OACIS

Outcomes After Critical Illness and Surgery

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Understanding & Improving Cohort Retention in Long-Term Outcome Studies

Dale M Needham MD, PhD

Professor, School of Medicine & School of Nursing

Johns Hopkins University

Email: dale.needham@jhmi.edu Twitter: @DrDaleNeedham

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R24 Grant Mechanism: Aims to enhance research infrastructure or to provide resources to other research projects

Improving Long-Term Outcomes Research for Acute Respiratory Failure (NHLBI Grant # R24HL111895)

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Aim 1: National web-based electronic database of validated and **recommended** survey instruments and clinical testing methods for long-term outcomes

Aim 2: Practical resources for maximizing retention in long-term, longitudinal research

Aim 3: Statistical methods & programs for evaluating functional outcomes in the presence of high patient mortality ("truncation due to death")

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Lessons learned about cohort retention?

Cohort retention in Post-Hospital Studies of ICU survivors (1970-2013)

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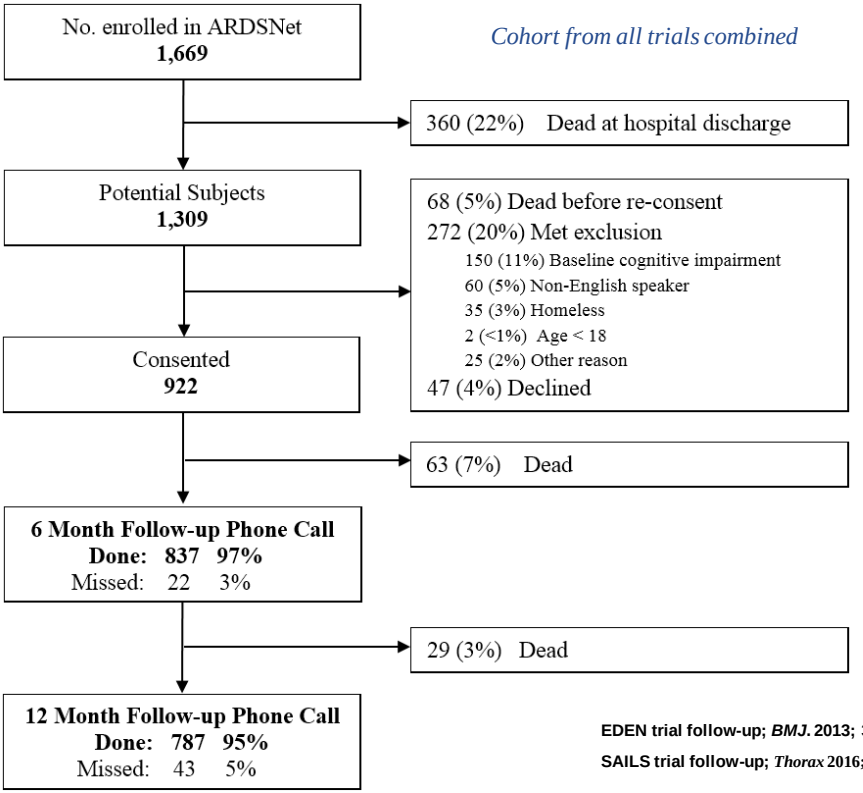
(*Crit Care Med*. 2016;44:1267-77)

- Threat to validity, results in loss of statistical power
- In RCTs, potential bias if differential loss to follow-up btwn treatment groups

NHLBI-Funded ARDSNet Long-Term Outcomes Study (ALTOS)



EDEN trial follow-up; *BMJ.* 2013; 346: f1532.

SAILS trial follow-up; *Thorax* 2016;71:401-410

Common Myths Regarding Follow-up

Myth: Follow-up = bothersome

After 280 questions & *repeated* calls/mailing, 92% "bothered" no more than a little bit

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"It's weird that you guys know what it's really like. The questions are kind of annoying, but it makes me feel better inside."

"Thank you again for being a caring person at a time when I most needed it…Be very proud of the work you and Johns Hopkins are conducting."

*"She is just going through a lot right now and is really tired, but **thank you** for calling to see how she's doing."*

"I want to help as much as I can but I can't do enough. I wouldn't wish this on anyone."

"If it'll help anyone else, it's all worthwhile."

Myth #2: Non-response = drop out

- Participants have lives outside of the study
  - Schedule calls/visits after work hours
- Away on vacation or really busy at work
  - e.g. participant who was tax accountant
- Extenuating circumstances
  - e.g. participant too depressed to answer phone. At study end, thankful for “not giving up on me”
- up to 50 calls req’d 10% of cohort for Stats Canada Census*
  - <15 calls to complete f-u for 90% cohort*

*Tolusso, Brisebois: *Ottawa: Household Survey Methods Division, Statistics Canada.* 2003

Myth # 3: Cohort retention = one size fits all

If you had any difficulty in participating in our surveys, what were the reasons for this?

Select all that apply.

Large majority had no difficulty
The rest had no common reasons for difficulty

Case Study: In-person visit - 5 year follow-up

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Study background

- In-person assessments at 3, 6 ,12, 24, 36, 48 and 60 mo.
  - Patient-reported outcome: 152 - 199 Qs requiring ~45 - 60 min.
  - After year 2, added 3x/year survey: 47 Qs ~ 20 min.
  - Clinical testing ~80 min.
    - Strength (Grip,MMT), Walk tests, Spirometry, MIP, DLCO, Anthro

3 and 6 mo. In-person Visit Challenges

- **3 months – partial visit, questions over phone**
  - Lack of time/busy work schedule
    - Works weekends/weekdays
  - Concern over keeping his job due to health
    - Wants to avoid time off work for any research visit

- **6 months – missed visit**
  - 3 mo. contact efforts blended into 6 mo. visit
  - Feeling overwhelmed early during recovery
  - Kept rapport and left door open for later visits

12, and 24 mo. In-person Visit Challenges and Strategies

- Only knows work schedule day or two in advance
- Utilize multiple methods to schedule visit:
  - Frequent calls per week
    - Listen to subject's requests regarding frequency of calls
    - Narrow down best time to talk: evenings or weekends
- Offer home visit and weekend visit to research clinic
  - MD/co-investigator to conduct home visit
  - Scheduled on same day of call

36 and 48 mo. In-person Visit Challenges

- **Consented to 3 more years of follow-up (new grant)!**
- **36 months – Partial phone/home visit**
  - Busy work schedule
  - Completed phone surveys and home visit in same day
    - Made patient aware of time-sensitivity of visit
- **48 months – Clinic Visit**
  - Visit facilitators (free parking, remuneration)
  - Emailed visit details since visit was soon
    - Obtained updated contact information

60 mo. In-person Visit Challenges

- **60 months – Clinic Visit**
  - Despite old and new challenges
    - Changed jobs
    - Mental health issues
    - Contact information changed
      - Phone number disconnected
      - Initially only able to speak with proxy; got new phone #
  - Called AM, scheduled and completed visit in PM
    - Staff flexibility to accommodate busy schedule
    - Use of visit facilitators (valet parking, remuneration)

Take Home Messages

- Embody the 3Ps essential to successful efforts
  - Pleasant
  - Patient
  - Persistent
- Be accommodating and flexible
- Build rapport with patients and proxies
- Ask study doctors to assist with challenging participants

R24 Aim 2 – Preparing to Create the Toolbox for Maximizing Cohort Retention

R24 Grant – Aim 2 (cohort retention)

1. Systematic review of retention methods

2. Semi-structured interviews of JHU researchers for unpublished retention methods

Systematic Review of Retention Strategies

- 21 studies of 3,068 citations eligible
  - Inclusion criteria: data on retention from a study, and information on strategies used for retention
- Analyzed **368** strategies & found 12 themes
- Studies analyzed reported a median of 17 strategies across median of 6 themes
- **Studies that utilized more strategies had retention rates greater than mean rate of 86%**

Robinson, Dennison, Wayman, et al. *J Clin Epidemiol* 2007; 60:757-765.

Updated Sys. Review of Retention Strategies

- identified 88 studies – 67 since our last review
  - 6/88 (7%) were designed to compare strategies
  - 82/88 (93%) were designed to describe strategies

Robinson, Dinglas, Sukrithan, et al. *J. Cli.n Epi.* 2015; 68:1481-7.

Updated Sys. Review of Retention Strategies

- Comparative studies
  ⬆ financial/cash incentives = ⬆ retention rates
- Descriptive studies
  ⬆ Number of strategies used = ⬆ retention rates
- Themes of “contact and scheduling” and “visit characteristics” represented largest & most frequently used
- Created searchable DB of all 618 strategies and 12 themes:
  – http://www.improvelto.com/sysrevstrategies/

Robinson, Dinglas, Sukrithan, et al. *J. Cli.n Epi.* 2015; 68:1481-7.

Searchable Database of Retention Strategies (systematic review)

Show 100 entries Search:

First Author	Publication Year	Theme	Strategies extracted from paper
Anastasi	2005	Reminders	The study coordinator gave each participant a reminder telephone call before each study visit.
Anastasi	2005	Contact and Scheduling Methods	The contact information for the study coordinator was also incorporated into the daily food diaries to provide an easy and accessible mechanism to reach the study team for questions or other issues.
Anastasi	2005	Contact and Scheduling Methods	Study participants were required to provide the study coordinator with instructions on leaving telephone messages at home, in the event a roommate, partner, or answering machine was available to take messagesThis procedure was instituted to protect the confidentiality of study participants' HIV status.

Semi-structured interviews - unpublished retention methods

- 19 studies from JHU:
  - ≥200 pts, ≥80% retention rates; ≥ 1 year follow-up
- Most common strategies involve:
  - Study reminders, study visit characteristics, emphasized study benefits, & contact/scheduling strategies
- Other key findings:
  - Well-functioning, organized, and persistent research teams
  - Strategies tailored to cohort and individual pts
  - Adapting & innovating strategies over time

BMC Medical Research Methodology. 2017; 17(1):30.

R24 Aim 2 – Cohort Retention Toolbox

“Menu” of tools – R24 Aim 2

http://www.improveLTO.com/cohort-retention-tools/

- Participant Contact Information Form
- Communication Templates and Manuals
- Retention Strategies from Systematic Review
- Locating Participants
- Follow-up Protocols
- Staff Training
- Other Tools
- Presentations

Detailed Contact Info Sheet Template

Participant contact information: ***(verify contact information with medical record or proxy)***

Name: _____ *Last Name,* _____ *First Name* _____ *Middle Name*

Alternative name (i.e. nicknames/alias): □1 None #1 _____ #2 _____

Date of Birth (mm/dd/yyyy): __ __ / __ __ / __ __ __ __ □1 N/A Social Security #: __ __ __ - __ __ - __ __ __ __ □1 N/A

Home Address: _____ *Street #* _____ *Street Name* _____ *Apartment #*

City, State and Zip: _____ *City,* _____ *State* _____ *Zip*

Home Phone: (___) ___ - ____ □1 Not Available Cell Phone: (___) ___ - ____ □1 Not Available

Alternate: (___) ___ - ____ □1 Not Available Alternate: (___) ___ - ____ □1 Not Available

Email Address: _____

Work Address: _____ *Street #* _____ *Street Name* _____ *Suite #*

City, State and Zip: _____ *City,* _____ *State* _____ *Zip*

Work Phone: (___) ___ - ____ □1 Not Available Alternate: (___) ___ - ____ □1 Not Available

Someone who lives with participant:

Name: _____ *Last Name,* _____ *First Name* _____ *Middle Name*

Home Phone: (___) ___ - ____ □1 Not Available Work Phone: (___) ___ - ____ □1 Not Available

Cell Phone: (___) ___ - ____ □1 Not Available Alternate Phone: (___) ___ - ____ □1 Not Available

Relationship to Patient (e.g., wife, father): _____

Someone with different address from participant: ***(obtain complete information for 2 people)***

Name: _____ *Last Name,* _____ *First Name* _____ *Middle Name*

Address: _____ *Street #* _____ *Street Name* _____ *Apartment #*

City, State and Zip: _____ *City,* _____ *State* _____ *Zip*

Communication Template

Home Visit Scheduling Script:

> ***"I understand that it would be very difficult for you to get to the research clinic/hospital. We would be willing to visit you at home for your follow up visit."***

Note: Identify a mutually agreeable time [verify the availability for the person doing the home visit -- consider driving time to and from appointment as well].

> ***"We could visit you at your home on [Day/Time options] ; would any of these times work for you?"***

If caller is unsure of availability for home visit:

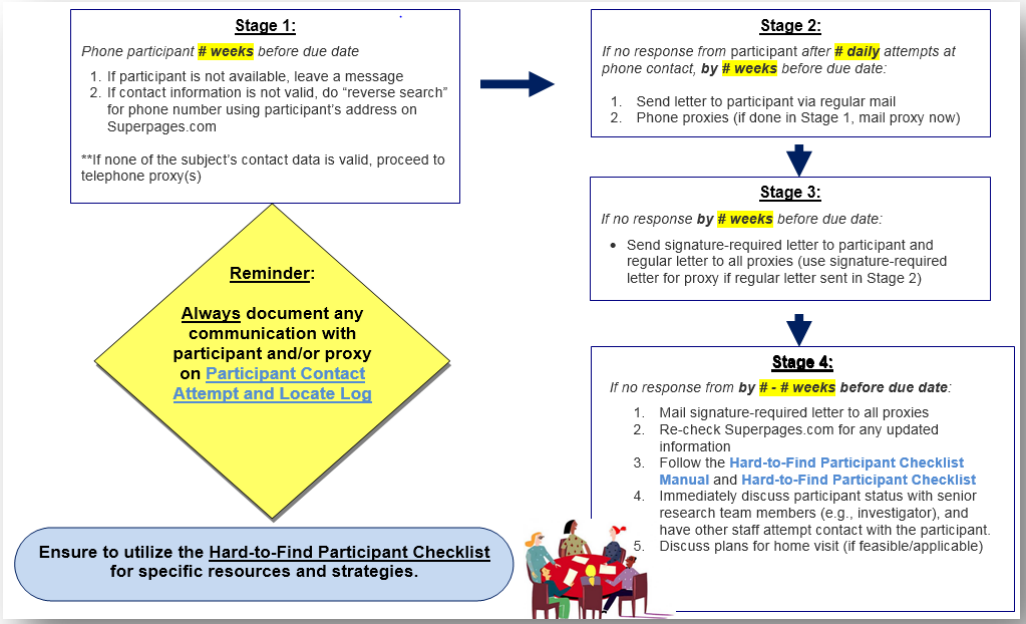
> ***"I will need to contact [Follow-up Supervisor's First and Last Name] , the follow-up supervisor, to find out when he/she is available to visit you at home. Can I call you back either later today or tomorrow to verify a time that will work for you?"***

Note: If the participant has indicated that a home visit is not possible due to work schedule or any other limitation, use the following script:

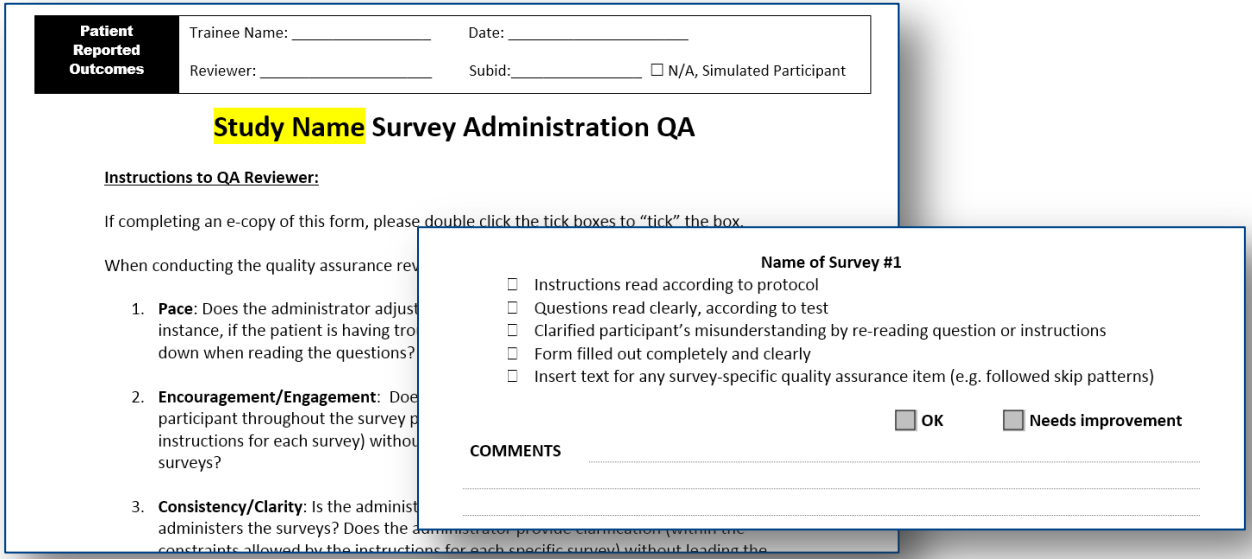
Hard-to-Find Participant Checklist

	Step 1 – Calling phone numbers *(Disconnected and other non-working phone numbers should be called frequently to check if the numbers are working again).* **If neither participant nor proxies have returned our phone calls within 3 days OR there are NO working phone numbers, immediately do the following:** • **send a "Hard to find" letter to the participant (see "Step 3 – Sending mail" further below), then** • **complete "Step 2 – Online searching," and** • **if appropriate, investigate if there have been any recent hospitalizations and/or new contact info (e.g., review your medical records system).**	
	Did you call all available phone numbers for the participant? ***Note: If you need to call from a different number, use Google© voice.***	☐ Done. Additional notes:
	Did you call all available phone numbers for the proxies?	☐ Done. Additional notes:
	Step 2 - Online searching *(Online searches should be repeated every 1-2 weeks, to check for updates).*	
	Did you "reverse search" the participant using name, phone number and address (e.g., using Superpages.com)?	☐ Done. Additional notes:
	Did you "reverse search" all proxies using name, phone number and address (e.g., using Superpages.com)?	☐ Done. Additional notes:
	Step 3 – Sending mail **If you have performed all of the above steps and have not made contact with a subject within 2 weeks of the *initial* call:** • **Send a "Hard to Find" (HTF) letter (see example at www.ImproveLTO.com)** • **If no response to above, send "Signature Required Letter" (SRL) via USPS 1 week later** • **Discuss with study supervisor or investigator regarding whether to send a "Hard to Find" (HTF) letter to any searched address.**	
	Did you send a Hard To Find letter to the participant?	☐ Done. Additional notes:
	Did you send a Hard To Find letter to each proxy?	☐ Done. Additional notes:

Protocol for Implementing Retention Strategies



Training & QA



Patient Reported Outcomes

Trainee Name: _____ Date: _____

Reviewer: _____ Subid:_____ ☐ N/A, Simulated Participant

Study Name Survey Administration QA

Instructions to QA Reviewer:

If completing an e-copy of this form, please double click the tick boxes to "tick" the box.

When conducting the quality assurance rev

1. **Pace**: Does the administrator adjust
   instance, if the patient is having tro
   down when reading the questions?
2. **Encouragement/Engagement**: Doe
   participant throughout the survey p
   instructions for each survey) withou
   surveys?
3. **Consistency/Clarity**: Is the administ
   administers the surveys? Does the a
   constraints allowed by the instructions for each specific survey) without leading the

Name of Survey #1

- ☐ Instructions read according to protocol
- ☐ Questions read clearly, according to test
- ☐ Clarified participant's misunderstanding by re-reading question or instructions
- ☐ Form filled out completely and clearly
- ☐ Insert text for any survey-specific quality assurance item (e.g. followed skip patterns)

☐ OK ☐ Needs improvement

COMMENTS _____

“Menu” of tools – R24 Aim 2

http://www.improveLTO.com/cohort-retention-tools/

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Communication Templates and Manuals

Phone Communication:

- **Phone Communication Procedures Manual** – Provides guidelines for different scenarios requiring phone calls with the participant or proxy
- **Telephone Scripts: Challenging Participants** – This script is intended to help research staff facilitate communication with participants who are more challenging than the typical participant, for a variety of reasons: health, family-life, lack-of-interest
- **Telephone Scripts: Phone Follow-up** – This script is intended to help research staff facilitate communication for scheduling and completing follow-up via phone
- **Telephone Scripts: Scheduling In-person or Home Visit** – This script is intended to help research staff facilitate communication for scheduling and completing in-person (e.g., research clinic) or home visits

Written Communication:

- **Written Communication Procedures Manual** – Provides guidelines for different scenarios requiring mail correspondence with the participant or proxy
- **Templates of Letters** – Provides example letters and postcards to mail to participants for varying scenarios, for example a "thank You" letter after completing an assessment or a "Hard-to-find" letter for unreachable participants
- **Newsletter Templates** (example) – Modifiable templates to inform participants of updated study information (e.g., new study staff, recent study publication, discussion about disease/ailment, research visit specifics, etc.)
  - Summer Newsletter – Featuring Study Publications Template
  - Winter Newsletter – Featuring Generic Topic Template
  - Instructions

MORE on this page

>30 tools available now

Staff Training

Quality Assurance:

- **Survey Administration QA** –This customizable Quality Assurance (QA) template allows the trainer/reviewer to thoroughly assess and comment on the trainee's abilities to administer surveys while adhering to study protocol.

Other Tools

Research Group Meeting:

- **Progress Report for Participant** – This modifiable report template summarizes the status of participants' scheduling and completion of follow-up visits, including notes on methods of communication to/from subject and/or proxies. This report is designed to be discussed during regular (e.g., weekly) meetings with the study leaders and team, with the purpose of devising an action plan for each participant.

Locating Participants

- **Participant Contact Attempt and Locate Log** – This document aids research staff in recording standardized information for each contact attempt (e.g., phone call, online search, mailed letter, etc.)
- **Hard-to-Find Participant Checklist and Manual** – A checklist of various strategies for contacting difficult-to-reach research participants.

Follow-up Protocols

- **Cohort Retention Protocol** – Outlines the participant follow-up process from initial recruitment into the study to maintaining contact with the research participant throughout the duration of the study.
- **Follow-up Assessment Timeline and Escalation of Retention Strategies Flow Diagram Template and Manual** – Provides a suggested protocol for escalating participant contact attempts and utilizing participant retention strategies. These issues are important in maximizing completion of timely assessments.
- **Home Visit Protocol** – Provides guidelines and safety tips for instances when it is necessary to visit patient's homes (e.g., scheduled home visit or when telephone and written correspondence produce no results).
- **Overcoming Follow-up Delay and Cancellation** – Provides methods for reducing delayed and missed follow-up assessments, for example communication tips for rescheduling the assessment and maintaining the participant's participation in the study.
- **Tools for Facilitating In-Person Assessment** – Provides suggested tools to help incentivize or facilitate an in-person follow-up assessment visit with a study participant.
- **Tools for Facilitating Phone Assessment** – Provides suggested tools to help incentivize or facilitate a phone-based follow-up assessment with a study participant.

Project website

www.ImproveLTO.com

Contact us: improveLTO@jhmi.edu

Follow us on Twitter: @improvelto