

# Informing and Consenting: What are the goals?

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# The Agenda

- Introduction: Pearl O'Rourke, MD
  - Waiver of consent
  - Is there a role for informing/notifying?
- Two examples
  - ICD-Pieces: Miguel Vazquez, MD
  - NUDGE: Michael Ho, MD, PhD
- Ethical considerations: Dave Wendler, PhD
- Discussion: All

# Background

- Informed consent (form and process) fundamental to ethical engagement of human subjects as articulated in the Belmont Principles
  - Informs (respect for persons) and
  - Allows choice (autonomy)



# If full regulatory consent not possible...

- Alteration
  - Some of the required elements of informed consent can be altered or not included
  - NOTE: There still is a consent form/process with a signature
- Waiver of consent
  - No consent

# The Regulations

- Regulatory criteria for waiver or alteration are the **same**
  - Research can involve no more than minimal risk
  - It is not practicable to conduct the research without a waiver/alteration
  - If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
  - The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
  - Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.
- Investigators must justify
  - How criteria are met
  - Why a waiver/alteration is being requested

# Waivers in PCTs

- Many trials:
  - Meet minimal risk criteria
  - Involve numerous institutions and thousands of subjects
- Concern that obtaining informed consent:
  - May alter the 'real-world' medical care being studied
  - May introduce an alteration of routine care
  - May introduce bias
  - Make research impossible to conduct

# The Challenge...

- How to justify waiver of consent as the request/demand for transparency has increased?
  - From the public, funders, regulatory bodies

# Request for transparency

- Studies of patients' reactions to hypothetical scenarios
  - Patients “wanted to be told about research and have a choice, but were very open to disclosures being streamlined”
    - Kass et al. AJOB Empirical Bioethics.20--:7;92-105
  - “...pragmatic clinical research without some type of notification and perhaps consent is currently not acceptable to the majority of the public and is associated with a lower trust in physicians and the places where care is provided.”
    - Weinfurt et al. Med Care.2017:55;970-978



# Consider

- Informed consent is not the only way to inform

# Consider

- Informed consent is not the only way to inform
- Think notification



# Consider

- Informed consent is not the only way to inform
- Think notification
- Talked with the PI's of six studies using a waiver of informed consent with some type of notification



# Notification with waiver of consent

- Amount of information...a range
  - Detailed study-specific to
  - General statement that research is being conducted
- Mode of presentation\*
  - Posters, flyers, emails, snail mail
  - Face-to-face discussion

\* Impact on level of certainty that the message was at least seen

# Consequences of notification

- Logistics and cost
- *For discussion in the future:*
  - When to offer an opt-out option
  - What if no opt-out and potential subjects
    - Have questions
    - Do not want to be in the research?

# The Agenda

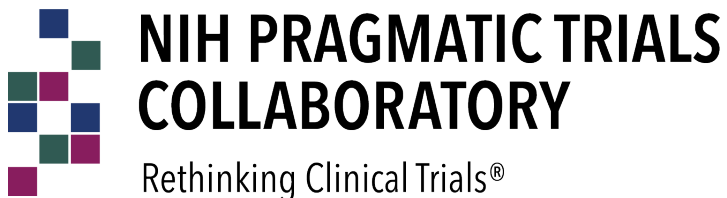
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# ICD-Pieces: Improving Chronic Disease Management with Pieces

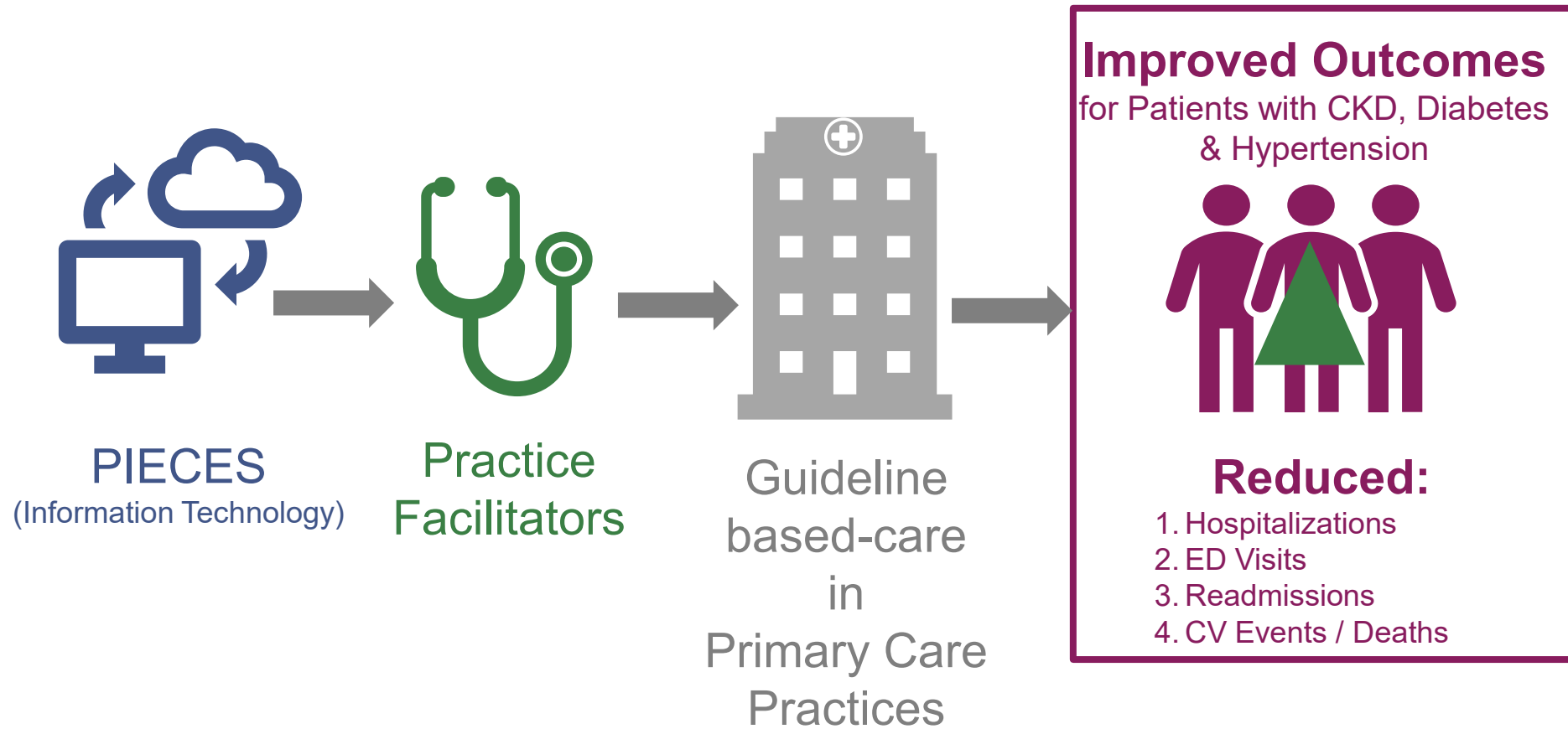
Miguel A. Vazquez, MD

Professor of Internal Medicine

University of Texas Southwestern Medical Center



# Hypothesis



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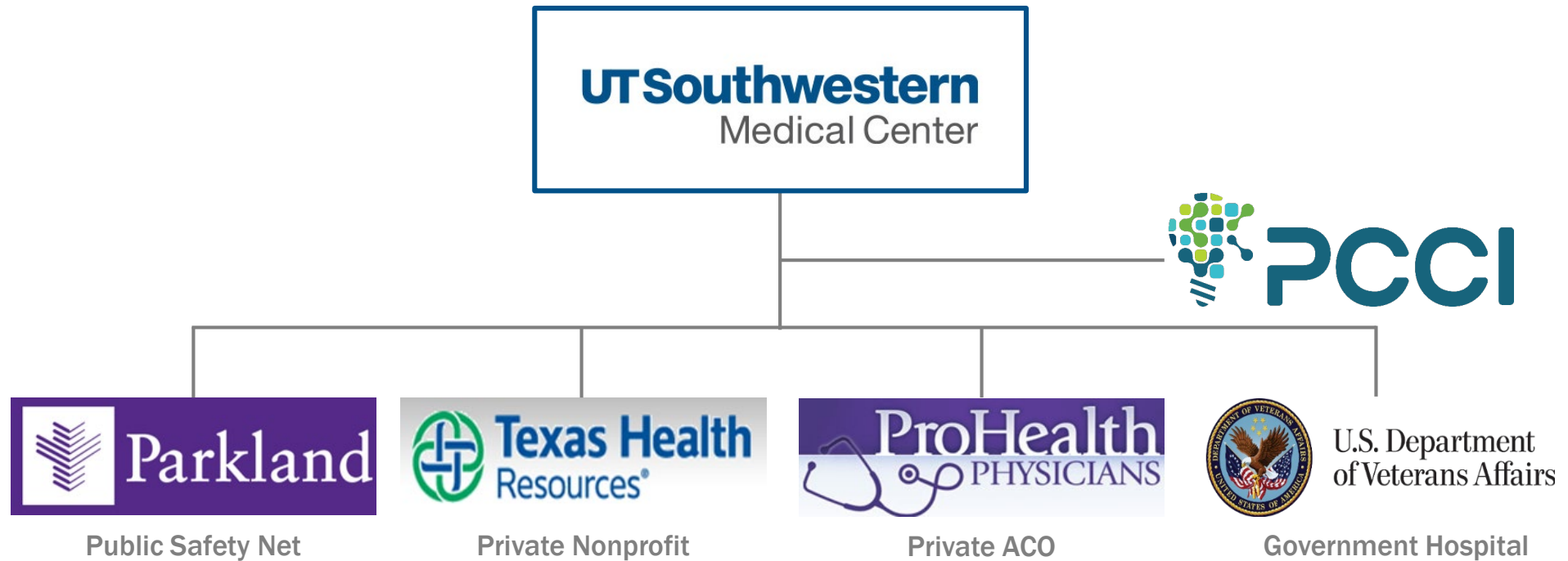
# ICD-Pieces

- Patient Population
  - Patients with triad of CKD, Diabetes and Hypertension
- Intervention
  - Facilitate delivery of guideline- based care
- Waiver of informed consent
  - Accepted interventions and primary care provider made final decisions to accept or not recommendations
  - Information provided in clinics: research study on CKD, Diabetes and HTN
  - Opt-out option provided (for patients and clinicians)

# Patient Information-Sheet (excerpts)

- This research study will help us learn how to help providers give the best care to patients who have these 3 health problems: Chronic Kidney Disease, Diabetes and High blood pressure (Hypertension).
- As part of this study, the study team will look at the information about you that Parkland collects at each of your clinic visits to see how your health is doing. The study team will not collect more data or do any extra tests just because you are in the ICD-Pieces research study. Even if your doctor did not use the information sent to him or her, your information is still important to the study. The privacy of your information is important, and we will use safe and secure ways to look at your personal information. At the end of the study, your name, date of birth, address, phone numbers, etc. will be taken off our records so nobody can link the information to you. The study team will not share any of your personal information with people who are not part of the study team.
- If you do not want your information sent used in this study, please call **214-590-3073** to leave a message and your information will be removed.

# Participating Health Systems



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# Patient Notification and Enrollment

Health System	Notification	Patients enrolled	Opt-outs
A	Poster	2,860	147
B	Flyer	2,821	17
C	Variable	3,865	0
D	Information sheet	1,454	18

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# ICD-Pieces

- Enrollment diverse population
- Health systems differed in population, geography, level of integration
- Flexibility in delivery of intervention and delivery information
  - Each health system used a different approach to inform patients
  - Lesson learned: Plan implementation strategy to inform potential participants

# Opting out of a Pragmatic Clinical Trial: The experience of the Nudge Study

P. Michael Ho, PhD, MD

Professor, School of Medicine

University of Colorado Anschutz Medical Center

VA Eastern Colorado Health Care System

# The Nudge Study - Overview

- Pragmatic clinical trial seeking to improve medication adherence to patients' already-prescribed cardiovascular (CV) medications through a series of theory-based text or voice messages to serve as “nudges”
  - Inclusion criteria: English/Spanish speaking patients with  $\geq 1$  CV condition of interest prescribed  $\geq 1$  medication of interest
- Due to our large enrollment numbers and patient identification procedures, traditional consent practices were not feasible

# Patient identification and notification process

- Patients meeting inclusion criteria were identified through EHR. Staff mailed each patient an opt out packet via USPS.
- The packet included an introductory letter signed by the Site PI, frequently asked questions about the study, an opt out form, a self-addressed stamped envelope, and a 3-page voluntary survey for patients opting out of the study.
  - Patients that returned opt out consent forms or had packets returned by USPS were removed from the study
  - If patients did not return the opt out form within one month, they were considered eligible and their medication refill activity was monitored.



# Introductory letter



**Title:** Personalized patient data and behavioral nudges to improve adherence to chronic cardiovascular medications (Nudge)

**Co-Principal Investigators:** Michael Ho, MD, PhD; Sheana Bull, PhD, MPH

**Protocol:** 18-2779

**Version date:** 12/1/2020

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The University of Colorado in collaboration with UCHealth is conducting a research study to see how well text messages could work to remind and encourage patients take medicines they have already been prescribed.

You are receiving this letter because you have been identified as a patient at UCHealth. We plan to send participants text messages to serve as reminders to fill your prescription for already prescribed cardiovascular related medications. In this study, we hope to follow you and other patients over 2 years.

Please review the information sheet attached in this packet. If you would like to join the study, you do not need to complete any forms. If you do not wish to participate, please complete the opt-out letter and send it in the self-addressed, stamped envelope, attached.

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Larry A. Allen".

Larry A. Allen, MD, MHS

# Frequently asked questions



## INFORMATION ON THE STUDY

### **What is the title of this research study?**

Personalized patient data and behavioral nudges to improve adherence to chronic cardiovascular medications (The Nudge Study)

### **Why is this research study being conducted?**

Half of patients with cardiovascular disease do not take their medications as prescribed. This behavior can lead to increased medical risk or even death. Our study plans to learn if sending different text messages, serving as reminders or encouragement, may help patients take their medication more often if they have had trouble keeping up with their medicines.

### **How does the study work?**

Our research team will identify patients taking prescription medicine that have already been prescribed by their doctor. If a patient does not refill their prescription within 7 days of their recommended refill date, they may receive a text message intervention.

At any time, participants can text STOP to stop receiving text messages. For voice messages/phone calls, pressing 0 will also opt you out of the study. The data that would otherwise be collected by your healthcare provider will continue to be viewed by the Nudge Study team after the intervention.

### **What if I don't have a cell phone?**

For patients that do not have a cell phone, a voice recording saying the same messages will be sent to your phone line instead.

### **What are you going to measure?**

... ..

# Opt out card



**OPT-OUT CONSENT FORM**

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**Title:** Personalized patient data and behavioral nudges to improve adherence to chronic cardiovascular medications (Nudge)

**Co-Principal Investigators:** Michael Ho, MD, PhD; Sheana Bull, PhD, MPH

**Protocol:** 18-2779

**Version date:** 02/01/19

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I **DO NOT** wish to take part in the above study.



Printed name of participant			
Signature of participant		Date	

Please return this self-addressed, stamped postcard by: 11/10/2020 to **no longer** be enrolled in the study.

# Secondary opt out during the intervention

- All patients enrolled in intervention arms had a secondary opportunity to opt out of the intervention by texting STOP after the first text message.
- Patients that texted STOP or expressed they would no longer like to receive texts in other words were removed from the study at any time during the intervention

This is a message from the  
Nudge Project at UCHHealth:

You are due to refill your meds.

If you have already filled your  
prescription let us know by  
replying DONE.

Reply STOP to quit, HELP for  
info. Msg&DataRatesMayApply

# The Independent Value of Disclosure

The views expressed in this talk are my own.  
They do not represent the position or policy of the NIH.

David Wendler  
Department of Bioethics  
NIH Clinical Center



# Conflicts

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- I have no conflicts of interest with respect to the present presentation.

# Background

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- Informed consent is frequently understood as one thing, with one goal (respecting autonomy).
- This framing suggests informing participants is valuable only when they are deciding whether to participate.

# Thesis

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- THAT is the role of disclosure as part of the full regulatory consent process.
- But, being informed can have value independent of full regulatory consent.
- Hence, even when conducting a study under a waiver of full regulatory consent: ask whether disclosure would be valuable.



# Claim #1

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Individuals are always informed to some extent and agree to something.

The practically relevant questions are: What should they know? What should they agree (not object) to?

# Claim #2

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To determine what should be disclosed, need to identify the goals of disclosure in the case.

# Claim #3

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Informed consent currently has the goal of respecting participant autonomy.

What should be disclosed is determined by what participants need to know to make a decision.

This suggests that when participants are not consenting there is no reason to inform them.

# Claim #4

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Information is often valuable even when it is not used to make a decision.

# Goal #1

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## Preparation

# Goal #2

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Understand what doing/relationships

# Goal #3

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Understand what contributing to

# Goal #4

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Participants can express any concerns



# Goal #5

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Can promote participant engagement/support

# Goal #6

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Reduces chances of unethical research

# Goal #7

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Promotes public trust

# Claim #5

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Informing can have negative consequences.

Tailor what disclose to the specific study  
and the goals of disclosure.

# Summary

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Participants always know some things and agree to some extent. When not getting full regulatory consent, the relevant questions are:

1. What should they know?

2. What should they agree (not object) to?