Caring for Outpatients after Acute Kidney Injury (COPE-AKI Consortium)

AKI and CRRT 2023
Session V: Future Trends in CRRT and Critical Care
4/1/23

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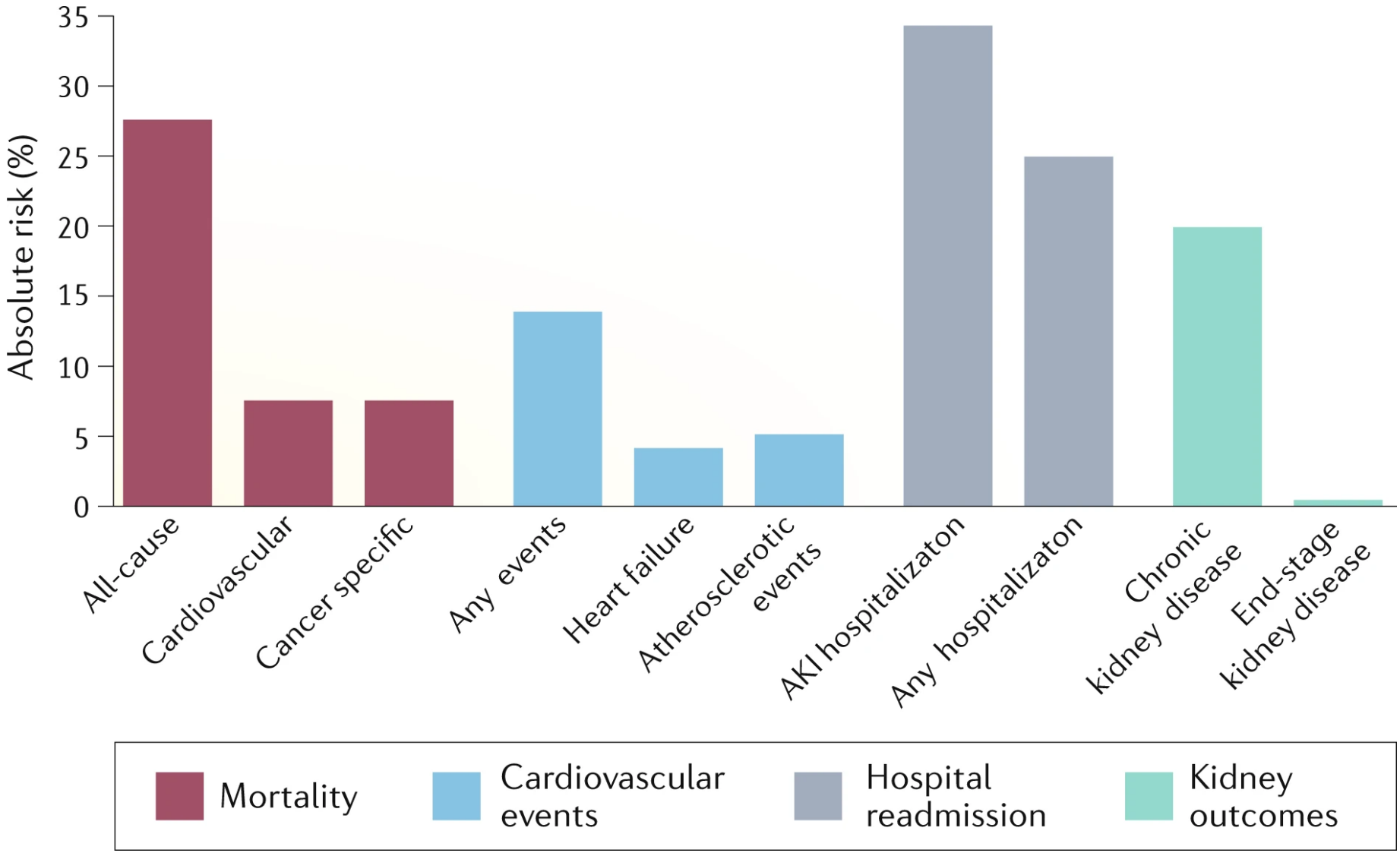
Disclosures

Edward Siew:

- Royalties: Author for UptoDate
- Editorial Activities: Associate Editor *Clinical Journal of the American Society of Nephrology*

Risks of Common Events After AKI

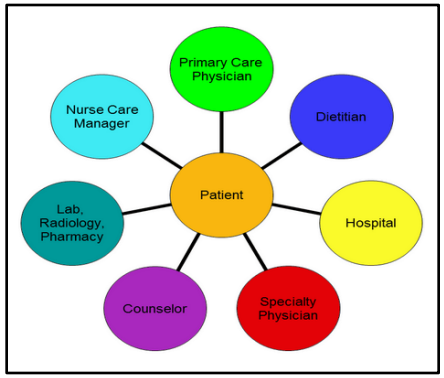


James MT et al. Nature Reviews Nephrology **volume 16**, pages193–205 (2020)

Short-Term Outcomes at Hospital Discharge

	Recent Hospitalized AKI	Stable CKD
Other Advanced Conditions	↑↑	↑
Acute Organ Dysfunction	↑↑	-
Worsening HTN/proteinuria/volume overload	↑↑	↑
Re-hospitalizations/Recurrent AKI	↑	-
Risk for ADE/Drug Omissions	↑↑	↑
Poor Quality of Life	↑↑	↑
Inadequate Solute/Fluid Intake	↑	-
Mortality	↑↑	↑

Factors Compounding These Risks



Fragmented/poorly coordinated care

Lack of timely kidney-based care

Suboptimal Medication Management

Poor patient awareness/knowledge

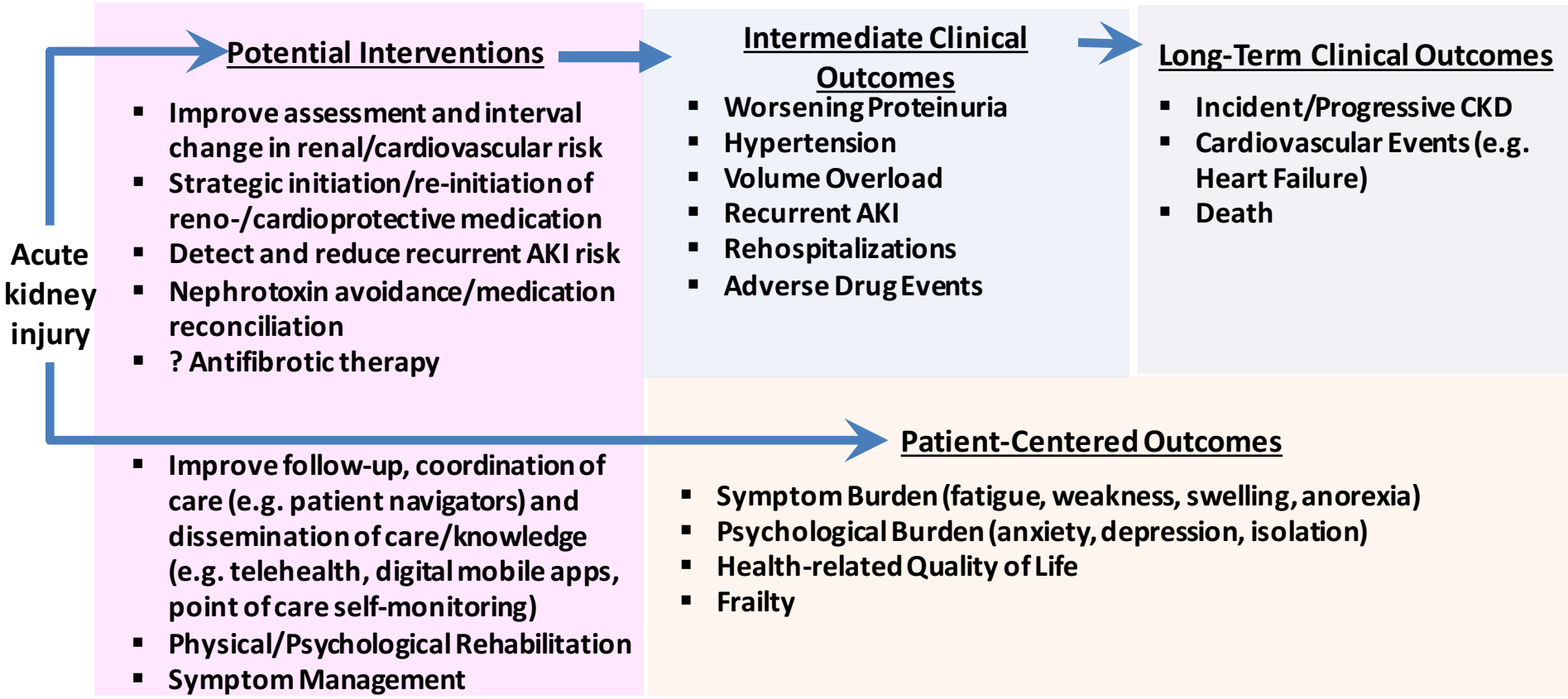
Lack of Social Support

Krumholz HM. 2013
Dharmarajan K, et al. 2013
Wennberg DE, et al. 2010
Ruppar TM, et al. 2016
McAlister FA, et al. 2004
Nair R, et al. 2020

IMPROVING CARE FOR PATIENTS AFTER HOSPITALIZATION WITH AKI

Natcher Conference Center **January 30–31, 2019**

Potential "Process Interventions"



Siew, et al. JASN 2020. Oct;31(10):2237-2241

COPE-AKI Consortium Goals

- To develop and test "process of care" interventions that aim to **reduce AKI disease burden** in patients after hospitalization with **moderate to severe AKI**.
- To produce a protocol that has
  1. outcomes that are important to patients, clinicians, and researchers
  2. feasible interventions,
  3. the ability to enroll sufficient study participants, and
  4. enough "scientific strength" to answer the primary question(s).

Centers / Sponsor

NIH National Institute of Diabetes and Digestive and Kidney Diseases

Study Hypotheses

- Primary
  - Compared to usual care, patients randomized to a multimodal, process-of-care intervention will experience more hospital-free days through 90 days
- Secondary
  - Compared to usual care, patients randomized to a multimodal, process-of-care intervention will have
    - lower rates of major adverse kidney events (at 90, 180, 365 days)
    - lower rates of recurrent AKI (90, 180, 365 days)
    - greater improvements in patient-reported outcomes (over 180 days)

Study Design

- Phase III, randomized, parallel-arm trial
- Anticipated N=2150

Intervention

- Multimodal process-of-care intervention including:

Nephrologist

Nurse navigator

Pharmacist

- Participants will receive:
  - Medication reconciliation, nephrotoxin screening, review of indications for disease-modifying therapies
  - Education re: kidney disease, nephrotoxin avoidance, symptoms, and importance of follow-up
  - Monitoring of blood pressure, weight, symptoms, kidney function
  - Facilitators/communication with PCP
  - Social Support/Motivational Interviewing

Study Population - Inclusion

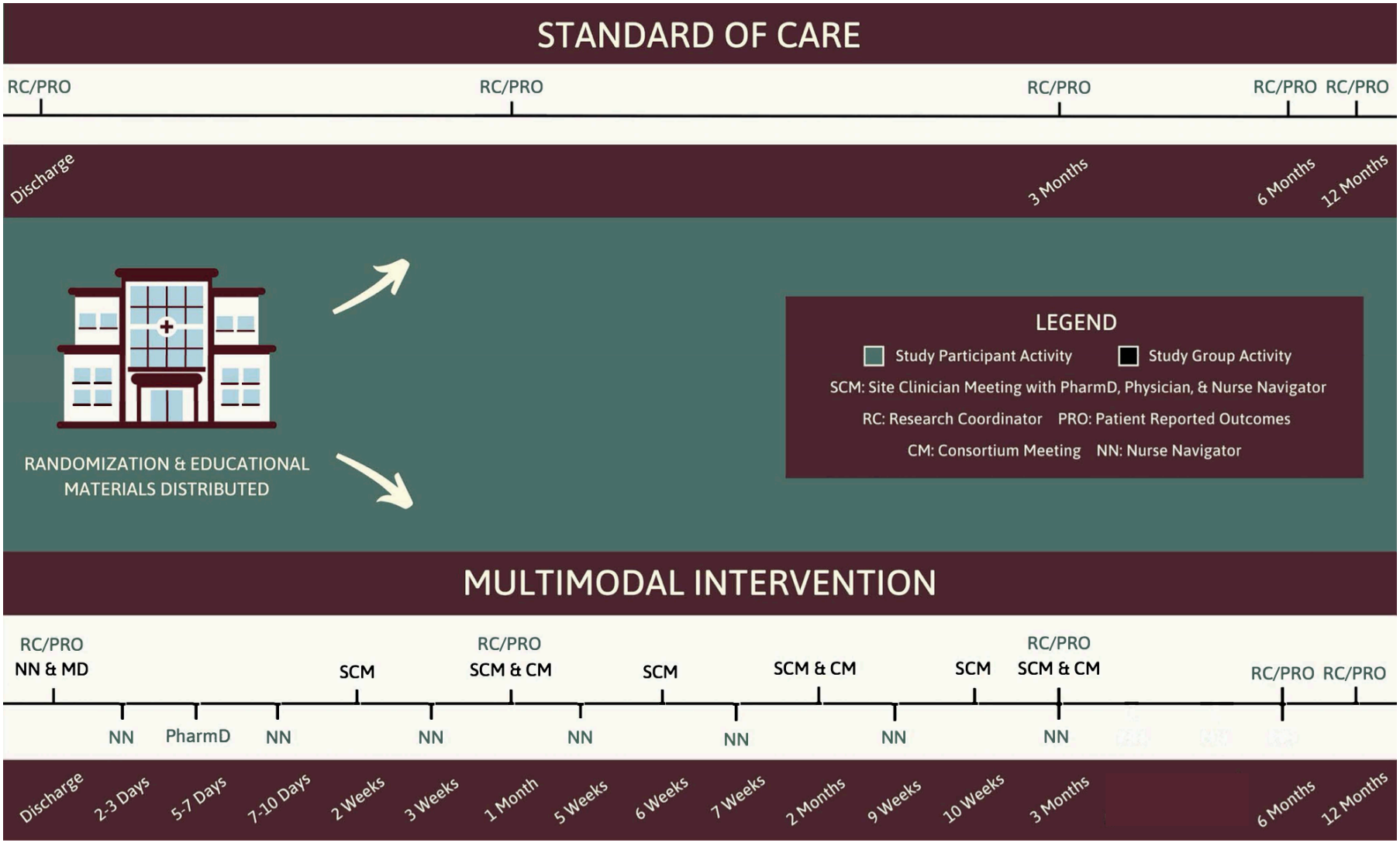
- Aged ≥ 18 years
- KDIGO Stage 2/3 AKI with evidence of persistence

Study Population - Exclusion

- ESKD on admission, dialysis dependence at discharge
- Index hospitalization involving solid organ transplant or stem cell/bone marrow transplant
- Metastatic malignancy or malignancy requiring active treatment (chemotherapy, immunotherapy), such as multiple myeloma
- AKI due to primary glomerulonephritis, renal vasculitis, or thrombotic microangiopathy, nephrectomy, obstruction (quickly reversed)
- Referral to a nephrologist for care specifically for GN, electrolyte disorders, AIN
- Life expectancy <6 months, Non-kidney end-stage organ failure
- Discharge to other acute facility
- Vulnerable populations – incarcerated, institutionalized, pregnancy
- Inability to consent

Primary and Key Secondary Endpoints

Primary Outcome
• Hospital-free days (HFDs) through day 90 defined as days alive and out of hospital between day of discharge from index hospitalization and post-hospital discharge day 90.
Key Secondary Outcomes
• MAKE-180 composite outcome of: ➢ death within 180 days of index hospital discharge; ➢ need for dialysis at 180 days after index hospital discharge; or ➢ serum creatinine >2x baseline at 180 days after index hospital discharge • MAKE-90 and MAKE-365 will be defined similarly
• Rates of recurrent AKI readmission at 180 days (also assessed at 90, and 365 days)
Key Secondary PROs (assessed at 30, 90, 180, and 365 days)
• Global HRQoL – assessed with 10-item PROMIS measure
• AKI-specific HRQoL – assessed with 6-item CKD-QoL
• Interaction with providers – assessed with 5-item PEPPI and 8-item CSQ
• Social support – assessed with 4-item emotional support and 4 item instrumental support PROMIS measures


STANDARD OF CARE
RC/PRO
RC/PRO
RC/PRO
RC/PRO
RC/PRO
Discharge
3 Months
6 Months
12 Months
RANDOMIZATION & EDUCATIONAL MATERIALS DISTRIBUTED
LEGEND
Study Participant Activity
Study Group Activity
SCM: Site Clinician Meeting with PharmD, Physician, & Nurse Navigator
RC: Research Coordinator
PRO: Patient Reported Outcomes
CM: Consortium Meeting
NN: Nurse Navigator
MULTIMODAL INTERVENTION
RC/PRO
NN & MD
NN
PharmD
NN
SCM
NN
RC/PRO
SCM & CM
NN
SCM
NN
SCM & CM
NN
SCM
NN
RC/PRO
SCM & CM
NN
RC/PRO
RC/PRO
Discharge
2-3 Days
5-7 Days
7-10 Days
2 Weeks
3 Weeks
1 Month
5 Weeks
6 Weeks
7 Weeks
2 Months
9 Weeks
10 Weeks
3 Months
6 Months
12 Months

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Usual Care

- Participants will receive basic written info regarding:
  - their kidney disease
  - importance of and need for follow up with physician