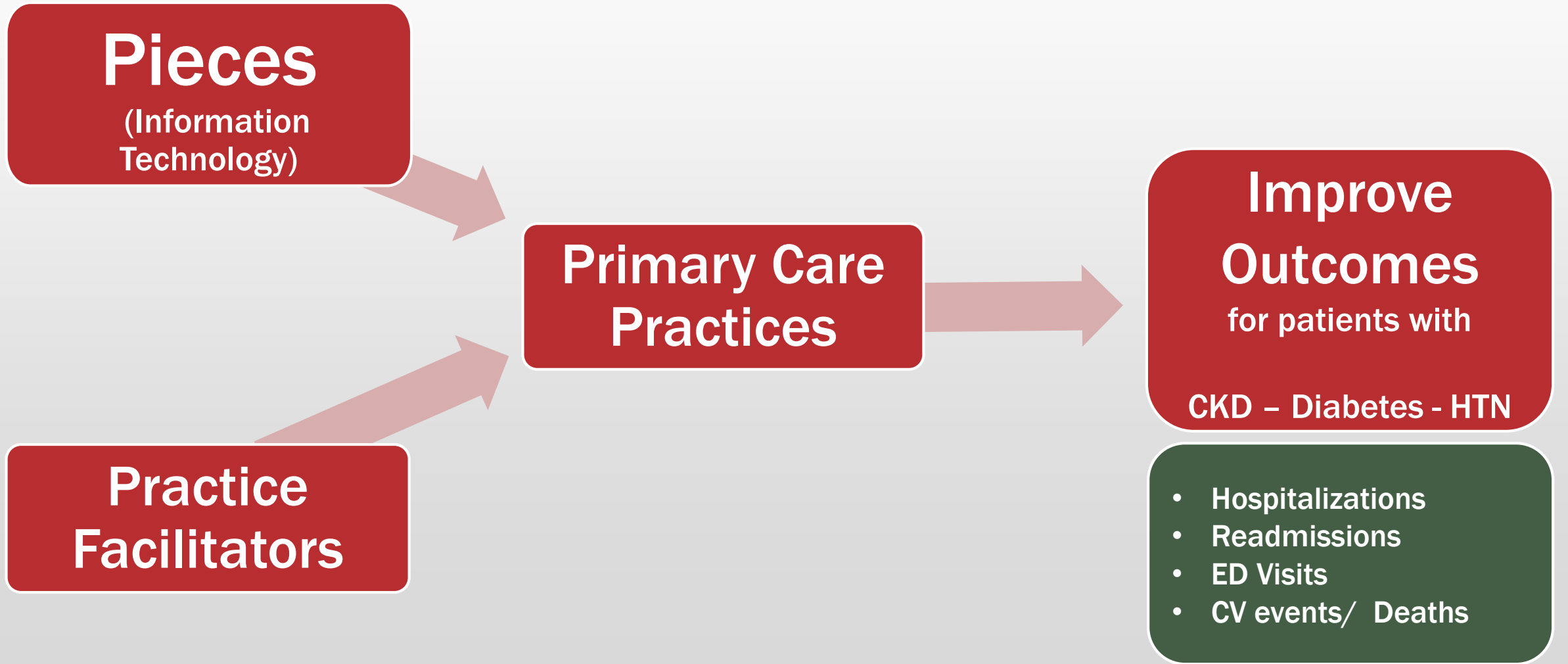




# Brief Overview





# Barriers Scorecard

Barriers	Level of Difficulty*				
	1	2	3	4	5
Enrollment and engagement of patients/subjects			X		
Engagement of clinicians and health systems			X		
Data collection and merging datasets					X
Regulatory issues (IRBs and consent)		X			
Stability of control intervention		X			
Implementing/delivering intervention across healthcare organizations			X		

\*Your best guess! 1 = little difficulty 5 = extreme difficulty

# Top Challenges



- **Data collection**
  - Variable access to data across the Health Systems
  - One Health System partner changed claims intermediary
  - Privacy concerns delayed sharing claims data with study team
- **Delivery of intervention**
  - Initial perception of “added work”
  - Turnover (from investigators to facilitators to frontline personnel)
- **Changes in usual practices**
  - Development and approval of new treatments
  - Dissemination of new guidelines

# Recent Generalizable Lesson Learned



- Importance Selection of Health System Partners
  - Who can you enroll and will enroll?
    - Number of clusters
    - Number of participants
    - Population representative of those affected
  - How the intervention will be implemented?
    - Fidelity to the intervention
  - How data will be collected?
  - How to deal with challenges?
    - Study champions (central and frontline)

# Current Data Sharing Plan & Obstacles



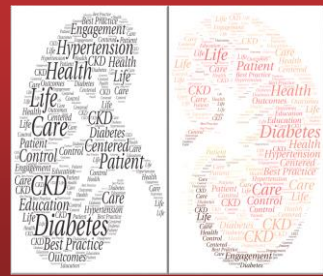
- Initial plans
  - 4 Health Systems—importance of anonymity of HS outcomes
  - 3 different IRBs involved
- Options
  - Study website
  - NIDDK data sharing policies
  - Enclave / NIDDK Central Data Repository
  - Concerns
    - Limitations due to waiver of informed consent participants
    - No consent from Health Systems or providers

# Data We're Planning to Share



- Availability of data from request to study team
- Patient-level selection criteria (Deidentified)
- Deidentified outcomes
  - Aggregate data
  - One Health System—only summary table





**Thank You**