What Does Care Optimization for Heart Failure Mean?

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AMERICAN COLLEGE of CARDIOLOGY

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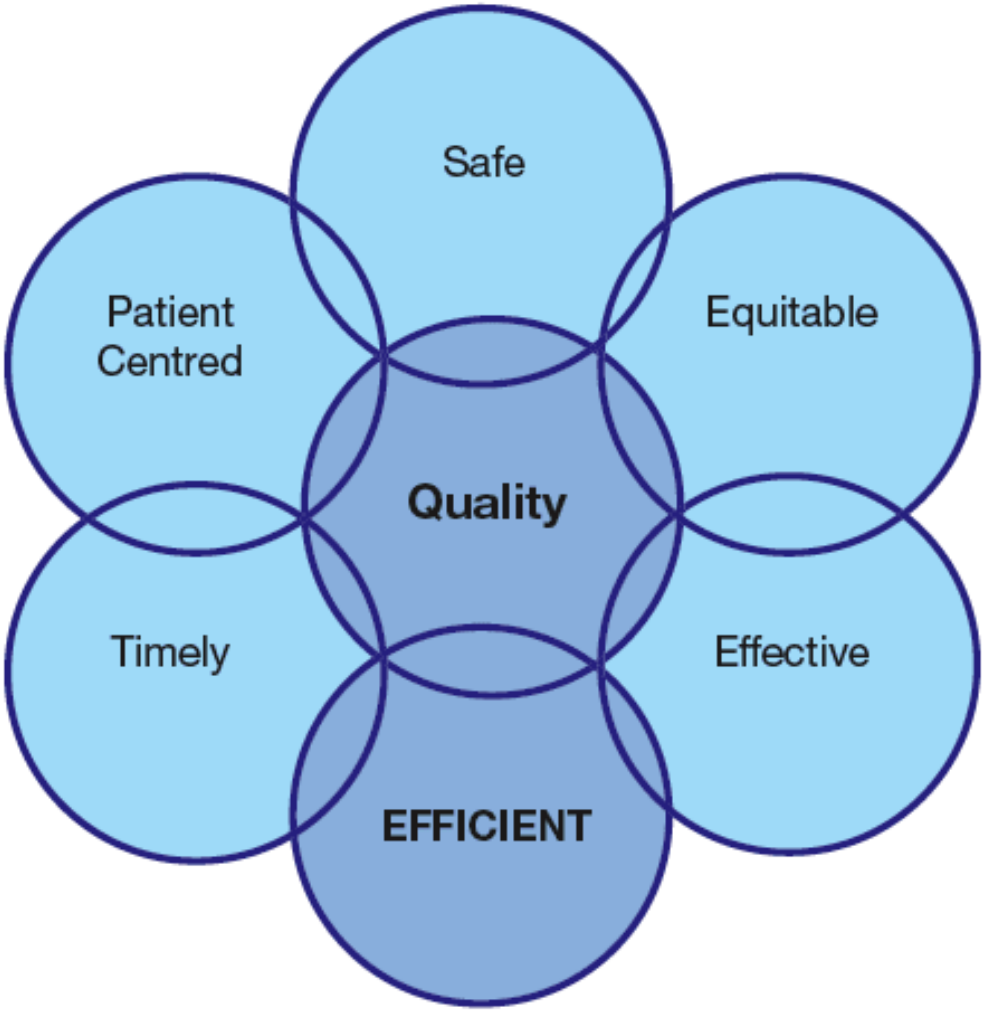
ANSCHUTZ MEDICAL CAMPUS

Presenter Disclosure Information

- I will not discuss off label or investigational use in my presentation.
- I have financial relationships to disclose:
  - Employee of: University of Colorado
  - Consultant for: J&J/Janssen, Novartis, St. Jude, ZS Pharma, Medscape
  - Stockholder in: None
  - Research support from: NIH / NHLBI, PCORI, AHA
  - Honoraria from: None

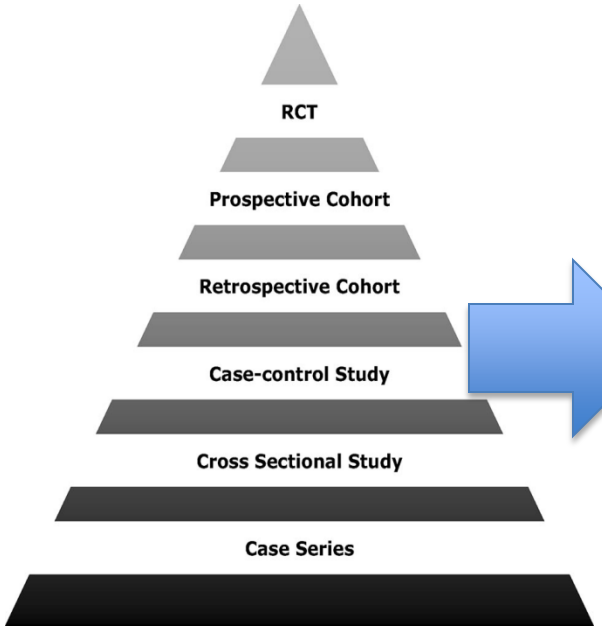
What does optimization mean?



A systems problem, a systems solution

Donabedian's Quality Framework

Evidence!



CLASS (STRENGTH) OF RECOMMENDATION

CLASS I (STRONG) — **Benefit >>> Risk**

Suggested phrases for writing recommendations:
- Is recommended
- Is indicated/useful/effective/beneficial
- Should be performed/administered/other
- Comparative-Effectiveness Phrases†:
  - Treatment/strategy A is recommended/indicated in preference to treatment B
  - Treatment A should be chosen over treatment B

CLASS IIa (MODERATE) — **Benefit >> Risk**

Suggested phrases for writing recommendations:
- Is reasonable
- Can be useful/effective/beneficial
- Comparative-Effectiveness Phrases†:
  - Treatment/strategy A is probably recommended/indicated in preference to treatment B
  - It is reasonable to choose treatment A over treatment B

CLASS IIb (WEAK) — **Benefit ≥ Risk**

Suggested phrases for writing recommendations:
- May/might be reasonable
- May/might be considered
- Usefulness/effectiveness is unknown/unclear/uncertain or not well established

CLASS III: No Benefit (MODERATE) — **Benefit = Risk**
(Generally, LOE A or B use only)

Suggested phrases for writing recommendations:
- Is not recommended
- Is not indicated/useful/effective/beneficial
- Should not be performed/administered/other

CLASS III: Harm (STRONG) — **Risk > Benefit**

Suggested phrases for writing recommendations:
- Potentially harmful
- Causes harm
- Associated with excess morbidity/mortality
- Should not be performed/administered/other

LEVEL (QUALITY) OF EVIDENCE‡

LEVEL A
- High-quality evidence‡ from more than 1 RCTs
- Meta-analyses of high-quality RCTs
- One or more RCTs corroborated by high-quality registry studies

LEVEL B-R (Randomized)
- Moderate-quality evidence‡ from 1 or more RCTs
- Meta-analyses of moderate-quality RCTs

LEVEL B-NR (Nonrandomized)
- Moderate-quality evidence‡ from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies
- Meta-analyses of such studies

LEVEL C
- Randomized or nonrandomized observational or registry studies with limitations of design or execution
- Meta-analyses of such studies
- Physiological or mechanistic studies in human subjects

LEVEL E

Consensus of expert opinion based on clinical experience when evidence is insufficient, vague, or conflicting

COR and LOE are determined independently (any COR may be paired with any LOE).

A recommendation with LOE C or E does not imply that the recommendation is weak. Many important clinical questions addressed in guidelines do not lend themselves to clinical trials. Although RCTs are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

* The outcome or result of the intervention should be specified (an improved clinical outcome or increased diagnostic accuracy or incremental prognostic information).

† For comparative-effectiveness recommendations (COR I and IIa; LOE A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

‡ The method of assessing quality is evolving, including the application of standardized, widely used, and preferrably validated evidence grading tools; and for systematic reviews, the incorporation of an Evidence Review Committee.

COR indicates Class of Recommendation; LOE, Level of Evidence; NR, nonrandomized; R, randomized; and RCT, randomized controlled trial.

PRACTICE GUIDELINE

2013 ACCF/AHA Guideline for the Management of Heart Failure

A Report of the American College of Cardiology Foundation/
American Heart Association Task Force on Practice Guidelines

Developed in Collaboration With the American College of Chest Physicians, Heart Rhythm Society and International Society for Heart and Lung Transplantation

Endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation

WRITING COMMITTEE MEMBERS*

Clyde W. Yancy, MD, MSc, FACC, FAHA, Chair†‡;

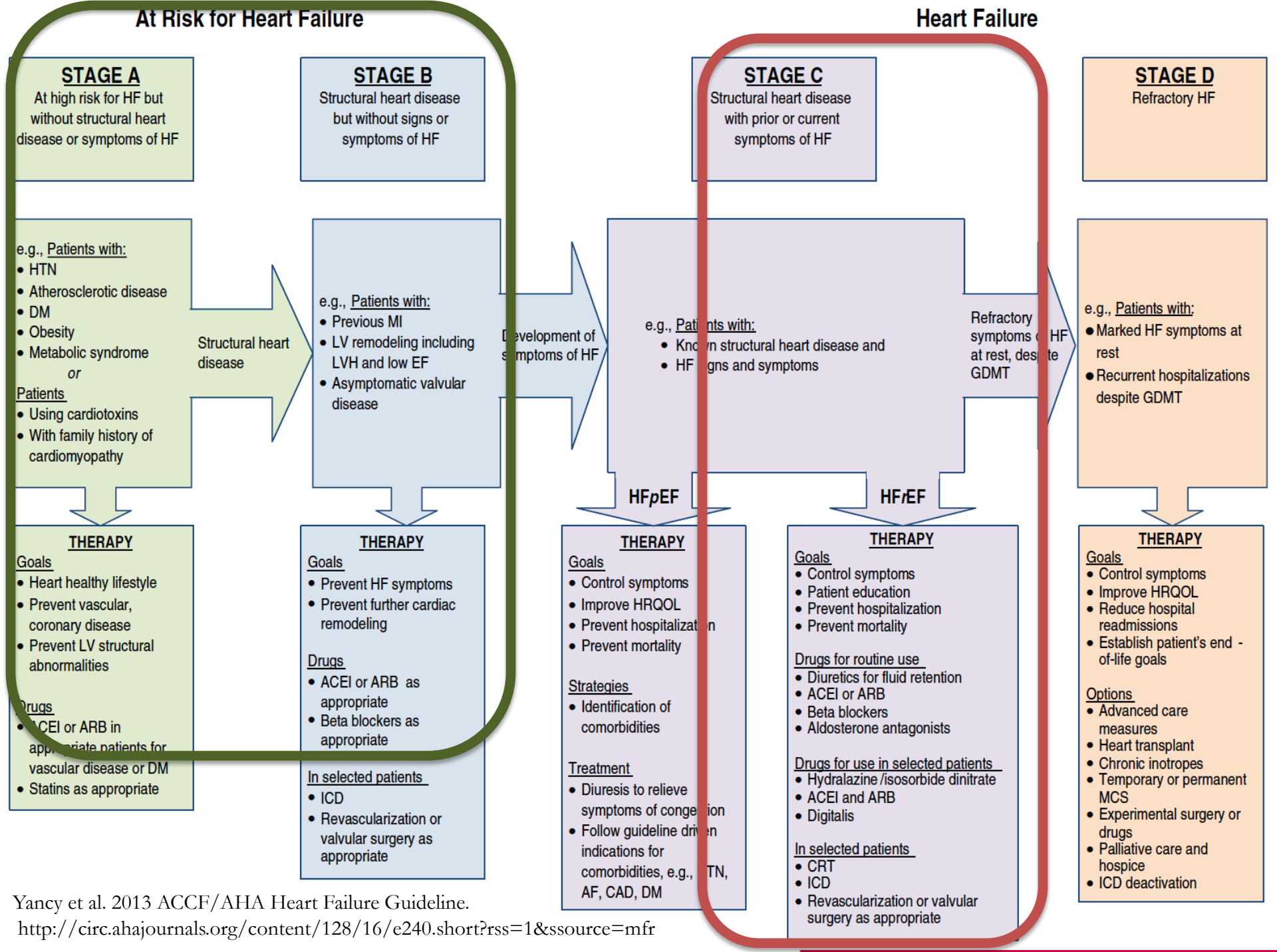
EUROPEAN SOCIETY OF CARDIOLOGY®

European Heart Journal
doi:10.1093/eurheartj/ehw128

ESC GUIDELINES

2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC)



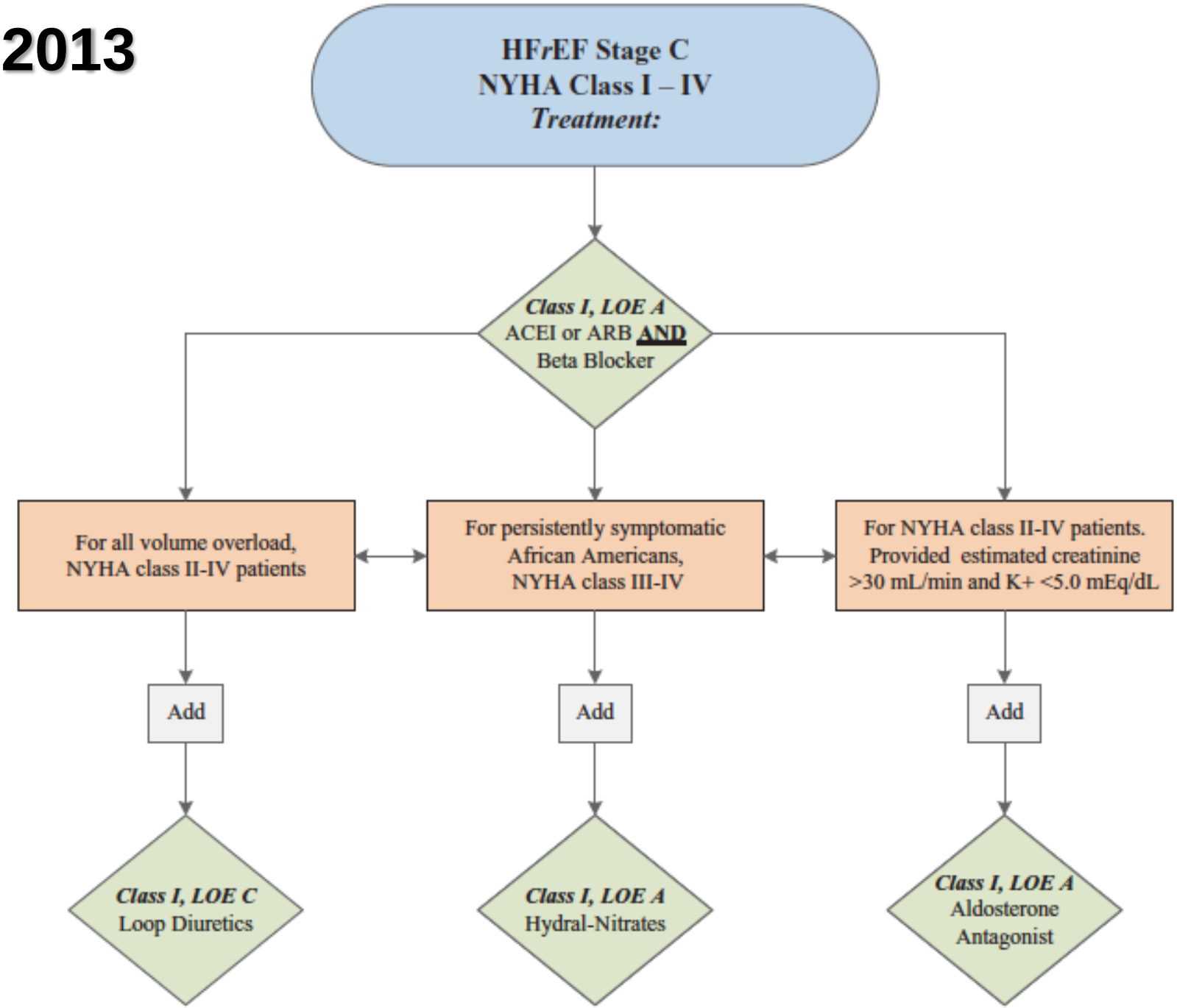
Yancy et al. 2013 ACCF/AHA Heart Failure Guideline.
http://circ.ahajournals.org/content/128/16/e240.short?rss=1&ssource=mfr

Categories of Stage C HF

	HFrEF (LVEF < 40%)	HFpEF (LVEF > 50%)	RV Failure
Chronic (Stable)		?	?
Acute (Unstable)	?	?	?

Volume Control

AHA 2013


HFrEF Stage C
NYHA Class I – IV
Treatment:
Class I, LOE A
ACEI or ARB AND
Beta Blocker
For all volume overload,
NYHA class II-IV patients
For persistently symptomatic
African Americans,
NYHA class III-IV
For NYHA class II-IV patients.
Provided estimated creatinine
>30 mL/min and K+ <5.0 mEq/dL
Add
Add
Add
Class I, LOE C
Loop Diuretics
Class I, LOE A
Hydral-Nitrates
Class I, LOE A
Aldosterone
Antagonist

After a decade of not much …

- CardioMEMS
- Cardiac rehabilitation
- Ivabradine
- Sacubitril/valsartan
- CRT refinements
- SQ-ICD
- MCS options

(ivabradine) 5 mg 7.5 mg tablets

(sacubitril/valsartan) tablets
24/26mg · 49/51mg · 97/103mg

Yancy CW, et al
Heart Failure Focused Update on Pharmacological Therapy

2016 ACC/AHA/HFSA Focused Update on New Pharmacological Therapy for Heart Failure: An Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure

A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 SEPTEMBER 11, 2014 VOL. 371 NO. 11

Angiotensin–Neprilysin Inhibition versus Enalapril in Heart Failure

John J.V. McMurray, M.D., Milton Packer, M.D., Akshay S. Desai, M.D., M.P.H., Jianjian Gong, Ph.D., Martin P. Lefkowitz, M.D., Adel R. Rizkala, Pharm.D., Jean L. Rouleau, M.D., Victor C. Shi, M.D., Scott D. Solomon, M.D., Karl Swedberg, M.D., Ph.D., and Michael R. Zile, M.D., for the PARADIGM-HF Investigators and Committees*

Articles

Ivabradine and outcomes in chronic heart failure (SHIFT): a randomised placebo-controlled study

*Karl Swedberg, Michel Komajda, Michael Böhm, Jeffrey S Borer, Ian Ford, Ariane Dubost-Brama, Guy Lerebours, Luigi Tavazzi, on behalf of the SHIFT Investigators**

Summary
Background Chronic heart failure is associated with high mortality and morbidity. Raised resting heart rate is a risk *Lancet* 2010; 376: 875–85

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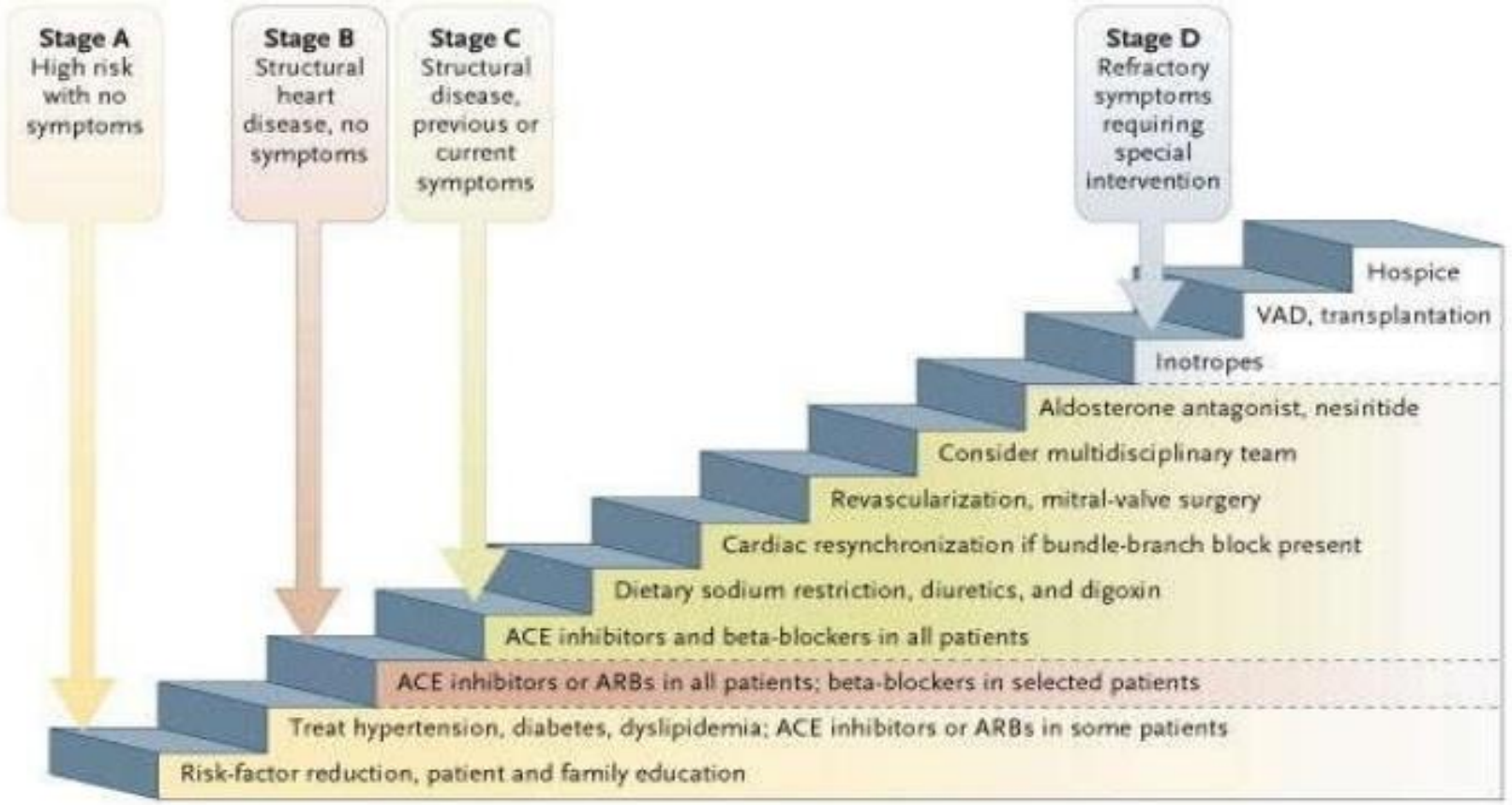
The cumulative burden of success

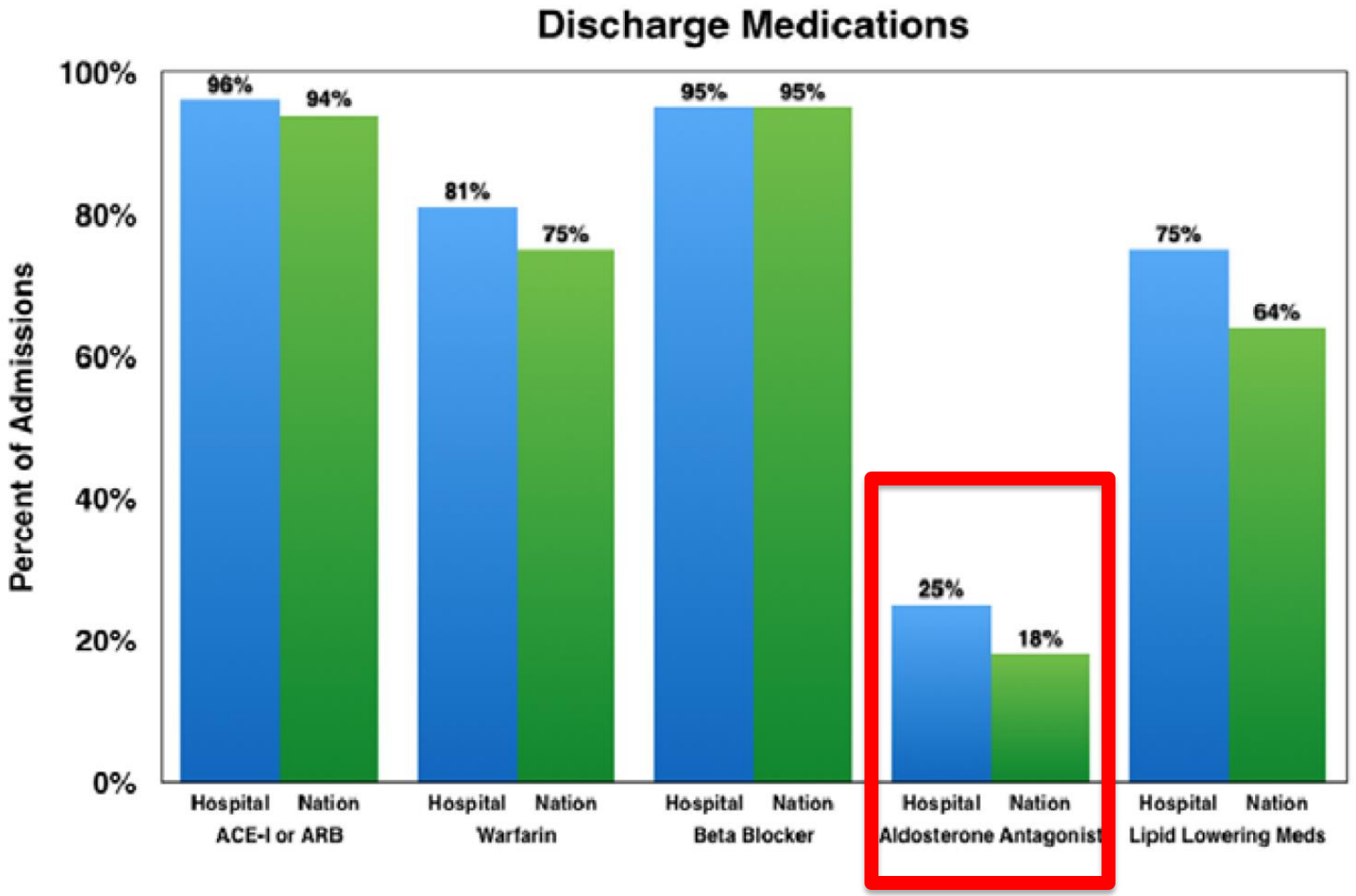


Jessup M, Brozena S. N Engl J Med 2003;348:2007-2018.

52%: 5+ co-occurring conditions

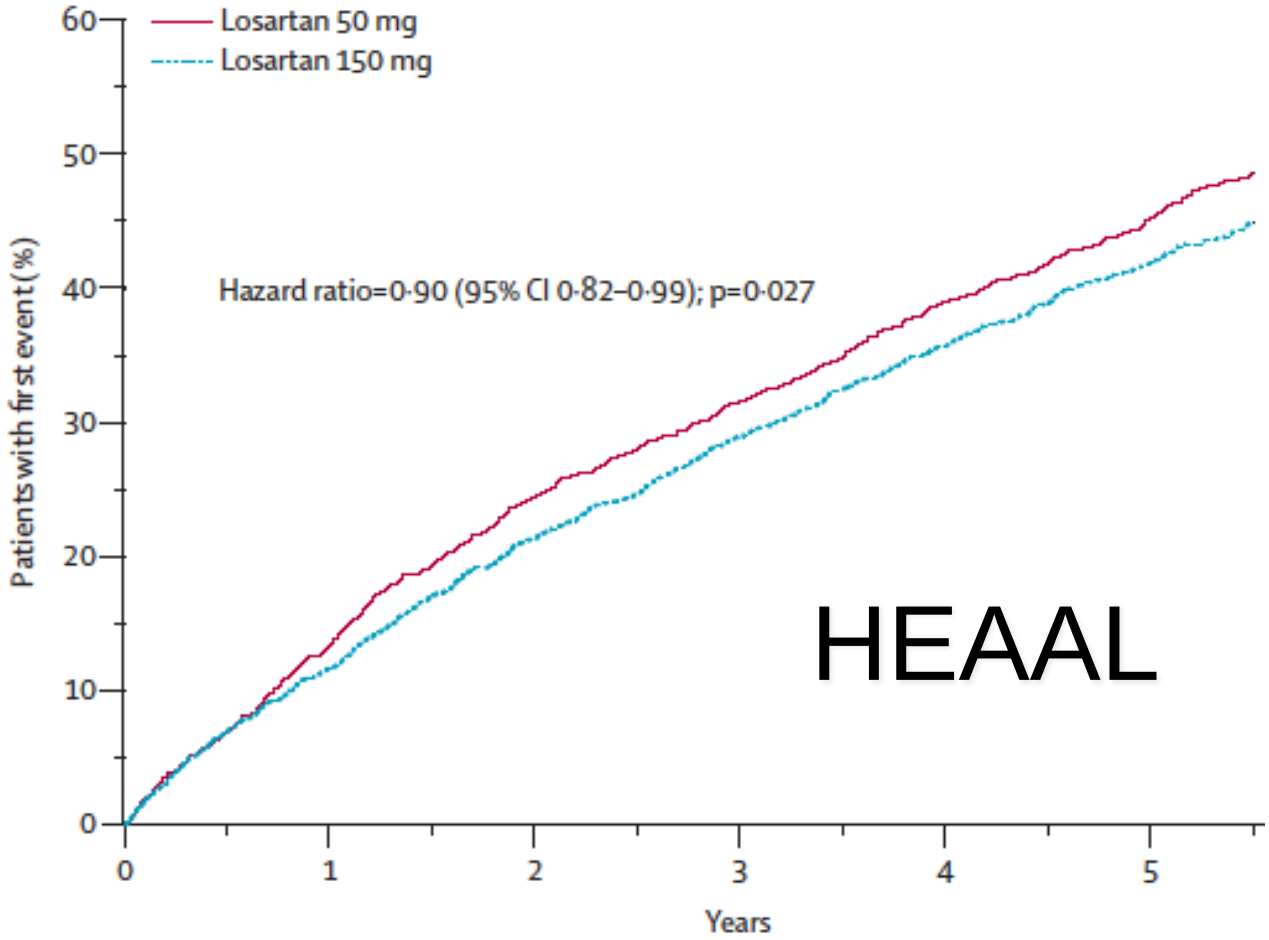
Hospital

Failure to prescribe the basics



Circ Cardiovasc Qual Outcomes. 2015;8:421-427.

Failure to dose maximize

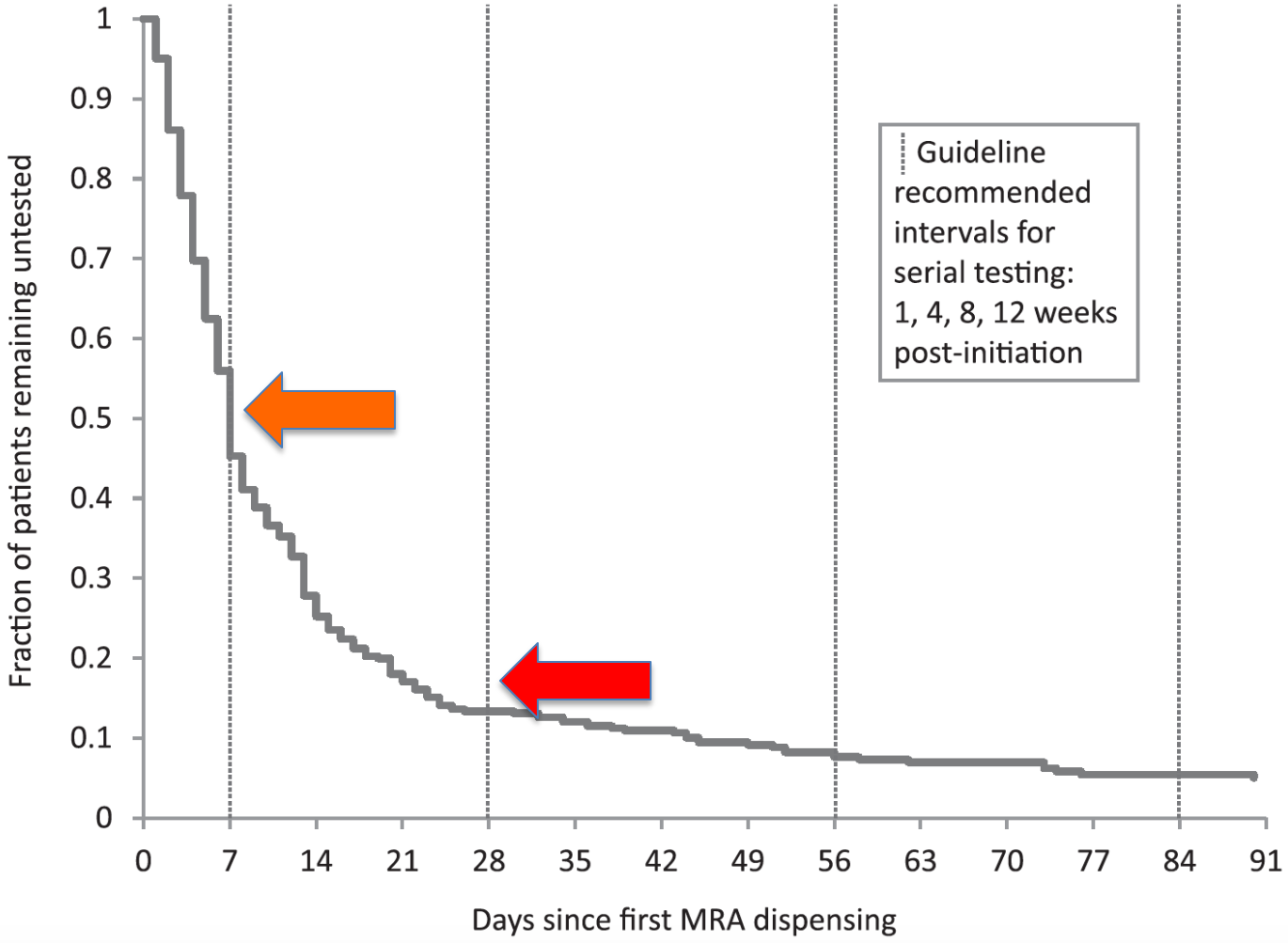


Number at risk					
Losartan 50 mg	1646	1422	1277	1126	644
Losartan 150 mg	1684	1493	1344	1205	711

Lancet 2009; 374: 1840–48

Failure to monitor

39.0983
B3 bcc
63.83°
759°
0.86
0.82
19
1
K
[Ar]4s¹
(Kalium)
Potassium



(*Circ Heart Fail.* 2014;7:43-50.)

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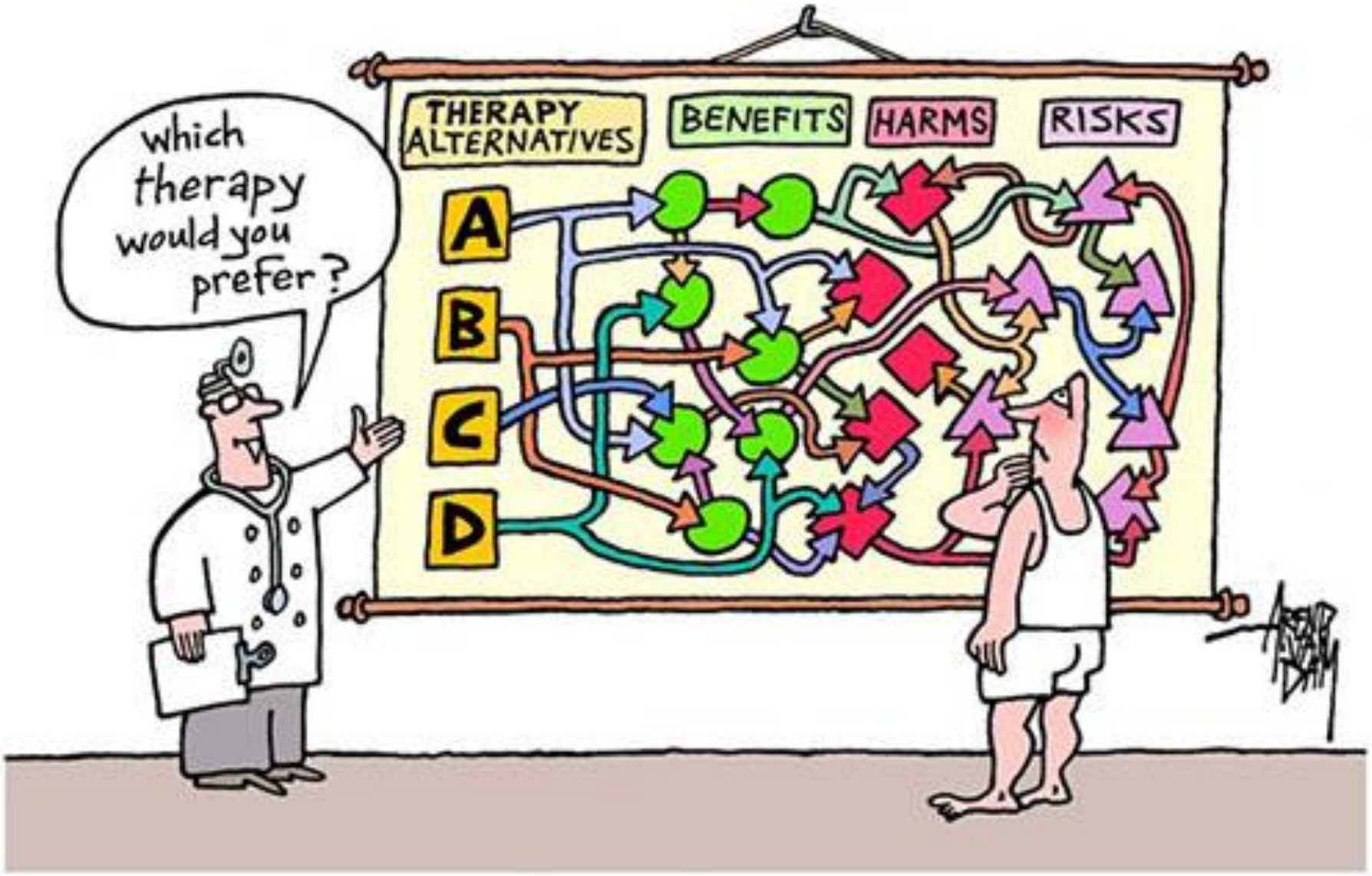
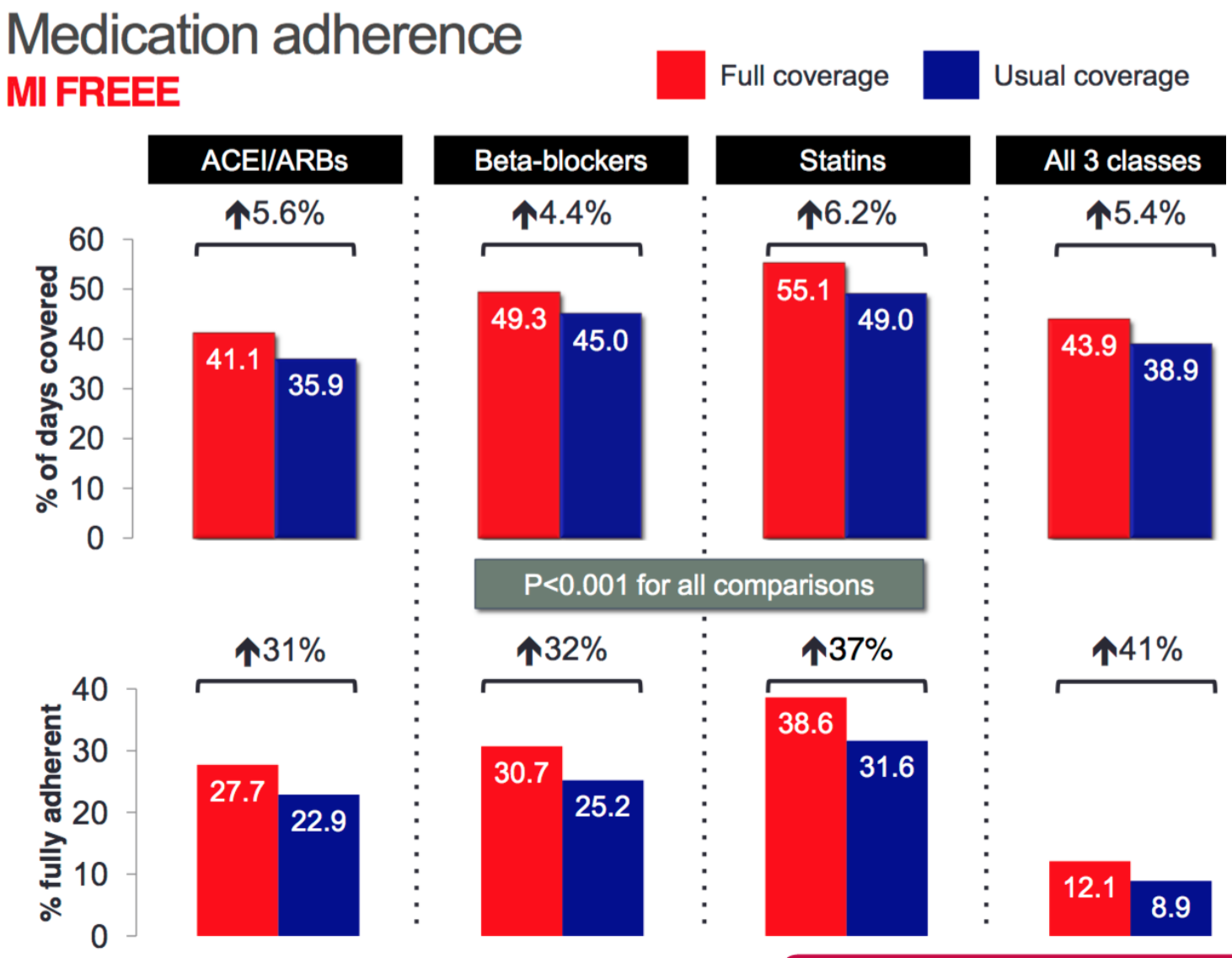
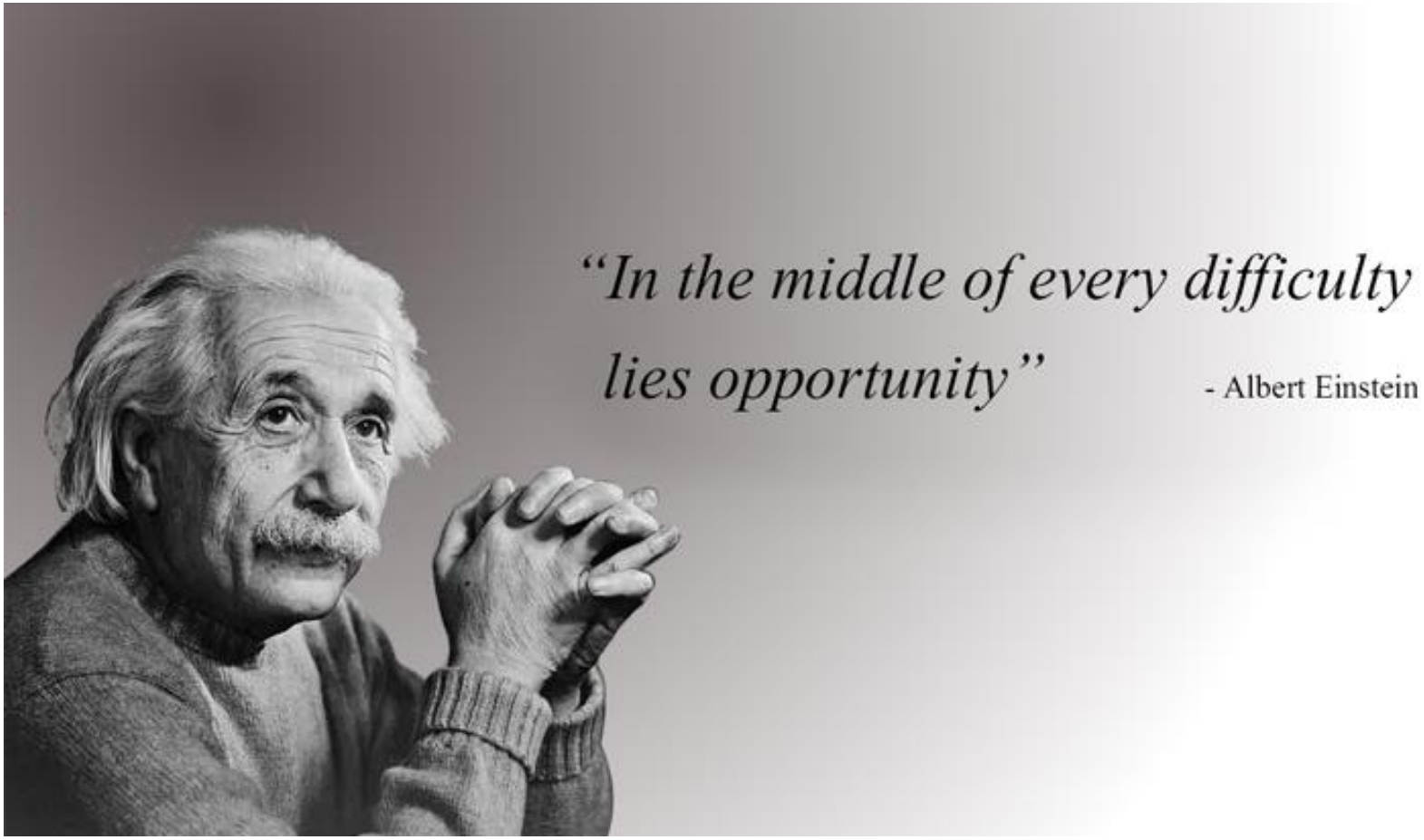
Failure to engage patients



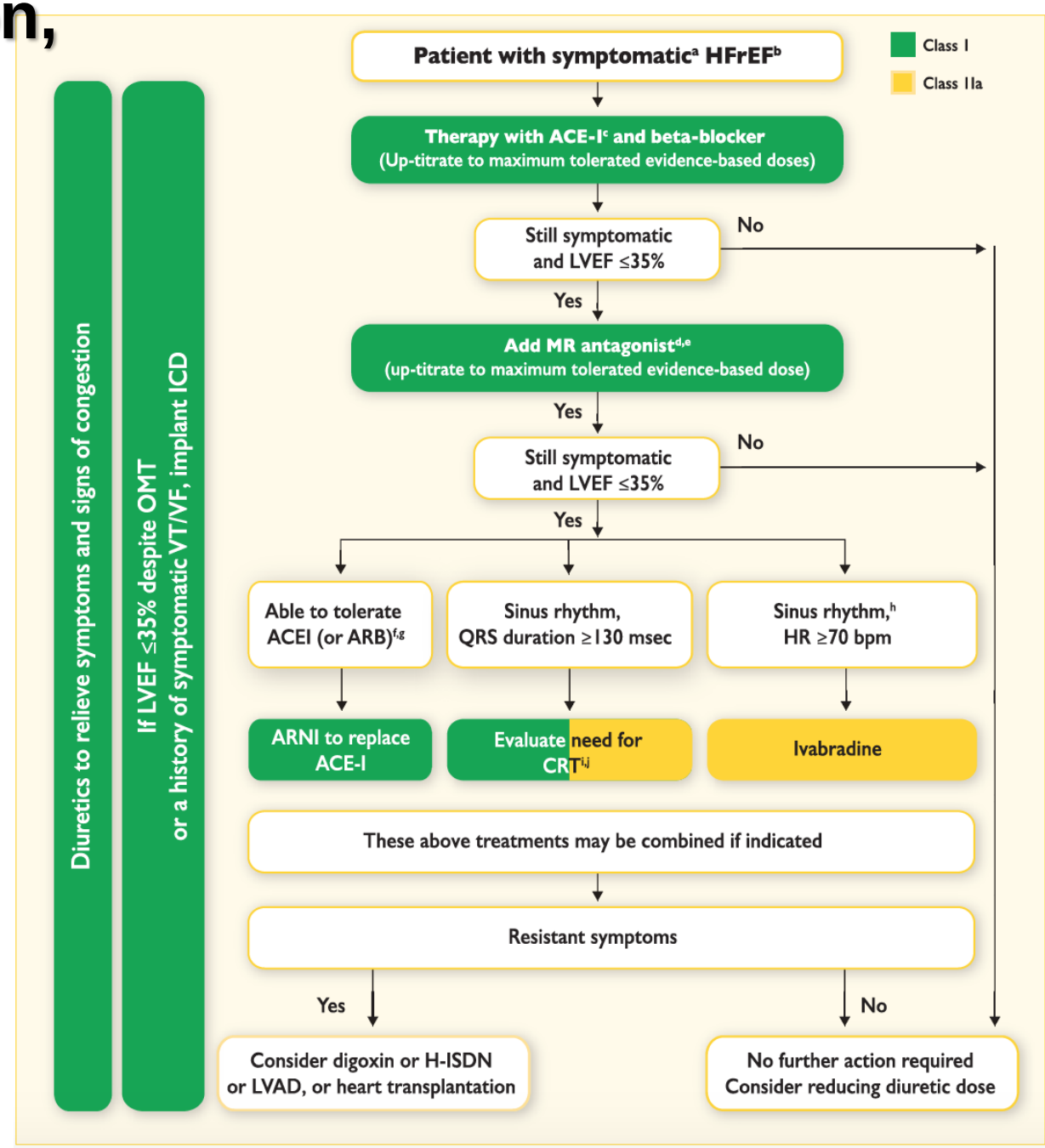
Failure to adhere



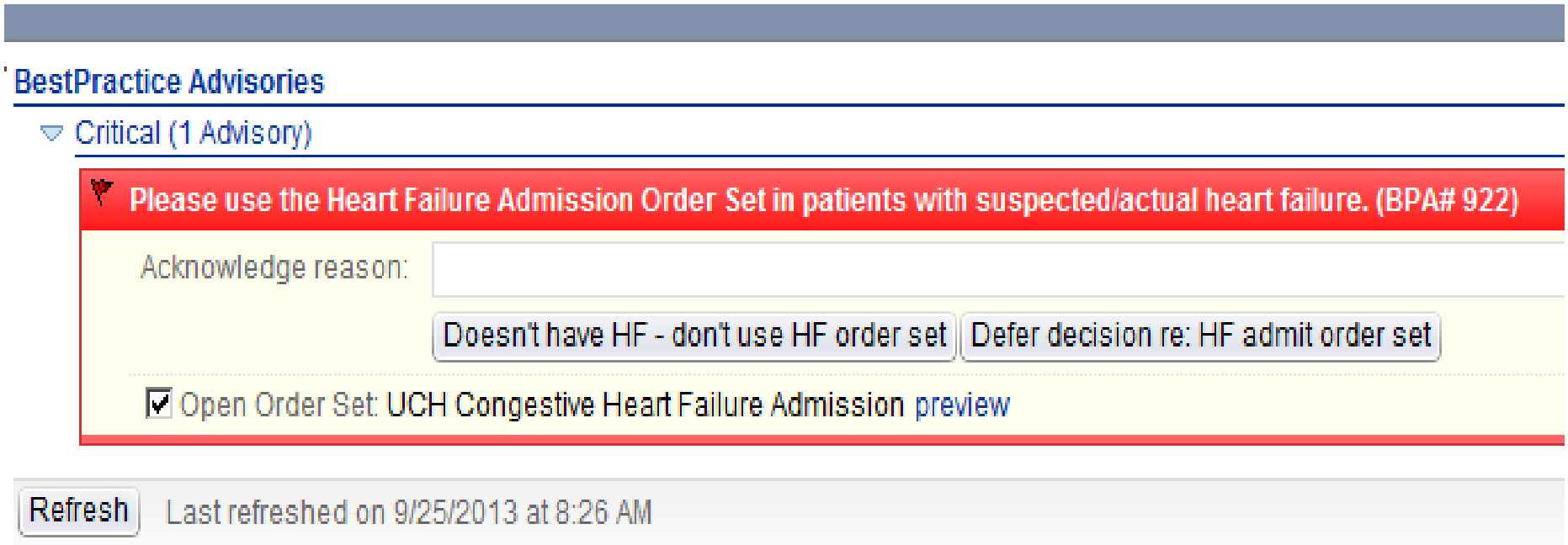

"In the middle of every difficulty
lies opportunity"
- Albert Einstein

#1: Simplification, Step-wise

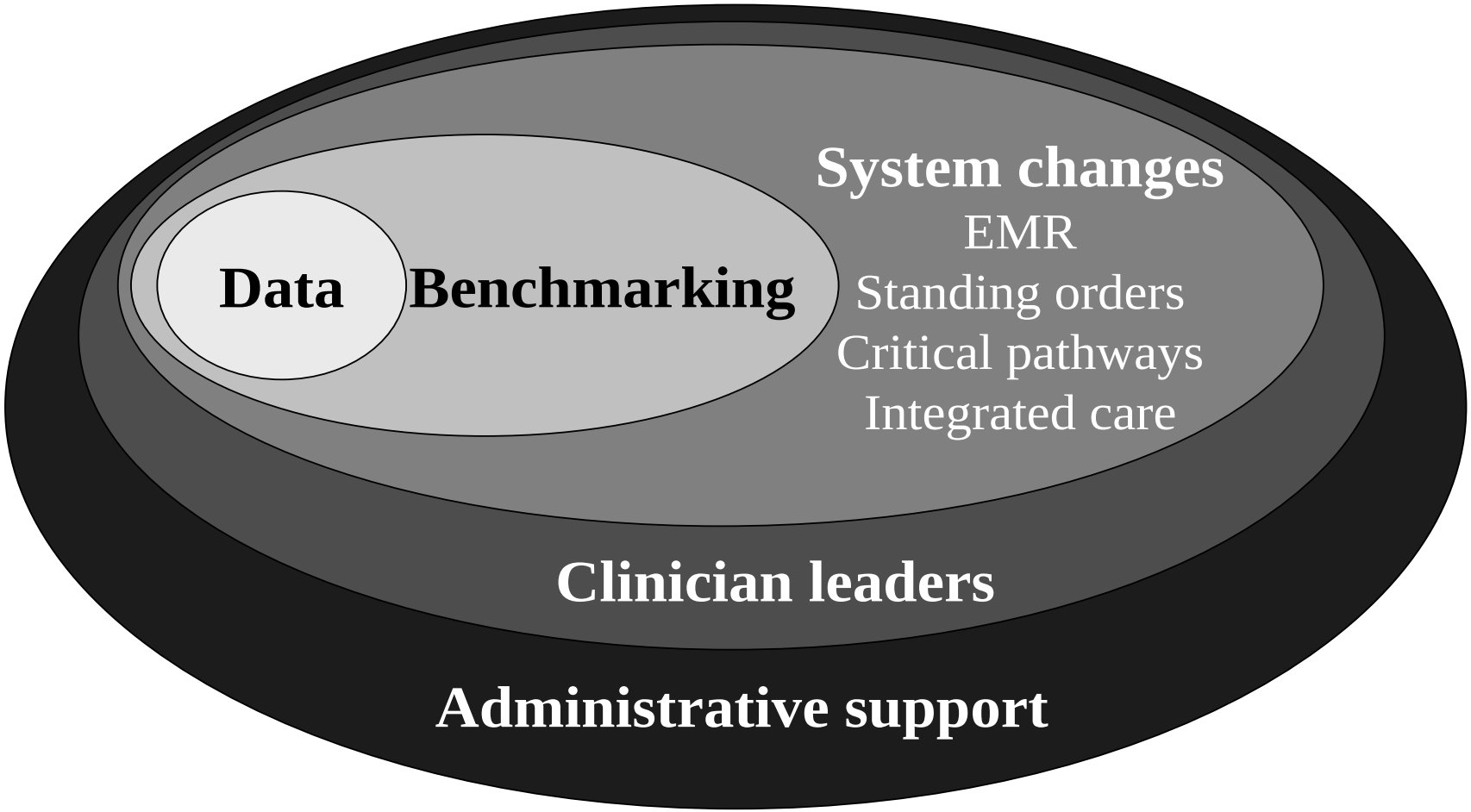
ESC 2016



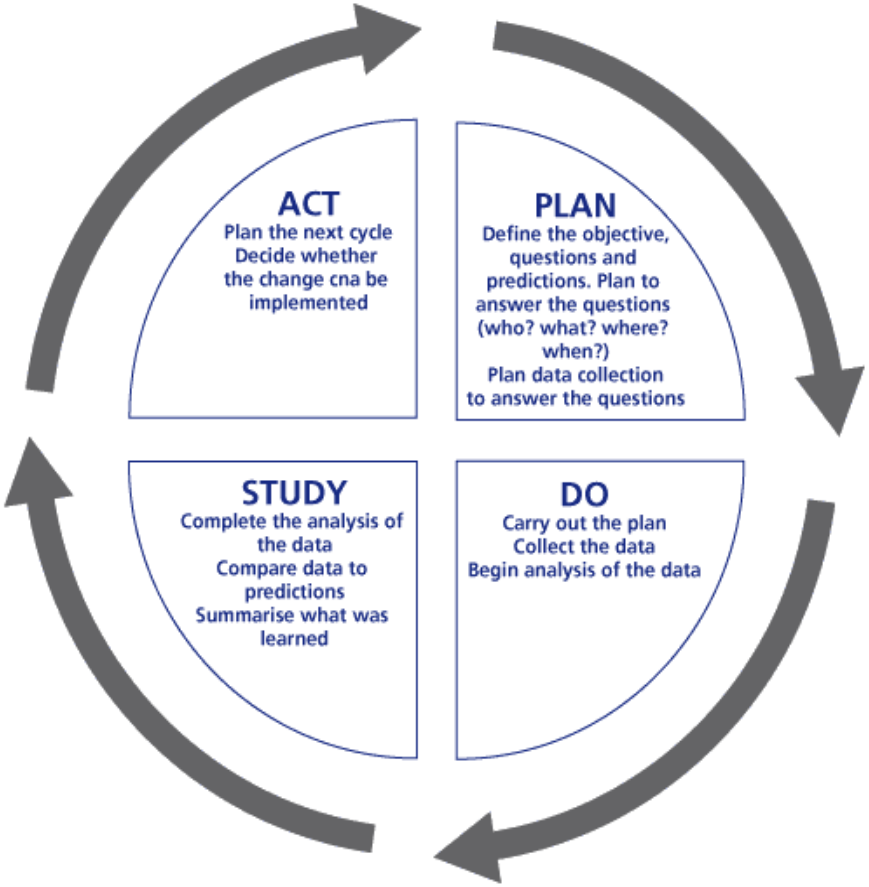
#2: Leverage information technology



#3: Measurement and Feedback
(e.g. NCDR, PINNACLE)

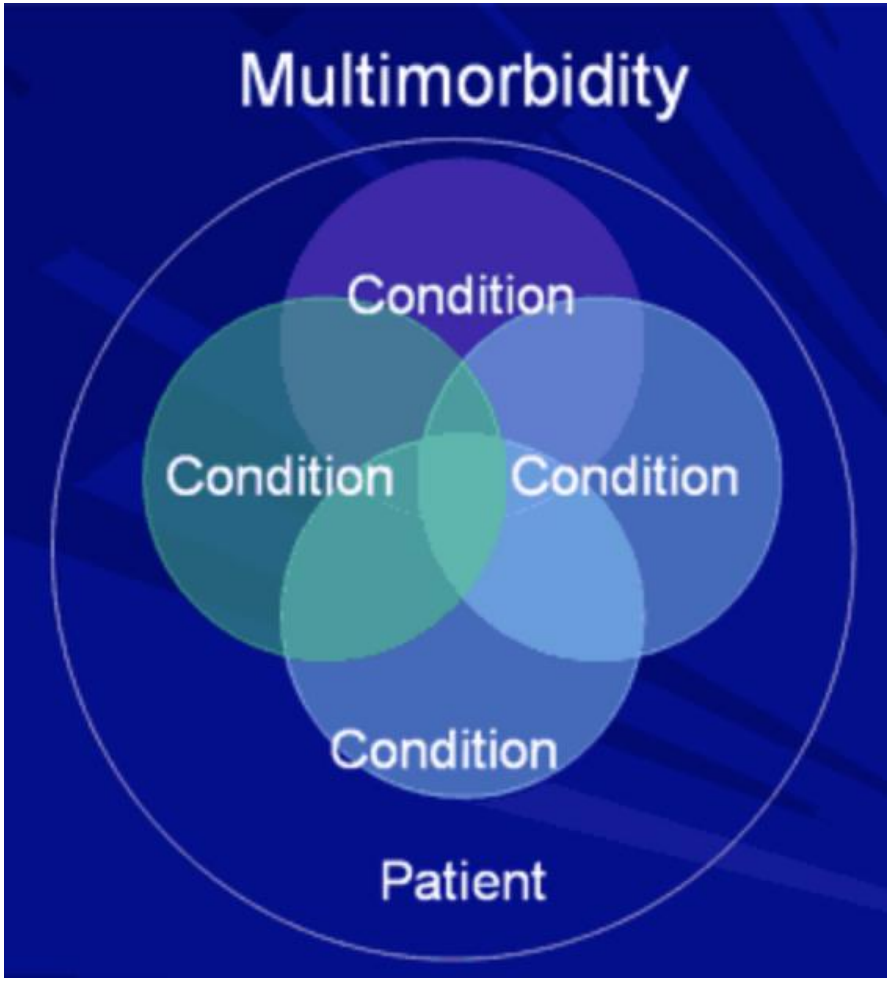


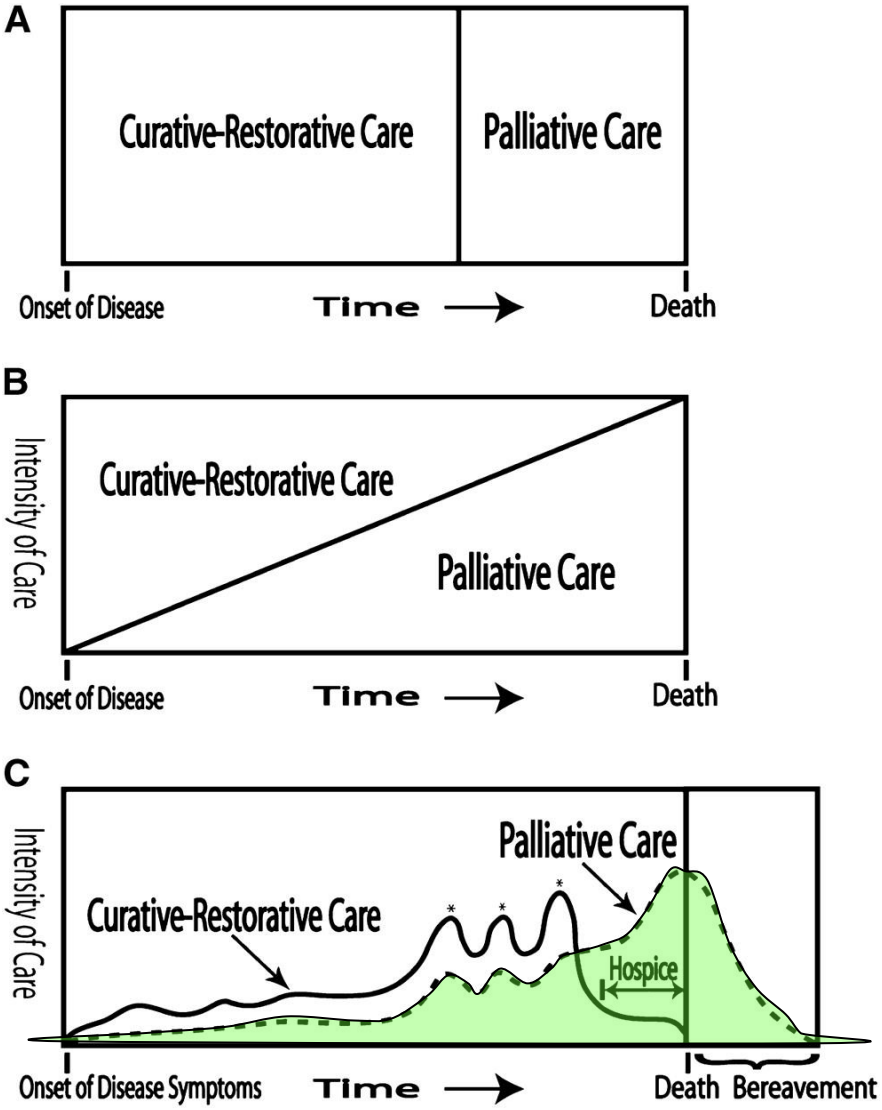
#4: Team-based, local solutions



Lanken PN et al. Am J Respir Crit Care Med 2008.

#5: Big picture context





Lanken PN et al. Am J Respir Crit Care Med 2008.

SUMMARY: What does care optimization for HF mean?

Having the TOOLS and INCENTIVES to provide …

The right treatment for the right patient at the right time!

(The Devil is in the details)

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