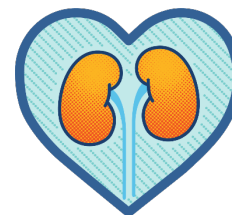




The Investment Proposition – Does the Means Justify the End?

The 14th **Bioshares**
Biotech
Summit 2018

Presentation by Mike McCormick
President and CEO



**be kind to
KIDNEYS**

Problem – Protecting Kidneys From Dye



Heart and leg vessel imaging requires the use of x-ray dye which is cleared by the kidney and can cause Contrast Induced Acute Kidney Injury (CI-AKI)

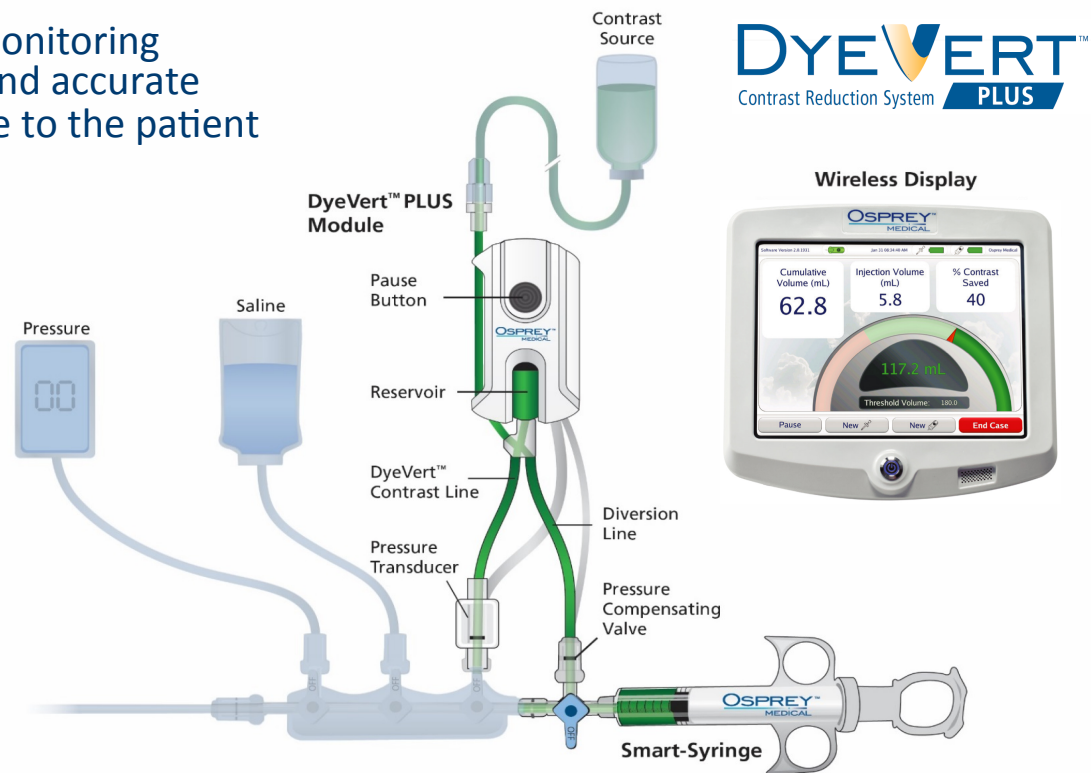


Osprey's Therapy Solution

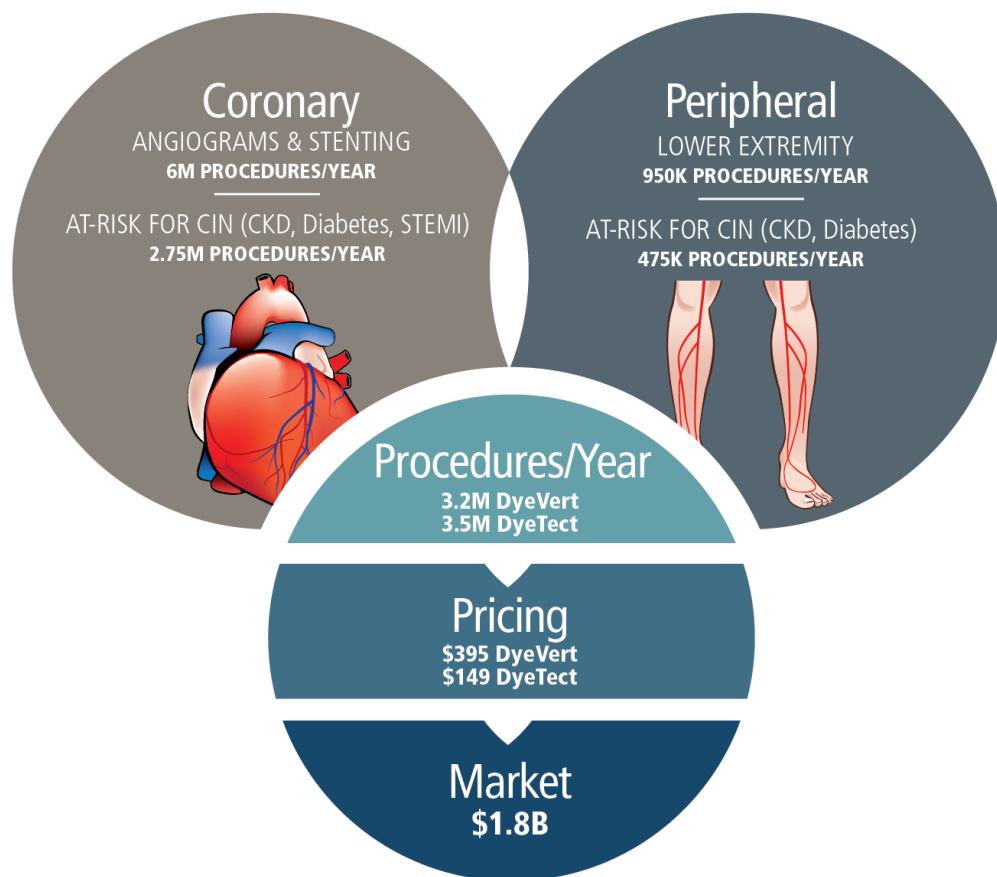
Osprey's technologies are the only FDA cleared product clinically proven to:

1. Reduce dye in angiographic procedures
2. No compromise to image quality
3. Allow for real-time contrast monitoring of maximum allowable dose and accurate measure of total contrast dose to the patient

**Over 40% average
dye reduction¹**



Large market opportunity



Why does it take so long to drive market adoption

Traditional path for new technology adoption

Science (Research), Evidence (Translation) & Care (Delivery) Operate in Silos All Have Impact on the Patient Experience



17 Year Latency

between knowledge
discovery & use in
practice

\$3 Trillion spent on health is wasted

100,000 deaths/year related to medical
errors

Providers need access to cutting edge
knowledge to become high performers
and succeed in value-based care

*Charles Friedman, "Towards a Complete and
Sustainable Learning Health System"; July 2015

Need for constant improvement



Sales execution



Marketing message



**Improvements and new
technology platforms**



FDA claims



**Publications and
Podium**



**Quality, predictability
and cost**



GPO partnerships



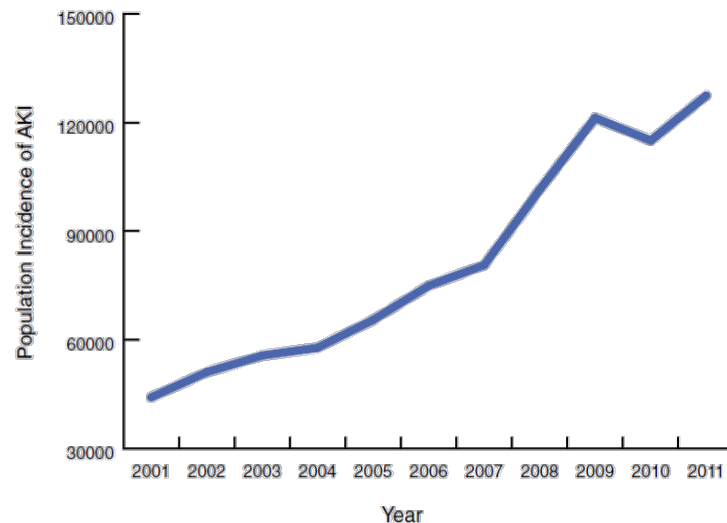
**Improves outcomes
and reduces cost**

Patient Impact From CI-AKI

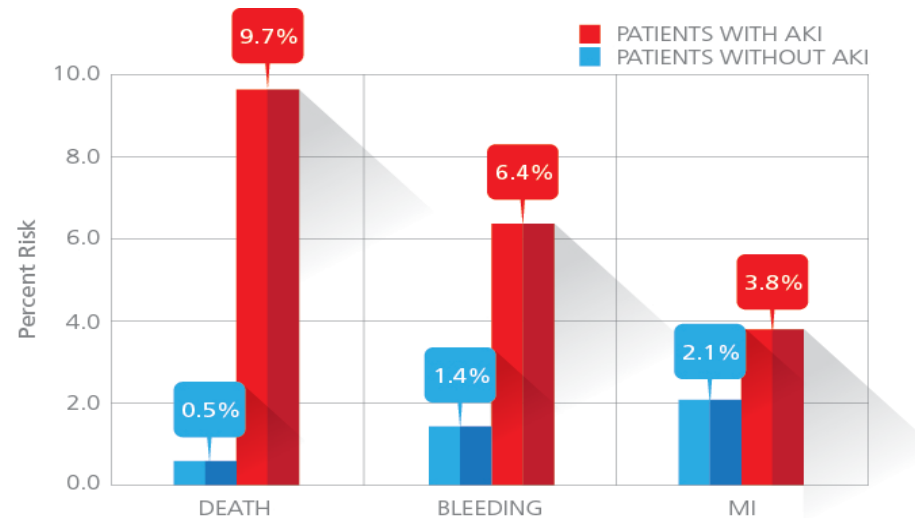


Improves outcomes
and reduces cost

CI-AKI is a growing problem associated with poor patient outcomes after coronary angiography or intervention



AKI incidence: population incidence of acute kidney injury among cardiac cath. and PCI patients in the United States from 2001 to 2011. AKI indicates acute kidney injury. Brown J et al. *J Am Heart Assoc.* 2016;5:e002739.



Tsai TT, Patel UD, Chang TI et al. Contemporary Incidence, Predictors, and Outcomes of Acute Kidney Injury in Patients Undergoing Percutaneous Coronary Interventions: Insights from the NCDR Cath-PCI Registry. *J Am Coll Cardiol Interv* 2014;7:1-9.

Hospital Impact From CI-AKI



Improves outcomes
and reduces cost

Hospital costs increase for patients with CI-AKI as most procedure-related poor outcomes are the responsibility of the hospital

1. Increased length of stay¹

2. Increased 30-day readmissions²

3. Increased bundled payment risk³



¹ Subramanian S, et al. Economic Burden of CIN: Implications for Prevention Strategies. *Journal of Medical Economics*. 2007;10:119-134.

¹ Pfunter A, et al. Agency for Healthcare Research and Quality Statistical Brief #168. December 2013. <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb168-Hospital-Costs-United-States-2011.pdf>

² Center of Medicare and Medicaid Services Website: <http://www.cms.gov/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-ReductionProgram.html>

² American Hospital Association Factsheet: Hospital Readmission Reduction Program. April 14, 2014. <http://www.aha.org/content/13/fs-readmissions.pdf>

³ American College of Cardiology CMS Releases Proposed 2018 Medicare QPP Rule <http://www.acc.org/latest-in-cardiology/articles/2017/06/20/17/40/cms-releases-proposed-2018-medicare-qpp-rule>

Physician Consensus Position on CI-AKI



Improves outcomes
and reduces cost

Practice guidelines from cardiovascular societies for reduction of CI-AKI¹⁻³

Class 1 Level B recommendation for CI-AKI reduction:

1. Patients should be assessed for risk of CI-AKI before PCI
2. Patients undergoing cardiac angiography should receive adequate hydration
3. In patients with CKD (eGFR <60 mL/min), the volume of contrast media should be monitored in real time and minimized as low as clinically possible

Table 1. Applying Classification of Recommendations and Level of Evidence

Levine et al. 2011 ACCF/AHA/SCAI PCI Guideline e577

CLASS	CLASS II	CLASS IIa	CLASS IIb	CLASS III
CLASS I	CLASS II	CLASS IIa	CLASS IIb	CLASS III
Recommendation that is strong and based on evidence from multiple randomized trials or meta-analyses.	Recommendation that is weak or of uncertain benefit, but the balance of benefits and risks favors treatment.	Recommendation that is weak or of uncertain benefit, but the balance of benefits and risks favors treatment.	Recommendation that is weak or of uncertain benefit, but the balance of benefits and risks favors treatment.	Recommendation that is weak or of uncertain benefit, but the balance of benefits and risks favors treatment.
Level of Evidence: A	Level of Evidence: B	Level of Evidence: C	Level of Evidence: D	Level of Evidence: E
Level of Evidence: A	Level of Evidence: B	Level of Evidence: C	Level of Evidence: D	Level of Evidence: E

A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical decisions addressed in the guideline do not have a Level of Evidence A or B. Although randomized trials are considered, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

"This guideline has clinical trial or negative about the usefulness of a treatment or device in different populations, such as sex, age, history of diabetes, history of prior direct myocardial infarction, history of heart failure, and prior aspirin use.

"For comparative effectiveness recommendations (Class II and Class III), studies that support the use of comparative tests should be included.

Influence the choice of tests or therapies are considered. When available, information from studies on cost is considered, but data on efficiency and outcomes are not considered.

In analyzing the data and developing recommendations and supporting text, the writing committee uses evidence-based methodologies developed by the Task Force. The Class of Recommendation (COR) is an estimate of the size of the treatment effect considering risks versus benefits in addition to evidence and/or agreement that a given treatment or procedure is or is not cost-effective or in some situations may cause harm. The Level of Evidence (LOE) is an estimate of the certainty or precision of the treatment effect. The writing committee reviews and ranks evidence supporting each recommendation with the weight of evidence ranked as follows:

LOE A, B, or C according to specific definitions that are included in Table 1. Studies are identified as observational, retrospective, prospective, or randomized where appropriate. For certain conditions for which inadequate data are available, recommendations are based on expert consensus and clinical experience and are ranked as LOE C. When recommendations or LOE C are supported by historical clinical data, appropriate references (including clinical reviews) are cited if available. For issues for which sparse data are available, a survey of current practice among the clinicians on the committee is the basis for LOE C recommendations. LOE is summarized in Table 1, which also provides suggested phrases for writing recommendations within each COR. A new addition to this methodology is separation of the



1 Levine GN, et al. ACCF/AHA/SCAI – Guideline for Percutaneous Coronary Intervention. A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. *Circulation*. 2011; 124:e574-e651.

2 Nallamothu, BK, et al. ACC/AHA/SCAI/AMA-Convended PCPI/NCQA 2013 Performance Measures for Adults Undergoing PCI: A Report of the ACC/AHA Task Force on Performance Measures, the SCAI and AMA-Convended Physician Consortium for Performance Improvement, and the National Committee for Quality Assurance. *Circulation* 2014;129(8):926-949.

3 Naidu, et al. SCAI Expert Consensus Statement: 2016 Best Practices in the Cardiac Cath. Lab. CCI (published on line ahead of print, April 2016. doi:10.1002/ccd.26551.

Economic Impact



Improves outcomes
and reduces cost

CI-AKI increases hospital costs through increased length of stay and 30-day readmissions

15x

CI-AKI patients are 15 times more likely to be hospitalized over 4 days

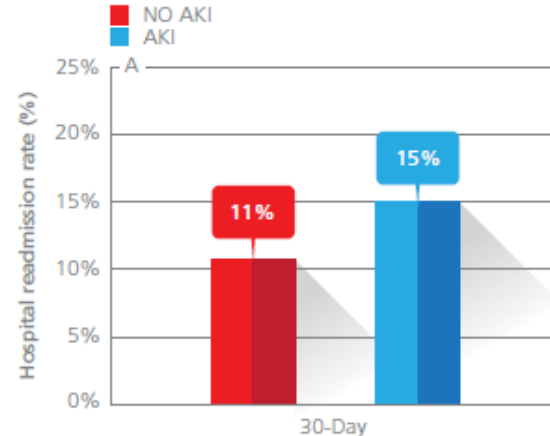
37%

CI-AKI patients have a 37% increase in 30-day readmissions

- CI-AKI patients average 4 days of extended hospitalization¹⁻³
- Additional hospitalization costs ~ \$12,000 for each CI-AKI patient⁴



NCDR[®]
NATIONAL CARDIOVASCULAR DATA REGISTRY



Source: Adapted from figure 1A of Koulouridis, et al.⁵

1 Pfunter A, et al. Agency for Healthcare Research and Quality Statistical Brief #168. December 2013. <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb168-Hospital-Costs-United-States-2011.pdf>.

2 Chertow GM, et al. Acute Kidney Injury, Mortality, Length of Stay, and Costs in Hospitalized Patients. J AM Soc Nephrol. 2005; 16:3365-3370.

3 Liangos O, et al. Economic Burden of CIN: Implications for Prevention Strategies. Journal of Medical Economics. 2007;10:119-134.

4 Subramanian S, et al. Economic Burden of CIN: Implications for Prevention Strategies. Journal of Medical Economics. 2007;10:119-134.

5 Koulouridis I, et al. Hospital - Acquired Acute Kidney Injury and Hospital Readmissions: A Cohort Study. Am Kidney Dis. 2015;65(2):275-282.

Osprey's Cost Neutrality Rebate (LoS)



Improves outcomes
and reduces cost

Osprey's "Be Kind to Kidneys" program rebates DyeVert Plus product costs that are not offset by savings related CI-AKI reduction

Southeastern US Medical Center

Cost of AKI to Hospital ^{1,2}	
Number of Annual Diagnostic and PCI Procedures	6,376
Risk Adjusted-AKI Rate per the NCDR Cath PCI Registry	15%
Estimated Number of At-Risk Patients Developing AKI Annually	956
Cost per AKI Patient – Additional Length of Stay ^{1,2}	\$12,000

Total Annual Cost of AKI

\$11,472,000

Device Cost to Hospital	
Number of Annual PCI's	6,376
DyeVert Plus (25% of Patients)	1,594
DyeVert Plus Price	\$350

Total Annual Device Cost to Hospital

\$557,900

Clear value
proposition

¹ Subramanian, *Jour Med Economics*; 2007; 10:119-134.

² Pfunter A, et al. Agency for Healthcare Research and Quality Statistical Brief #168. December 2013. <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb168-Hospital-Costs-United-States-2011.pdf>.

Reducing Readmission Penalties



Improves outcomes
and reduces cost

CI-AKI reduction will lower unplanned 30-day readmissions - reducing hospital readmission penalties

Southeastern US Medical Center

Medical Discharges, Reimbursements, Readmissions Reduction Program Penalty

FY 2017 Readmission Penalty	0.39%
Total Medicare Reimbursement	\$142,940,832
Readmission Penalty	\$557,469

Excess Readmission Ratio		Number of Cases
Acute Myocardial Infarction	.99	1,166
Heart Failure	.99	1,221

AKI related complications
driving readmissions penalty

Unreimbursed Charges for AKI



Improves outcomes
and reduces cost

CI-AKI is a source of Medicare unreimbursed charges for the care of patients with kidney damage

Southeastern US Medical Center

2016 Hospital Charges for DRG 698, 699, 700

Description - Other Kidney and Urinary Tract Diagnosis including Radiographic Contrast Agent Nephropathy

Hospital Charges for DRG 698, 699, 700	\$7,794,148
Payments to Hospital	\$2,379,969
Payment Percentage	30%

Unreimbursed Hospital Charges

\$5,414,179

Medicare normally pays
60-70% of charges

The shift to value based care is underway



GPO partnerships

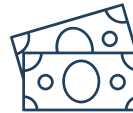
Supporting the triple aim:

BETTER CARE • SMARTER SPENDING • HEALTHIER POPULATION

Payment Reform

balanced

Delivery Reform



**INCREASED
VALUE**

(Health outcomes
per dollar spent)¹

Improved Quality



Smarter Spending

An ongoing shift from **volume to value** requires all healthcare stakeholders to use **quality measures** to better define their value and aid consumer decision-making

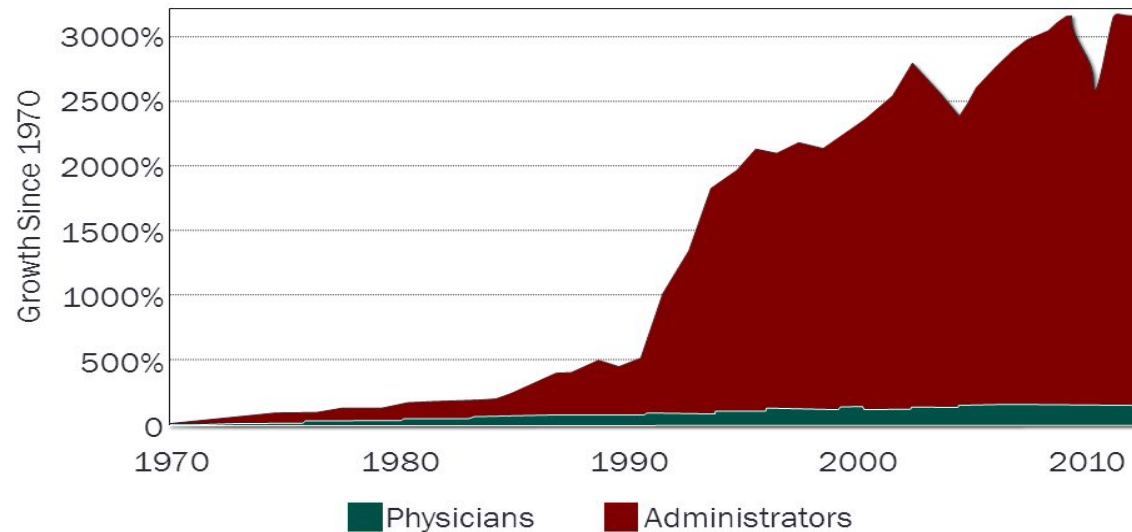
1. Porter ME. What is value in healthcare? NEJM 2010; 363:2477-2481.

Rise in GPO's



GPO partnerships

Growth of Physicians vs Administrators



Data updated through 2013
Source: Bureau of Labor Statistics; NCHS;
Himmelstein/Woolhandler analysis of CPS

PROVIDENCE
Healthcare

PREMIER

vizient

Advocate
Health Care

Bon Secours

Northwell
Health™

HEALTHTRUST

KAISER PERMANENTE

Banner Health

Dignity Health

Department of
Veterans Affairs

ASCENSION

HCA
Hospital Corporation of America™

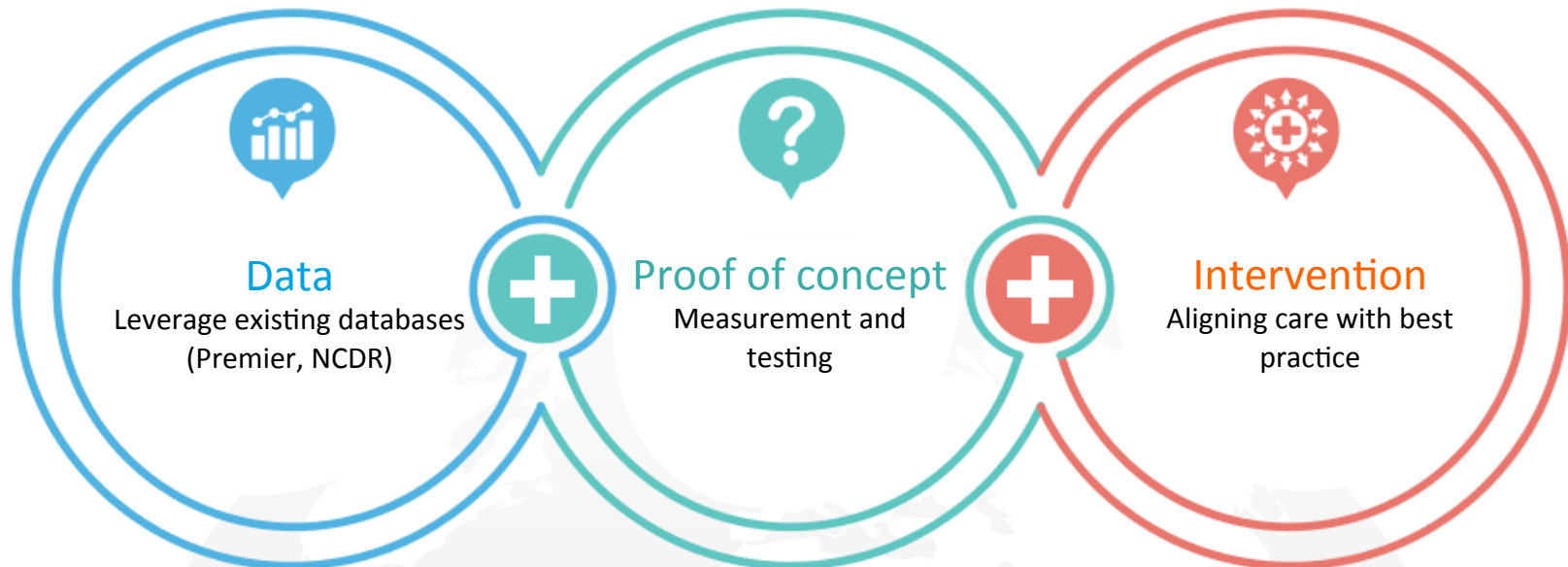
CHRISTUS
Health.

UHS

Osprey's GPO strategy



GPO partnerships



Burden of illness

- Awareness of AKI
- Cost of disease
- DyeVert impact on AKI

Support IDN's to publish:

- CKD Care-Path-Protocol
- Establish benchmarks
- Evidence generation, publication

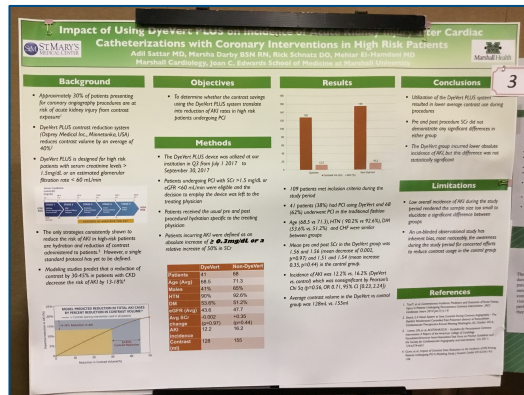
Socialize Best Practice

- Kidney Care Protocol
- Clinical decision support
- Benchmark tracking

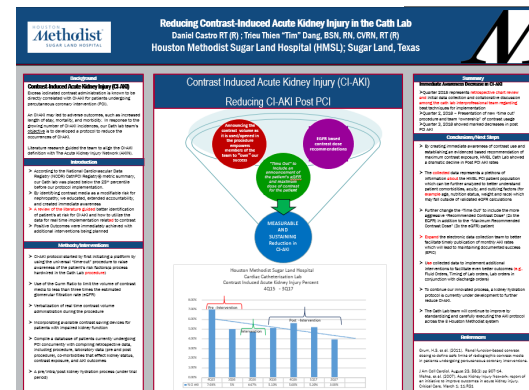
AKI Reduction Studies



GPO partnerships



- Presented at ACC West Virginia meeting April 2018
- 25% AKI reduction with DyeVert Plus
- Full manuscript planned



- Presented at NCDR meeting March 2018
- 22% AKI reduction with DyeVert Plus
- June Cathlab Digest publication

Focused on improving patient outcomes

AKI is NOT OK

About one in three angiography patients are at risk for contrast-induced acute kidney injury (AKI) due to chronic kidney disease (CKD) and comorbidities. For these patients, the dye used for visualization during procedures can be toxic, leading to serious complications. But you can make angiography safer for CKD patients by following clinical society guidelines.¹

Screen Patients with an eGFR < 60 ml/min are at high risk for AKI events.

Hydrate Adequate preparatory hydration should be given to at-risk patients.

Reduce Minimize contrast dosage to high-risk patients.

The DyeVert[™] Plus contrast reduction system allows you to reduce dye volume and monitor usage real-time without compromising image quality. The only FDA-cleared technology for dye volume reduction, the DyeVert system is an effective tool in following clinical society guidelines. To learn more visit www.ospreymed.com/bekindtokidneys.

be kind to KIDNEYS

1 Levine GN, et al. Circulation. 2011; 124:454-463.
2 Kidney guidelines from the National Kidney Foundation.
3 Quinn, et al. JGIM. 2006; 21: 568-575.

HANDLE WITH CARE.

About one in four of your cath lab patients have Chronic Kidney Disease (CKD) or other risk factors for developing Acute Kidney Injury (AKI). What are you doing to reduce the risk of AKI for them? American College of Cardiology Guidelines are clear: **Screen for risk. Introduce hydration. And reduce dye dosage.¹**

The DyeVert[™] Plus Contrast Reduction System can help. It's the only FDA-indicated technology for contrast volume reduction. And it doesn't compromise image quality. So remember: fix the heart. But don't forget the kidneys. Your high-risk patients' health depends on it.

To learn more visit www.ospreymed.com/technology

DYEVERT[™] PLUS
Contrast Reduction System

be kind to KIDNEYS

1 Levine GN, et al. Circulation. 2011; 124:454-463.
2 Davis, S. A. Heart System to Save Contrast during Coronary Angiography - The DyeVert[™] Randomized Controlled Trial. Presented Abstract at Transcatheter Cardiovascular Therapeutics Annual Meeting, Washington, DC, October 2010.
Please consult product labels and package inserts for indications, contraindications, warnings, precautions, complications, and information for use statement. Rx only.
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