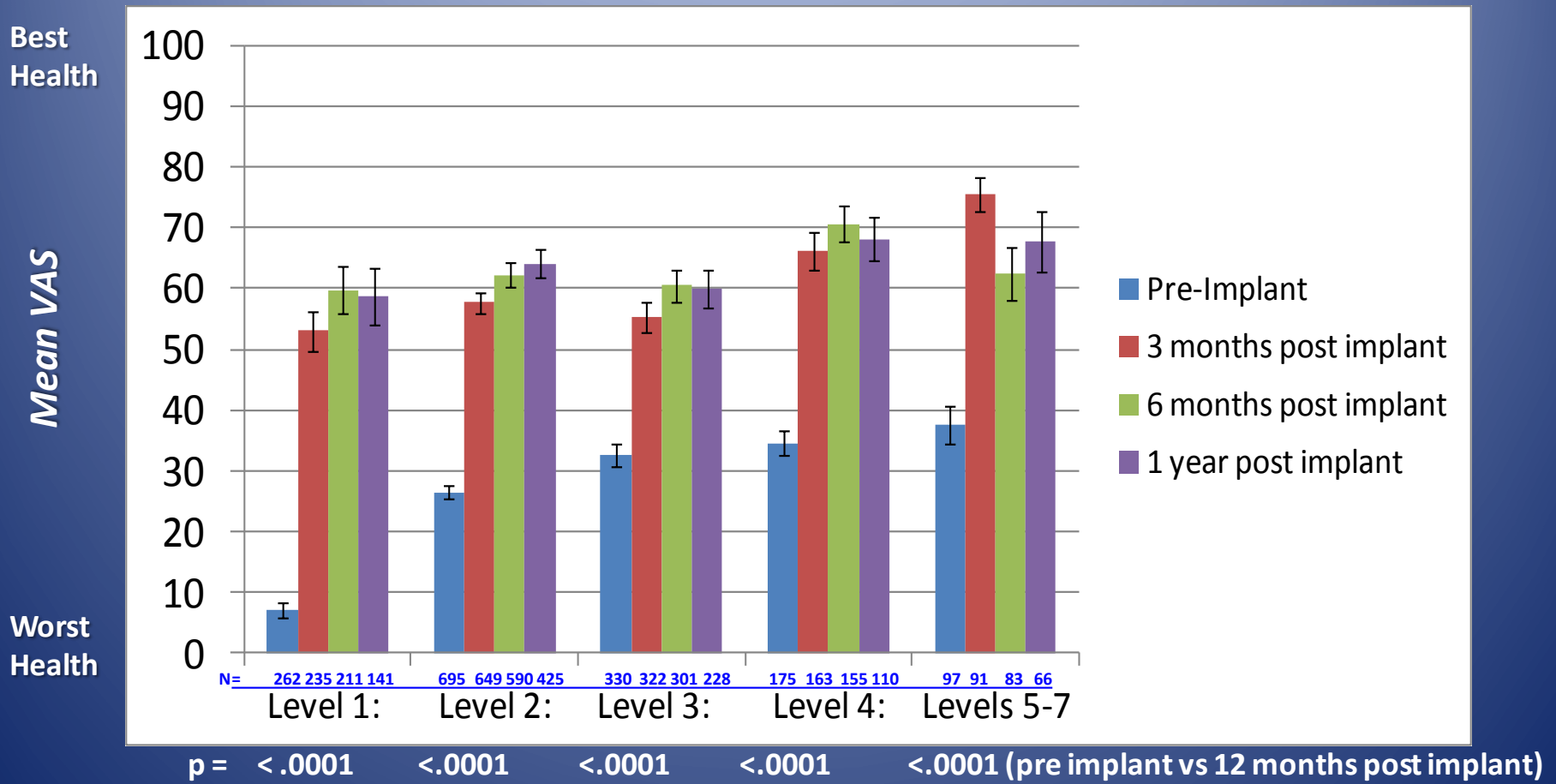
* based on a scale of 0-1; 0=least satisfied, 1=most satisfied

Grady K, et al. JHLT, 2007



HRQOL after VAD implant EQ-5D Visual Analog Scale

INTERMACS Patient Profile Levels



Utilizes all EQ-5D data available at each time period; too sick assigned "0"

Caregiver Burden

“ I think that the lived experience of spouses providing care to patients with a left ventricular assist device (LVAD)... is under appreciated by healthcare professionals, and the outcomes of this situation are not obvious.”

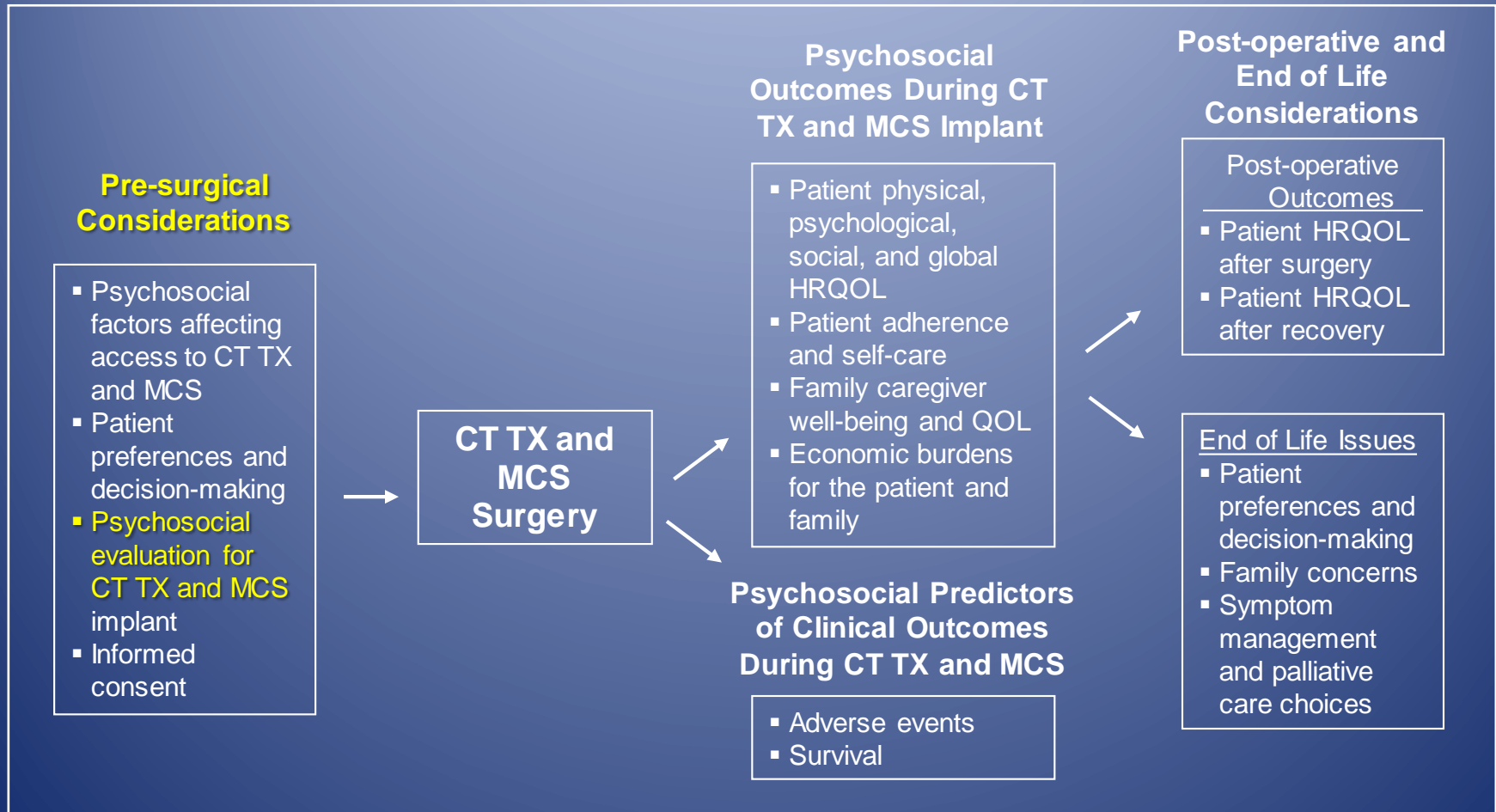
Barletti MH. Editorial, AJCC 2005:14; 143-144.

Caregiver Burden

Four major domains of burden:

	<u>HT</u>	<u>VAD</u>
• Task performance	↑	↑↑
• Time constraints	↑	↑↑
• Worry about patient health	↓	↑↓
• Financial burden	↑↑	↑↑

Psychosocial factors at each stage of the transplant & mechanical circulatory support process



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Need for Psychosocial Evaluation

- Pre-transplant psychosocial factors predict outcomes after cardiothoracic transplantation
 - patients' history of medical adherence
 - mental health
 - substance use
 - social support
- Outcomes include
 - transplant-related morbidities
 - mortality
 - medical adherence
 - quality of life (QOL)

Value of Psychosocial Evaluation

Despite recognition of the value of the psychosocial evaluation by ISHLT guidelines ... issues and challenges of conducting evaluations include:

- What is the full range of psychosocial domains that should be assessed?
- What processes should be used to conduct the evaluation?
- How should findings be reported?
- What are the processes for monitoring patients' receipt of interventions for any identified problems?

A Consensus Document



The Journal of
Heart and Lung
Transplantation
<http://www.jhltonline.org>

ISHLT CONSENSUS

The 2018 ISHLT/APM/AST/ICCAC/STSW recommendations for the psychosocial evaluation of adult cardiothoracic transplant candidates and candidates for long-term mechanical circulatory support



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Methods

Strategies to come to consensus:

- Synthesis of expert opinion on the content of the psychosocial evaluation
- Synthesis of expert opinion on the processes and procedures for
 - conducting the evaluation
 - reporting its results
 - implementing any additional testing or treatment
- Literature reviews of empirical evidence to support the Committee's recommendations regarding both evaluation content / process.

Methods

Strategies to come to consensus:

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Content Recommendations

Rationale for recommendation of 10 domains:

- Assess risk factors for poor posttransplantation / postimplantation outcomes
- Collect information on factors related to patients' knowledge, understanding, and capacity to engage in decision-making about transplantation and/or MCS
- Collect information to characterize patients' personal, social and environmental resources and circumstances, including factors that may mitigate the impact of any psychosocial risk factors on posttransplantation / postimplantation outcomes
- Unique to MCS candidates, evaluate patients' knowledge about and capacity to operate the device.

Domains

Risk factors for poor outcomes after surgery

1. Treatment adherence and health behaviors

- Past and current level of adherence to the required medical regimen
- Knowledge and understanding of rationale and specific requirements of the current medical regimen (e.g., medication dosing; other self-management requirements; appointments)
- Willingness and intent to modify self-management and lifestyle behaviors to meet changing regimen requirements

Domains

Risk factors for poor outcomes after surgery

2. Mental health history	<ul style="list-style-type: none">• Past and current <u>mood, anxiety or other disorders</u>• <u>Symptom severity and course</u>, chronicity of symptoms• Receipt, adherence, and response to <u>psychiatric treatment</u>• Current or past <u>suicidal ideation</u>• Mental health <u>history of immediate family</u>
3. Substance use history	<ul style="list-style-type: none">• <u>Tobacco/alcohol/drug</u> (licit and illicit) frequency, amount, etc.• Level of <u>impairment</u> to health/work/relationships, legal issues• <u>Insight</u> into problem, commitment to remain abstinent• Prior and any current <u>treatment</u>, willingness to seek treatment• Substance use/abuse <u>history of immediate family</u>

Domains

Factors related to patient knowledge, understanding, capacity for decision making

4. Cognitive status and capacity to give informed consent

- Evidence of cognitive impairment that would compromise capacity to comprehend information and engage in decision making about treatment options
- Capacity to make judgments and decisions voluntarily without undue pressure from others

Domains

Factors related to patient knowledge, understanding, capacity for decision making

5. Knowledge and understanding of current illness

- Knowledge and understanding of the causes and course of the organ disease and its impact on daily functioning
- Understanding of rationale for treatments received and inadequacy of treatments to manage symptoms/disease progression
- Understanding of reasons for referral for transplant / MCS

6. Knowledge and understanding of current treatment options

- Knowledge and understanding of risks and benefits of the surgical intervention under consideration
- Understanding of post-intervention medical regimen, self-care and lifestyle requirements
- Attitudes about the intervention, e.g., receptiveness; expectations; concerns; values, preferences and goals

Domains

Factors specific to patients' personal, social, and environmental resources and circumstances

7. Coping with illness

- Emotional response to illness; acceptance or denial about severity of illness, prognosis and treatment options
- Coping strategies used to manage illness and its impact on daily life (e.g., problem solving strategies, reliance on others, avoidance)

Domains

Factors specific to patients' personal, social, and environmental resources and circumstances

8. Social support	<ul style="list-style-type: none">• Availability, and capacity of family and others to provide <u>support</u>• Understanding and knowledge among <u>family</u> and other supports of treatment options and current care needs• Expectations of family and other supports about <u>care needs</u> after intervention
9. Social history	<ul style="list-style-type: none">• <u>Demographics</u> (e.g., education, religion, literacy)• <u>Relationship</u> history (e.g., marital status, stability of relationships)• <u>Employment</u> experience and occupation• <u>Financial status</u> (e.g., insurance, living arrangements, dependents)• History of legal issues• Concurrent <u>life stressors</u> and history of exposure to traumatic events

Domains

Factors specific to patients under consideration for MCS

10. Knowledge about and capacity to operate MCS device

- Knowledge and understanding of basic device operation and malfunction
- Cognitive or physical limitations, that would compromise capacity to operate the device or to perceive and respond to device alarms
- Safety of the home environment for device operation (e.g., source of electricity)

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Processes and Procedures Related to the Psychosocial Evaluation

1. Qualifications and experience of the evaluator

- The evaluator should have training in a healthcare discipline relevant to the content of the psychosocial evaluation.
- The evaluator should be registered or licensed in their discipline
- For individuals new to the evaluator role, orientation to the transplant and/or MCS program
- Ongoing evaluator education and training

Processes and Procedures Related to the Psychosocial Evaluation

2. Performance of the psychosocial evaluation

- The patient should be informed about the evaluation's purpose and goals
- Conducted in a language in which the patient can engage in interactive conversation. Interpreter services should be utilized, as needed.
- The evaluation interview should be expanded beyond a one-time meeting with the patient if complex issues are uncovered.
- After the initial evaluation, patients who are awaiting surgery should be reevaluated at regular intervals.
- The patient should be directly interviewed when possible.
- When the patient cannot complete the full interview or is unable to be interviewed, the evaluator should collect collateral information as possible.
- Given that transplant and MCS teams commonly require that the patient have a primary support person, this individual should be interviewed to determine understanding of the patient's needs and his/her willingness and ability to provide assistance.

Processes and Procedures Related to the Psychosocial Evaluation

3. Use of templates or checklists as adjuncts for completing the psychosocial evaluation

- The evaluator should consider routinely using a standard template or checklist that includes each element of the psychosocial evaluation.

Processes and Procedures Related to the Psychosocial Evaluation

4. Screening for capacity to give informed consent

- If cognitive impairment is suspected, use of a standardized, validated screening tool should be considered.
- The evaluator should consider whether additional steps (use of interpreter, additional education at literacy level of patient, treatment for medical conditions) are needed before capacity can be determined.
- Formal evaluation of the patient's capacity to make medical decisions may be needed.

Processes and Procedures Related to the Psychosocial Evaluation

5. Communication with the transplantation or MCS team about psychosocial evaluation findings

- A written evaluation report should be placed in the patient's medical record.
- The report should contain a concise summary of findings (and detail as needed) and recommendations for additional testing and/or interventions.
- When psychosocial risk factors are identified, the report should state whether the risk factors can be ameliorated and, if so, recommend treatment and timing (i.e., before or after surgery).
- Recommendations stated in the report should take into account what is feasible.
- The report should be shared at a multidisciplinary meeting when transplant listing decisions or MCS decisions are discussed.

Processes and Procedures Related to the Psychosocial Evaluation

6. Coordination of recommended psychosocial treatments or interventions, and assessment of progress

- The evaluator should coordinate all intervention activities, or designate another team member.
- The evaluator should identify who will monitor intervention progress and communicate progress to the team.
- The evaluator should specify before an intervention is initiated how progress/success will be defined.
- The evaluator should provide specific criteria (e.g., a time line or clinical benchmarks) indicating when any psychosocial re-evaluation should be performed.

Methods

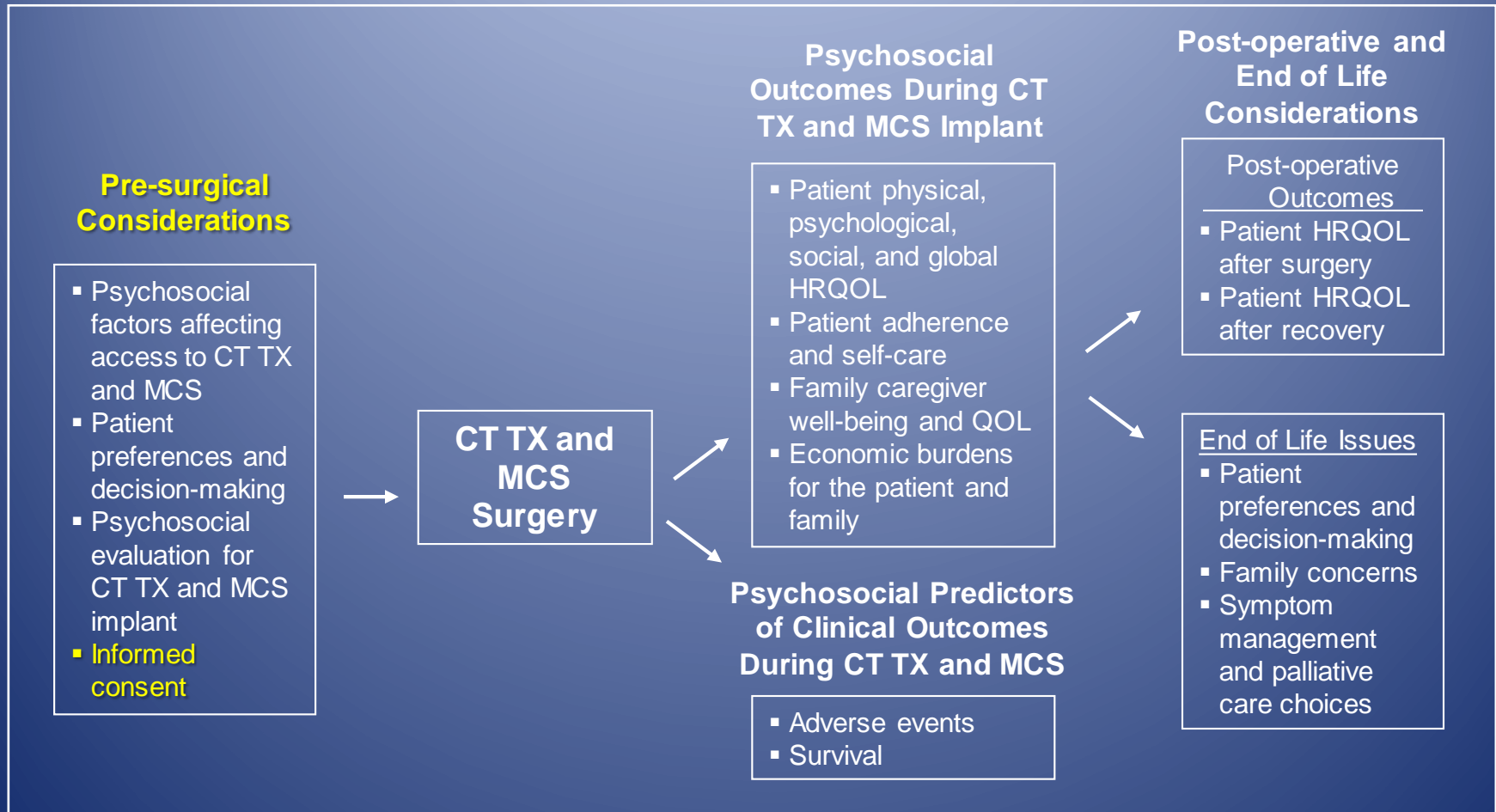
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Literature Review

- Rigorous and robust
 - Peer reviewed articles (English language only)
 - Focus on adults (≥ 18 years)
 - Publication dates between 2000 – mid 2017
 - Seminal articles published before 2000
 - as per Writing Committee member recommendations
- Provides strong evidence for both content and process / procedure recommendations

Psychosocial factors at each stage of the transplant & mechanical circulatory support process



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Informed Consent

- Informed consent is a process, not an event, followed by documentation of that process (i.e., signing of a consent form)
- 4 basic elements:
 - (1) decision-making capacity of the patient or surrogate
 - (2) disclosure of sufficient details of the proposed treatment by the physician
 - (3) demonstration of understanding of the disclosed information by the patient or surrogate
 - (4) voluntary agreement to the treatment

Importantly, this process is patient-centric

Informed Consent and Advanced Heart Failure Therapies

Informed consent is a process

Includes informing patients about:

Current medical condition and natural history

Prognosis re both quantity and quality of life re options

Risks and benefits of therapeutic options

Uncertainty

Need for self-care of therapeutic options

Effect on lifestyle

Costs

Caregiver burden

End-of-life considerations with each therapeutic option

Includes understanding the patients preferences, values
and goals

Allen L, Stevenson L, Grady K, et al. Circulation, 2012.

Grady K & Dew MA. In MCS, A Companion to Braunwald's Heart Disease, 2012

Summary

- The pre-surgical time period is a critical time consisting of referral, shared decision making, evaluation, and informed consent.
- Evaluation for cardiothoracic transplantation and mechanical circulatory support must be thorough and processes must be based on best practices.
- Only then, can potential candidates for advanced surgical therapies provide truly informed consent.

“Thoracic organ transplantation improves the length and quality of life of patients with severe heart or lung disease. It is a societal endeavor bound by ethical principles.”



**International Society for Heart and Lung Transplantation,
Statement of Transplant Ethics, approved: April 2007.**