

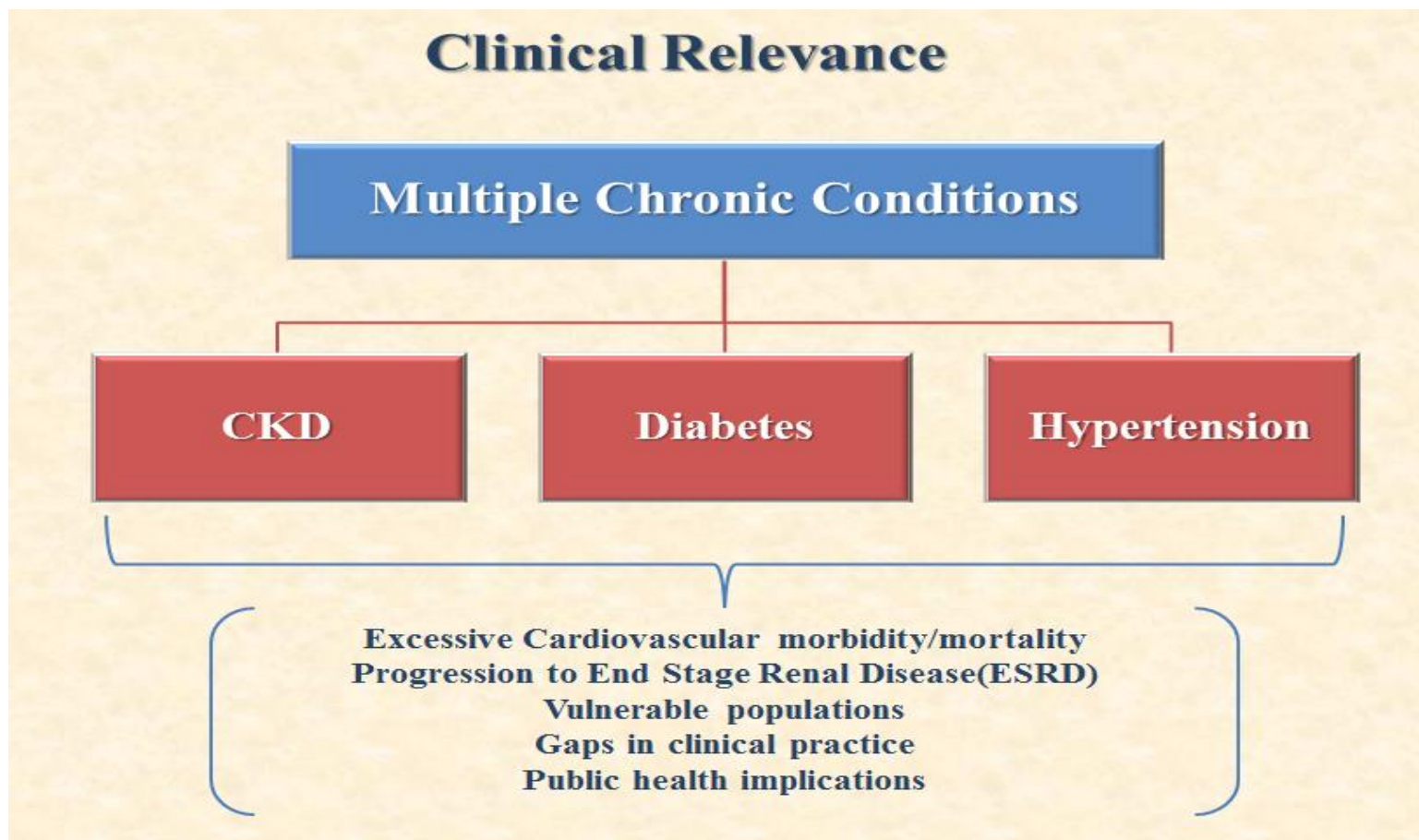
# **Top Barriers/Challenges and Recent Generalizable Lessons Learned**

## **Improving Chronic Disease Management with Pieces (ICD-Pieces™)**

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# Study Overview



# Enrollment and engagement of patients/subjects

- Waiver of consent with opportunity for patient opt-out
- Efficient and Effective Practice Facilitator operations
- Some “no shows” for clinic appointment
- Staff shortage in smaller clinics
- Slower enrollment at Parkland and THR due to IT issues

# Engagement of clinicians and Health Systems

- Obtain Executive Leadership Support
- Engage Study site PI, Co-PIs and Practice Facilitators
- Adapt study activities to clinic workflow
- Integrate study activities into HCS quality metrics
- Recognize competition with drug company paid research
- Change in locus of control  Provider Resistance

# Regulatory issues (IRBs and consent)

- Three IRB approvals needed – UT Southwestern, THR, VA
- THR and UT Southwestern planning to merge under the Southwestern Health Resources agreement
- Regular DSMB Input – In-person meeting, teleconference, emails

# Data collection and merging datasets

- Business Associated Agreement (BAA) in place
- Data Use Agreement (DUA) in place
- Data transmission issues
- No anticipated problem with merging of de-identified dataset from 3 sites
- VA does not allow cloud storage and merging

# Stability of control intervention

- ESRD American Indians/ Alaska-MMWR-Narva, 2017
- Sprint Study – Outcomes with lower BP target
- CKD Quality Indicators-Canada-CJASN, 2017

# Implementing/Delivering Intervention Across Healthcare Organizations

- Differences in Practice Facilitator personnel at each site
- Disparate Electronic Health Records
- Site-specific data transfer and clinic workflow
- Integration of study activities to HCS QI projects
- Competing HCS projects and changes prompted by research
- Provider merger, retirement and drop out



# Recent Lesson Learned

- Rapid Response Team → Address Personnel Turnover
  - Co-investigators (main study site and HCS)
  - Practice Facilitators
  - IT engineers
  - Data Analyst
  - Other team members