



MONITOR

*Monitoring Organ donors to
Improve Transplantation Results*



www.monitorstudy.org



Grant #R38OT10587

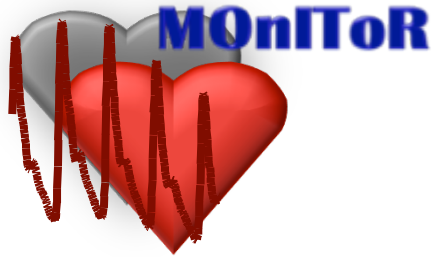


A grass-roots effort

Table F1. MOnIToR Planning and Executive Committees

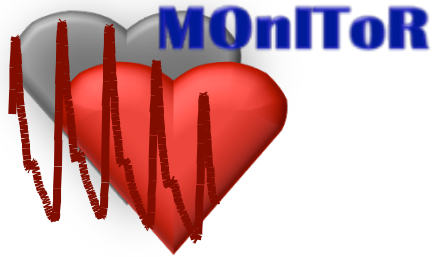
		PC	EC
Ali Al-Khafaji, MD	University of Pittsburgh	■	■
Luis Angel, MD	University of Texas		■
Michelle Berens, RN	Gift of Hope, Elmhurst, IL	■	
Christine Cottingham, RN, MS	University of Washington, Harborview, Seattle, WA	■	
Michele Elder, RN	University of Pittsburgh	■	
Mike Harmon, RN	Gift of Hope, Elmhurst, IL	■	
J. Steven Hata, MD	University of Iowa	■	■
Ibtesam Hilmi, MD	University of Pittsburgh	■	
John A. Kellum, MD	University of Pittsburgh	■	■
Dan Lebovitz, MD	Cleveland Clinic/LifeBanc	■	■
Ken McCurry, MD	University of Pittsburgh	■	
Martin Mozes, MD	Gift of Hope, Elmhurst, IL	■	■
Raghavan Murugan, MD	University of Pittsburgh	■	
C. Lee Parmley, MD, JD	Vanderbilt University	■	■
Ali Salim, MD	Cedars-Sinai Hospital		■
Alan Spriggs	CORE, Pittsburgh, PA	■	
Mike Souter, MD	University of Washington, Harborview, Seattle, WA	■	■
Susan Stuart RN, MPM	CORE, Pittsburgh, PA	■	■
Ken Wood, MD	University of Wisconsin	■	■

PC – Protocol Planning Committee; EC – Executive Committee



Purpose

- “ To increase the number of organs transplanted per donor using protocol-guided donor fluid management strategy after brain death ”
 - Goals of management is to optimize:
 - Intravascular volume status
 - Blood pressure
 - Cardiac output
 - Oxygen delivery to transplantable organs
 - (Evaluate inflammatory biomarkers in brain dead donors)



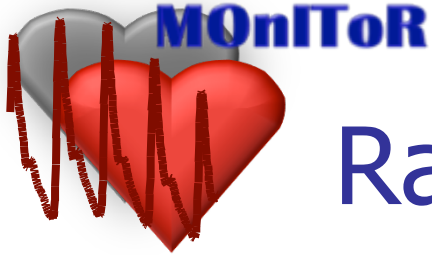
Outcomes

■ Primary

- Mean number of organs transplanted per donor

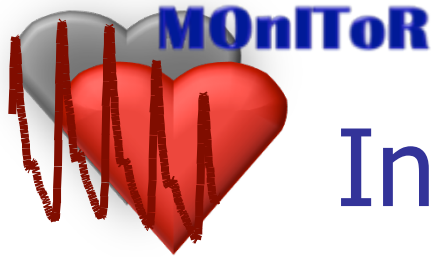
■ Secondary

- 6 month hospital-free survival in recipients
- Mean number organs transplantable
- Changes in inflammatory markers (IL-6)



Randomized Clinical Trial

- Enroll 960 Brain Dead Donors over 18 months period
 - 80% statistical power to detect a 0.5 organ/donor increase (16% increase)
 - Randomized 1:1 protocol arm versus usual care (by site and age).
 - Randomization done via secure website.
 - Goal of involving as many OPOs as possible to expedite data collection.
 - Currently 6 OPOs are enrolling
-



Inclusion/Exclusion Criteria

Inclusion Criteria

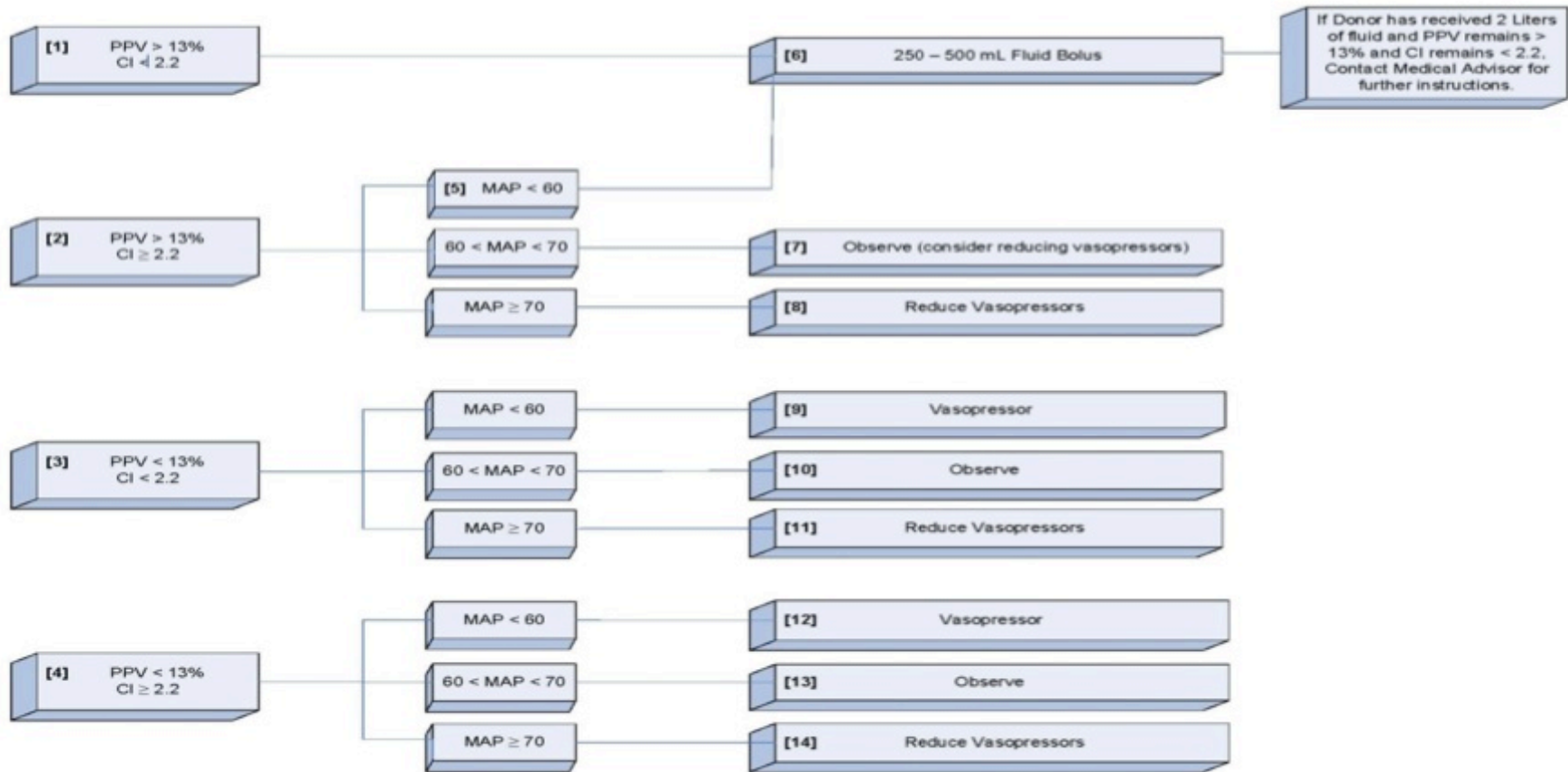
Declared brain dead
Suitable for donation
Standard & extended
criteria apply

Exclusion Criteria

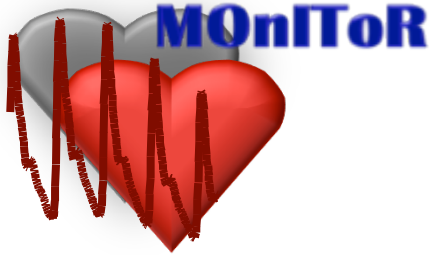
<16 years
Pregnant donor
Inability to perform
LiDCO monitoring
Immunosuppressive Rx



Resuscitation Algorithm



Monitoring Organ donors to Improve Transplantation Results



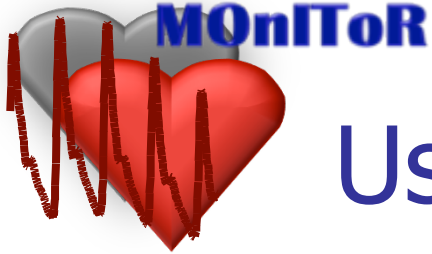
Protocol Guided Management Using FHM

■ LiDCO Plus Monitor

Target values:

- **MAP 60-70 mmHg**
- **CI \geq 2.2**
- **PPV \leq 13%**

**NO CONTROL OF ANY OTHER INTERVENTIONS
SUCH AS HORMONAL REPLACEMENT,
STEROIDS etc....**



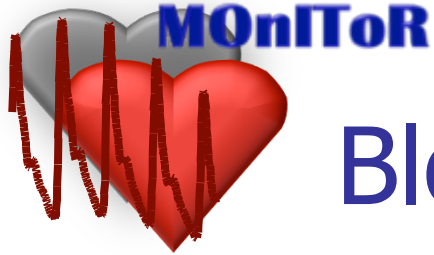
Usual Care Management

- Will follow site standard of care
- LiDCO not connected-not used
- Donor will be randomized
 - Cannot add donor if LiDCO not available



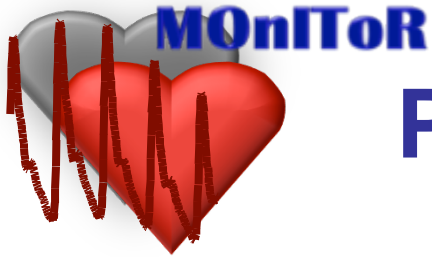
Why LiDCOplus?

- Calibrated system
 - Lithium dilution indicator
 - Non-calibrated systems based on algorithms –not validated in brain death
 - 15% of cardiac output to cerebral circulation
 - 20% of oxygen consumption is the brain
 - Support of company
 - Training
 - Troubleshooting
 - Equipment
-



Blood Sampling

- Collection time
 - After randomization
 - Prior to explanation-Before donor is transferred to the OR.
- Bulk shipping of specimens to DCC.
 - Quarterly return to center
 - IL-6



Participating Organizations



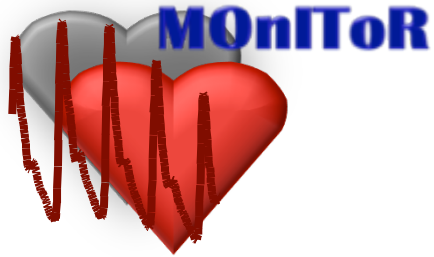
LIFECENTER NORTHWEST
Serving Washington, Montana, Alaska, and North Idaho





Executive Committee

- Dan Lebovitz, MD
LifeBanc
- Mike Souter, MD
LifeCenter Northwest
- Susan Stuart, RN
CORE
- Shri Bharadwaj, MPH, MBA
LifeLink of Georgia
- Clifford Parmley, MD
Tennessee Donor Services
- Ladora Dils
LifeLine of Ohio
- John Kellum, MD
University of Pittsburgh
- Ali Al-Khafaji, MD, MPH
University of Pittsburgh



Advisory Committee

Rupert Pearse MD, Chair

Senior Lecturer & Consultant in Intensive Care Medicine
Queen Mary's University of London, UK

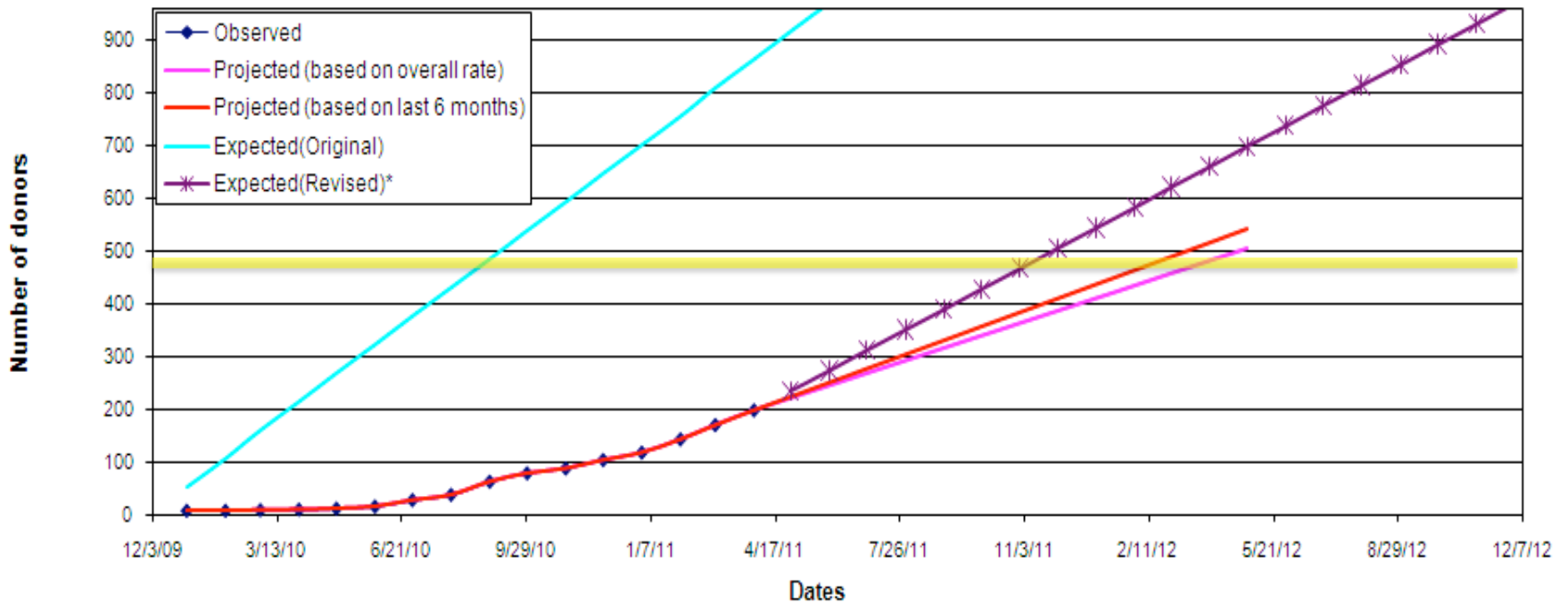
Luis Angel, MD, Committee member
University of Texas

Howard Rockette, PhD, (Independent statistician)
Professor of Biostatistics
University of Pittsburgh

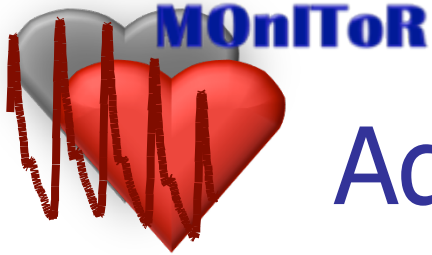


Enrollment

Observed, Expected, and Projected Enrollment



Monitoring Organ donors to Improve Transplantation Results



Advantages of Participating

- Ensure the success of the OPO community's first multi-center RCT
- Membership in a research collaboration with a proven track record
- Early adoption of a therapy that will increase organ recovery