Acute Kidney Disease in the Outpatient Setting:

From Big Data Phenotyping to Novel Biomarker Validation using the NGAL and DNlite-IVD103 Tests

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Background

Epidemiology investigation and diagnosis of End Stage Renal Disease amongst Acute Kidney Injury /Disease outpatients.
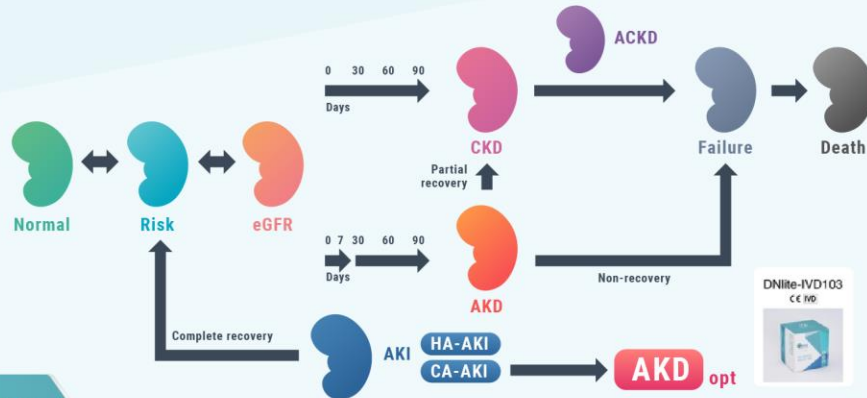
Study Deign

A quasi-experimental study (QES: Dec. 2017-Dec 2020) with pragmatic clinical trial design (PCT: Dec. 2020-Dec. 2021).

Population

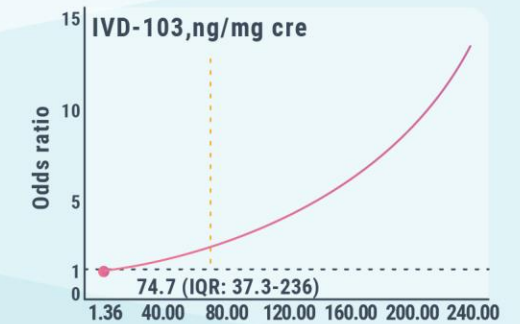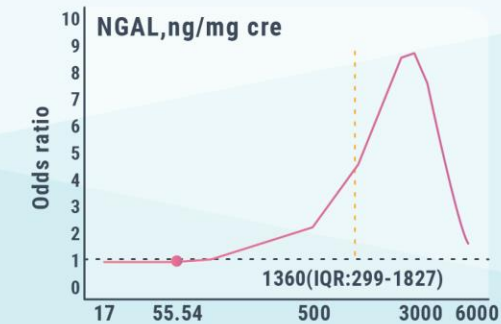4,592 Taiwanese patients (QES) and 56 patients with eGFR < 45ml/min/1.73m2 (PCT).

Outcome

Progression to dialysis (QES) and doubling of serum creatinine (PCT).

Exposure

4592 Taiwanese patients in the quasi-experimental trial and 56 patients with the last eGFR < 45ml/min/1.73m2 were enrolled in the PCT

CMUH-AKIDS Screening Flow adn Action

AKI Status	Latest eGFR	Action
No AKI	≧60	No action
Stable AKI	≧60	f/u eGFR;no referral
C Deteriorating AKI	≧60	f/u eGFR;no referral
No AKI	45≦~<60	f/u eGFR;no referral
B Stable AKI	45≦~<60	f/u eGFR;no referral
Deteriorating AKI	45≦~<60	Refer to Nephrology
No AKI	<45	Refer to Nephrology
A Stable AKI	<45	Refer to Nephrology
Deteriorating AKI	<45	Mandatory referral

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BIG DATA CENTER — CHINA MEDICAL UNIVERSITY HOSPITAL
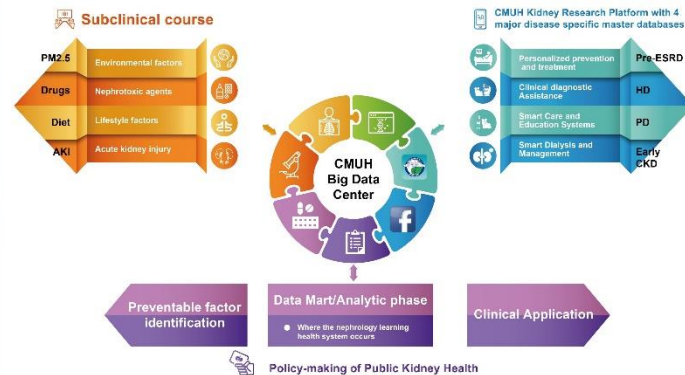
BPM — BIO PREVENTIVE MEDICINE

A novel digital kidney risk management model for hospital, community, and home care

Cost-Efficient AI Tool: Machine-learning algorithms

AKD Diagnosis / Prediction / Risk Stratification / Clinical Effectiveness

Cost-Effective Solution: Non-invasive biomarker

Nephrological Big Data Ecosystem

Subclinical course

- PM2.5 — Environmental factors
- Drugs — Nephrotoxic agents
- Diet — Lifestyle factors
- AKI — Acute kidney injury

CMUH Big Data Center

CMUH Kidney Research Platform with 4 major disease specific master databases

- Personalized prevention and treatment — Pre-ESRD
- Clinical diagnostic Assistance — HD
- Smart Care and Education Systems — PD
- Smart Dialysis and Management — Early CKD

Preventable factor identification

Data Mart/Analytic phase
- Where the nephrology learning health system occurs

Clinical Application

Policy-making of Public Kidney Health

- **Operational full-time since 2017**
- **"Smart" data cleaning module**
- **100% Interoperated and integrated database**
- **An efficient clinical trial infrastructure**

Clinical Outcome Validation

- **First study to systematically investigate ESRD amongst AKD patients**

National Health Insurance Research Database (NHIRD)
1998 — Contains comprehensive computerized NHI records of the entire population of Taiwan. Facilitated academic research in scientific discipline.

PharmaCloud System
2013 — Physicians or pharmacists can check patient's previous medication records, increase medication safety and the visit quality.

My Health Bank System
2014 — Insurant can check their personal medical record by their self. Provide more proactive personal care virtual assistant.

- **Significant risk association with ESRD progression**

Biomarker Validation

- **First time to verify the kidney injury status by a novel biomarker**
- **Showed DNlite-IVD103 may have potential to replace NGAL**

DNlite-IVD103 CE Marked IVD

- **Non-invasive** urine test
- Predict progressive decliner **months to years earlier**
- **ELISA-based** & perfect for clinical practice
- Risk Assessment for **Predicting Renal Function Loss**
- **Precision DKD Management** & Complementary Test
- **Proven Quality**