AST AMERICAN SOCIETY OF TRANSPLANTATION

LVAD Complications - Understanding Risks and Rewards in the Context of Appropriate Use Benchmarks

Liviu Klein, MD, MS
University of California San Francisco

CEOT CUTTING EDGE of TRANSPLANTATION

TRANSPLANT SUMMIT 2018

Breaking Through Regulatory Barriers to Unleash Transplant Innovation

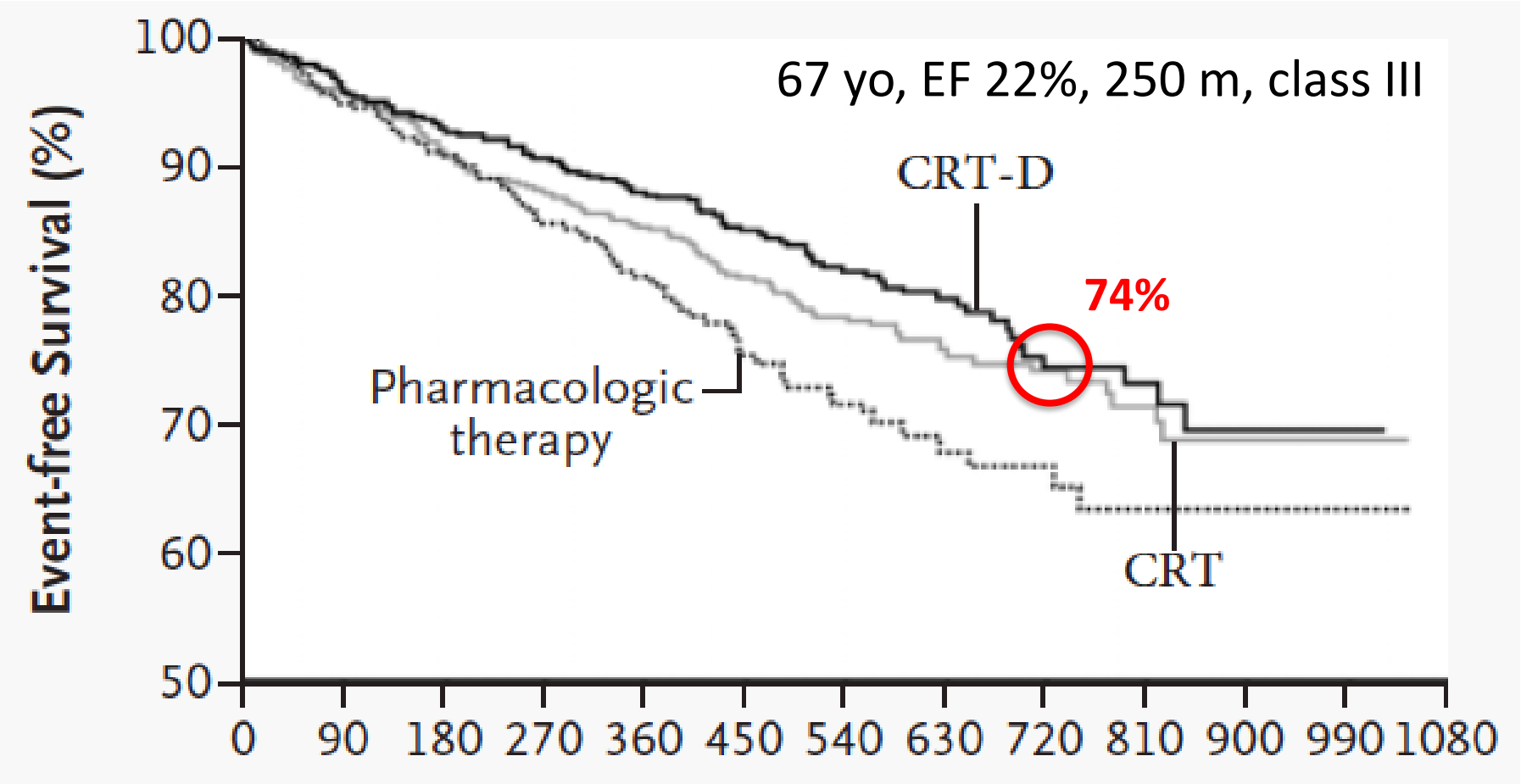
FEBRUARY 8–10, 2018

ARIZONA BILTMORE • PHOENIX, AZ

Disclosure

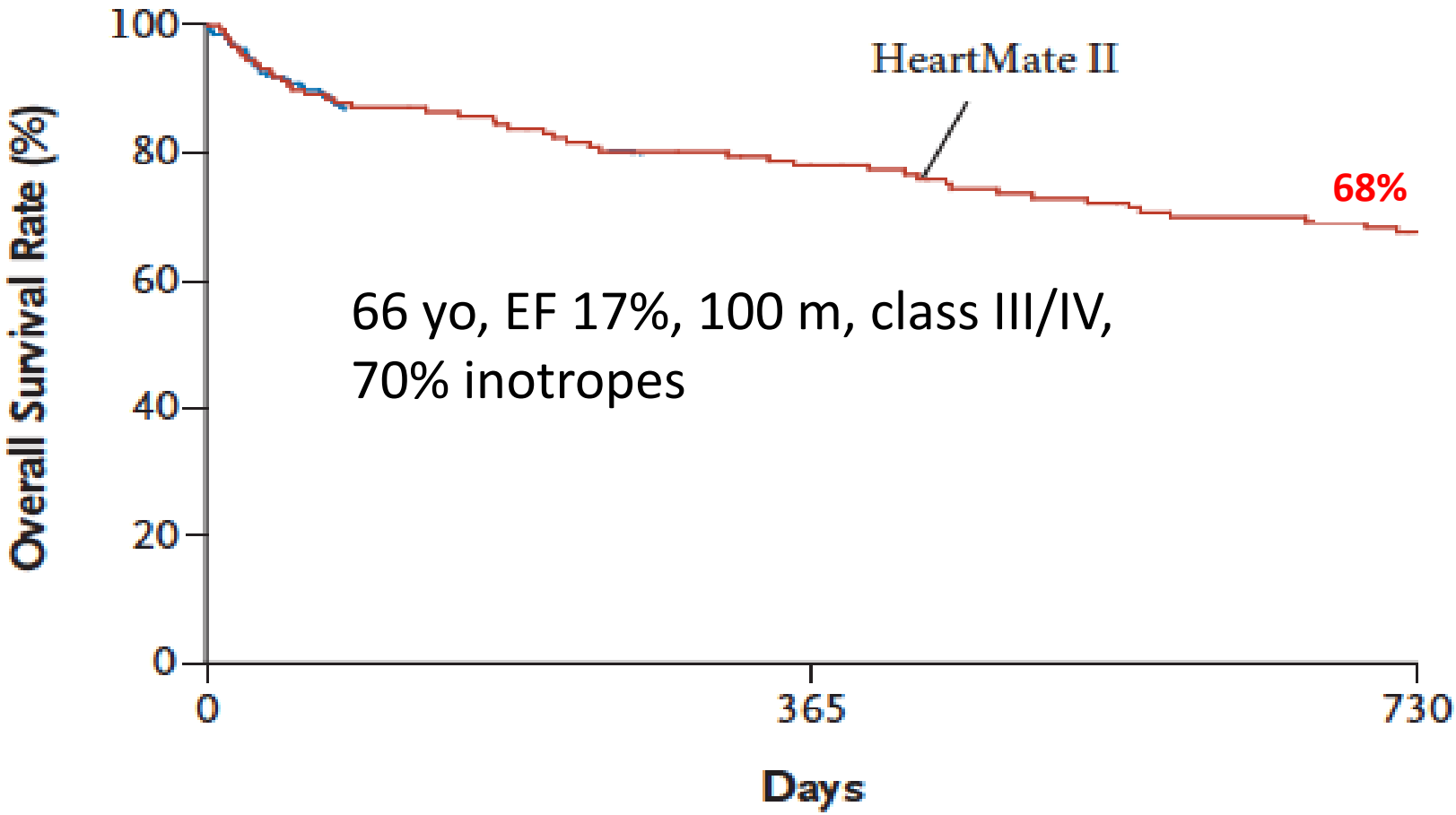
Related to the presentation: Abbott (consultant), Medtronic (consultant), NHLBI (research grants).

Survival in Advanced Heart Failure: A Decade of Progress (COMPANION)



Bristow MR et al. N Engl J Med. 2004;350:2140-2150.

Survival in Advanced Heart Failure: A Decade of Progress (ENDURANCE)



Rogers JG et al. N Engl J Med. 2017;376:451-460.

Current Estimate of Stage D Patients

280 million US adults

↓

~ 2% with HF => ~ 6.5 million

↙ ↘

55% with EF > 40%
~ 3.6 million

45% with EF < 40%
~ 2.9 million

↘

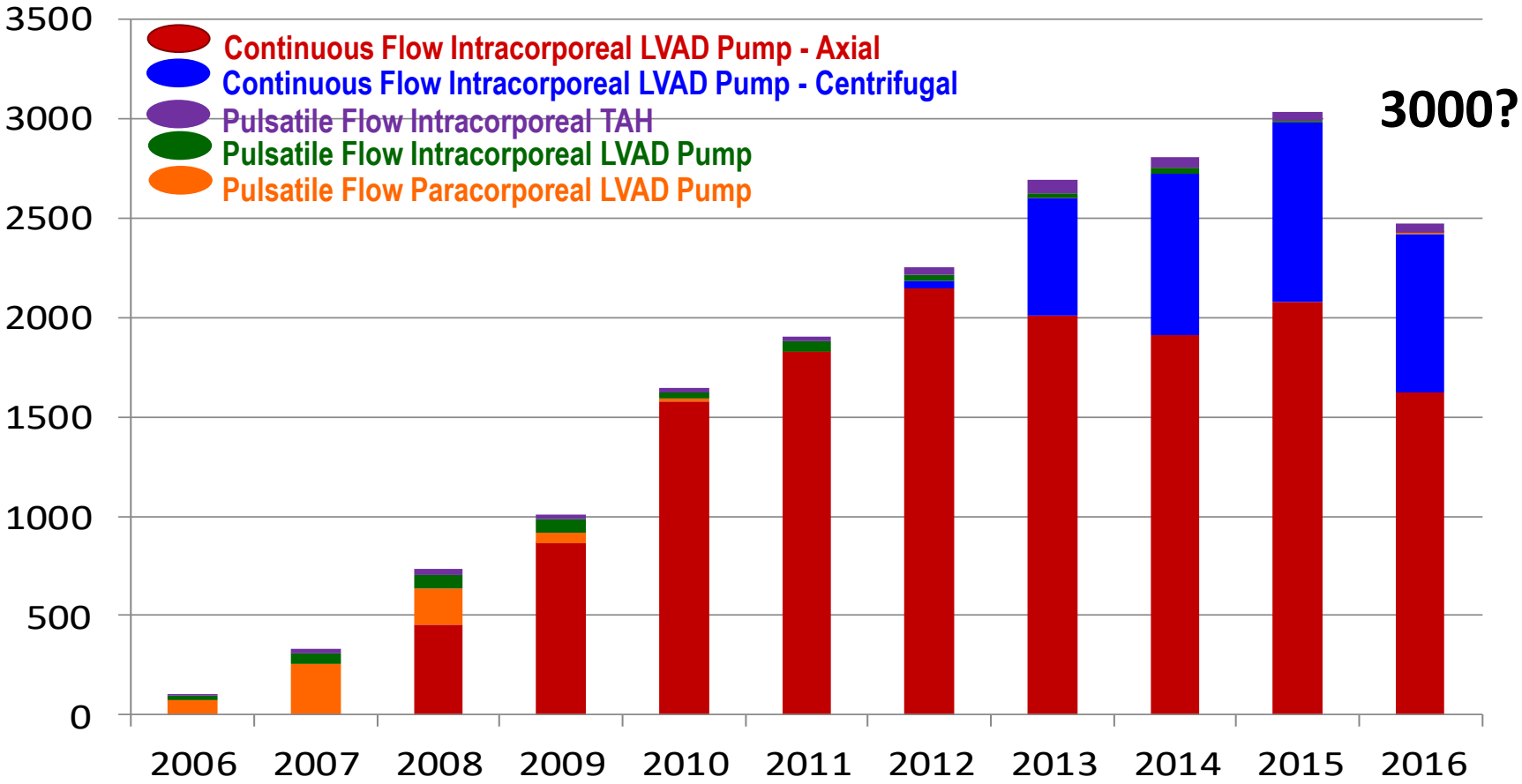
35% NYHA class I
35% NYHA class II
20% NYHA class IIIA
5% NYHA class IIIB
5% NYHA class IV

← EF < 25%, NYHA IIIB/ IV, < 80 yrs.
~ 100,000 pts.

← VADs as BTT/ DT

Adapted from Miller LW et al. Circulation. 2011;123:1552-1558.

Current Estimate of VAD Implants



Kirklin JK et al. J Heart Lung Transplant. 2017;36:1080-1086.

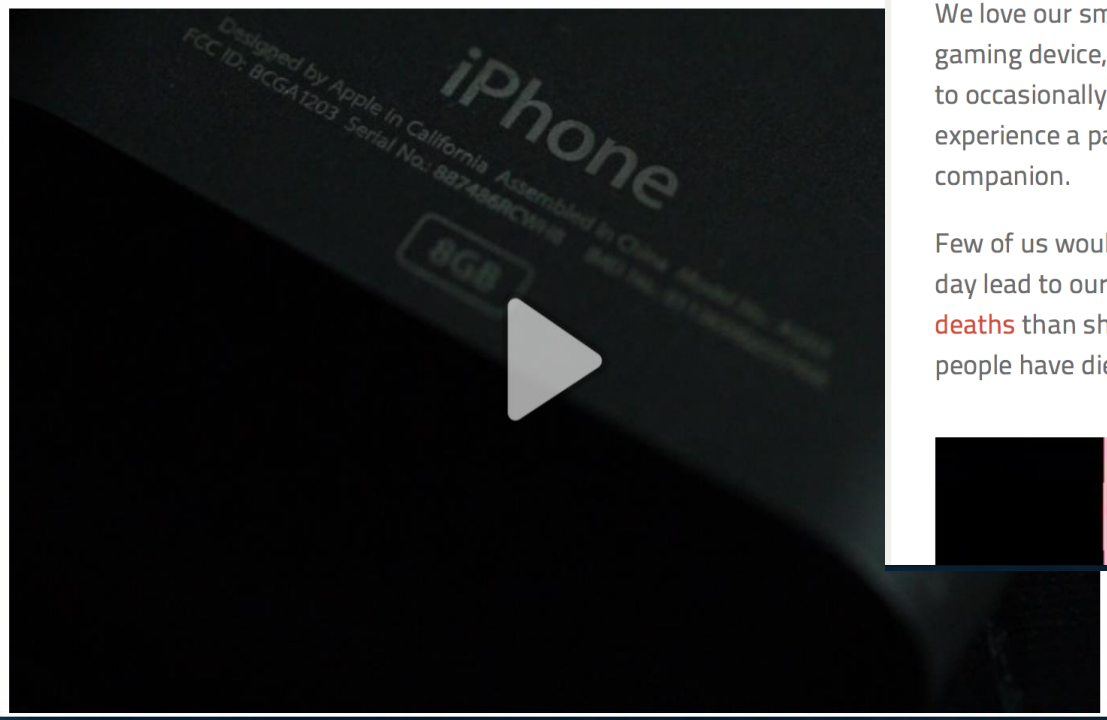

Abbott
life. to the fullest.™
Medtronic

CNN Opinion + Live TV U.S. Edition +

7 ways the iPhone h worse

By Kara Alaimo

Updated 10:09 AM ET, Thu June 29, 2017



Knowledge Lifestyle Science Society More

FACTS

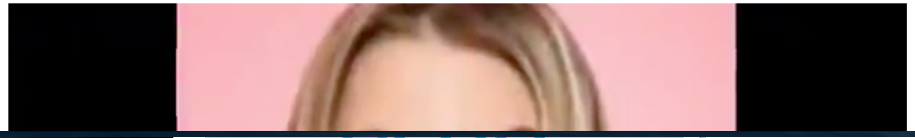
10 Horrific Deaths Caused By Cell Phones

ELLIOT ROSENHAUS MARCH 25, 2016

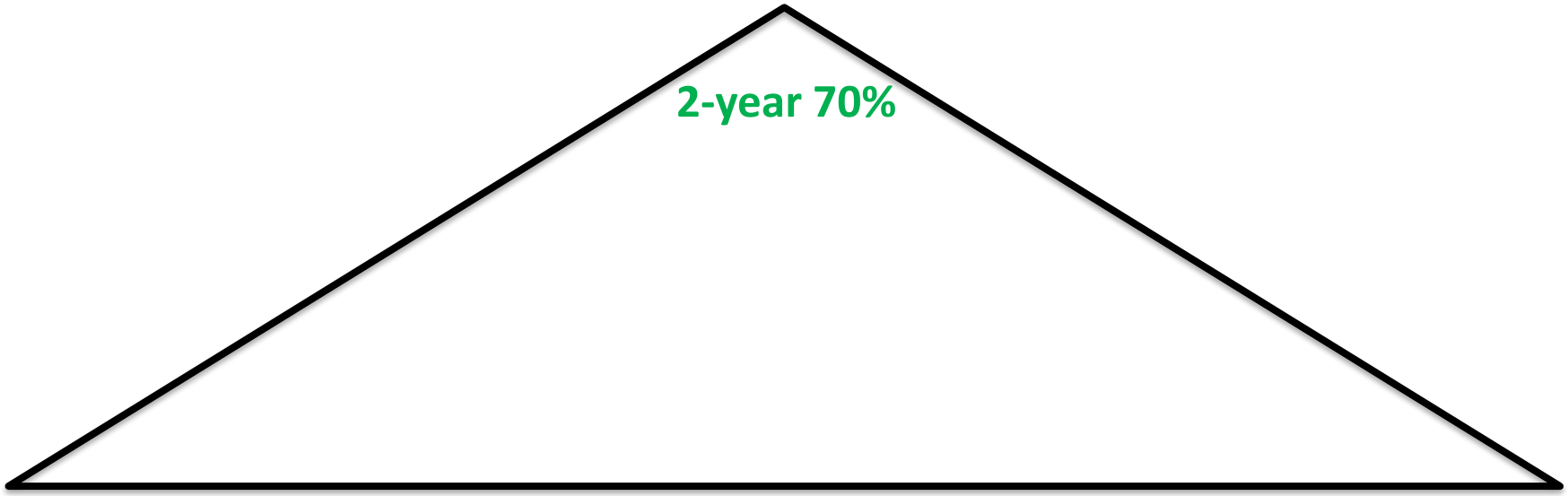
405 14 7 4 430 SHARES

We love our smartphones. They're everything to us—our GPS, our video gaming device, our way to connect with the world socially, and lastly, a way to occasionally communicate when necessary. Many of us will quickly experience a panic attack if we realize that we left home without our digital companion.

Few of us would ever think that the very thing we love so much could one day lead to our death. In fact, more people are now killed in selfie-related deaths than shark attacks! Below are 10 of the most bizarre ways that people have died due to their favorite electronic devices.



Pillars of LVAD Therapy: Risks & Rewards



Adverse Events

High event rate @ 2 years

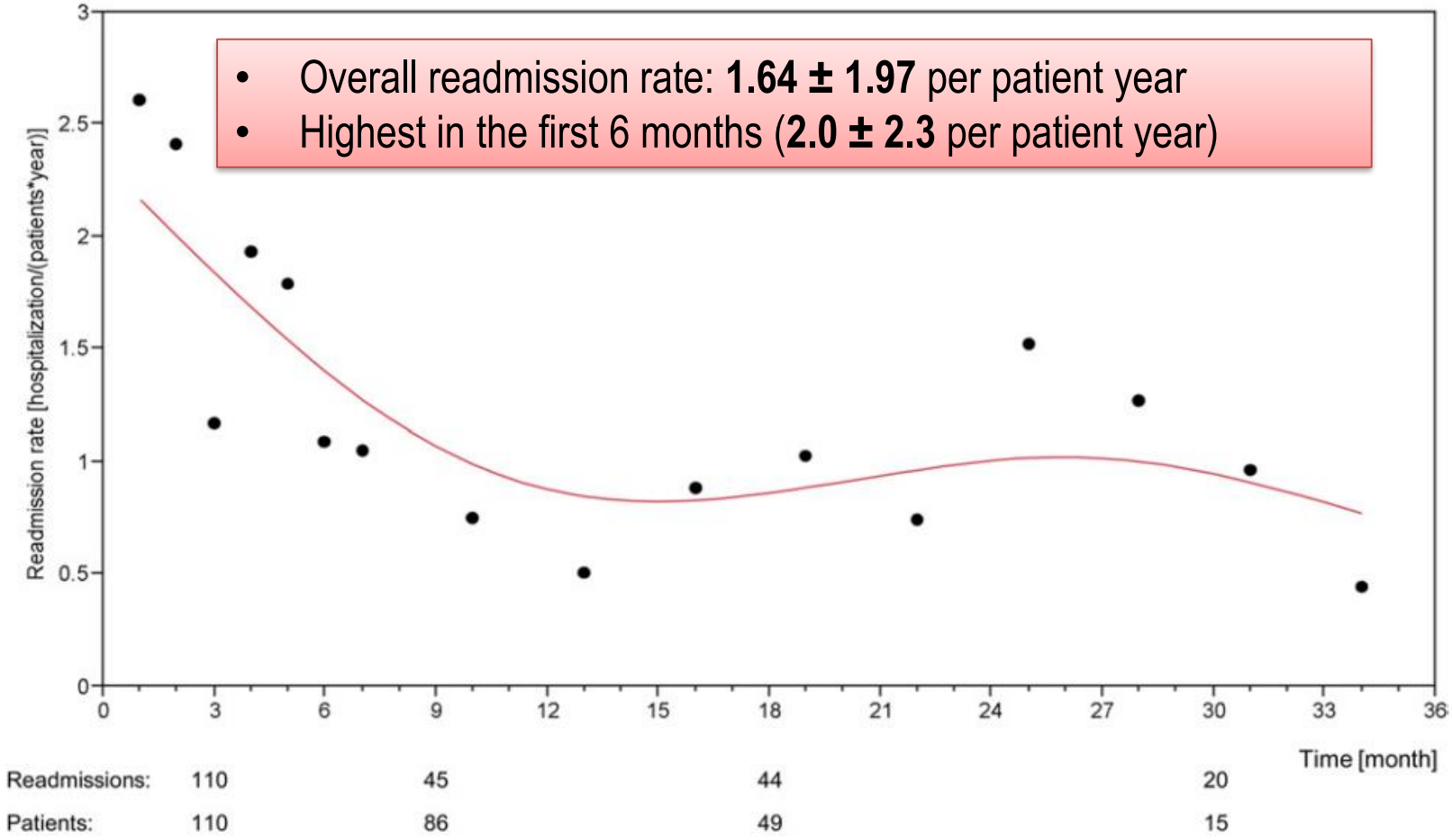
- GI bleeding (25-35%)
- Pump thrombosis leading to replacement (10%)
- Stroke (10-15%)
- Driveline infections (15-20%)
- Hospitalizations (80-90%)

Quality of Life

Improved significantly

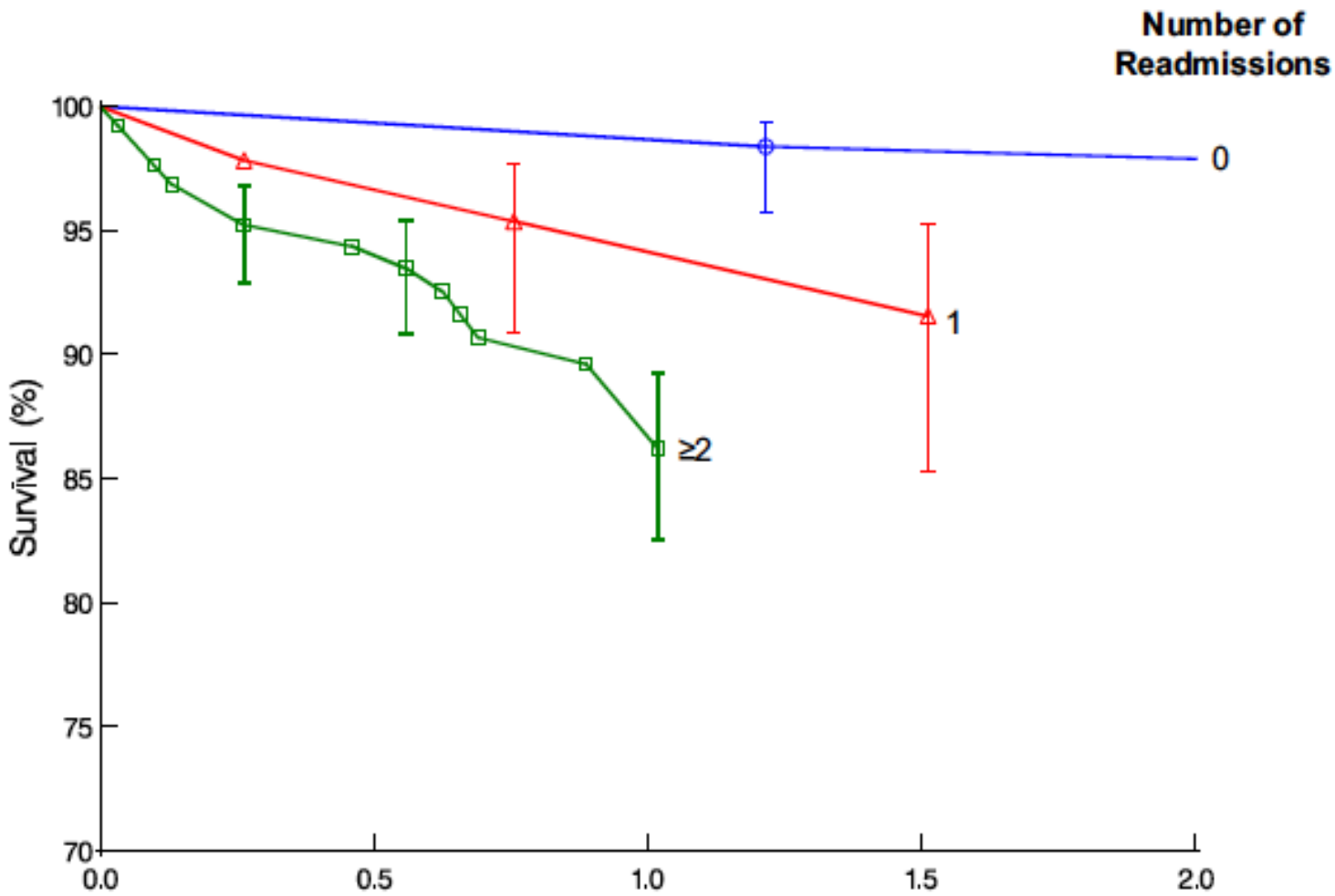
Kirklin JK et al. J Heart Lung Transplant. 2017;36:1080-1086.

Readmissions After LVAD Implant



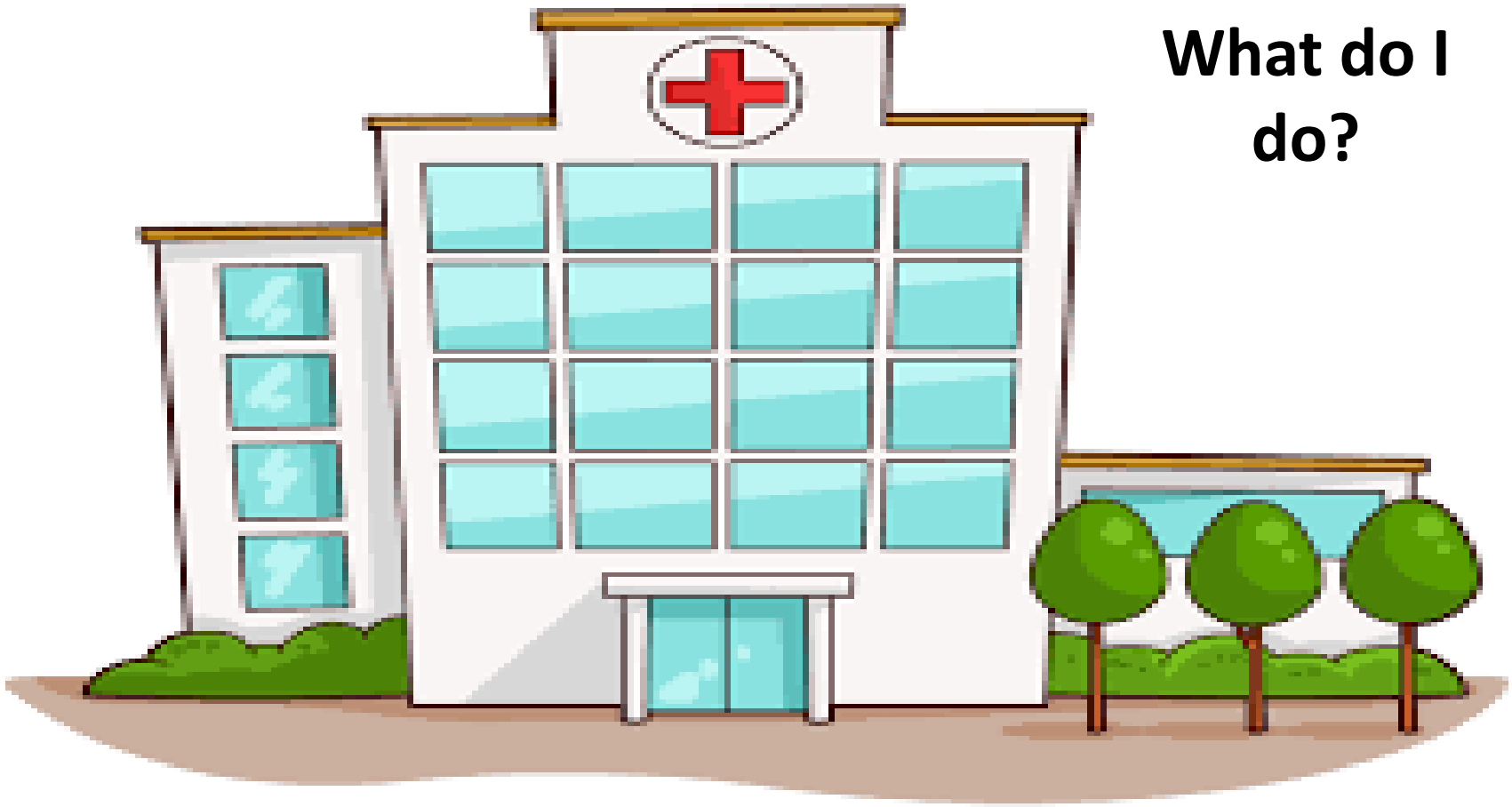
Hasin T et al. J Am Coll Cardiol. 2013;61:153-163.

Readmissions Relate to Survival



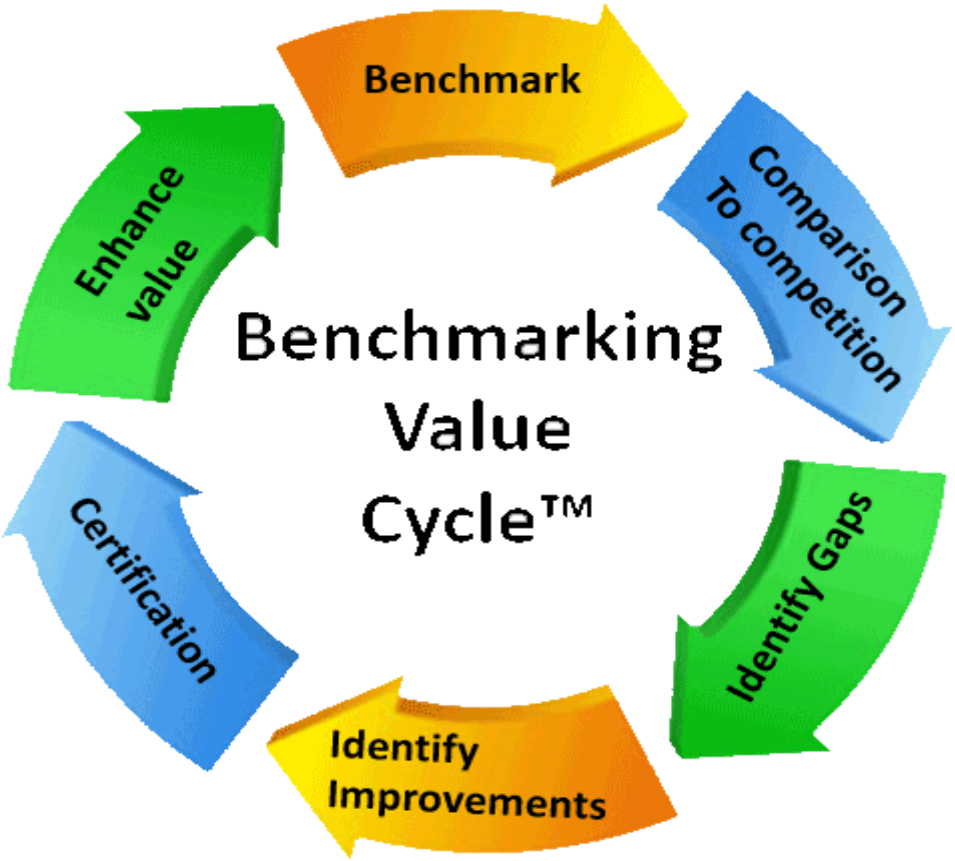
Smedira NG et al. J Am Coll Cardiol: Heart Fail. 2013;1:31-39.

Who's Benchmarking LVAD Therapy?



What do I do?

Benchmarking: a standard or point of reference against which things may be compared or assessed



- What are acceptable AE rates to benchmark against?
- Should we demand/ wait the perfect LVAD that has no AEs?
- Can we use existing technology to lower AEs/?
- Who should keep track, incentivize/ coerce (and how) centers to lower AEs?

How Should LVAD Benchmarking Work?

We will mandate long term (5 yrs) real world data (post-approval registry), we can withdraw approval if AEs are high

We will mandate real world data (QOL PROs, cost effectiveness data) and pay (MIPS) accordingly

We'll help (share best practices), hold you accountable (public data)

We'll make data available in real time, actionable (comparisons across centers)

We'll restrict therapy to CoEs (not just saying it, but actually redirect our members to CoEs and support it $$)

Using Technology to Decrease AEs@ UCSF

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http://dx.doi.org/10.1016/j.jacc.2015.04.031

EDITORIAL COMMENT

Remote Monitoring and Outcomes in Pacemaker and Defibrillator Patients

Big Data Saving Lives?*

James V. Freeman, MD, MPH, MS,† Leslie Saxon, MD‡

Using Technology to Decrease AEs@ UCSF

Can we apply remote monitoring concepts to LVADs?

Preventing	Monitoring
• Bleeding (GI and others)	-> INR
• Stroke	-> INR, BP
• Pump thrombosis	-> INR, VAD parameters
• Heart failure	-> VAD, BP, Weight
• Arrhythmias	-> ICD
• Infections (DL)	-> DL Pictures

Using Technology to Decrease AEs@ UCSF

- Since 2015 all LVAD pts are discharged with Alere VAD Watch or ActiCare home monitoring system
  - Scale, Roche INR, Terumo or A&D BP Cuff or Doppler ICD remote to UCSF
  - Direct download to EPIC
  - Smartphone on all patients -> DL pictures to EPIC
- Weight/ VAD parameters input daily (90% compliance)
- BP checked daily (SBP 90-100; MAP 70-85)
- INR Mon/ Thu if stable (2-2.5), more often if not (enoxaparin 40 mg QD if INR < 2)
- Labs on demand (Quest/ LabCorp) -> download to EPIC

Using Technology to Decrease AEs@ UCSF

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My Lists

- AHFS
- AURORA
- CARDIOM...
- CVRx
- HP2E
- LK Patients
- LVAD Active
- LVAD Inac...
- LVAD Wor...
- MV CLIP
- REPORT

Available Lists

- Recent Searc...
- System Lists
- Case Manag...
- Pended Babies
- Preadmitted ...
- Procedural Ar...
- Recently Disc...

LVAD Active

Refreshed 1 minute ago | Search Parnassus P...

Implant Date	Reason	Date (Speed, Flow, Pwr)	Speed	Flow	Power	Alere Weight Date	Alere Weight	Alere INR Date	Alere INR	Alere Data Reviewed	Last LDH Date	Last LDH (< 90 days)
02/05/2016	DT	02/07/2018	8000 RPM	! 12 L/min	10.2 watts	02/07/2...	182.6 lbs	02/07/2...	✓ 2.5	✓ Yes	02/07/2018	✓ 213
03/13/2014	DT	02/06/2018	9390 RPM	✓ 5.1 L/min	5.6 watts	02/06/2...	162.8 lbs	02/06/2...	✓ 2.4	✓ Yes	01/17/2018	⚠ 353
04/05/2016	DT	02/07/2018	9200 RPM	✓ 4.2 L/min	5 watts	02/07/2...	230.5 lbs	02/06/2...	✓ 2	No	01/12/2018	✓ 190
04/13/2016	DT	01/25/2018	10200 RPM	! 6.5 L/min	7.3 watts	01/25/2...	352.5 lbs	01/09/2...	✓ 2.4	—	01/26/2018	✓ 198
04/13/2017	DT	02/07/2018	9000 RPM	✓ 3.9 L/min	4.6 watts	02/07/2...	180.4 lbs	02/05/2...	✓ 2.8	—	01/13/2018	✓ 149
04/28/2014	DT	02/07/2018	9800 RPM	✓ 4.6 L/min	5.7 watts	02/07/2...	190 lbs	02/05/2...	! 1.7	—	12/09/2017	✓ 201
05/11/2016	DT	02/06/2018	9400 RPM	✓ 5.8 L/min	5.8 watts	02/06/2...	280.5 lbs	02/06/2...	✓ 2.1	✓ Yes	01/22/2018	✓ 231
05/16/2016	DT	02/07/2018	9000 RPM	✓ 4.5 L/min	4.9 watts	02/07/2...	206.4 lbs	02/07/2...	✓ 2	—	11/18/2017	✓ 215
05/26/2016	DT	02/07/2018	9610 RPM	✓ 4.7 L/min	5.7 watts	02/07/2...	234 lbs	02/07/2...	✓ 2	✓ Yes	10/19/2017	—
06/24/2016	BTT	02/07/2018	2810 RPM	✓ 5.1 L/min	5.5 watts	02/07/2...	241 lbs	02/05/2...	✓ 2	—	12/19/2017	✓ 184
07/06/2016	BTT	02/06/2018	3000 RPM	! 6.2 L/min	5.2 watts	02/06/2...	273 lbs	02/02/2...	✓ 2.7	—	01/31/2018	⚠ 268
07/07/2015	DT	02/07/2018	9000 RPM	✓ 3.5 L/min	4.5 watts	02/07/2...	236 lbs	02/06/2...	✓ 2.4	No	01/09/2018	⚠ 371
07/22/2013	BTT	02/07/2018	2900 RPM	✓ 3.6 L/min	5.3 watts	02/07/2...	198.6 lbs	02/05/2...	! 3	—	01/30/2018	✓ 195
08/03/2017	BTT	02/07/2018	2700 RPM	✓ 5 L/min	4.9 watts	02/07/2...	196 lbs	02/05/2...	✓ 2.6	—	01/30/2018	⚠ 279
08/19/2016	BTT	02/07/2018	2700 RPM	✓ 4.6 L/min	4.1 watts	02/07/2...	206.4 lbs	02/05/2...	✓ 2.7	—	02/05/2018	⚠ 254

LVAD Patient Report | Profile | Med List

LVAD Patient Report

LIVIU KLEIN | 0 | 5:46 AM

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04/05/2016	DT	02/07/2018	9200 RPM	✓ 4.2 L/min	5 watts	02/07/2...	230.5 lbs	02/06/2...	✓ 2	No	01/12/2018	✓ 190

LVAD Patient Report | Profile | Med List

LVAD Patient Report

	1/28/2018	1/29/2018	1/30/2018	1/31/2018	2/1/2018	2/2/2018	2/3/2018	2/5/2018
Flow (L/min):	10.6 L/min	5.6 L/min	5.1 L/min	12 L/min	11.3 L/min	12 L/min	12 L/min	12 L/min
Power (W) :	7.8 watts	5.3 watts	5 watts	8.8 watts	8 watts	8.9 watts	8.7 watts	8.6 watts
PI/ Pulsatility:	4.4	6	6.1	4.2	4.5	4.3	4.2	4.6
Systolic BP (VAD):	93	97	89	90	103	84	85	93
Diastolic BP (VAD):	67	71	74	76	84	67	71	78
Alere pulse (bpm):	95 bpm	86 bpm	85 bpm	85 bpm	98 bpm	90 bpm	95 bpm	95 bpm
Alere weight (lbs):	182.2 lbs	181 lbs	183 lbs	180.2 lbs	181.2 lbs	181.2 lbs	181.6 lbs	182.6 lbs
Alere temperature (F):	98.6	98.5	99	98.6	98.6	98.6	98.6	99.5
Alere INR:	1.2	1.2	1.4	-	-	2.4	3.1	5.9

	2/6/2018	2/7/2018
Flow (L/min):	12 L/min	12 L/min
Power (W) :	8.7 watts	10.2 watts
PI/ Pulsatility:	4.6	4
Systolic BP (VAD):	97	97
Diastolic BP (VAD):	78	77

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LVAD Patient Report | Profile | Med List

LVAD Patient Report

Last 3 WBC Values

	1/21/2018 4:57 PM	1/23/2018 12:12 PM	2/2/2018 1:27 PM
WBC	7.22	5.4	5.6

Last 3 Hemoglobin Values

	1/21/2018 4:57 PM	1/23/2018 12:12 PM	2/2/2018 1:27 PM
HGB	13.8	13.1 (L)	12.7 (L)

Last 3 Hematocrit Values

	1/17/2018 5:29 AM	1/23/2018 12:12 PM	2/2/2018 1:27 PM
HCT	41.4	38.6	37.2 (L)

Last 3 INR Values

	2/6/2018	2/7/2018	2/7/2018 3:55 PM
INR	4.8	2.5	2.1 (H)

Last 3 Lactate Dehydrogenase Values

	1/23/2018 12:12 PM	2/2/2018 1:27 PM	2/7/2018 3:55 PM
LDEXQ	204	217	213

Last 3 Plasma Free Hemoglobin Values

	1/15/2018 9:06 AM	1/16/2018 7:38 AM	1/17/2018 5:29 AM
PHGBS	<8	<8	<8

Last 3 BNP Values

	8/11/2017 1:12 PM	1/13/2018 6:08 AM	1/13/2018 2:05 PM
BNP	173 (H)	306 (H)	251 (H)

Last 3 Creatinine Values

	1/17/2018 5:29 AM	1/23/2018 12:12 PM	2/2/2018 1:27 PM
CREAT	1.19	1.50 (H)	1.23

Last 3 Potassium Values

	1/21/2018 4:48 PM	1/23/2018 12:12 PM	2/2/2018 1:27 PM
K	4.0	4.7	4.3

Recent Procedure Details

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04/05/2016	DT	02/07/2018	9200 RPM	✓ 4.2 L/min	5 watts	02/07/2...	230.5 lbs	02/06/2...	✓ 2	No	01/12/2018	✓ 190

LVAD Patient Report | Profile | Med List | LVAD Patient Report

Sig - Route: Inject 0.4 mLs (40 mg total) under the skin every 12 (twelve) hours. When instructed by MCS - Subcutaneous

hydrALAZINE (APRESOLINE) 25 mg tablet 180 tablet 11 5/18/2017
Sig - Route: Take 2 tablets (50 mg total) by mouth every 8 (eight) hours. - Oral

magnesium oxide (MAG-OX) 400 mg tablet 60 tablet 3 9/8/2017
Sig - Route: Take 2 tablets (800 mg total) by mouth Daily. - Oral

potassium chloride 20 mEq/15 mL solution 300 mL 3 12/29/2017
Sig - Route: Take 7.5 mLs (10 mEq total) by mouth Daily. - Oral

spironolactone (ALDACTONE) 50 mg tablet 90 tablet 3 7/27/2017
Sig - Route: Take 1 tablet (50 mg total) by mouth Daily. - Oral

warfarin (COUMADIN) 5 mg tablet 30 tablet 11 7/1/2017
Sig - Route: Take 1 tablet (5 mg total) by mouth Daily. Use as instructed - Oral

Quick Encounters

Orders Only Encounter	Anticoag Encounter	Documentation Only Encounter
Click to create new	Click to create new	Click to create new

LIVIU KLEIN | 0 | 5:47 AM

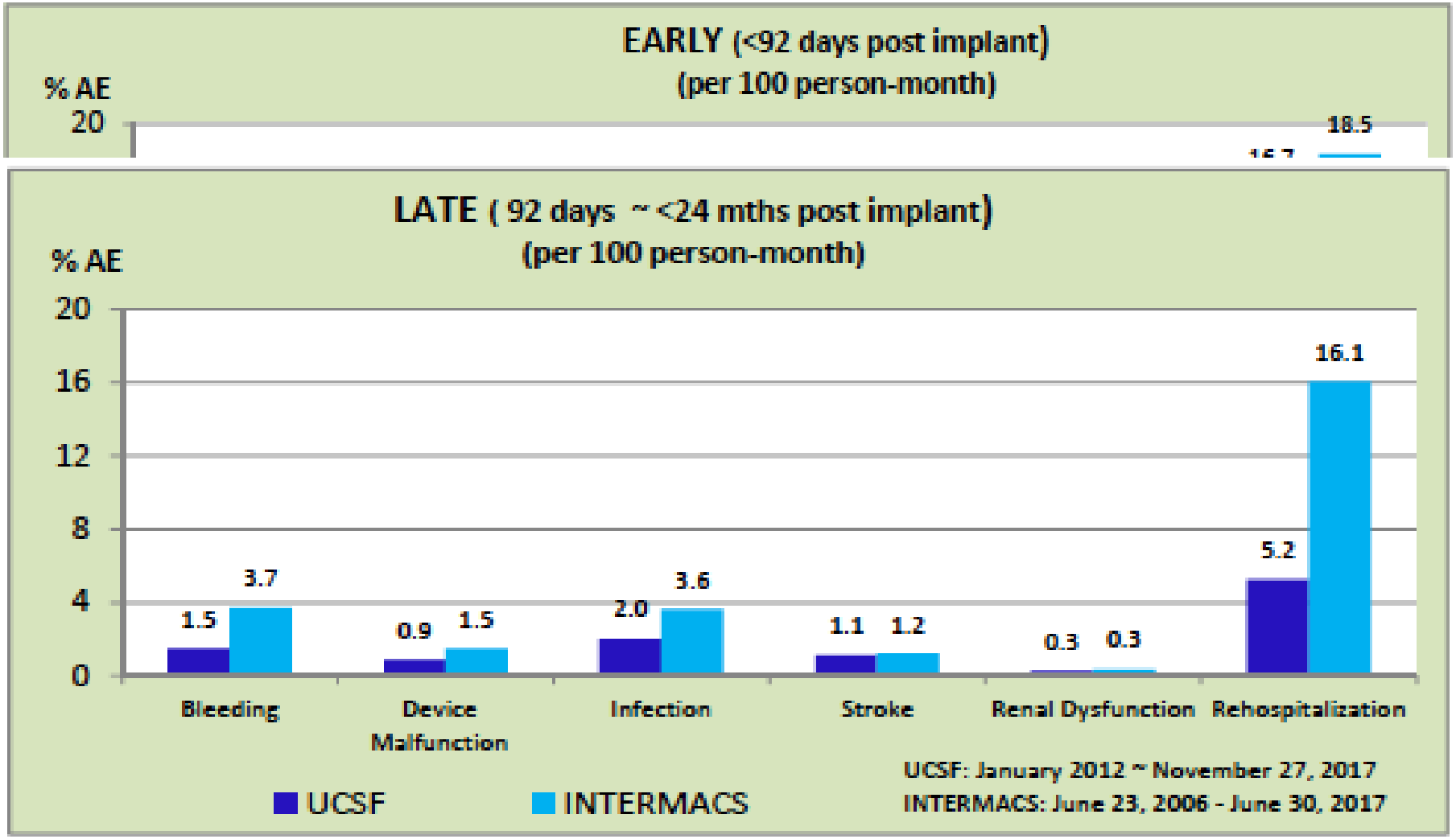
Using Technology to Decrease AEs@ UCSF

- 150 IT hours (~ $20,000) from UCSF -> 3 months implement
- Partnered with vendors (Alere, ActiCare)

- LVAD RN time spent per patient per day ~ 7 min

- Time in therapeutic range: INR (82%), BP (85%)
- 22% reduction in all cause readmissions
- 39% reduction in VAD related readmissions (GI bleed, pump thrombosis, stroke, arrhythmias, heart failure, DL infections)
- 21% reduction in GI bleed
- 54% reduction in stroke/ pump thrombosis
- All pump thrombosis episodes (n=15 over 2 years) treated medically (both HM2 and HVAD), no pump exchange

Using Technology to Decrease AEs@ UCSF



LVAD Complications: Understanding Risks, Rewards and Benchmarking

- MCS community needs to agree on acceptable AE rates over time (5 yrs+), QOL (PROs) and how to monitor them
- LVAD programs need to work with Industry, FDA, CMS, TJC, INTERMACS, Private payers on establishing benchmarks and being held accountable for them (including limiting the number of programs that offer LVADs)
- Until Elon Musk invents the perfect pump that has no thrombosis, no stroke, no GI bleeding and without driveline and is powered indefinitely by a low energy battery we ***should use existing technology to improve AEs NOW***