Creative Scientist Workshop 2021

A Translational Science Perspective on Remote Trial Methods

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November 5, 2021

Disclosures and Acknowledgements

Disclosures: **Few**

- PI/Co-I on various NIH-funded research projects
- Persistent passion for translational science approaches to improving CTR

Acknowledgements: **Many!**

- Funding:
  - NCATS - Buffalo and MUSC CTSAs: UL1 TR001412 and UL1TR001450
  - NCI - R01CA206193
- People:
  - Research Collaborators:
    - Martin Mahoney, Jen Dahne, Matt Carpenter, Robbie Schnoll…
  - CSW Organizing Committee:
    - Jennifer Dahne, Erin O'Byrne, Andy Burnett, Tim Murphy, Mary Sienkiewicz, Brahm Segal, & Royce Sampson
  - Speakers:
    - Dan Ford, Andy Coravos, Jen Dahne, Eric Hekler, & Eliseo Pérez-Stable
  - Our KnowInnovation (KI) partners/facilitators
  - YOU!

In this talk, I will…

1. Consider *where we want to be*
2. Address *where we are now*
3. Consider *paths* from where we are to where we want to be
4. Provide *examples* of a translational science approach
5. Encourage us all to embrace the opportunity

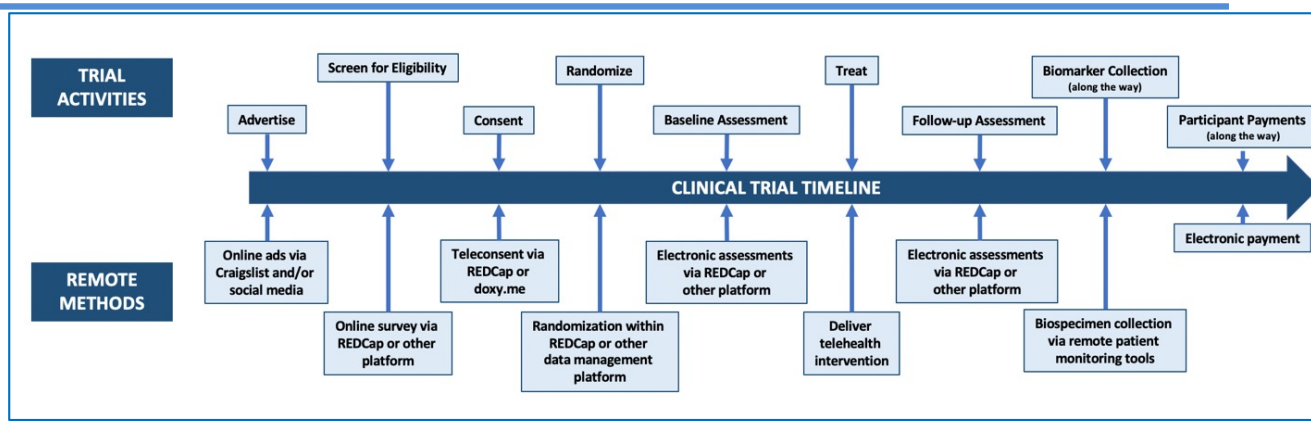
1. Where we want to be

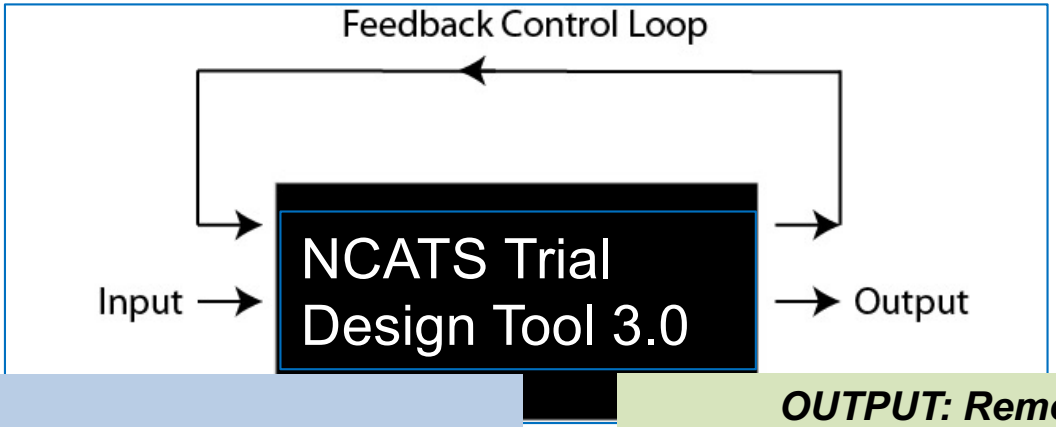
We have lots of choices →

Imagine a…

"precision medicine"

approach to <u>trial design</u>





INPUT:

P = Population?
I (E) = Intervention (Exposure)?
C = Comparator?
O = Outcome?
T = Timing?
S = Setting?

OUTPUT: Remote method ____ will _____

Accrual rate
Cost
Rigor/fidelity
Inclusion of ____
Retention
Clinical outcomes

Real-worldness (mult param – PRECIS2)

PPT experiences (e.g., burden, trust…)

2. Where are we now? Expert Opinion

Lots of anecdotal evidence and expert opinion for candidate "best practices", with relatively little rigorous evaluation.

- So, let's take a look…

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2. Where are we now? Surveys

- Surveys – CTSA Network

Journal of Clinical and Translational Science

www.cambridge.org/cts

Clinical research during the COVID-19 pandemic: The role of virtual visits and digital approaches

Research Methods Technology Special Communic

Cite this article: Loucks TL, Ty Garovic VD, Hill J, McSwain SD, Sonnenberg FA, Weis JA, and Br research during the COVID-19 p role of virtual visits and digital *Journal of Clinical and Translati* e102, 1–8. doi: 10.1017/cts.2021

Received: 18 December 2020
Revised: 26 February 2021
Accepted: 26 February 2021

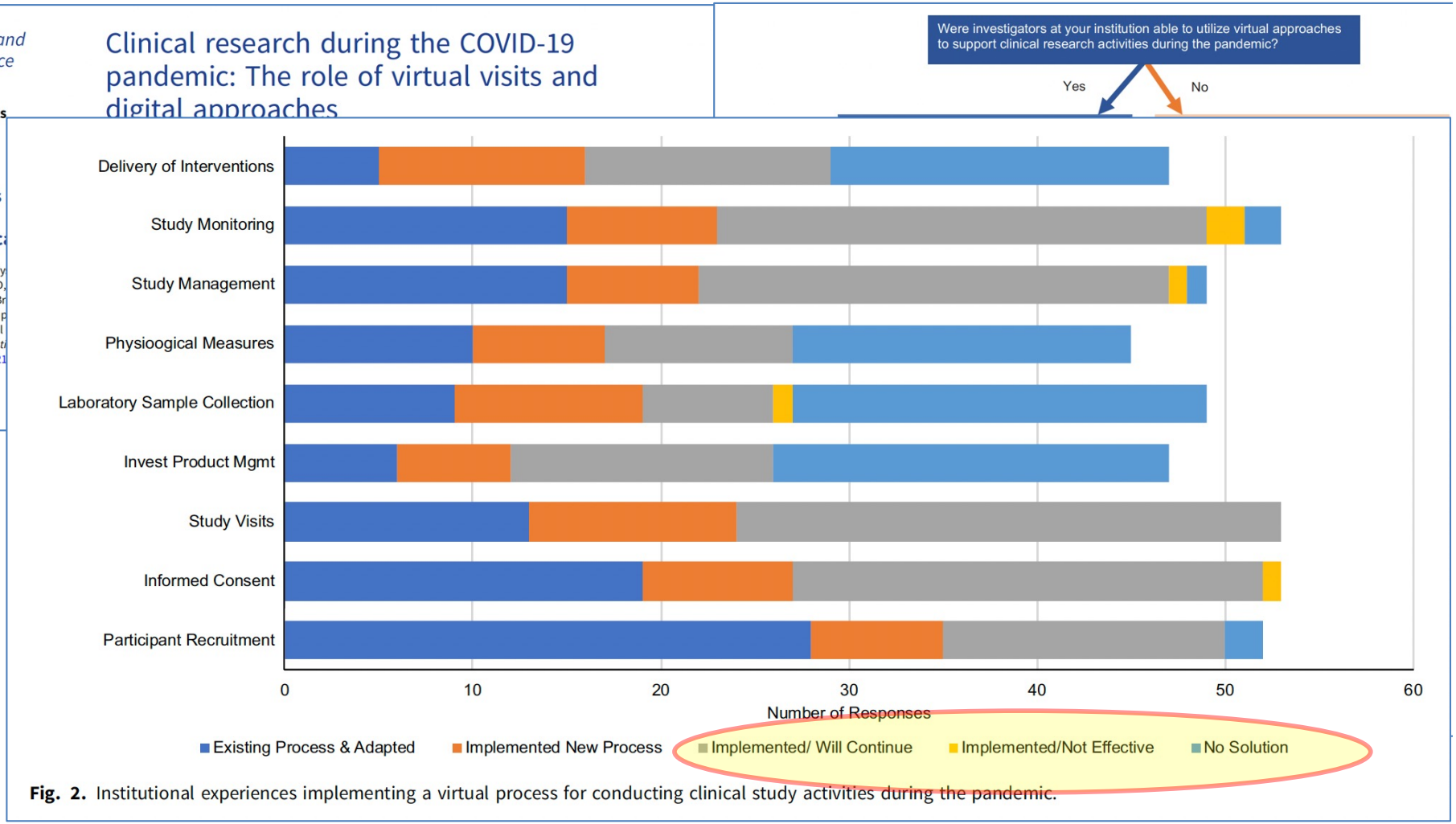


Fig. 2. Institutional experiences implementing a virtual process for conducting clinical study activities during the pandemic.

Loucks et al (2021). Clinical research during the COVID-19 pandemic: The role of virtual visits and digital approaches. *JCTS* 5:e102, 1–8. doi: 10.1017/cts.2021.19

2. Where are we now? Surveys

- Surveys – Industry https://www.oracle.com/a/ocom/docs/industries/life-sciences/clinical-trial-management-post-covid.pdf

Key Findings from the Research

Newly adopted methods embraced during the pandemic had a positive impact on clinical trials.

82%

of respondents who implemented new clinical trial approaches during the pandemic report they have had a positive impact on clinical trials overall, including 26% reporting a "significantly" positive impact.

The industry is confident in the data generated from newly adopted clinical trial approaches.

92%

of respondents who implemented new clinical trial methods during the pandemic are equally or more confident in the data collected from these methods, compared data collected via pre-pandemic methods.

Newly adopted clinical trial methods are here to stay.

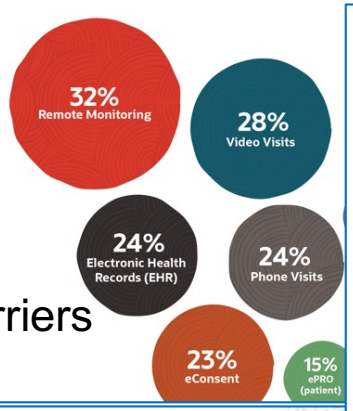
97%

of respondents who implemented new clinical tria methods during the pandem indicated their organization v continue using at least one o these new methods.

Industry anticipates persistence of remote models and specific methods

Newly Adopted Approaches Planned for Continued Use Post-Pandemic

Based on the results of this research, these newly adopted clinical trial methods are here to stay. Of the respondents who implemented new clinical trial methods during the pandemic, 97% indicated their organization will continue using at least one of these new methods, with remote monitoring, video visits, EHR, and phone visits being the approaches most likely to continue.



Expected Change in Use of Select Clinical Trial Models Post-Pandemic

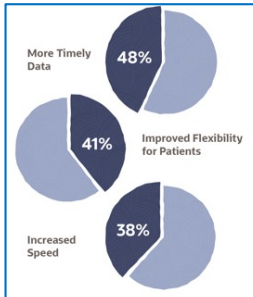
The adoption of new clinical trial approaches reflects the movement on the continuum of clinical trial models from site-based to decentralized, which occurred during the pandemic — but what shifts are expected going forward?

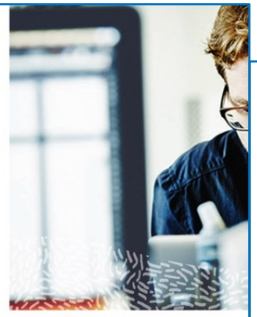
Survey respondents who implemented new clinical trial methods during the pandemic expect their organizations to increase their use of hybrid (44%) and fit-for-purpose models (42%) after the pandemic. Of the four models considered — site-based, fit-for-purpose, hybrid, and decentralized — respondents expect the use of the site-based model to decrease the most (24%).

	Site-based Model	Fit-for-purpose Model	Hybrid Model	Decentralized Model
Increase	26%	42%	44%	36%
No Change	44%	45%	38%	47%
Decrease	24%	8%	9%	10%
Uncertain	6%	5%	9%	7%

Base: Respondents implementing new approaches (n = 225)

There were notable perceived benefits *and* barriers



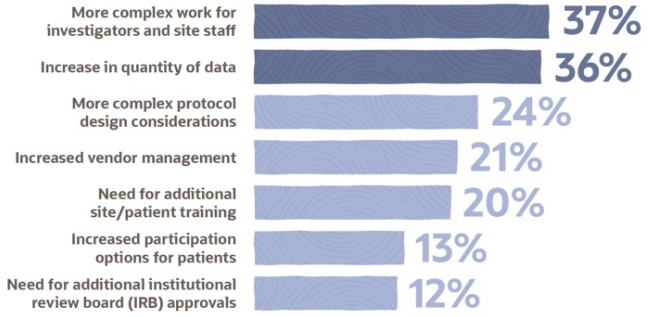


OTHER NOTED IMPACTS

30% Higher Quality Data	30% More Frequent Data	29% Increased Protocol Compliance	25% Improved Retention
23% More Robust Data	23% Increased Visibility Into the Clinical Trial	19% Improved Patient Engagement	17% Improved Recruitment

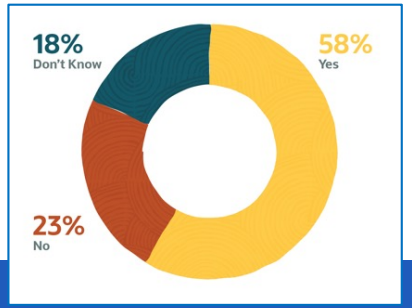
Top Two Consequences of Continuing to Use Newly Implemented Approaches

When probed regarding the effects of continuing to use newly implemented approaches in clinical trials, more complex work for investigators and site staff (37%) and increased volume of data (36%) emerged as the most significant consequences.



Base: Respondents planning to keep at least one newly implemented approach; up to two responses permitted (n = 217)

Most intend to allow patients to choose how they participate



3. What's next?

- Lots of successful research teams (AND lots of failures)
- Lots of anecdotal evidence and expert opinion for candidate "best practices"…

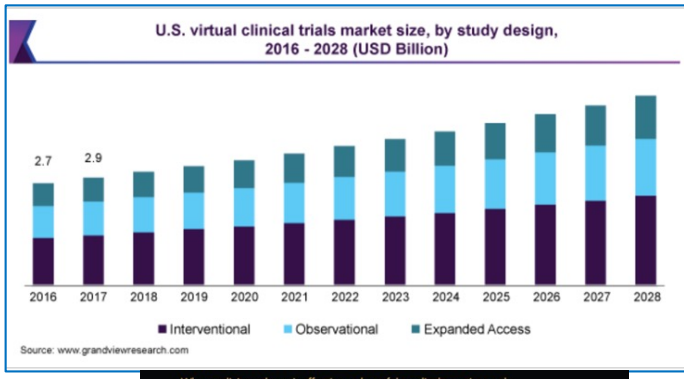
- Anecdotes, expert opinion and surveys are great starting points
- But are they the best basis for choosing our future?

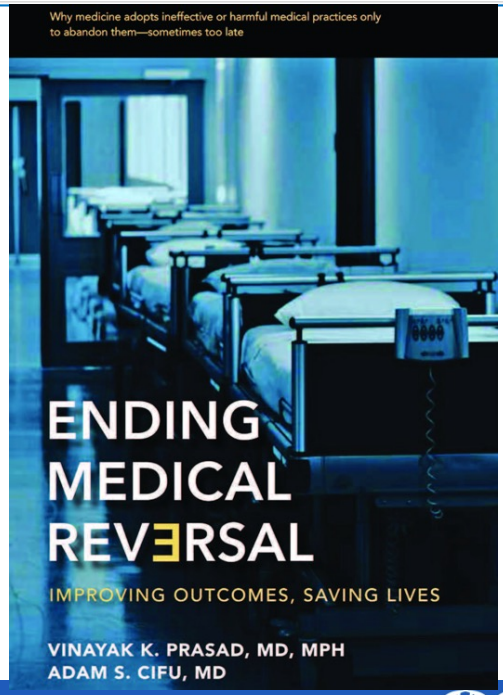
- **What's next?**
  - 3.1. More of the same? (or is it already a "done deal"?)
  - 3.2. Rigorous translational science?

3.1. What's next? More of the same?

Stick with the expert opinion and surveys and do the best we can?

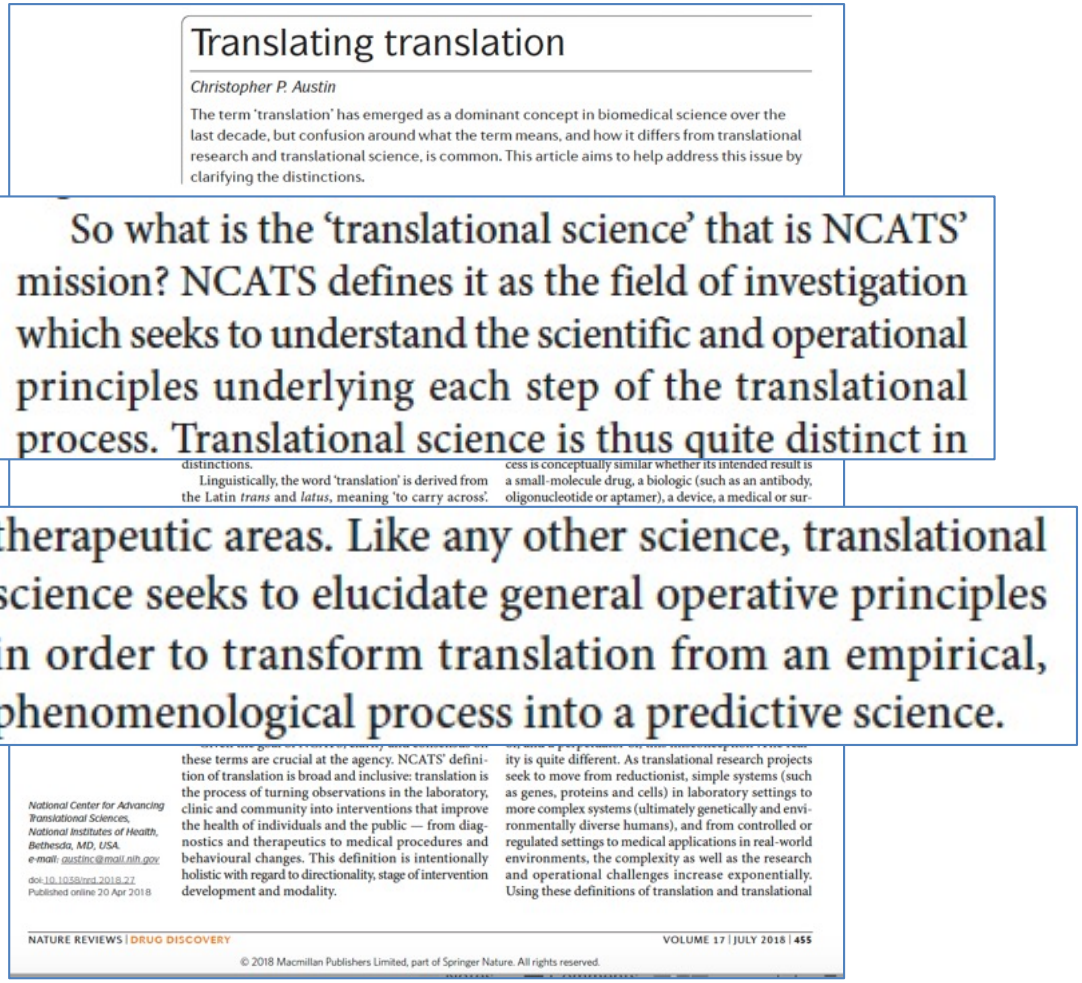
- **Advantages?**
  - Practical use of our recent efforts and (subjective) experience
  - For the moment, its all we have
- **Disadvantages?**
  - Short-term costs:
    - Time and money for us to develop, refine, implement
    - And industry is counting on us →
      - 7.4B in 2020, ~15B/yr in 2028
  - Long-term costs:
    - ***What if some remote trial methods are ineffective – or worse – and we don't <u>know</u> that for 15-20 years?***
    - Unfortunately, the conditions are right for this to happen →
      - And deimplementation is hard





3.2. What's next? Translational science?

- Translational science is at the core of the NCATS/CTSA mission



Translating translation

Christopher P. Austin

The term 'translation' has emerged as a dominant concept in biomedical science over the last decade, but confusion around what the term means, and how it differs from translational research and translational science, is common. This article aims to help address this issue by clarifying the distinctions.

So what is the 'translational science' that is NCATS' mission? NCATS defines it as the field of investigation which seeks to understand the scientific and operational principles underlying each step of the translational process. Translational science is thus quite distinct in therapeutic areas. Like any other science, translational science seeks to elucidate general operative principles in order to transform translation from an empirical, phenomenological process into a predictive science.

distinctions.

Linguistically, the word 'translation' is derived from the Latin *trans* and *latus*, meaning 'to carry across'. cess is conceptually similar whether its intended result is a small-molecule drug, a biologic (such as an antibody, oligonucleotide or aptamer), a device, a medical or sur-

these terms are crucial at the agency. NCATS' definition of translation is broad and inclusive: translation is the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public — from diagnostics and therapeutics to medical procedures and behavioural changes. This definition is intentionally holistic with regard to directionality, stage of intervention development and modality.

ity is quite different. As translational research projects seek to move from reductionist, simple systems (such as genes, proteins and cells) in laboratory settings to more complex systems (ultimately genetically and environmentally diverse humans), and from controlled or regulated settings to medical applications in real-world environments, the complexity as well as the research and operational challenges increase exponentially. Using these definitions of translation and translational

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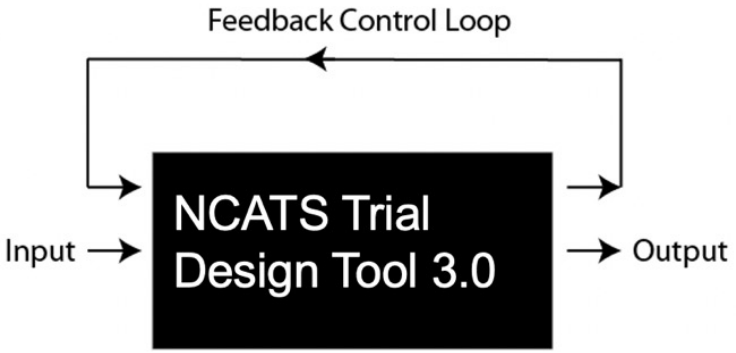
doi:10.1038/nrd.2018.27
Published online 20 Apr 2018



3.2. What's next? Translational science?

Rigorous criteria for trial design 'best practices' – as we would for other *treatments*

- Safety and Efficacy (including moderators)
- Generalizability
- Understanding mechanisms

Cost-effectiveness

Acceptability

Using the same "strength of the evidence" criteria we apply to "treatments"

https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/methods-and-processes/grade-definitions

Grade	Definition
A	…recommends the service. There is high certainty that the net benefit is substantial.
B	…recommends the service. There is high certainty that the net benefit is moderate…
C	…recommends selectively offering…based on professional judgment and patient preferences…
D	…recommends against the service…moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.
I	…Evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

Level of Certainty	Description
High	…usually includes consistent results from well-designed, well-conducted studies in representative …populations...
Moderate	…confidence…is constrained by… number, size, or quality of individual studies…inconsistency of findings…Limited generalizability…
Low	…evidence is insufficient...

3.2. What's next? Translational science?

- **What questions do we most need to answer?**
  - In this trial with these specific PICOTS and my specific priorities, which combination of remote and in-person components will optimize the following outcomes:
    - Accrual rate? Inclusion of _____?
    - Cost? Retention?
    - Rigor/fidelity? Clinical outcomes?
    - Real-worldness (mult param – PRECIS2)
    - PPT experiences (burden, trust…)

- **Where is the evidence strong right now?**
- **How can *we* strengthen the translational science evidence base?**

4. Examples of a trans sci approach

A. (Multi-Site) Randomized Controlled Trials (RCTs)
   1. *Standard RCTs: Hawk et al. 2021 U01 Proposal*
   2. SMART designs, MOST designs, microRCTs (upcoming talk by Eric Hekler)

B. Study Within a Trial Approach (SWATS)*
   1. *Quasi-Experimental: Mahoney et al., 2021 JMIR Formative Research*
   2. Experimental

C. The importance of a combination of approaches
   – Telehealth as an example

*Treweek et al (2018), *Trials,* **19**,138; https://doi.org/10.1186/s13063-018-2535-5

4A. Example of a remote methods RCT

- The NCATS CCIA U01 mechanism (PAR-19-099; soon to be reinvented)
  - addressing "widely appreciated systematic barriers" to trial participation
  - "quality and efficiency of translational research, particularly multisite trials"
- A perfect opportunity to experimentally evaluate the impact of remote trial methods?
  - *Improving Clinical Trial Efficiency, Quality, Equity, and Efficacy:*
    A Randomized Controlled Evaluation of Remote vs. In Person Methods
  - 3 CTSAs: Buffalo (Hawk, Mahoney)
    MUSC (Carpenter, Dahne)
    UPenn (Schnoll)
  - Use case: Medication and behavioral counseling for smoking cessation

4A. Example of a remote methods RCT

Improving Clinical Trial Efficiency, Quality, Equity, and Efficacy: A Randomized Controlled Evaluation of Remote vs. In Person Methods

Aim 1: Evaluate the accrual efficiency of the Remote vs. In-Person Intake Groups.

Aim 2: Examine key metrics of trial quality (fidelity and rigor) in Remote vs. In-Person Treatment and Assessment Groups.

Randomization #1: R vs. IP Intake

Randomization #2: R vs. IP Treatment/Assessment

Trial Module	Screening		Treatment and Assessment						
Week			**1**	**2**	**3**	**5**	**7**	**10**	**25**
Activity	Phone Screen	Intake	C1	C2	C3	C4	C5	F/U EOT	F/U 6M
Group		R	R	R	R	R	R	R	R
			IP	IP	IP	IP	IP	IP	IP
		IP	R	R	R	R	R	R	R
			IP	IP	IP	IP	IP	IP	IP

Notes. 6M=6-month; C=clinic; EOT=end of treatment; F/U=follow-up; IP=In-Person; R=Remote.

Aim / Outcome
Aims 1 and 3: Trial Accrual
Intake Visit Attendance
Aims 2 and 3: Trial Quality
Retention (# visits complete)
Medication adherence (%)
Counseling fidelity
Biospecimen completion/return rate
Aim 4: Clinical Outcomes
Bio-verified smoking abstinence

Exploratory Aim 3: Examine the impact of R vs. IP trial efficiency (Aim 1) and quality (Aim 2) for members of select health disparities.
Exploratory Aim 4: Conduct a preliminary evaluation of clinical outcomes for the R vs. IP Treatment and Assessment Groups.

4A. Example of a remote methods RCT

Improving Clinical Trial Efficiency, Quality, Equity, and Efficacy: A Randomized Controlled Evaluation of Remote vs. In Person Methods

- **Scored! Now we wait on a funding decision…**

- **Strengths of the RCT Approach:**
  - Significance: Without a strong evidence base, we're all flying blind
  - Innovation: To our knowledge, never been done before for remote vs. in-person trial methods
  - Approach: RCTs are the gold standard for testing whether something 'works'

- **Limitations of the RCT Approach:**
  - Cost: It's slow and expensive
  - Fit: Many trialists are not interested in running a "methods" trial
    Even with an excellent use case, questions about generalizability

- **If only there was something we could do…**

4B. Example of a remote methods SWAT

Study Within a Trial Approach (SWATS)*

*Treweek et al (2018), *Trials,* **19**,138; https://doi.org/10.1186/s13063-018-2535-5

"A SWAT is a self-contained research study that has been embedded within a host trial with the aim of evaluating or exploring alternative ways of delivering or organising a particular trial process."

JMIR FORMATIVE RESEARCH 2021;5(4):e25541 doi: 10.2196/25541 Mahoney et al

Original Paper

Transitioning to Remote Clinic Visits in a Smoking Cessation Trial During the COVID-19 Pandemic: Mixed Methods Evaluation

- How does switching from in-person to remote visits impact:
  - Clinic visit completion? (retention)
  - Biospecimen return? (rigor)

4A. Example of a remote methods SWAT

JMIR FORMATIVE RESEARCH 2021;5(4):e25541) doi: 10.2196/25541 Mahoney et al

Table 1. Selected demographic, smoking, and visit attendance characteristics among smoking cessation clinical trial participants by study cohort.

Characteristic	Values		*P* value
	COVID-19 cohort[a] (n=23)	Pre–COVID-19 cohort[b] (n=51)	
Age (years), mean (SD)	53.8 (9.6)	54.8 (9.3)	.68
Female sex, n (%)	10 (44)	28 (55)	.36
Did not self-identify as White, n (%)	7 (30)	12 (24)	.53
Household income <US $50,000, n (%)	9 (39)	19 (37)	.48
High school degree or less, n (%)	9 (35)	15 (29)	.64
Baseline CPD[c], mean (SD)	20.5 (8.4)	19.5 (7.4)	.60
Baseline CO[d], mean (SD)	20.9 (12.1)	16.6 (18.8)	.32
FTCD[e] score, mean (SD)	5.9 (1.8)	6.2 (1.7)	.52
Clinic visits during transition window[f] (range 1-5), mean (SD)	2.8 (1.5)	2.9 (1.4)	.70
Lost to follow-up, n (%)	1 (4)	0 (0)	.13
Withdrew from study, n (%)	1 (4)	5 (10)	.43

[a]COVID-19 cohort: participants with mix of in-person and remote clinic visits due to the COVID-19 pandemic.

[b]Pre–COVID-19 cohort: participants with all in-person clinic visits scheduled during a comparable time period during the calendar years 2018 and 2019.

4A. Example of a remote methods SWAT

Table 2. Clinic visit attendance among smoking cessation clinical trial participants for the COVID-19 cohort (n=23).

Last in-person visit	n	Remote clinic visit completion, n (%)[a]					Remote visit attendance (%)
		Visit #2	Visit #3	Visit #4	Visit #5	Visit #6	95% CI
Visit #1	5	4 (80)	4 (80)	3 (60)	3 (60)	3 (60)	68
Visit #2	6	N/A[b]	5 (83)	5 (83)	4 (67)	4 (67)	75
Visit #3	4	N/A	N/A	4 (100)	3 (75)	3 (75)	83
Visit #4	4	N/A	N/A	N/A	4 (100)	4 (100)	100
Visit #5	4	N/A	N/A	N/A	N/A	4 (100)	100
Total	23	4 (80)	9 (82)	12 (80)	14 (74)	18 (78)	83.6[c] 73%-91%

Retention

Table 3. Clinic visit attendance among smoking cessation clinical trial participants by last in-person visit for the pre–COVID-19 cohort (n=51).

Matching in-person visit[a]	n	On-site clinic visit completion, n (%)[b]					On-site visit attendance (%)
		Visit #2	Visit #3	Visit #4	Visit #5	Visit #6	
Visit #1	11	11 (100)	11 (10)	10 (91)	10 (91)	8 (73)	91
Visit #2	9	N/A[c]	7 (78)	7 (78)	7 (78)	7 (78)	78
Visit #3	14	N/A	N/A	14 (100)	14 (100)	13 (93)	98
Visit #4	7	N/A	N/A	N/A	6 (86)	6 (86)	86
Visit #5	10	N/A	N/A	N/A	N/A	10 (100)	100
Total	51	11 (100)	18 (90)	31 (91)	37 (93)	44 (86)	89.8[d] 84%-94%

4A. Example of a remote methods SWAT

Table 4. Saliva sample collection rates among smoking cessation clinical trial participants by last in-person visit for the COVID-19 cohort (n=23).

Last in-person visit	n	Remote saliva sample collection, samples/visits completed (%)					Saliva sample collection rate (%)
		Visit #2	Visit #3	Visit #4	Visit #5	Visit #6	95% CI
Visit #1	5	3/4 (75)	3/4 (75)	3/3 (100)	3/3 (100)	3/3 (100)	88
Visit #2	6	N/A[a]	5/6 (83)	5/6 (83)	4/4 (100)	4/4 (100)	90
Visit #3	4	N/A	N/A	4/4 (100)	3/3 (100)	3/3 (100)	100
Visit #4	4	N/A	N/A	N/A	4/4	4/4	100
Visit #5	4	N/A	N/A	N/A	N/A	4/4	100
Total	23	3/4 (75)	8/10 (80)	12/13 (92)	14/14 (100)	18/18 (100)	93.2[b] 84%-98%

Biospec return

Table 5. Saliva sample collection rates among smoking cessation clinical trial participants by last in-person visit in the pre–COVID-19 cohort (n=51).

Matching in-person visit[a]	n	On-site saliva sample collection, samples/visits completed (%)					Saliva sample collection rate (%)
		Visit #2	Visit #3	Visit #4	Visit #5	Visit #6	
Visit #1	11	11/11 (100)	11/11 (100)	10/10 (100)	10/10 (100)	8/8 (100)	100
Visit #2	9	N/A[b]	7/7 (100)	7/7 (100)	7/7 (100)	7/7 (100)	100
Visit #3	14	N/A	N/A	14/14 (100)	14/14 (100)	13/13 (100)	100
Visit #4	7	N/A	N/A	N/A	6/6 (100)	6/6 (100)	100
Visit #5	10	N/A	N/A	N/A	N/A	10/10 (100)	100
Total	51	11/11 (100)	18/18 (100)	31/31 (100)	37/37 (100)	44/44 (100)	100[c] 97%-100%

4A. Example of a remote methods SWAT

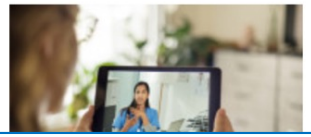
JMIR FORMATIVE RESEARCH 2021;5(4):e25541) doi: 10.2196/25541 Mahoney et al

- **Do we conclude:**
  - Remote not "significantly worse" OR limited statistical power
  - We will do even better next time OR all patients had initial in-person and transition planning, + stay at home order
- **There are serious limitations:**
  - How much can we generalize from a pandemic context?
  - What other confounds are hidden in this multiple cohort study?
- **Still, there are major possibilities:**
  - We all have data like this – let's look and synthesize?
  - *Looking ahead, we can embed randomized SWATs of specific remote vs. in-person methods in our upcoming trials*
    - c.f., revert to full in-person or plunge deeper into remote without a strong evidence base

4C. Combining approaches - telehealth

Special Collection - Coronavirus (COVID-19): remote care through telehealth

Cochrane has released a Coronavirus (COVID-19) Special Collection: remote care through telehealth



Telehealth refers to the provision of personalized health care over a distance. It

https://www.cochrane.org/news/special-collection-coronavirus-covid-19-remote-care-through-telehealth

This Special Collection includes Cochrane Reviews that address using telehealth to support clinical management of various conditions, including asthma, diabetes, cardiovascular disease, dementia, reproductive health, and skin cancer. It includes

patient.[1,3] While telehealth has much to offer in the provision of remote care to patients, accessing it may prove a significant challenge to those most in need, including older people, those from socio-economically disadvantaged backgrounds, and those with physical or learning disabilities.

Real-world data suggest these disparities persisted (worsened?) in the pandemic

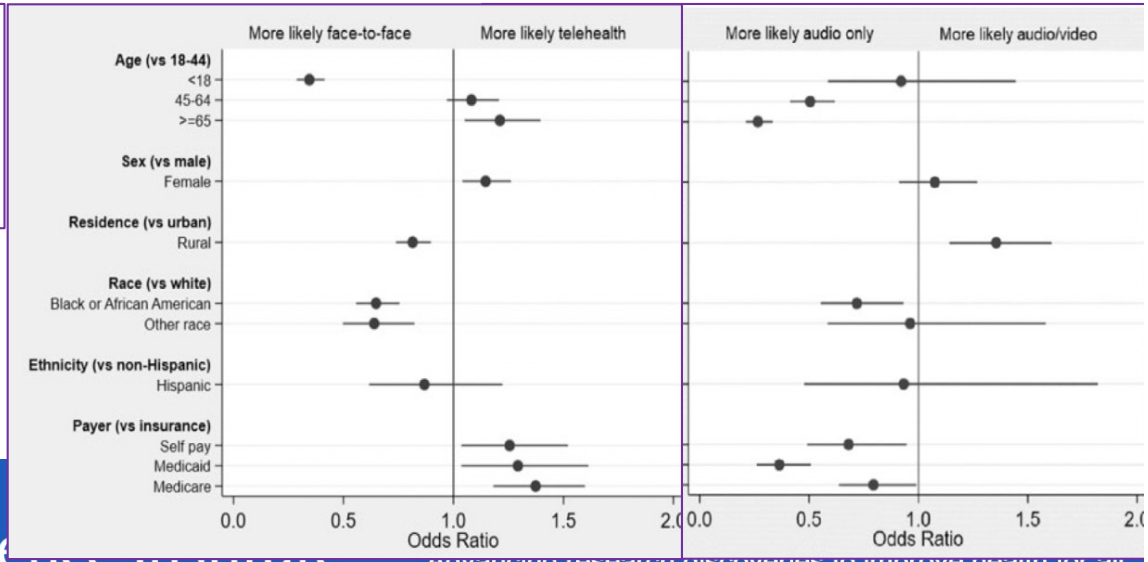
Disparities in use of telehealth at the onset of the COVID-19 public health emergency

Journal of Telemedicine and Telecare
0(0) 1–7

DOI: 10.1177/1357633X20963893
journals.sagepub.com/home/jtt
SAGE

Robert P Pierce and James J Stevermer

DOI: 10.1177/1357633X20963893



4. Examples of a trans sci approach

A. (Multi-Site) Randomized Controlled Trials (RCTs)
   1. *Standard RCTs: Hawk et al. 2021 U01 Proposal*
   2. SMART designs, MOST designs, microRCTs (upcoming talk by Eric Hekler)

B. Study Within a Trial Approach (SWATS)*
   1. *Quasi-Experimental: Mahoney et al., 2021 JMIR Formative Research*
   2. Experimental

C. The importance of a combination of approaches
   – Telehealth as an example

What other examples are available?

What questions are most important to answer – for you, for the field?

Let's do this!

The time is right…. to *collaboratively* **advance *translational science* of trial methods**

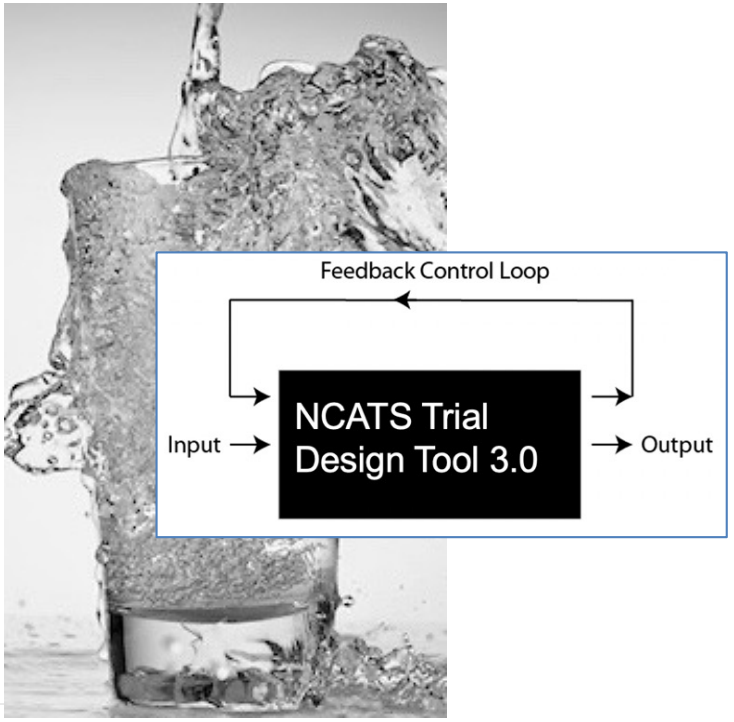
…To make the next generation of trials systematically…

…more inclusive? …more efficient? …more _____?

…without (greatly?) compromising rigor or clinical outcomes…

…and ultimately, better "improve health for all"

We have the responsibility *and* the opportunity



2009 2019 2029