

**Amit Garg** MD, MA (Education), FRCPC, PhD

Nephrologist  **London Health  
Sciences Centre**

Associate Dean of Clinical Research,  
Professor of Medicine, Epidemiology & Biostatistics



Senior Scientist, ICES  
Chaired ICES Trials working group



Chair, HDRN Canada – ACT Consortium Committee  
NPI, CIHR grant HDRN Canada Training Program in Pragmatic Trials



Réseau de recherche sur les données de santé du Canada  
**Health Data Research Network Canada**

&

**ACT  
AEC** Accelerating   
Clinical Trials  
Accélérer les  
Essais Cliniques



**For each hemodialysis treatment we set the temperature of dialysis fluids on the machine**

standard temperature of dialysis fluids 36.5 °C

For the perceived benefits, ~ 8 years ago, several hemodialysis centre directors adopted a default centre-wide policy of **lower temperature dialysis fluids**

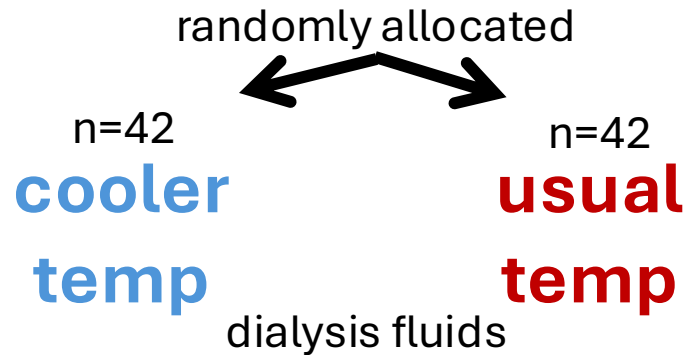
As often done in routine care, this change in default policy was not discussed with patients (or approved by them)



photo by Anna Frodesiak/Wikimedia

# cluster RCT

84 hemodialysis centres in Ontario



- ~ 15,000 patients
- trial embedded in routine care, no research coordinators at dialysis centres
- designed and authored with patient partners
- most baseline and follow-up information from large administrative databases
- anonymous data on blood pressure and self-reported symptoms

Results Lancet 2022

- no between-group difference in major CV events or BP
- more reported discomfort with cooler temp

Patient consent to:



Be in the trial

Receive the Intervention

- unaware

- notified

- opt in



- opt out



Analyze their coded data in large databases



Complete anonymous self-reported surveys

## Practice in Ontario after trial

No more centres adopted colder temperature dialysate as a centre-wide policy.

Centres returned to using a standard dialysate temperature of 36.5 °C as their centre-wide policy.

Resulted in patients having less discomfort from hemodialysis.



## Transplant Access

JAMA Intern Med 2023  
cluster RCT  
26 renal programs  
~ 20,000 patients



## Mg in dialysis fluid

cluster RCT  
137 dialysis centres  
~ 25,000 patients



## Bicarb in dialysis fluid

individual patient RCT  
provincial health card for randomization  
~ 2200 patients of 8000+ so far recruited



## Patient consent to:

Be in the trial

Receive the Intervention

- unaware
- notified
  - opt in
  - opt out

Analyze their coded data in large  
databases

Complete self-reported surveys

- Nature of notification
- Consent documented as done in routine care



<https://www.schulich.uwo.ca/pragmatictrialstraining/index.html>