

Bird's Eye View of Collaboratory Demonstration Projects

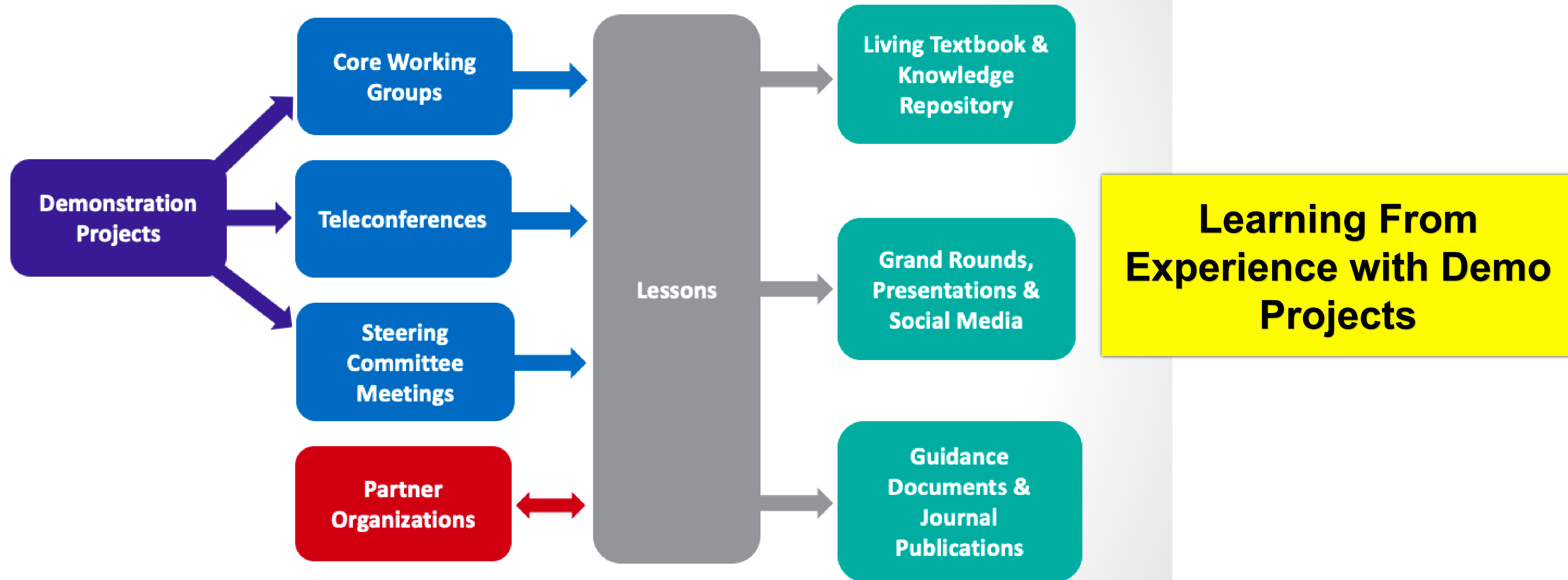
Discussion: *In what settings/situations do we need to learn more about how best to conduct embedded PCTs?*

Kevin Weinfurt, PhD

“Curious Loon”



Flow of Information



Trial Designs

Design	Trials
Parallel Groups Individual Randomization	
Cluster Randomization	
Stepped-Wedge - Cluster Randomization	

Design	Trials			
Parallel Groups Individual Randomization	Acu-OA OPTIMUM Nudge SPOT			
Cluster Randomization	FM TIPS HiLo EMBED	GGC4H ICD-Pieces PROVEN PPACT	STOP CRC TIME ABATE	
Stepped-Wedge - Cluster Randomization	NOHARM PRIM-ER TSOS LIRE ACP PEACE			

Approaches to Notification/Authorization

Design	Waiver	Indiv Informed Consent	Notification/ Opt-out
Parallel Groups Individual Randomization			
Parallel Groups Cluster Randomization			
Stepped-Wedge - Cluster Randomization			

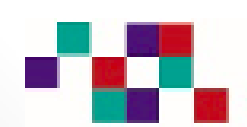
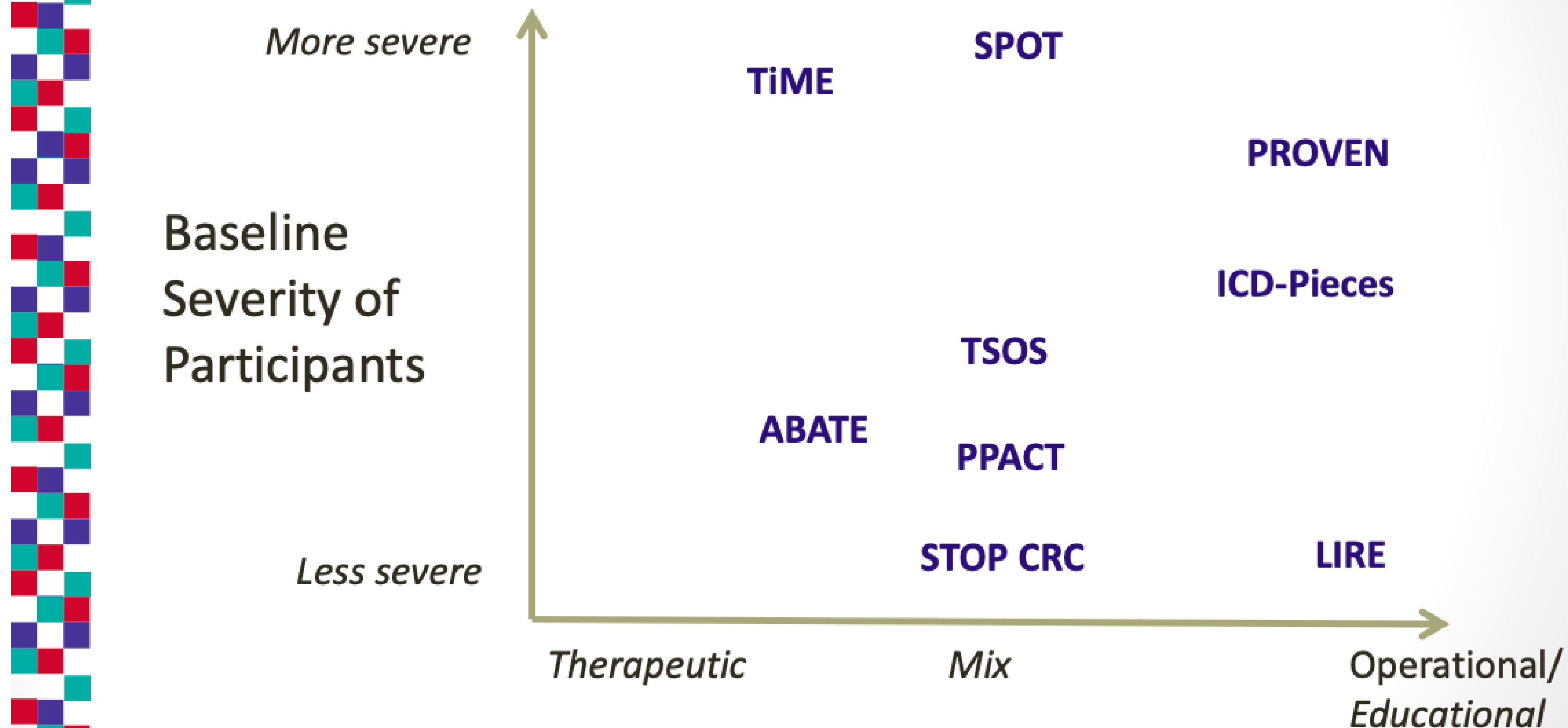
Design	Waiver	Indiv Informed Consent	Notification/ Opt-out
Individual Randomization Parallel Groups	SPOT	OPTIMUM	Nudge
Cluster Randomization	PROVEN EMBED STOP CRC ABATE	FM TIPS HiLo GGC4H PPACT	ACP PEACE ICD-Pieces TIME
Stepped-Wedge - Cluster Randomization	NOHARM PRIM-ER TSOS LIRE		

(Acu-OA is TBD)

Severity, Intervention Type and Target

An Older Picture

UH2s/UH3s by Severity and Intervention



NIH Collaboratory

Rethinking Clinical Trials®

Health Care Systems Research Collaboratory



**Baseline
Severity**

<i>End-of-Life</i>	
<i>Metastatic Cancer</i>	
<i>Acute</i>	
<i>Multiple Chronic Conditions</i>	
<i>1 Chronic Condition</i>	
<i>Healthy</i>	

Therapeutic

Operational/Educational

Type of Intervention

Baseline Severity

<i>End-of-Life</i>				PROVEN
<i>Metastatic Cancer</i>				ACP PEACE
<i>Acute</i>	TSOS ABATE		EMBED SPOT	NOHARM PRIM-ER
<i>Multiple Chronic Conditions</i>	Acu-OA HiLo TiME			Nudge ICD-PIECES
<i>1 Chronic Condition</i>	FM TIPS OPTIMUM PPACT			LIRE
<i>Healthy</i>			STOP-CRC	GGC4H

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<i>Healthy</i>		STOP-CRC		GGC4H

Target = *Patient*
Clinician
Patient & Clinician

Therapeutic

Operational/Educational

Type of Intervention

Lifespan Representation
(not hard to guess)

Age of Patients in Trials



Adults

Adolesc

Younger
Children

Uses of EHR

Use of EHR

<i>Trial</i>	<i>Eligibility</i>	<i>Intervention Delivery</i>	<i>Outcome Assessment</i>
Acu-OA			
NOHARM			
FM TIPS			
OPTIMUM			
ACP PEACE			
HiLo			
PRIM-ER			
EMBED			
Nudge			
GGC4H			
ICD-Pieces			
TSOS			
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PPACT			
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Target = <i>Patient</i> <i>Clinician</i> <i>Patient & Clinician</i>		Type of Intervention <i>Therapeutic</i> <i>Operational/Educational</i>		

Age of Patients in Trials

Age Group	Acu-OA	ACP PEACE	NOHARM	FM TIPS	OPTIMUM	HiLo	PRIM-ER	EMBED	Nudge	ICD-PIECES	TSOS	SPOT	PROVEN	LIRE	PPACT	STOP-CRC	TiME	ABATE
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