PROVEN

PRagmatic Trial of Video Education in Nursing Homes

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2020 NIH Collaboratory Steering Committee Meeting
Novel Data Management and Integration Approaches

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Novel Data Integration Approaches: An Exemplar for Pragmatic Trials

- Nursing Homes have Standard Functional Assessment Instrument; Computerized Minimum Data Set (MDS)

- MDS updated at least quarterly

- EMRs combine MDS with Billing & Clinical data

- NH EMRs can add supplemental records

- Using Medicare Beneficiary ID and other identifiers can match NH data with CMS data

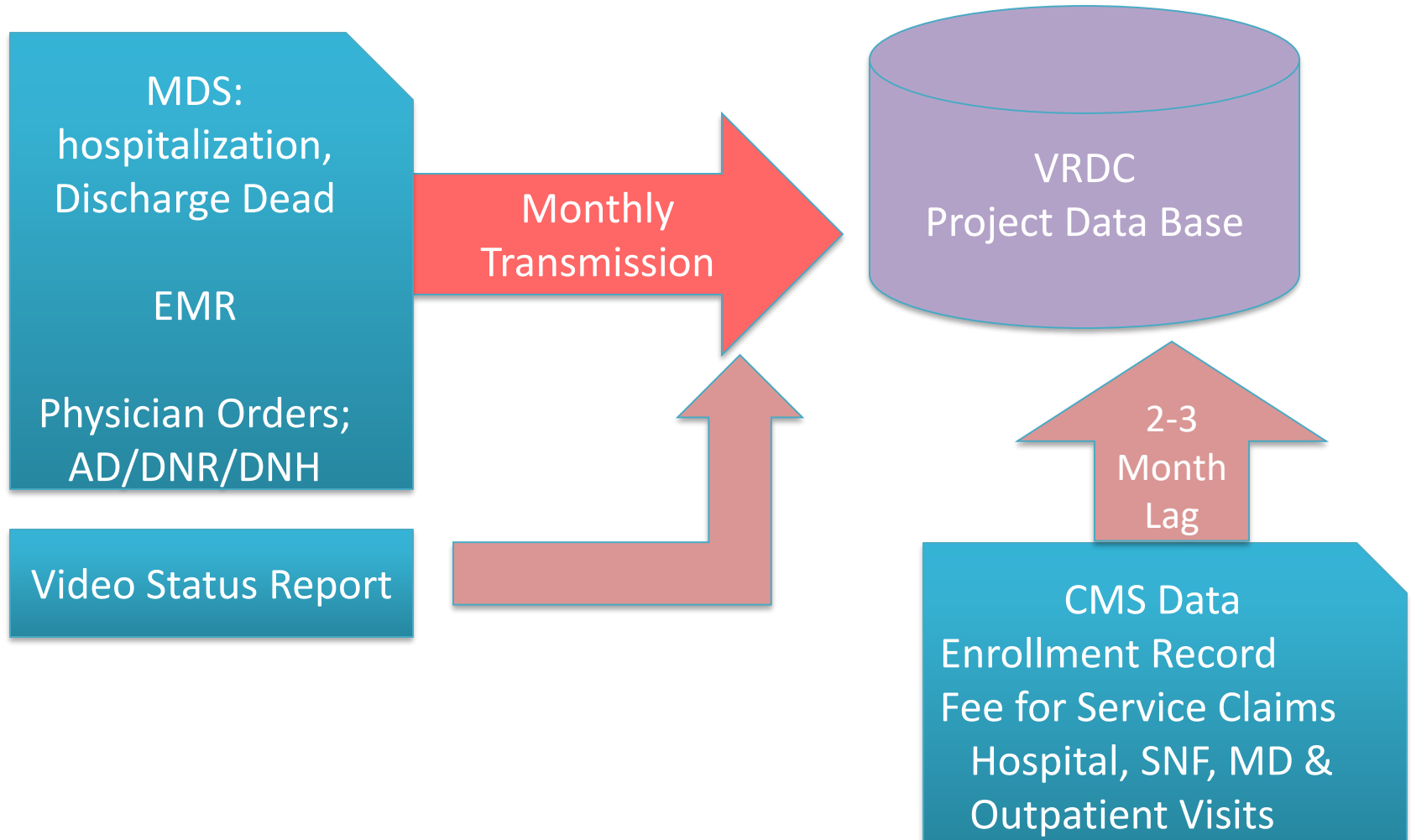- Virtual Research Data Center (VRDC) allows uploading MDS & EMR data for merging, matching & analysis

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Top Barriers/Challenges and Recent Generalizable Lessons Learned
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PROVEN: Data Sources

Data Element	Purpose	SOURCE		
		EMR	MDS	Medicare
Facility-Level				
Case-mix	recruitment		X	
Admission volume	randomization		X	
Patient-Level				
Demographic	covariate	X	X	
Long vs. short-stay	cohort definition		X	
Functional status	sub-population identification		X	
Cognitive status	sub-population identification		X	
Medical condition	sub-population identification	X	X	
Insurance	covariate			X
Advance directives	2º outcome	X		
Health services use	1º and 2º outcome	X	X	X
Burdensome treatments	2º outcome	X	X	X
Death	description, competing risk	X		X
Video implementation	monitoring fidelity	X		

Data Integration Plan

- MDS data AND new video exposure record obtained monthly from partners' EMRs

- Integrated and updated with ID match

- Data uploaded to CMS Virtual Research Data Center (VRDC) for matching to Bene ID

- All Part A and B claims assembled for analyses

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NIA LTC Data 12-4-2015

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PROVEN: Data Flow

MDS:
hospitalization,
Discharge Dead

EMR

Physician Orders;
AD/DNR/DNH

Video Status Report

Monthly
Transmission

VRDC
Project Data Base

2-3
Month
Lag

CMS Data
Enrollment Record
Fee for Service Claims
Hospital, SNF, MD &
Outpatient Visits

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Accomplishments

- Last PROVEN patient's 12 month follow-up:

- Last Data delivered from Partners

- Last upload of clinical data to VRDC

- Primary Outcome Analyses Completed

- May 31, 2019

- July 15, 2019

- September 30, 2019

- November 30, 2019

Advantages & Disadvantages

- Advantages
  - Claims very complete within 3 months; faster for inpatient claims;
  - Claims Linkage quick
  - Can track study subjects across settings;
  - NO loss to follow-up; Vital Status updated every 2 weeks

- Disadvantages
  - VRDC Limited to one Analyst
  - Output checked before released
  - Only SAS & Stata
  - Bayesian modeling very challenging
  - Heavy CPU time means analyses very slow
  - Data Sharing Prohibited

Summary

- Game Changer to use "real time" data

- Linking EMR and other data to VRDC permits many novel kinds of Cluster RCTs

- Disadvantages are largely technical;

- Increased Access possible if Privacy issues adequately addressed