

# Treatment Dosage in Aphasia Rehabilitation: From Research Efficacy to Real-World Evidence

Robert Cavanaugh PhD, CCC-SLP, Brianne Olivieri-Mui PhD, Louisa Smith PhD

Roux Institute, Northeastern University, Portland, ME  
Bouvé College of Health Sciences, Northeastern University, Boston, MA



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**Observational Health Data  
Sciences and Informatics Center**



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2023 American Speech-Language Hearing Association Convention, Boston, MA



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## Rob Cavanaugh

- Employed by Northeastern University
- No relevant non-financial relationships

## Brianne Olivieri-Mui

- Employed by Northeastern University
- No relevant non-financial relationships

## Louisa Smith

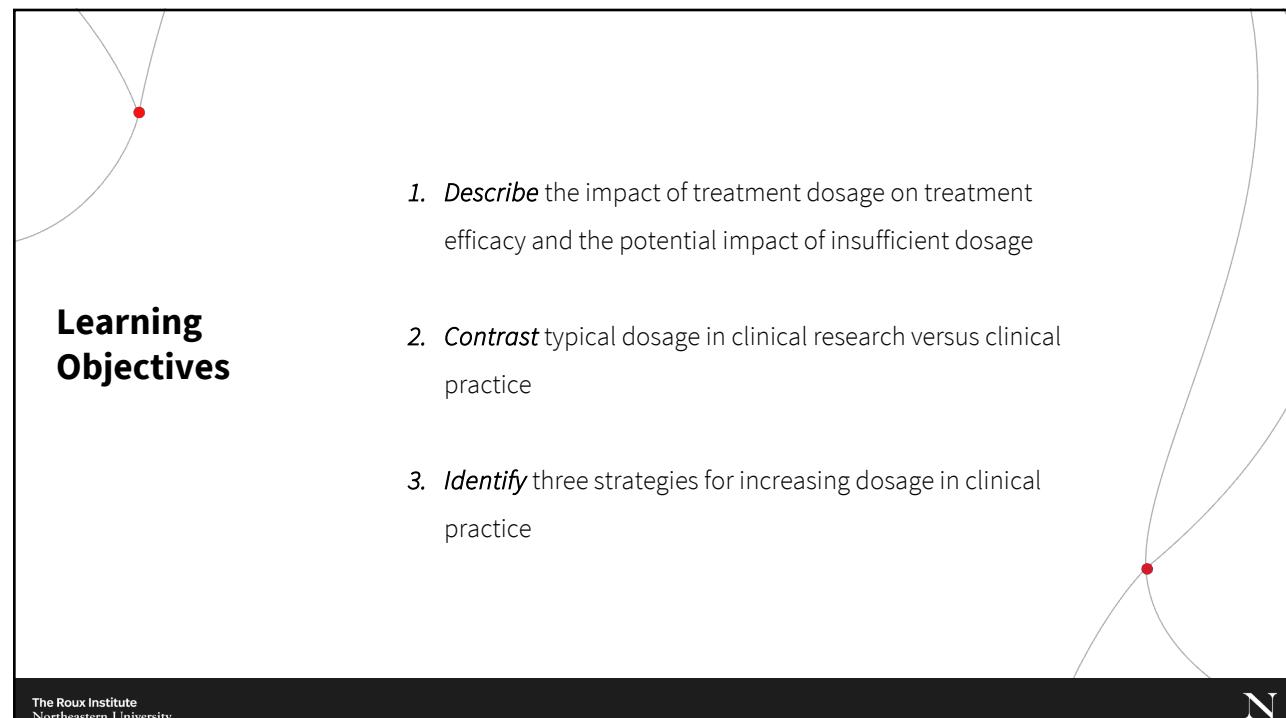
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## Disclosures

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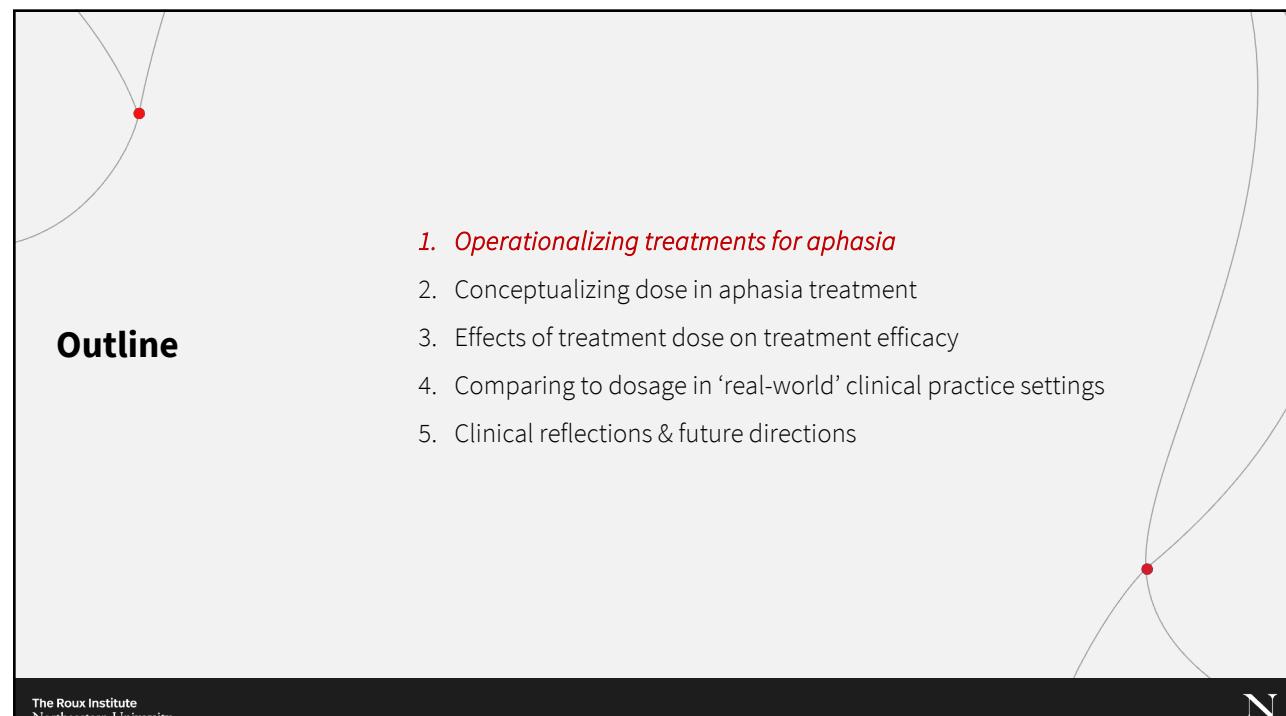


**Learning Objectives**

1. *Describe* the impact of treatment dosage on treatment efficacy and the potential impact of insufficient dosage
2. *Contrast* typical dosage in clinical research versus clinical practice
3. *Identify* three strategies for increasing dosage in clinical practice

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**Outline**

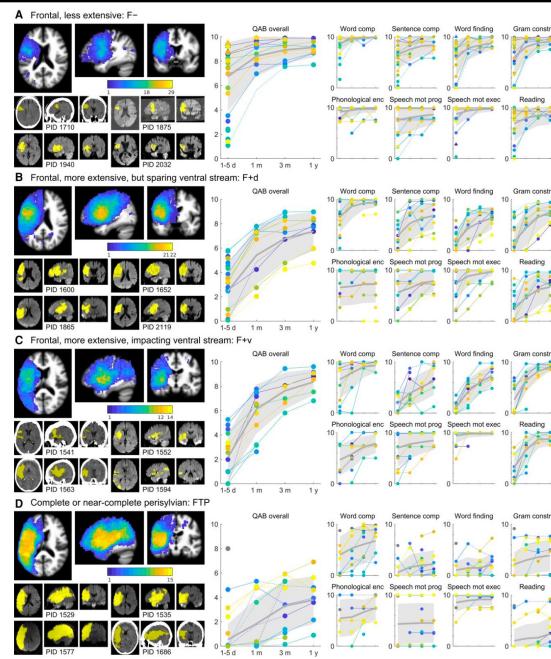
1. *Operationalizing treatments for aphasia*
2. Conceptualizing dose in aphasia treatment
3. Effects of treatment dose on treatment efficacy
4. Comparing to dosage in ‘real-world’ clinical practice settings
5. Clinical reflections & future directions

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## Aphasia

- Language disorder caused by brain that affects any area of language (e.g., talking, understanding others, reading, writing)
- Affects 1/3 of stroke survivors, with more than 180,000 new cases annually (Pedersen et al., 2004)
- Profound impact on health-related quality of life, including greater rates of social isolation and depression compared to stroke survivors without aphasia

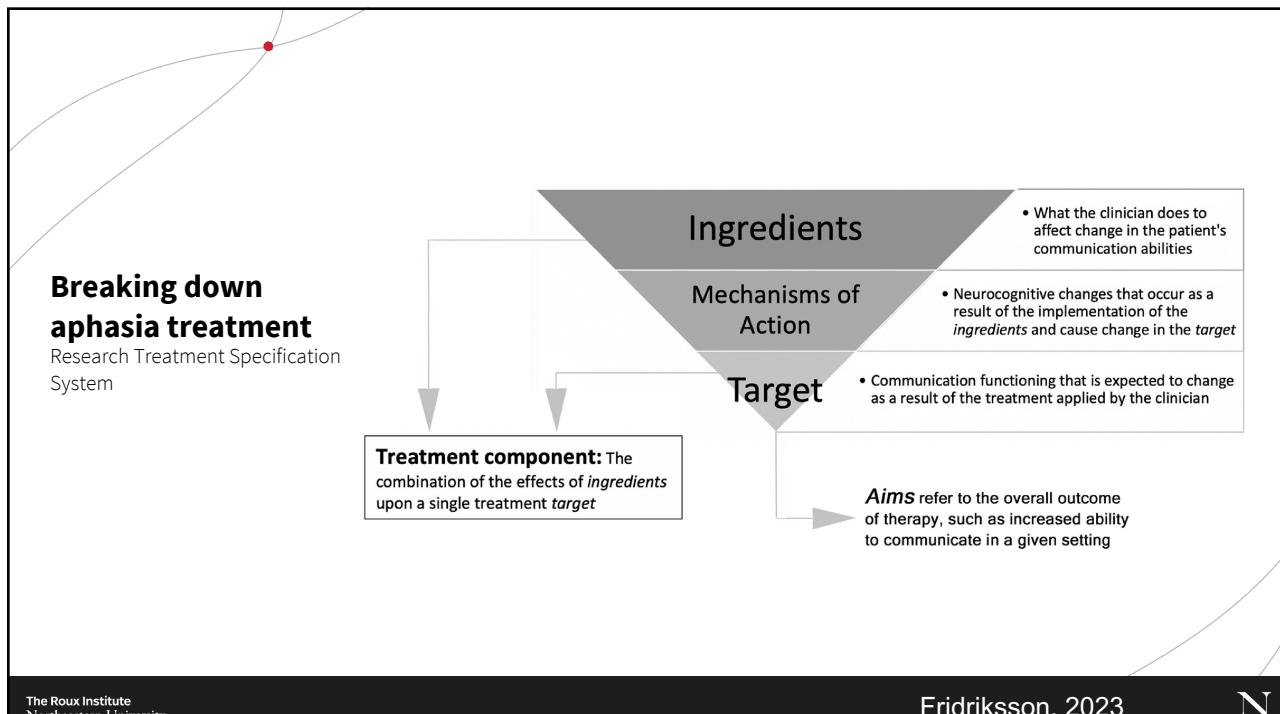


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Recovery from aphasia in the first year after stroke. Reprinted from Wilson et al., (2023)

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Fridriksson, 2023

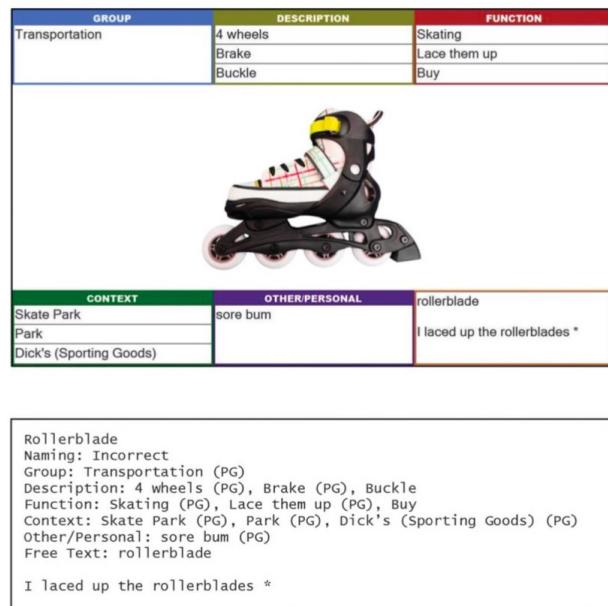
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## Example:

### Semantic Feature Analysis Treatment (SFA)

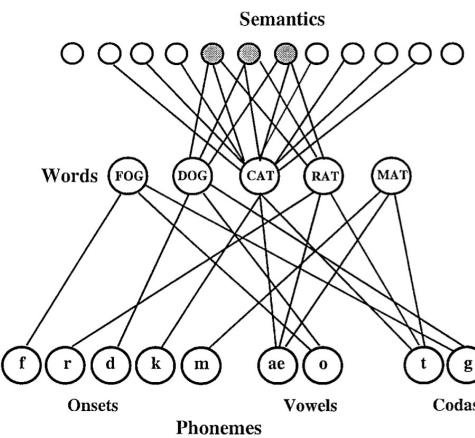
- Interleaved, effortful retrieval of target words and semantic features across several semantic categories (ingredients)
  1. Name the item
  2. Generate semantic features
  3. Name the item again
  4. Repeat with a new item
- Steps 1-3 = 1 “treatment trial”



## Example #1

### SFA Restorative Mechanism

- Elicitation and production of semantic features spreads activation of the features within the semantic network to their associated concepts and ultimately to associated lexical items.
- Repeated production of target words and semantic features strengthens the connections between conceptual and lexical representations (figure)
- Alternatively, repeated feature generation and naming of target items may improve the resting activation for both the target item and other items within a semantic category.



**Operationalizing aphasia treatment**  
Research Treatment Specification System

- **Ingredients:** Semantic feature generation, naming practice, feedback, cueing hierarchy
- **Mechanism:** Spreading activation
- **Target:** Naming ability
- **Aim:** Improved word finding in conversation

**Ingredients**

- What the clinician does to affect change in the patient's communication abilities

**Mechanisms of Action**

- Neurocognitive changes that occur as a result of the implementation of the ingredients and cause change in the target

**Target**

- Communication functioning that is expected to change as a result of the treatment applied by the clinician

**Aims** refer to the overall outcome of therapy, such as increased ability to communicate in a given setting

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### Example #2

SFA Compensatory Mechanism

- SFA “promotes habituation of semantic self-cueing and semantically appropriate circumlocution, strategies that facilitate communication even if specific lexical retrieval fails” Antonucci (2009)
- Retrieval of semantically related content may also help individuals with aphasia navigate to their intended lexical item (i.e., self-cueing)

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@nathanwpyle Strange Planet

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**Operationalizing aphasia treatment**  
Research Treatment Specification System

- **Ingredients:** Semantic feature generation, naming practice, feedback, cueing hierarchy
- **Mechanism:** Habituation of circumlocution or self-cueing facilitates word finding during anomia
- **Target:** Naming ability
- **Aim:** Improved word finding in conversation

**Ingredients**

- What the clinician does to affect change in the patient's communication abilities

**Mechanisms of Action**

- Neurocognitive changes that occur as a result of the implementation of the ingredients and cause change in the target

**Target**

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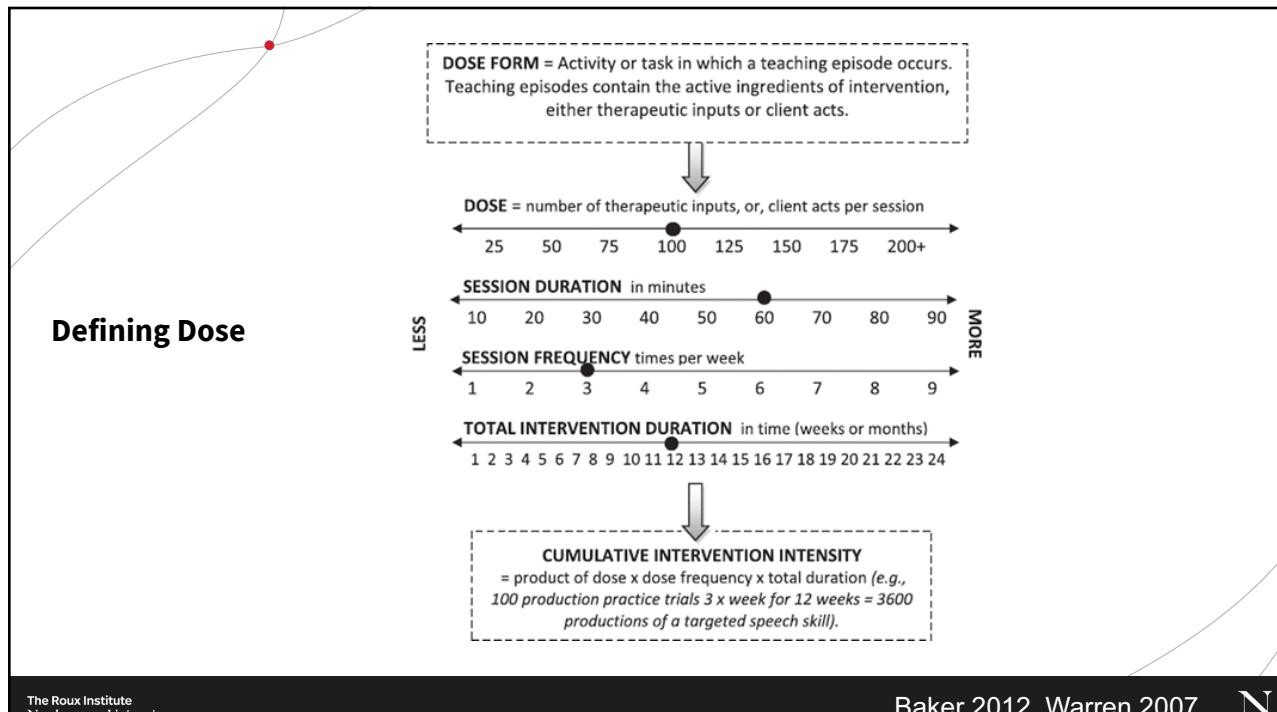
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**Outline**

1. Operationalizing treatments for aphasia
2. *Conceptualizing dose in aphasia treatment*
3. Effects of treatment dose on treatment efficacy
4. Comparing to dosage in 'real-world' clinical practice settings
5. Clinical reflections & future directions

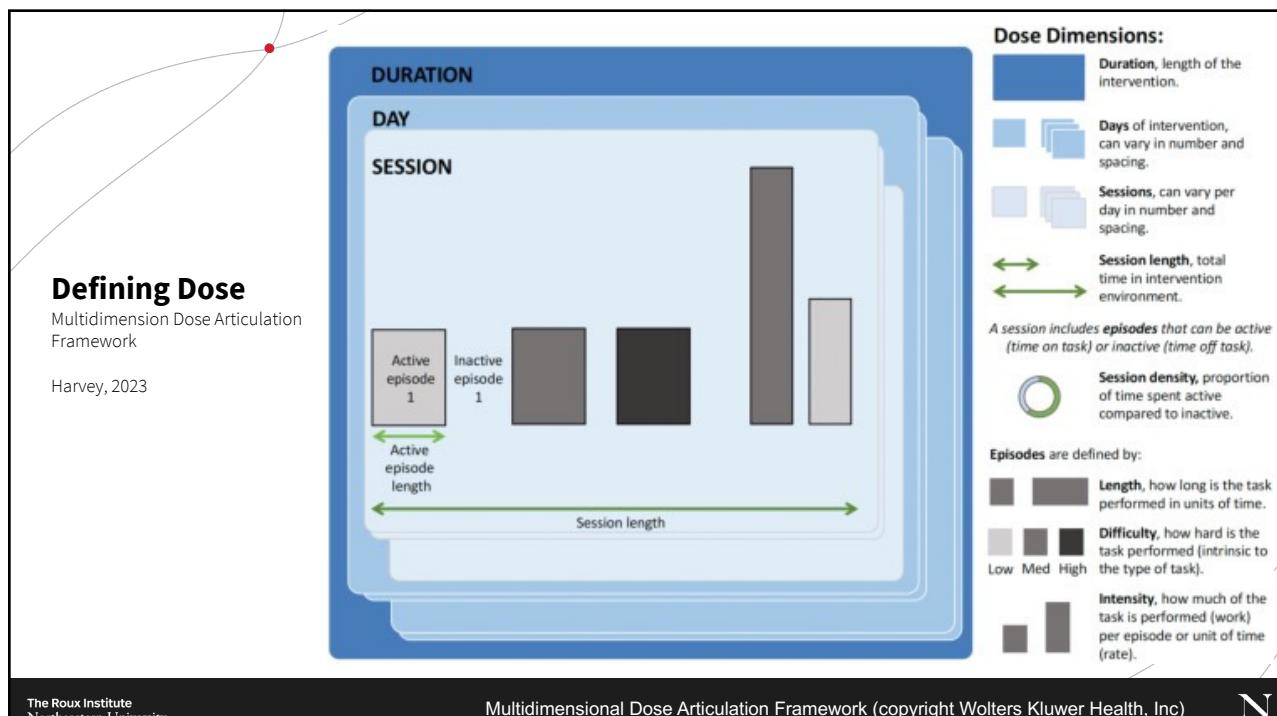
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Baker 2012, Warren 2007 N

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**Key dosage variables**

- Therapeutic Element**
  - The basic unit of therapy; either a therapeutic input or a client act
- Session Dose**
  - The amount of therapeutic content provided in a session, in minutes or therapeutic elements.
- Session Frequency**
  - E.g., The number of therapy sessions per week..
- Session Duration**
  - How long the treatment lasts (e.g., 10 weeks)
- Total Dose**
  - Amount of therapy provided or received over an intervention period, in time or therapeutic inputs, e.g., total hours, total number of therapeutic elements

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**Operationalizing aphasia treatment**  
Research Treatment Specification System

- Therapeutic Elements**
  - Semantic feature generation, naming practice, feedback, cueing hierarchy

|                             |   |
|-----------------------------|---|
| <b>Ingredients</b>          | • What the clinician does to affect change in the patient's communication abilities                                     |
| <b>Mechanisms of Action</b> | • Neurocognitive changes that occur as a result of the implementation of the ingredients and cause change in the target |
| <b>Target</b>               | • Communication functioning that is expected to change as a result of the treatment applied by the clinician            |

**Aims** refer to the overall outcome of therapy, such as increased ability to communicate in a given setting

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**Operationalizing aphasia treatment**  
Research Treatment Specification System

**Ingredients**

- Therapeutic Elements
- Semantic feature generation, naming practice, feedback, cueing hierarchy

**Mechanisms of Action**

- Session dose: Number of SFA treatment trials in a single session (e.g., 15 trials/session)
- Session intensity: Rate at which treatment trials are given (E.g., 20 trials/hour over the course of treatment)
- Session frequency: The number of therapy sessions per week.
- Total dose:  $15 \text{ trials/session} * 2 \text{ sessions/week} * 5 \text{ weeks} = 150 \text{ trials}$

**Target**

- What the clinician does to affect change in the patient's communication abilities
- Neurocognitive changes that occur as a result of the implementation of the ingredients and cause change in the target
- Communication functioning that is expected to change as a result of the treatment applied by the clinician

**Aims** refer to the overall outcome of therapy, such as increased ability to communicate in a given setting

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## Reporting dose in the research literature

(Harvey 2020)

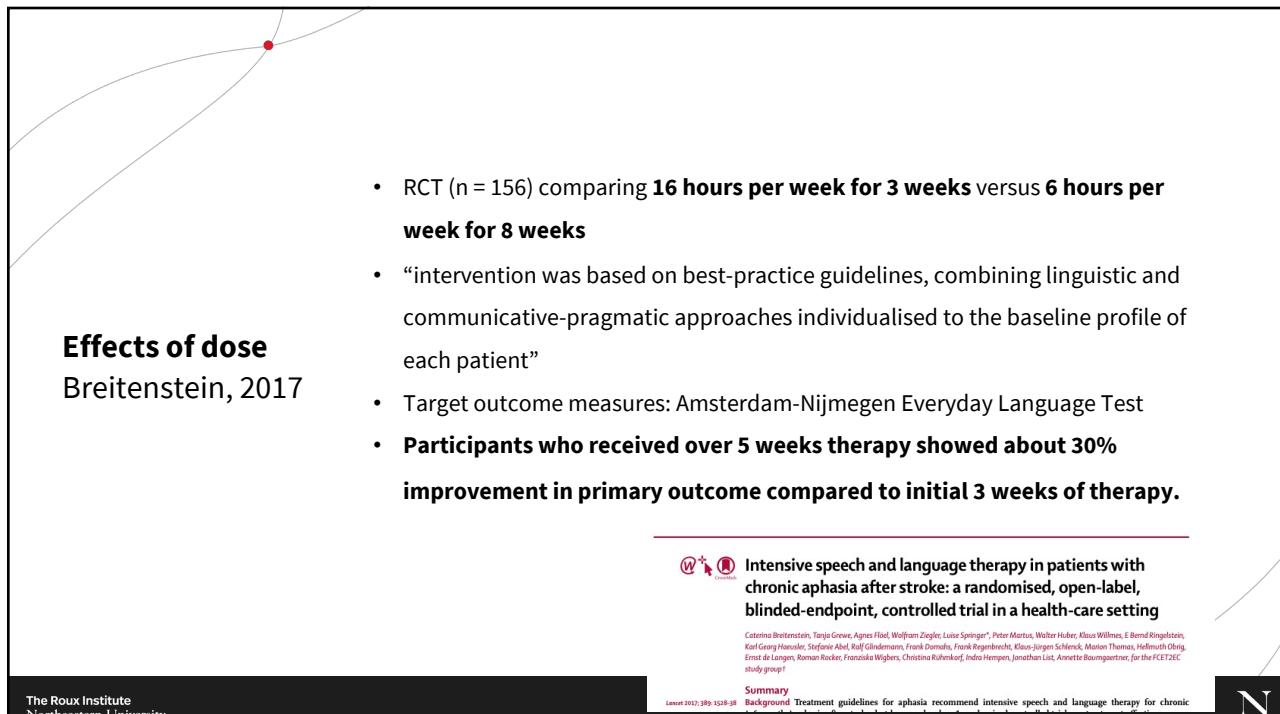
- Most treatment studies report dosage in terms of therapy minutes / hours  
~25% report dosage in terms of therapeutic elements delivered
- Many studies report the prescribed schedule but not the amount of treatment participants actually receive
- Home practice time rarely included or tracked

Most discussions of dose in aphasia treatment focus on **the distribution of in-person treatment time as a proxy for the total treatment dose**

## Effects of dose

Bhogal, 2003

- Meta-analysis of 10 controlled trials that investigated SLT for aphasia after stroke published between 1/1975 and 5/2002 (**864 total participants**)
- Target outcome measures were the Token Test, PICA, and FCP
- “**Studies that demonstrated a significant treatment effect provided 8.8 hours of therapy per week for 11.2 weeks versus the negative studies that only provided ≈2 hours per week for 22.9 weeks**”
- Shorter, more intense treatments were correlated with greater improvements
- More treatment hours correlated with greater improvements



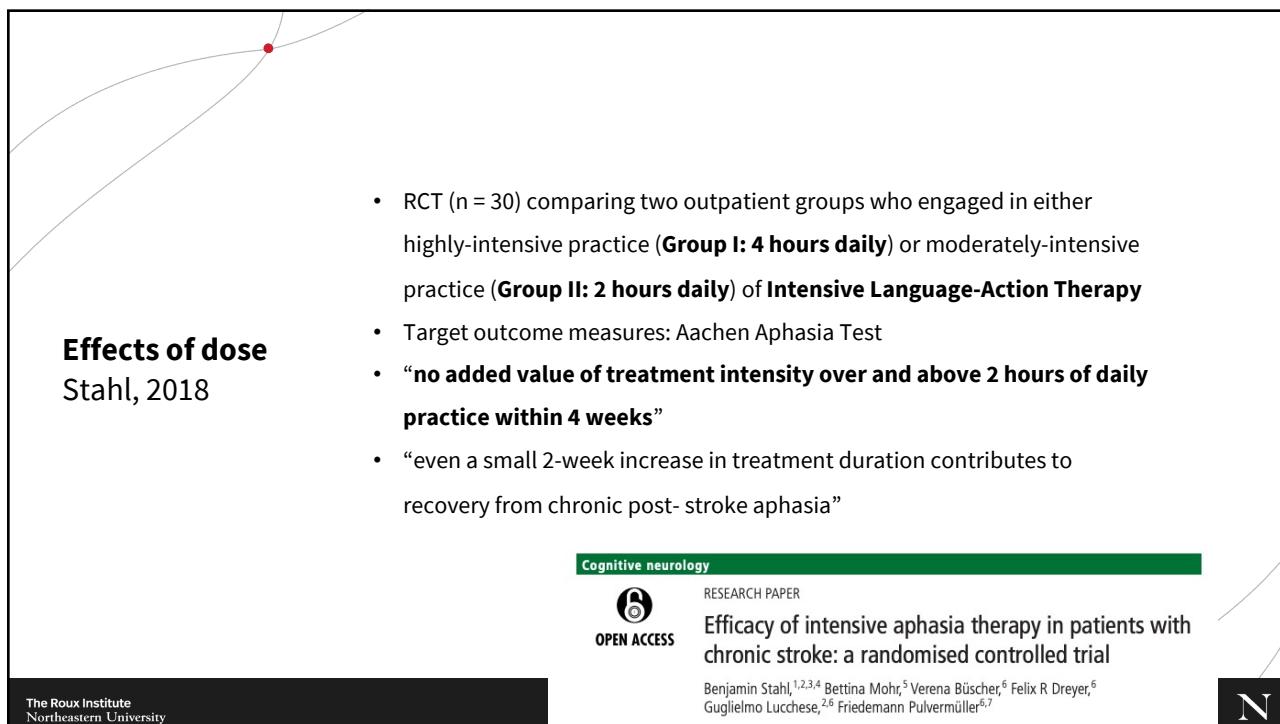
**Effects of dose**  
Breitenstein, 2017

- RCT (n = 156) comparing **16 hours per week for 3 weeks** versus **6 hours per week for 8 weeks**
- “intervention was based on best-practice guidelines, combining linguistic and communicative-pragmatic approaches individualised to the baseline profile of each patient”
- Target outcome measures: Amsterdam-Nijmegen Everyday Language Test
- **Participants who received over 5 weeks therapy showed about 30% improvement in primary outcome compared to initial 3 weeks of therapy.**

 Intensive speech and language therapy in patients with chronic aphasia after stroke: a randomised, open-label, blinded-endpoint, controlled trial in a health-care setting  
Caterina Breitenstein, Tanja Greve, Anne Flöel, Wolfgang Ziegler, Lothar Springer\*, Peter Martus, Walter Huber, Klaus Willmes, E Bernd Boenigk, Karl Georg Haeseler, Stefanie Abel, Rolf Glindemann, Frank Daniels, Frank Regenbrecht, Klaus-Jürgen Schenck, Marion Thoms, Ingrid Münch-Döhr, Erich da Cunha, Konstanze Kucke, Ursula Wiegert, Christiane Küller, Jutta Hempel, Jonathan Liss, Annette Baumgärtner, for the FCE72C study group\*  
Summary | Background | Treatment guidelines for aphasia recommend intensive speech and language therapy for chronic aphasia. This study investigated whether more intensive therapy is better than less intensive therapy.  
Lancet 2017; 389: 1518–26

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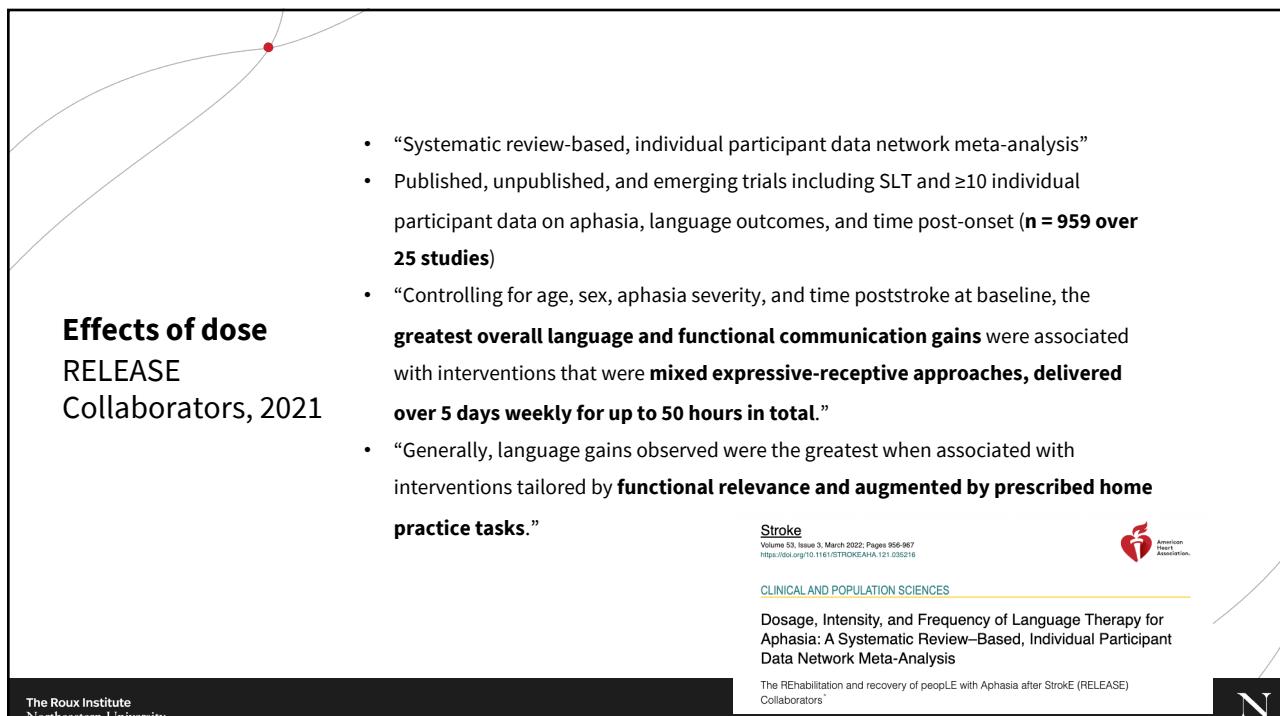
**Effects of dose**  
Stahl, 2018

- RCT (n = 30) comparing two outpatient groups who engaged in either highly-intensive practice (**Group I: 4 hours daily**) or moderately-intensive practice (**Group II: 2 hours daily**) of **Intensive Language-Action Therapy**
- Target outcome measures: Aachen Aphasia Test
- **“no added value of treatment intensity over and above 2 hours of daily practice within 4 weeks”**
- “even a small 2-week increase in treatment duration contributes to recovery from chronic post- stroke aphasia”

Cognitive neurology  
RESEARCH PAPER  
 OPEN ACCESS  
Efficacy of intensive aphasia therapy in patients with chronic stroke: a randomised controlled trial  
Benjamin Stahl,<sup>1,2,3,4</sup> Bettina Mohr,<sup>5</sup> Verena Büscher,<sup>6</sup> Felix R Dreyer,<sup>6</sup> Guglielmo Lucchese,<sup>2,6</sup> Friedemann Pulvermüller<sup>6</sup>

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**Effects of dose**  
RELEASE  
Collaborators, 2021

- “Systematic review-based, individual participant data network meta-analysis”
- Published, unpublished, and emerging trials including SLT and  $\geq 10$  individual participant data on aphasia, language outcomes, and time post-onset (**n = 959 over 25 studies**)
- “Controlling for age, sex, aphasia severity, and time poststroke at baseline, the greatest overall language and functional communication gains were associated with interventions that were **mixed expressive-receptive approaches, delivered over 5 days weekly for up to 50 hours in total.**”
- “Generally, language gains observed were the greatest when associated with interventions tailored by **functional relevance and augmented by prescribed home practice tasks.**”

**Stroke**  
Volume 53, Issue 3, March 2022; Pages 956-967  
<https://doi.org/10.1161/STROKEAHA.121.035216>

 American Heart Association

CLINICAL AND POPULATION SCIENCES

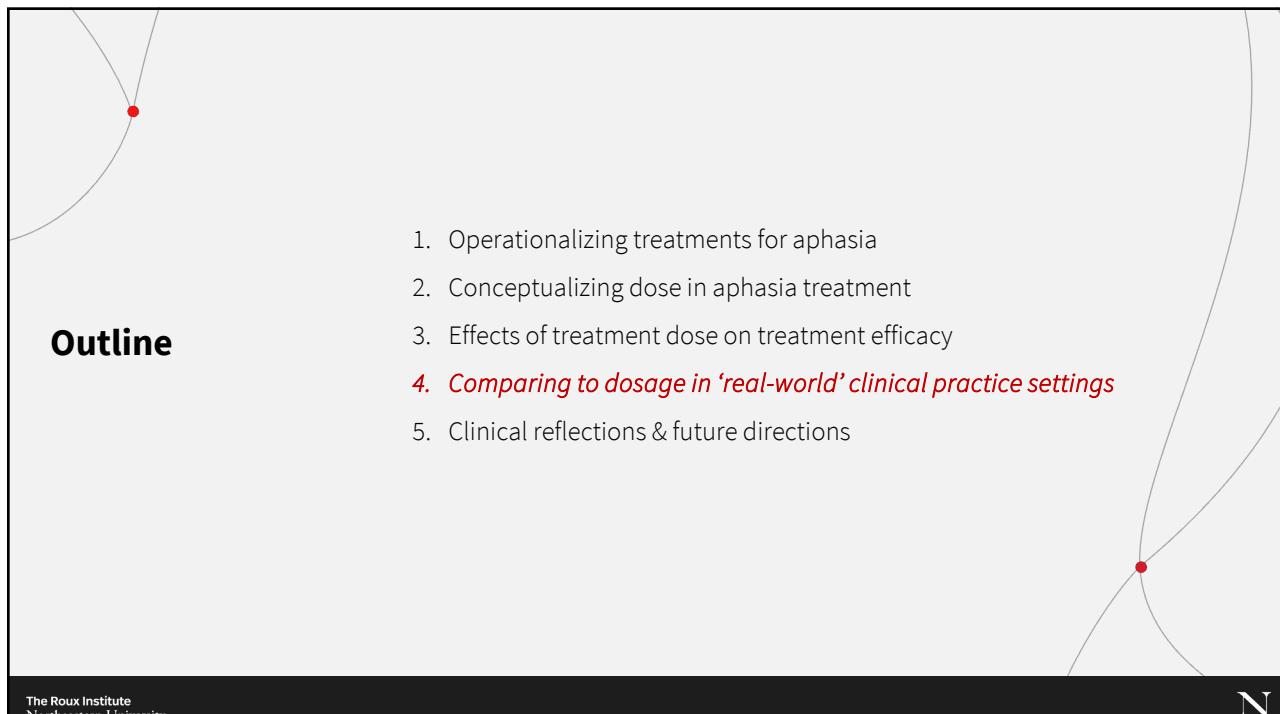
Dosage, Intensity, and Frequency of Language Therapy for Aphasia: A Systematic Review-Based, Individual Participant Data Network Meta-Analysis

The REhabilitation and recovery of peopLE with Aphasia after Stroke (RELEASE) Collaborators\*

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## Is there a research practice dosage gap in aphasia rehabilitation?

**Q:** What can happen when real-world clinical practice differs from the research evidence base?

**A: Voltage Drop**

Reduced treatment fidelity in clinical settings → Poorer treatment effectiveness/outcomes in clinical practice

AJSLP

Research Article

### Is There a Research–Practice Dosage Gap in Aphasia Rehabilitation?

Robert Cavanaugh,<sup>a</sup> Christina Kravetz,<sup>b</sup> Lillian Jarold,<sup>a,c</sup> Yina Quique,<sup>a</sup> Rose Turner,<sup>a</sup> and William S. Evans<sup>a</sup>



National Center for Advancing Translational Sciences of the National Institutes of Health Award TL1TR001858.

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## Research Practice dosage Gap

Cavanaugh, 2021



What is the typical treatment dose administered to people with aphasia in **contemporary clinical aphasia studies**?



What is the typical treatment dose received by people with post-stroke aphasia in an episode of care in **outpatient rehabilitation** clinical settings?



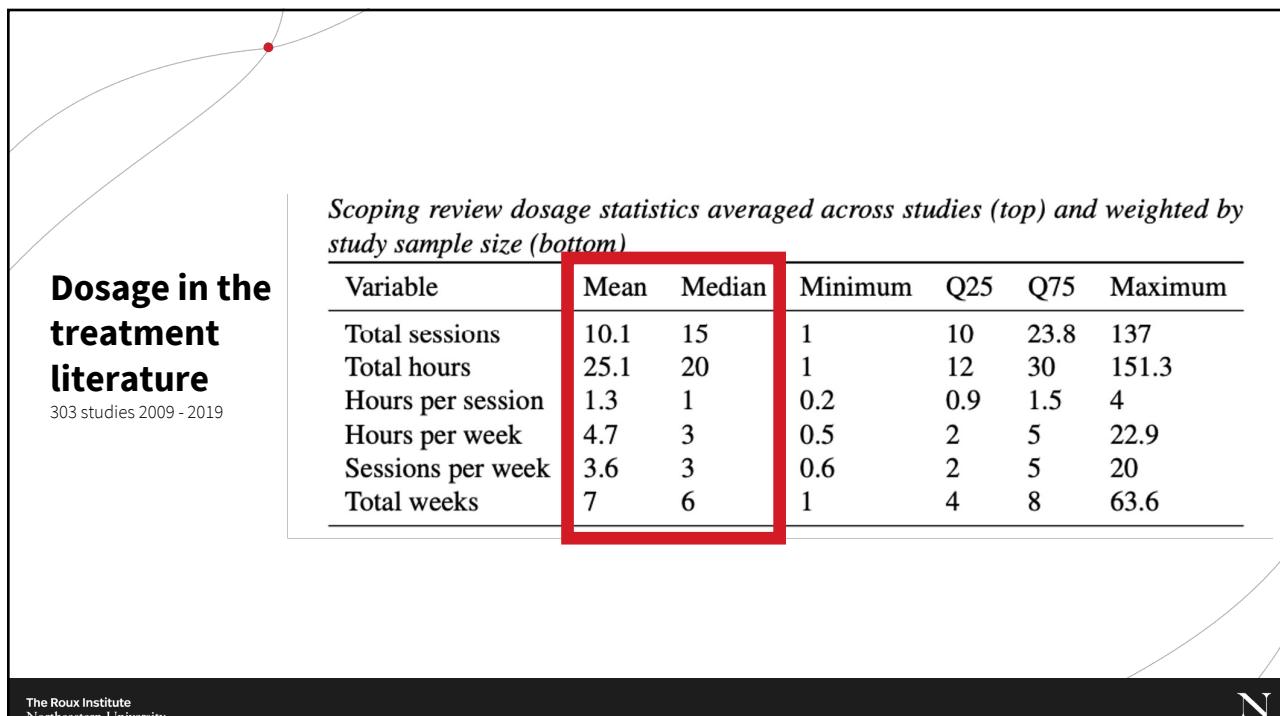
To what extent is the dosage in contemporary aphasia treatment research **aligned** with current outpatient clinical practice settings?

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Is there a research practice dosage gap in aphasia rehabilitation? AJSLP Cavanaugh, 2021

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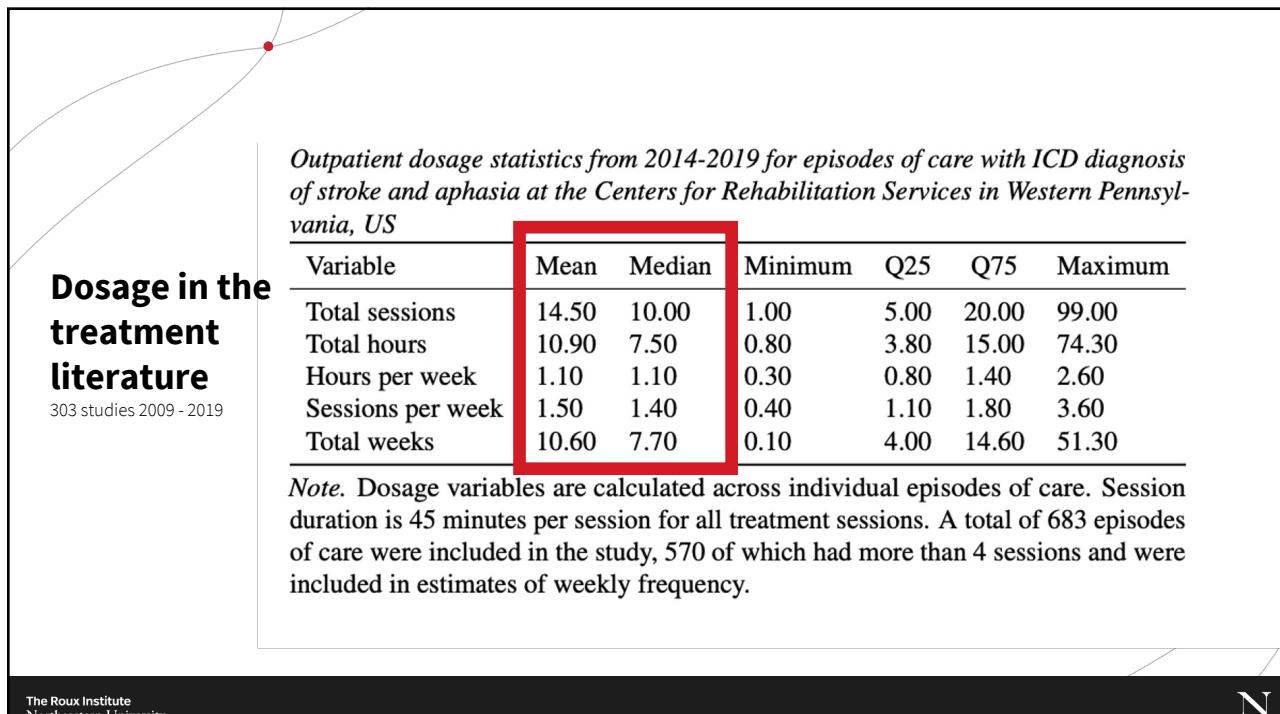
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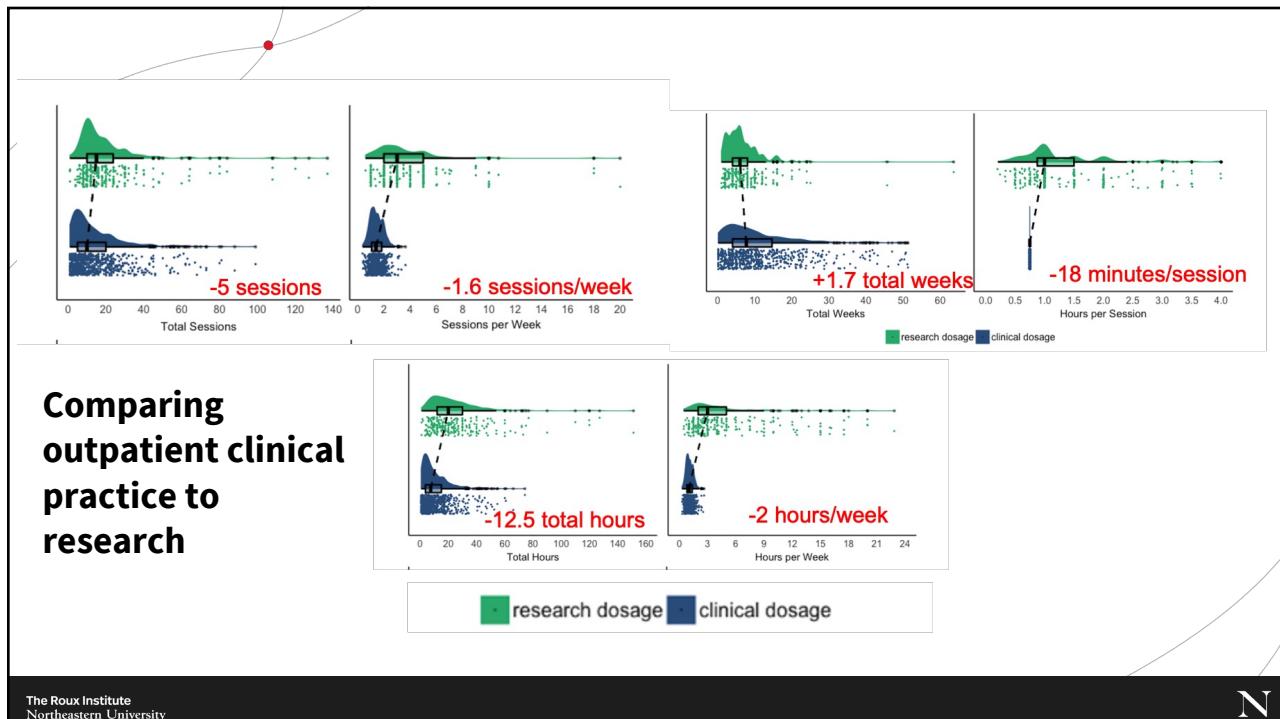
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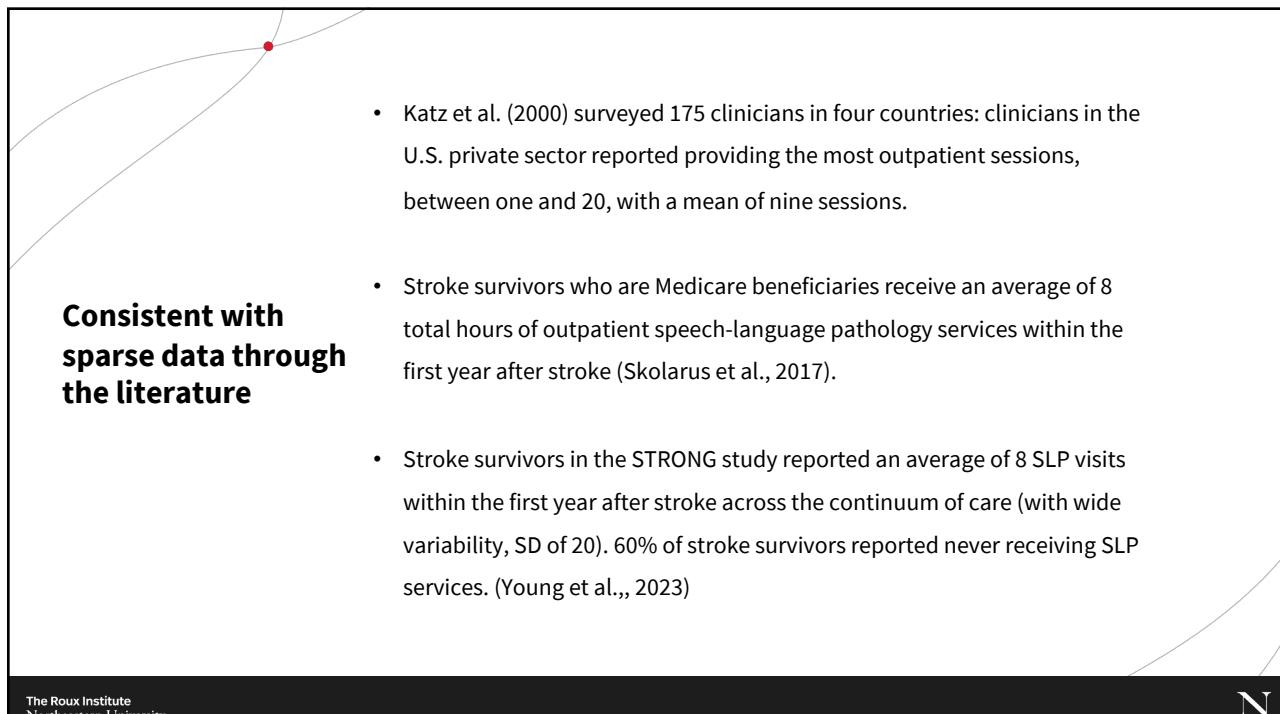
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## Dose in aphasia clinical settings

2023 update

- The **Observational Health Data Sciences and Informatics (OHDSI)** program is an international, multi-stakeholder, interdisciplinary collaborative to bring out the value of health data through large-scale analytics.
- Northeastern University's OHDSI Center maintains a network of standardized clinical data covering nearly 10% of the world's population. We support research collaborations among academia, industries, and governments across disciplines and around the globe.
- OHDSI real-world evidence generation uses the **Observational Medical Outcomes Partnership (OMOP) Common Data Model** (Sherman, 2016)



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## Dose in aphasia clinical settings

2023 update

The PharMetrics Plus database for Academics (IQVIA) is a private, commercial adjudicated claims database with health information for 34 million enrollees

The data include enrollee age, prescription drug information (drug name, dose, day supply), and physician diagnosis according to ICD10, standardized to the OMOP CDM.

Northeastern has licensed access to this database from January 1, 2017, to December 31, 2021, that included >16 million enrollees with at least 1 year of enrollment.

Fact Sheet



### IQVIA PharMetrics® Plus for Academics Enhanced with Mortality Data

*Real-world data on commercially insured patients enhanced with the most complete source of mortality data on the market*

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## Dose in aphasia clinical settings

2023 update

### Defining a post-stroke aphasia cohort

- >18 years of age or older
- >= 1 diagnosis of stroke during an inpatient visit
- >= 2 diagnosis codes of aphasia
- >= 6 months of observation prior to index date (first CVA code) without any stroke codes
- >= 1 year of continuous observation following CVA



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**OHDSI**  
OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS

Fact Sheet



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## Dose in aphasia clinical settings

2023 update

### Cohort statistics

- 6,560 patients/enrollees
- ~ 30% of patients had an OP SLP eval + tx
- 49% female
- mean age: 70.8 years (median: 74; middle 50%: 66-80)

### Provider plans:

- 45% Medicare Supplement (i.e., Medicare FFS + medigap)
- 28% Medicare Advantage
- 27% Commercial
- 1% managed Medicaid



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**OHDSI**  
OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS

Fact Sheet



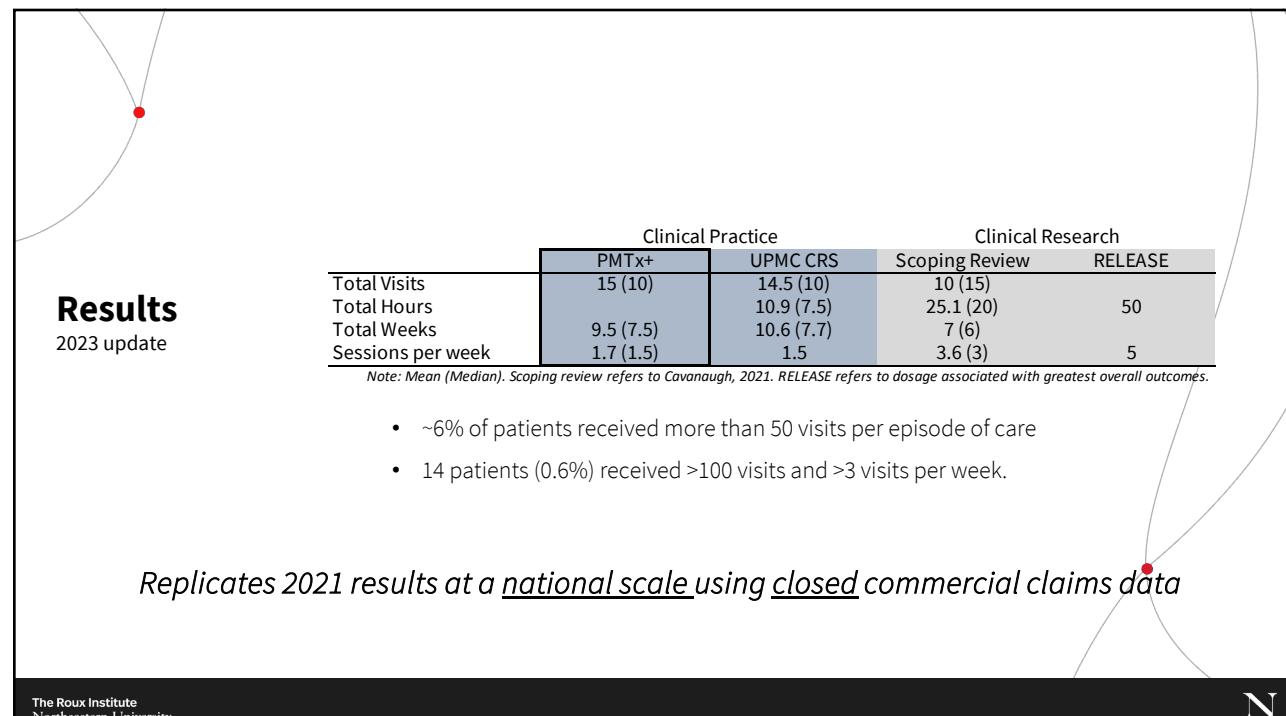
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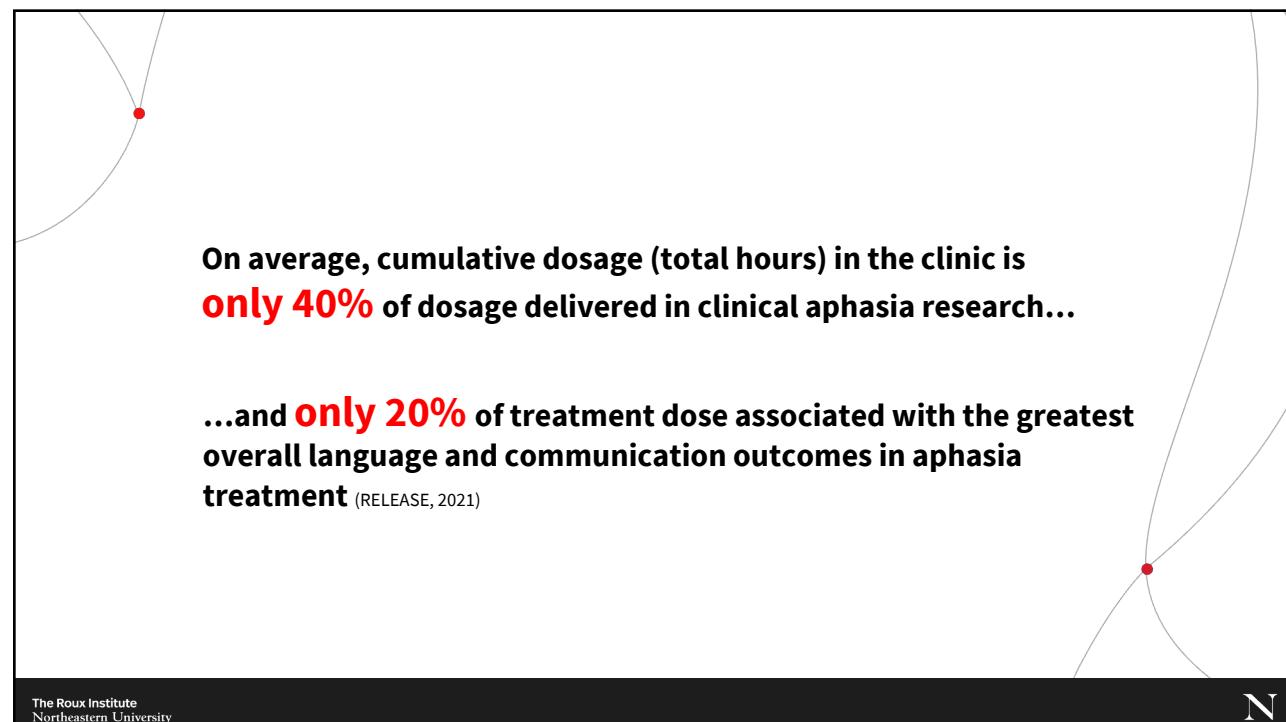
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**Factors that might influence real-world dose**

- Patient Factors:**
  - Financial costs (e.g., copays, coinsurance)
  - Transportation
  - Family support / reliance on others
  - Comorbidities
  - Motivation
- Clinician Factors**
  - Experience
  - Awareness & fidelity to dosage
  - Differences in d/c criteria
  - Cultural bias/sensitivity
- System Factors:**
  - insurance coverage
  - provider availability

**Consolidated Framework for Implementation Research (CFIR) 2.0**

The CFIR 2.0 model is a conceptual framework for implementation research. It consists of five interconnected components:

- Outer Setting:** Critical incidents, Values and beliefs, Economic resources, Policies and laws.
- Inner Setting:** Structural characteristics, Administrative characteristics, Communications, Clinical culture, Reasons for change, Comparability.
- Individuals:** Relative priority, Personal characteristics, Motivations, Attitudes, Access to knowledge about the innovation.
- Process:** Training, Assessing Needs, Assessing Current Capabilities, Tailoring Strategies, Planning, Doing, Monitoring & Evaluating, Adapting.
- The Wkld (innovation):** Source, Evidence Base, Implementation Strategy, Adequacy, Feasibility, Acceptability, Usability, Complexity, and Cost.

**CFIR 2.0**

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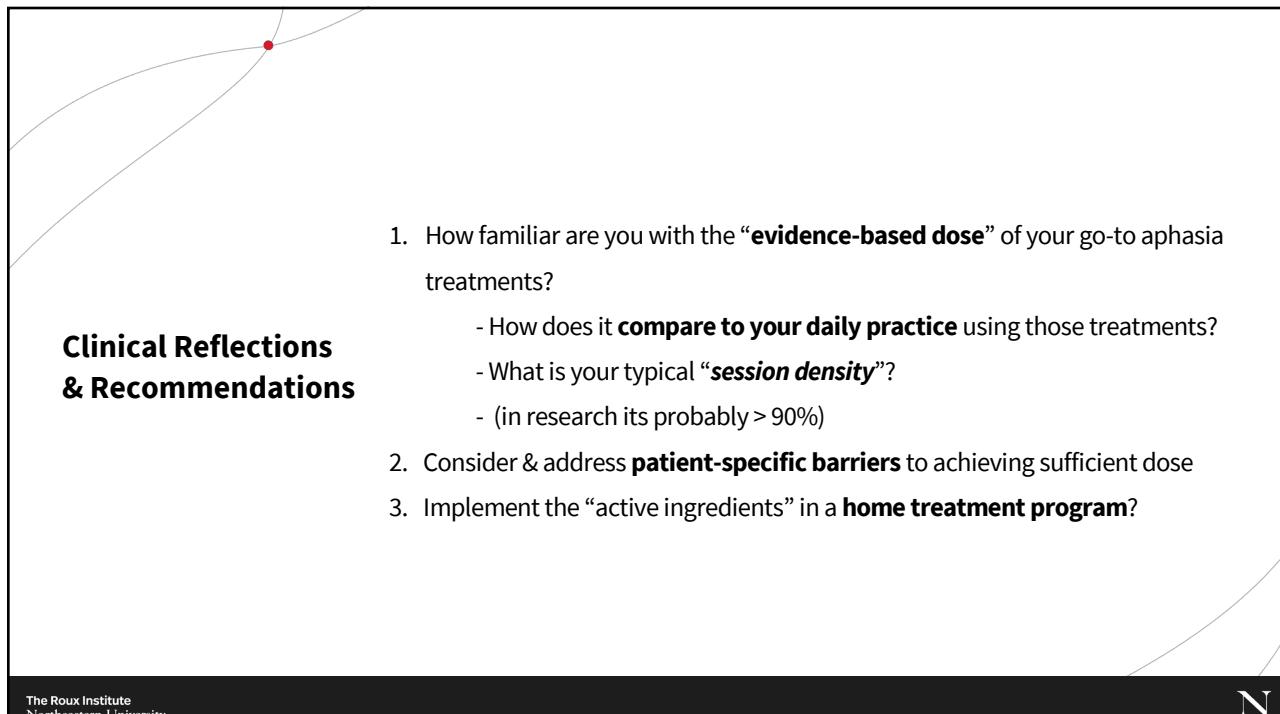
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**Clinical Reflections & Recommendations**

1. How familiar are you with the “**evidence-based dose**” of your go-to aphasia treatments?
  - How does it **compare to your daily practice** using those treatments?
  - What is your typical “**session density**”?
  - (in research its probably > 90%)
2. Consider & address **patient-specific barriers** to achieving sufficient dose
3. Implement the “active ingredients” in a **home treatment program**?

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**Generating more features is associated with better outcomes in SFA**

*Treatment-specific dose-response relationship*

Gravier et al., (2018), Evans et al., (2020)

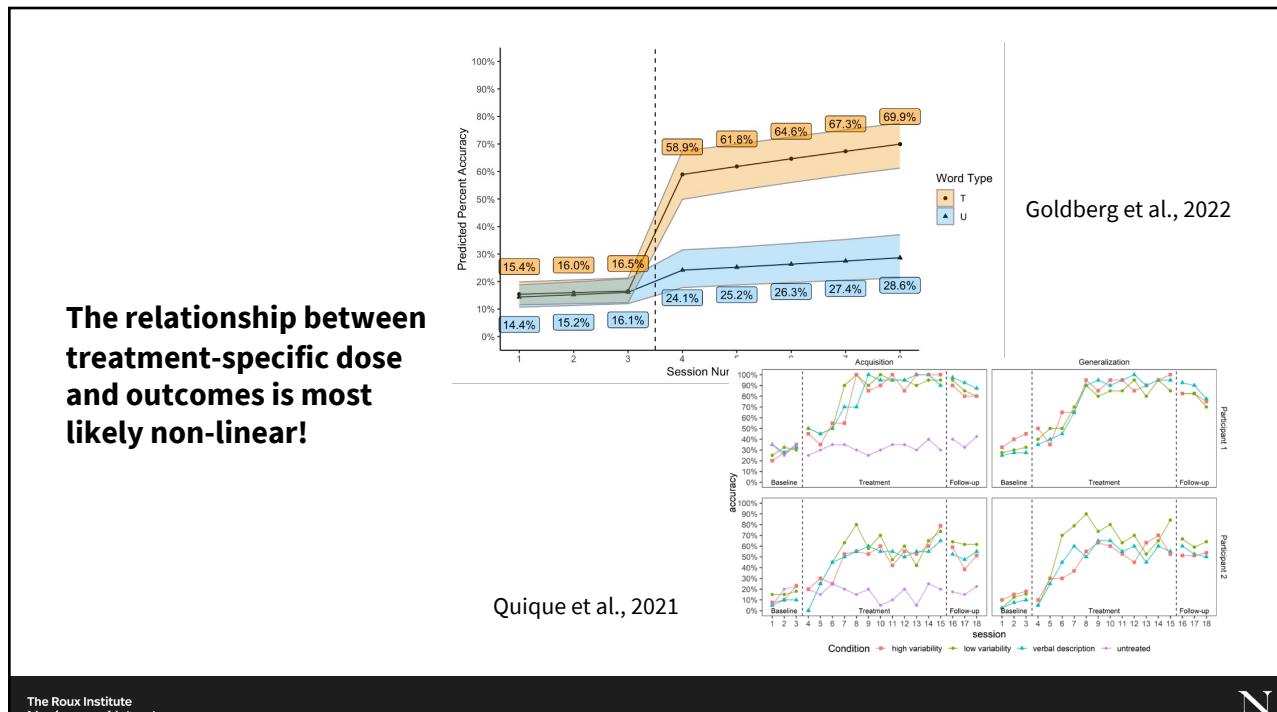
**...the greatest overall language and functional communication gains were associated with interventions that were mixed expressive-receptive approaches, delivered over 5 days weekly for up to 50 hours in total**

*Utilization-level dose-response relationship*

RELEASE Collaborators, 2021

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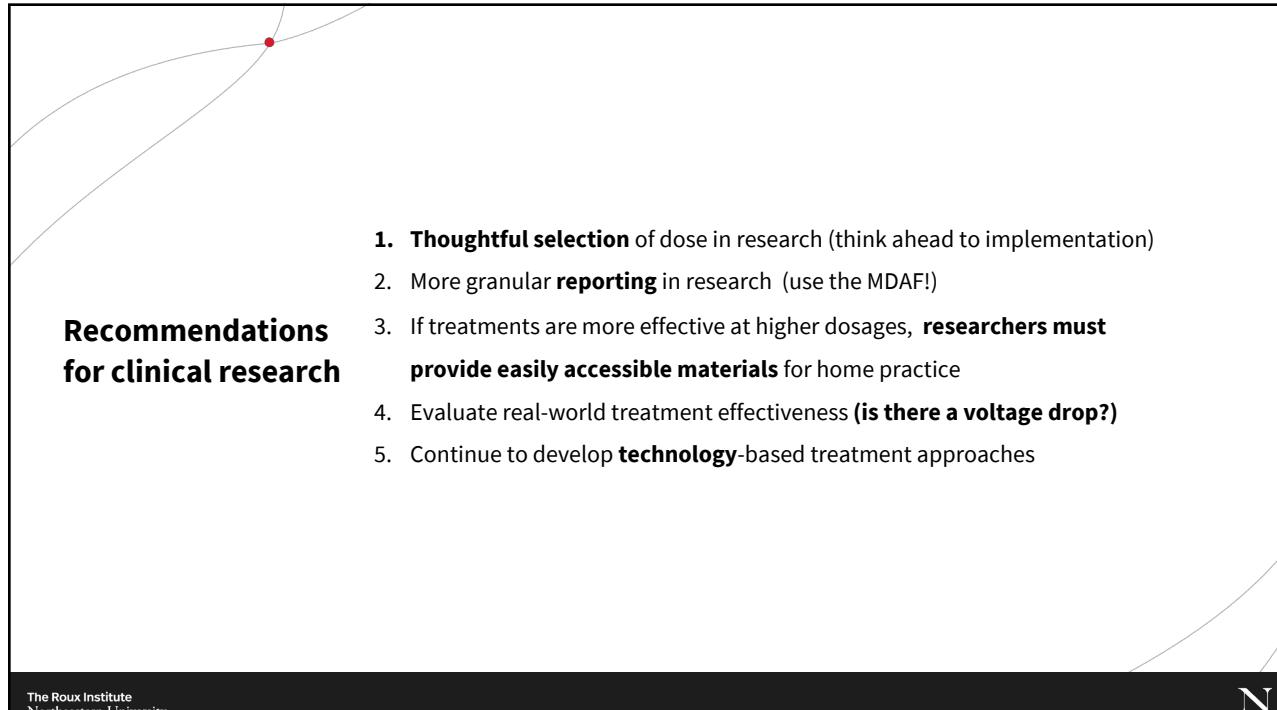
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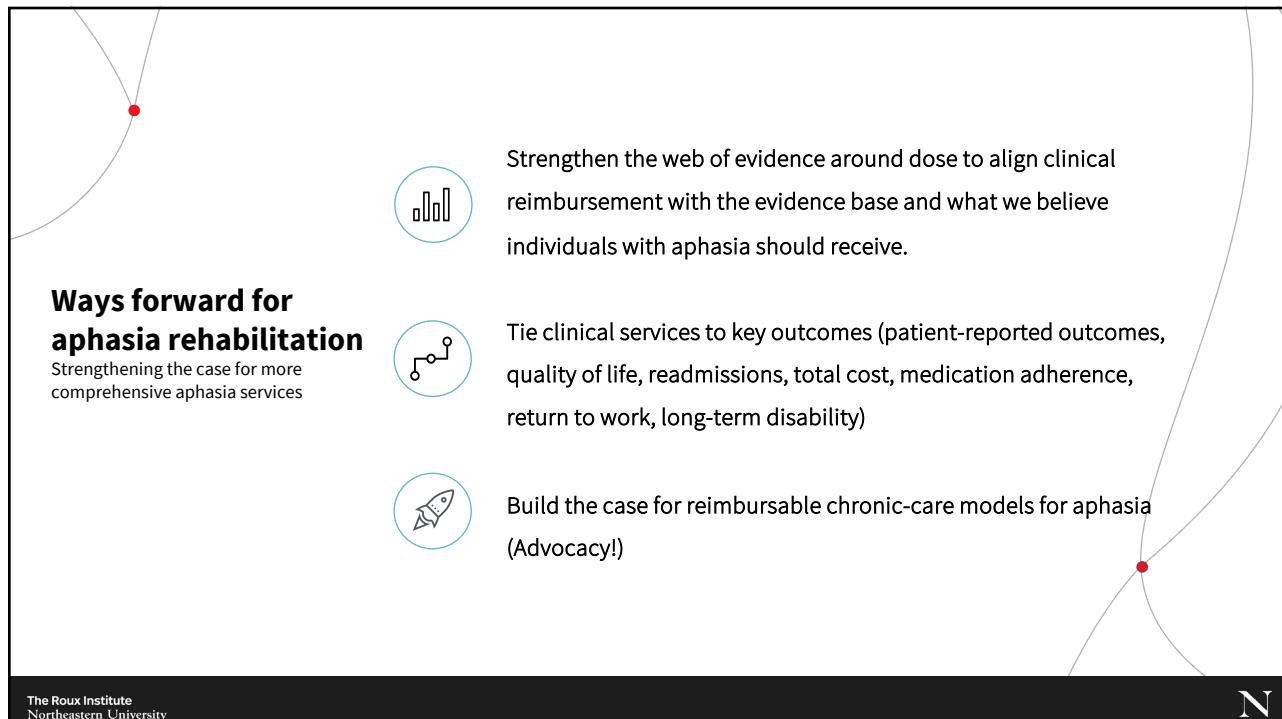
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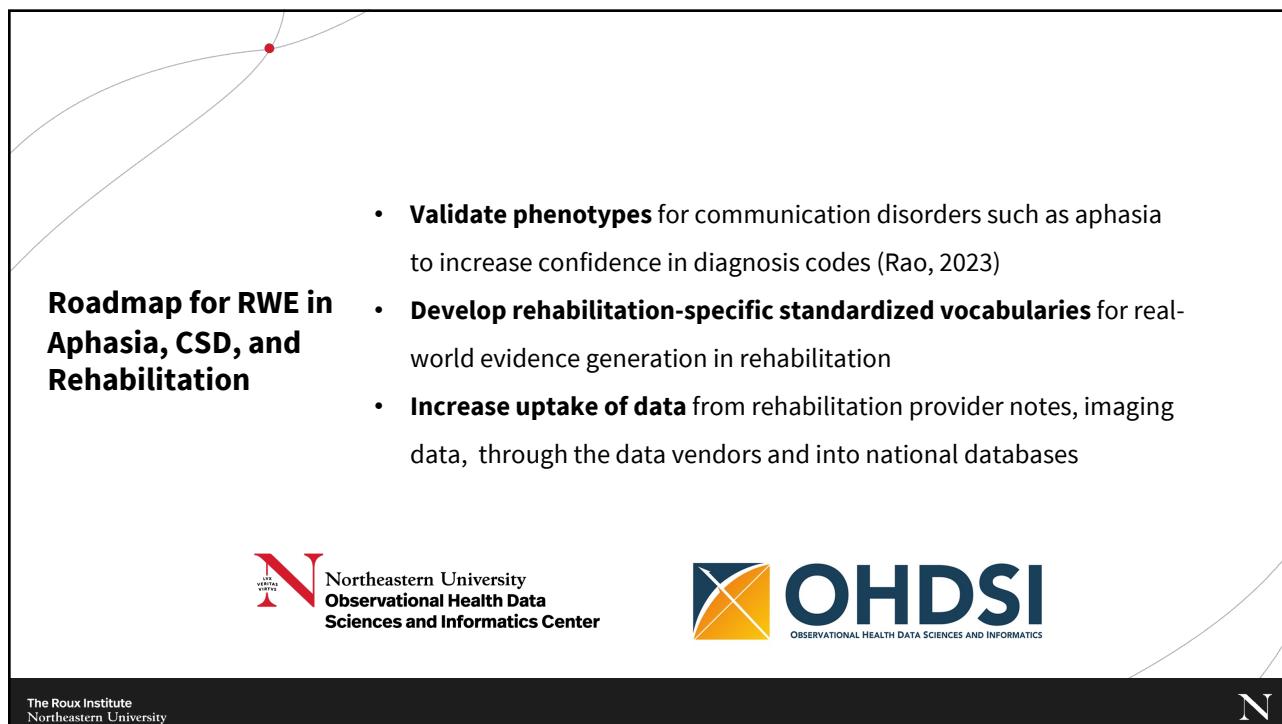


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