

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

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

Brianne Olivieri-Mui

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

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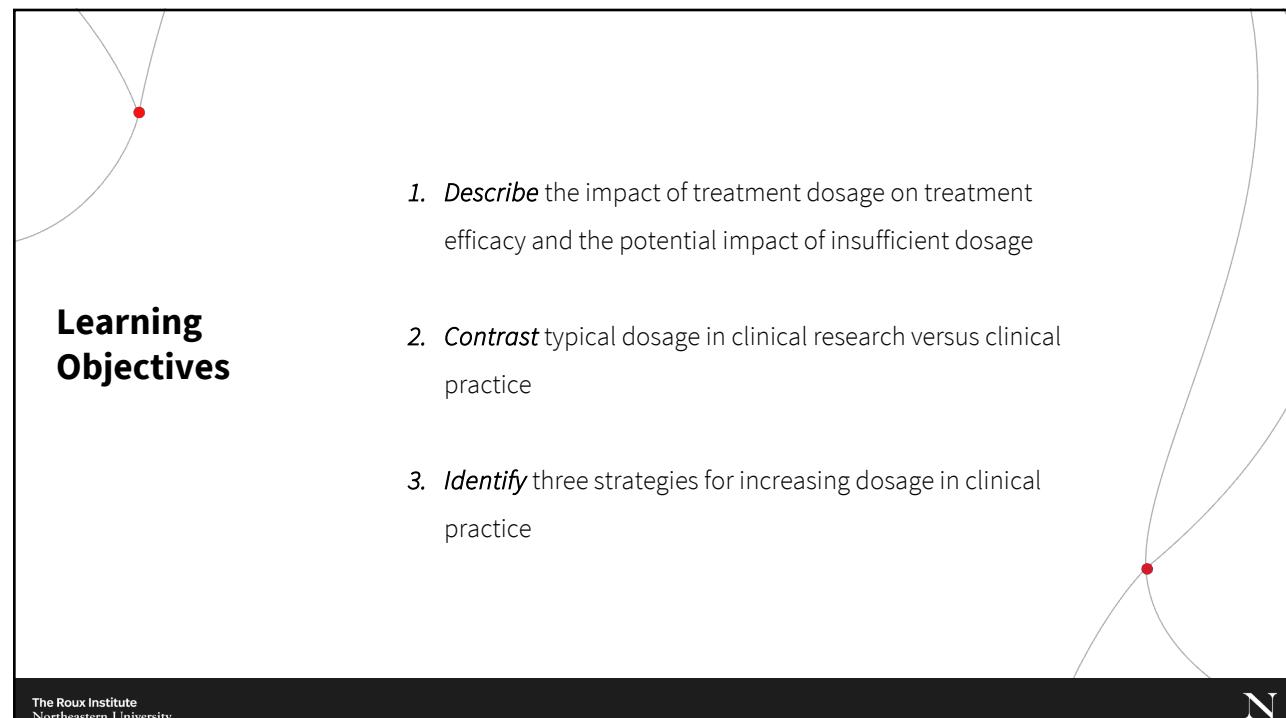
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Disclosures

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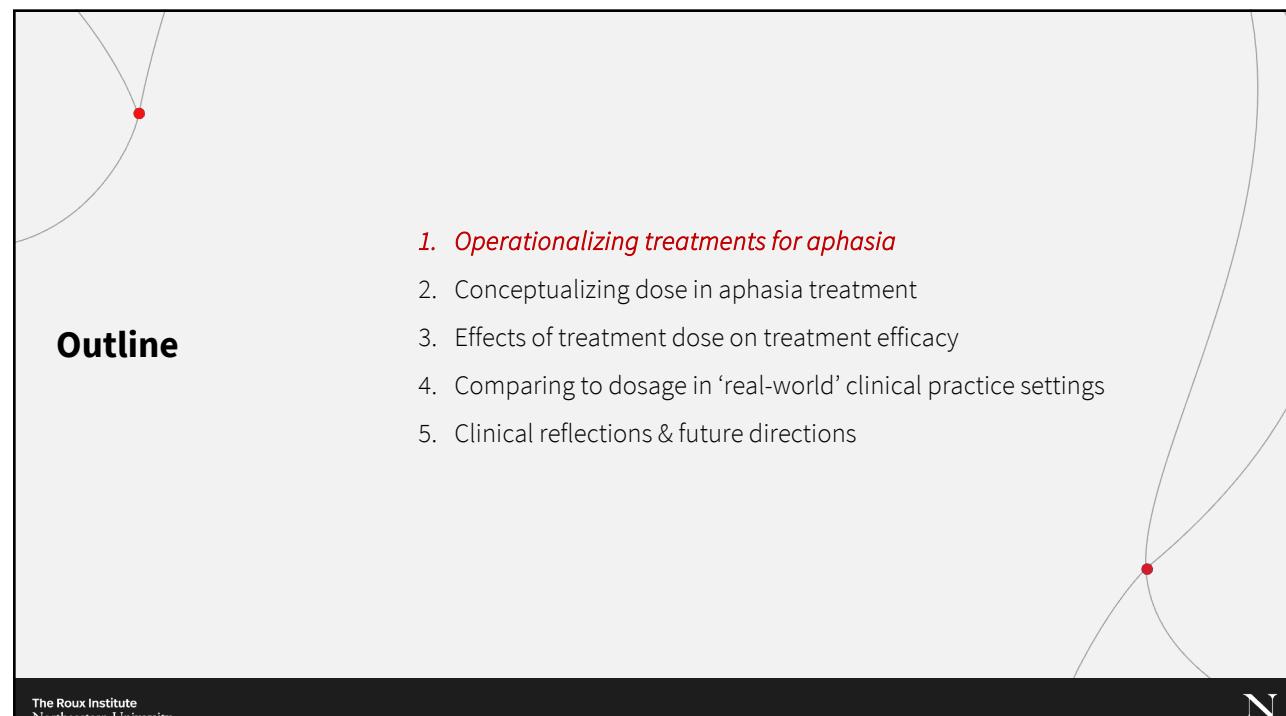


Learning Objectives

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

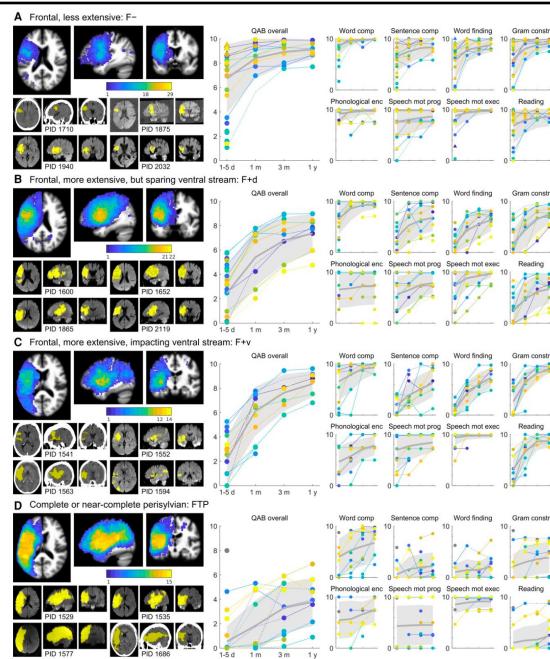
1. *Operationalizing treatments for aphasia*
2. Conceptualizing dose in aphasia treatment
3. Effects of treatment dose on treatment efficacy
4. Comparing to dosage in ‘real-world’ clinical practice settings
5. Clinical reflections & future directions

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Aphasia

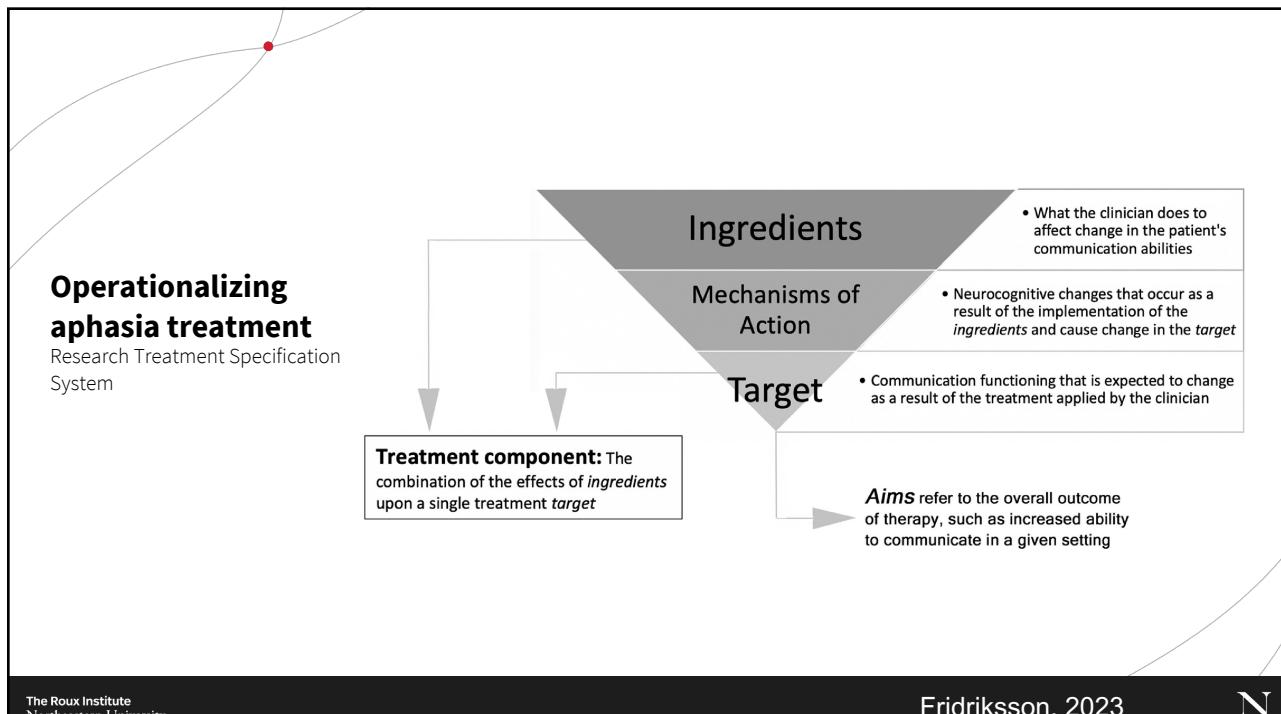
- Language disorder caused by brain damage that affects any area of language (e.g., talking, understanding others, reading, writing)
- Affects 1/3 of stroke survivors, with more than 180,000 new cases annually (Pedersen et al., 2004)
- Profound impact on health-related quality of life, including greater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



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Trajectories of recovery for patients with frontal lobe damage. Reprinted from Wilson et al., (2023) N

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Fridriksson, 2023

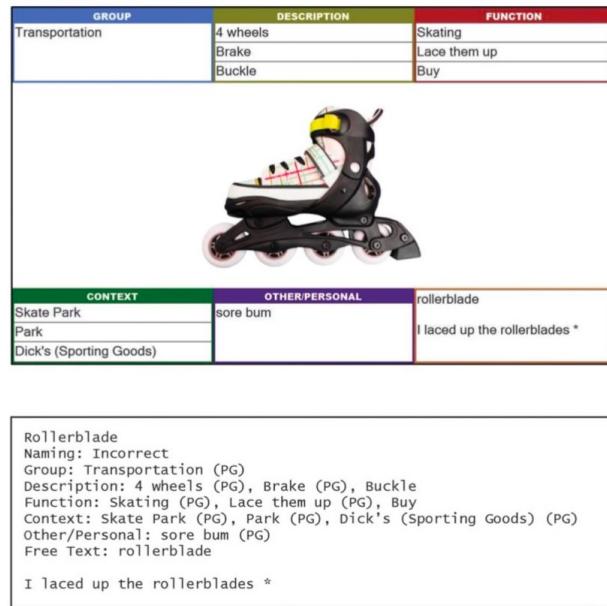
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Example:

Semantic Feature Analysis Treatment (SFA)

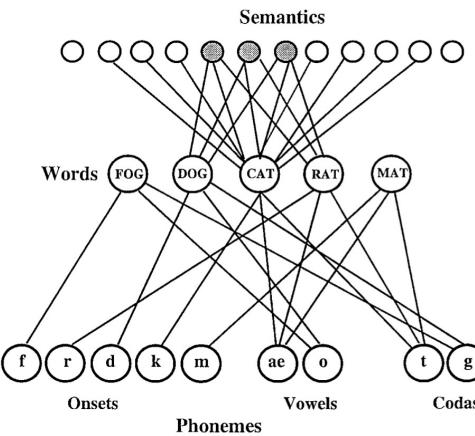
- Interleaved, effortful retrieval of target words and semantic features across several semantic categories
1. Name the item
 2. Generate semantic features
 3. Name the item again
 4. Repeat with a new item
- Steps 1-2 = 1 “treatment trial”

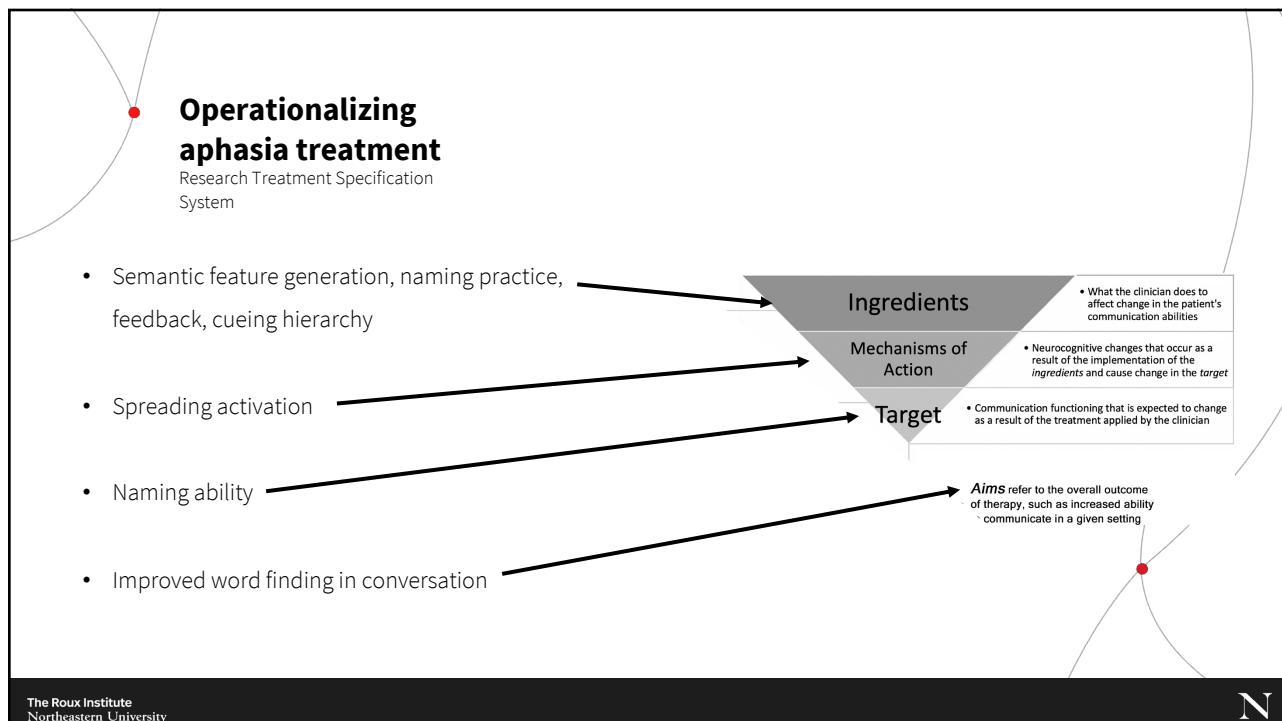


Example #1

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.



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Example #2

SFA Compensatory Mechanism

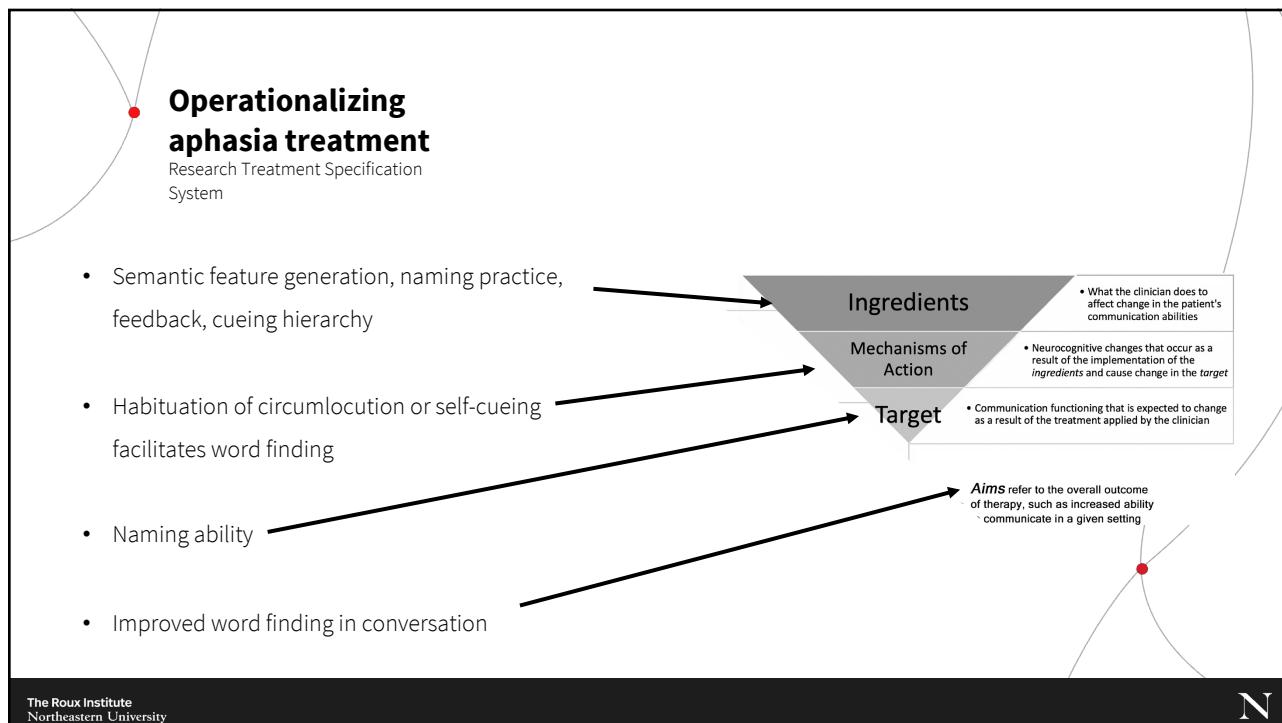
- SFA “promotes habituation of semantic self-cueing and semantically appropriate circumlocution, strategies that facilitate communication even if specific lexical retrieval fails” Antonucci (2009)
- Retrieval of semantically related content may also help individuals with aphasia navigate to their intended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

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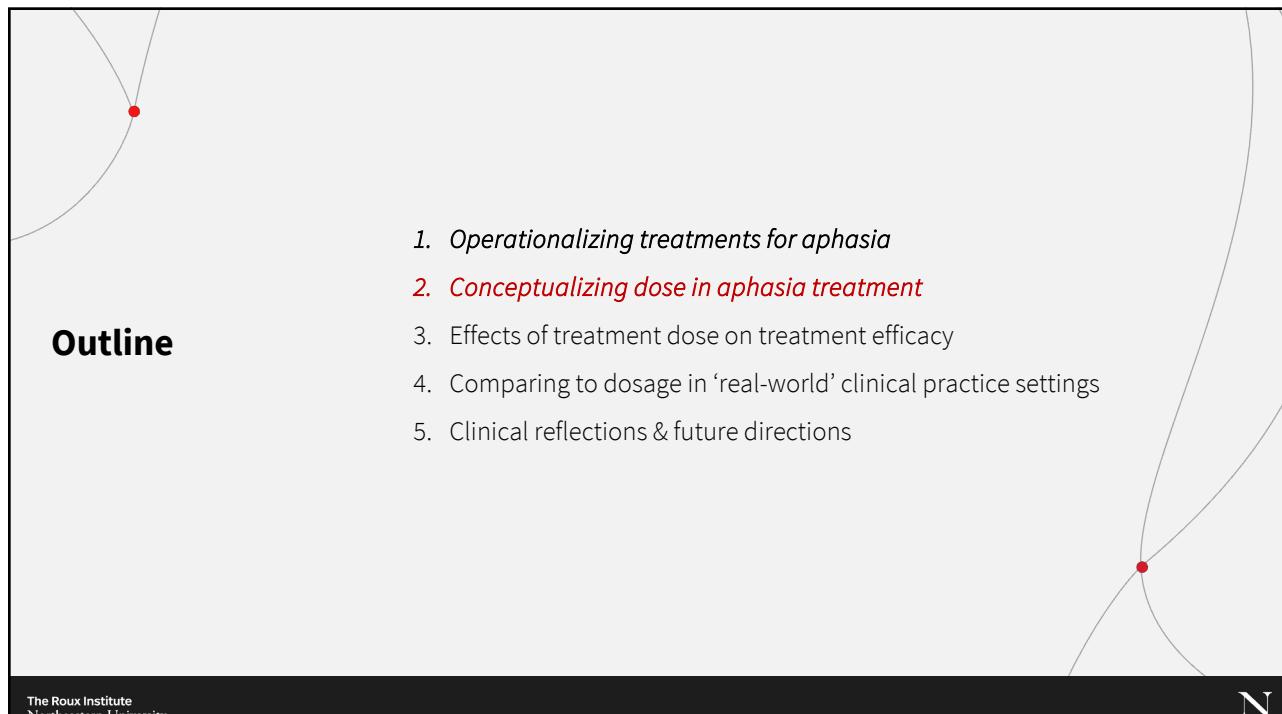
@nathanwpytle Strange Planet

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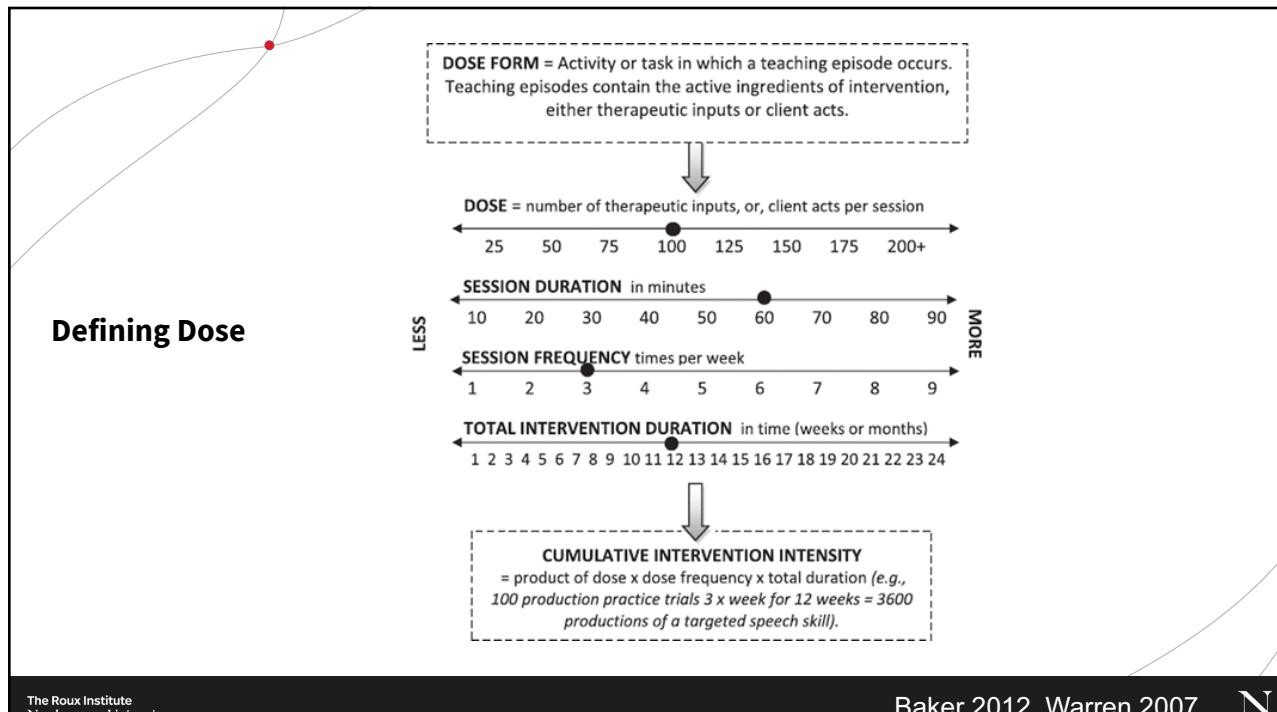
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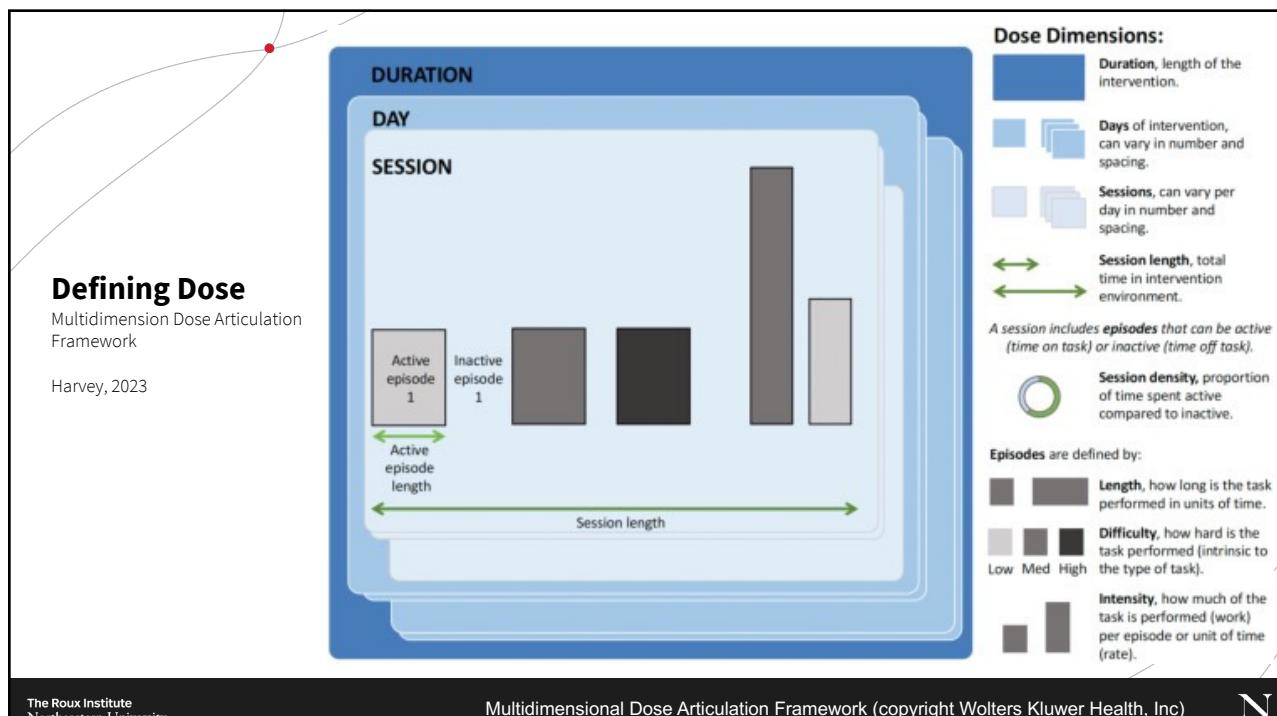


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Baker 2012, Warren 2007 N

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Therapeutic Element

- The basic unit of therapy; either a therapeutic input or a client act

Session Dose

- A quantitative measure of the therapeutic content provided in a session, in minutes or therapeutic elements.

Key Dosage Parameters

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

Dose Dimension

Diagram illustrating the components of a dose dimension:

- SESSION DAY:** Session duration, Session frequency, Session dose.
- SESSION:** Session duration, Session frequency, Session dose.
- DAY:** Day duration, Day frequency, Day dose.
- DOSE DIMENSION:** Total dose, Total frequency, Total duration.
- IMPLEMENTATION:** Implementation duration, Implementation frequency, Implementation dose.
- INTERVENTION:** Intervention duration, Intervention frequency, Intervention dose.
- OUTCOME:** Outcome duration, Outcome frequency, Outcome dose.
- SESSION DURATION:** Session duration, Session frequency, Session dose.
- SESSION FREQUENCY:** Session duration, Session frequency, Session dose.
- SESSION DOSE:** Session duration, Session frequency, Session dose.
- DAY DURATION:** Day duration, Day frequency, Day dose.
- DAY FREQUENCY:** Day duration, Day frequency, Day dose.
- DAY DOSE:** Day duration, Day frequency, Day dose.
- IMPLEMENTATION DURATION:** Implementation duration, Implementation frequency, Implementation dose.
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Operationalizing aphasia treatment

Research Treatment Specification System

Therapeutic Elements

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

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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OUTCOME: Outcome duration, Outcome frequency, Outcome dose.

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SESSION FREQUENCY: Session duration, Session frequency, Session dose.

SESSION DOSE: Session duration, Session frequency, Session dose.

DAY DURATION: Day duration, Day frequency, Day dose.

DAY FREQUENCY: Day duration, Day frequency, Day dose.

DAY DOSE: Day duration, Day frequency, Day dose.

IMPLEMENTATION DURATION: Implementation duration, Implementation frequency, Implementation dose.

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INTERVENTION DOSE: Intervention duration, Intervention frequency, Intervention dose.

OUTCOME DURATION: Outcome duration, Outcome frequency, Outcome dose.

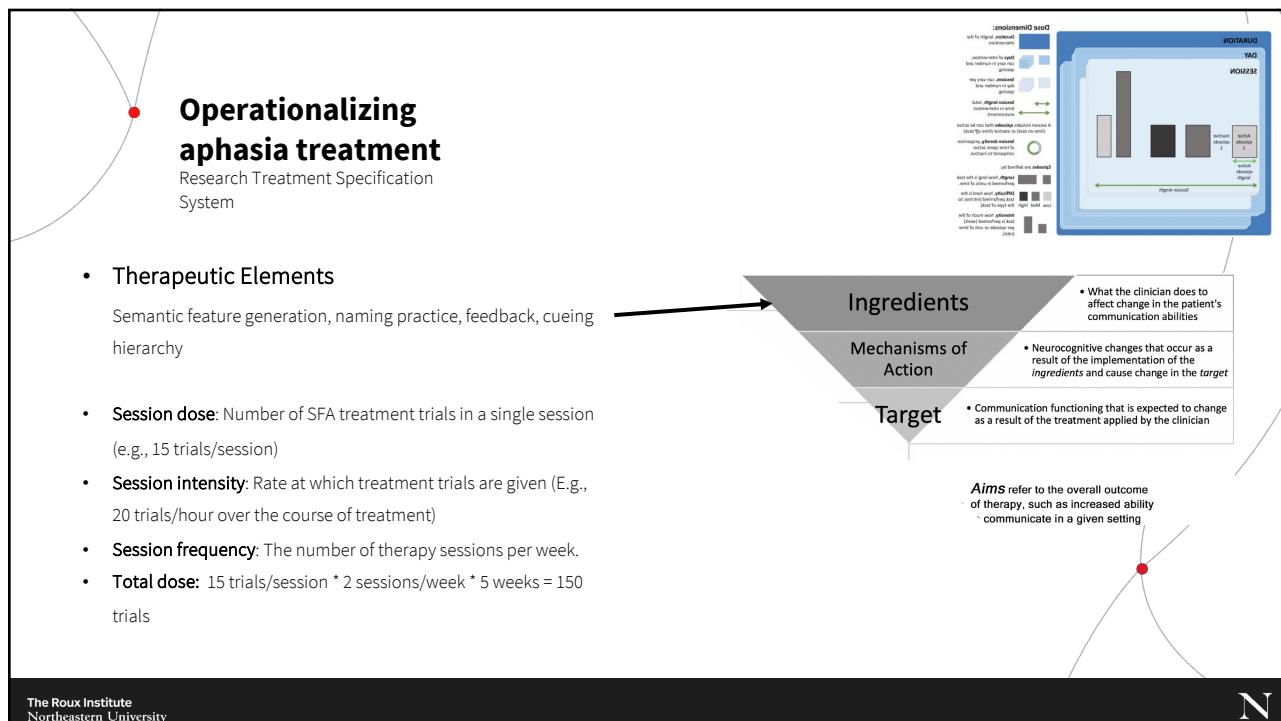
OUTCOME FREQUENCY: Outcome duration, Outcome frequency, Outcome dose.

OUTCOME DOSE: Outcome duration, Outcome frequency, Outcome dose.

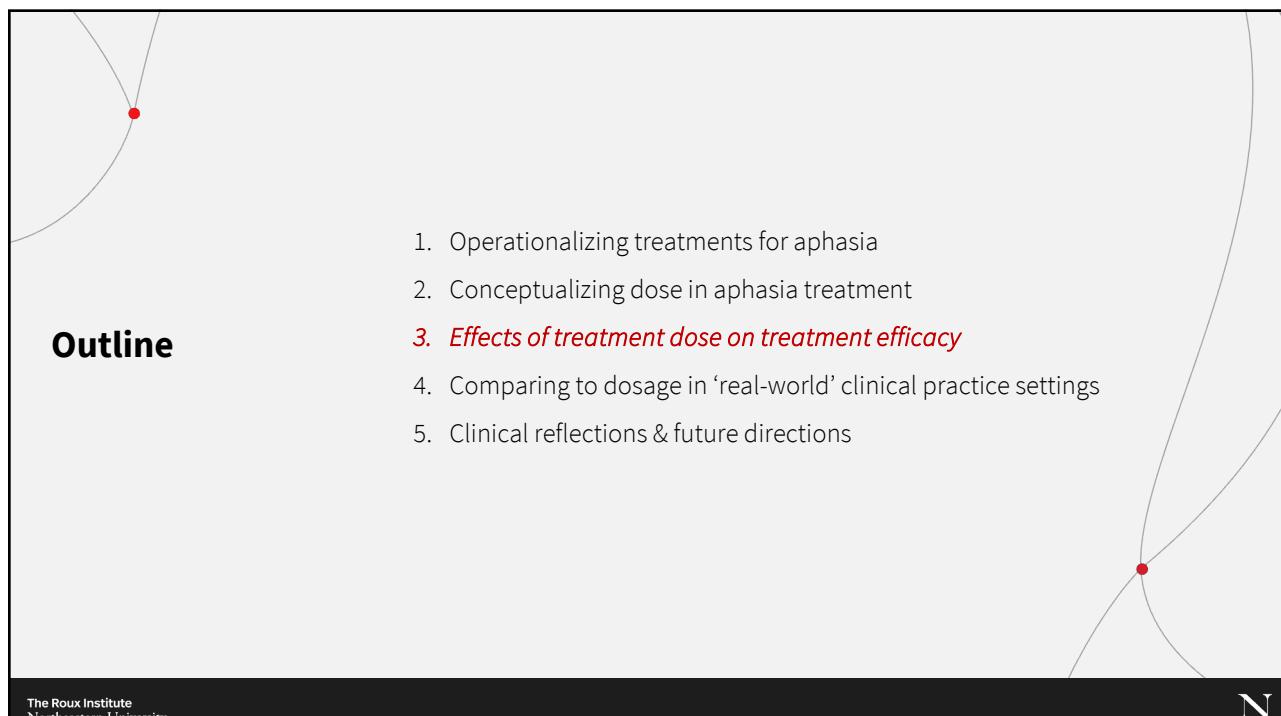
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Reporting dose in the research literature

(Harvey 2020)

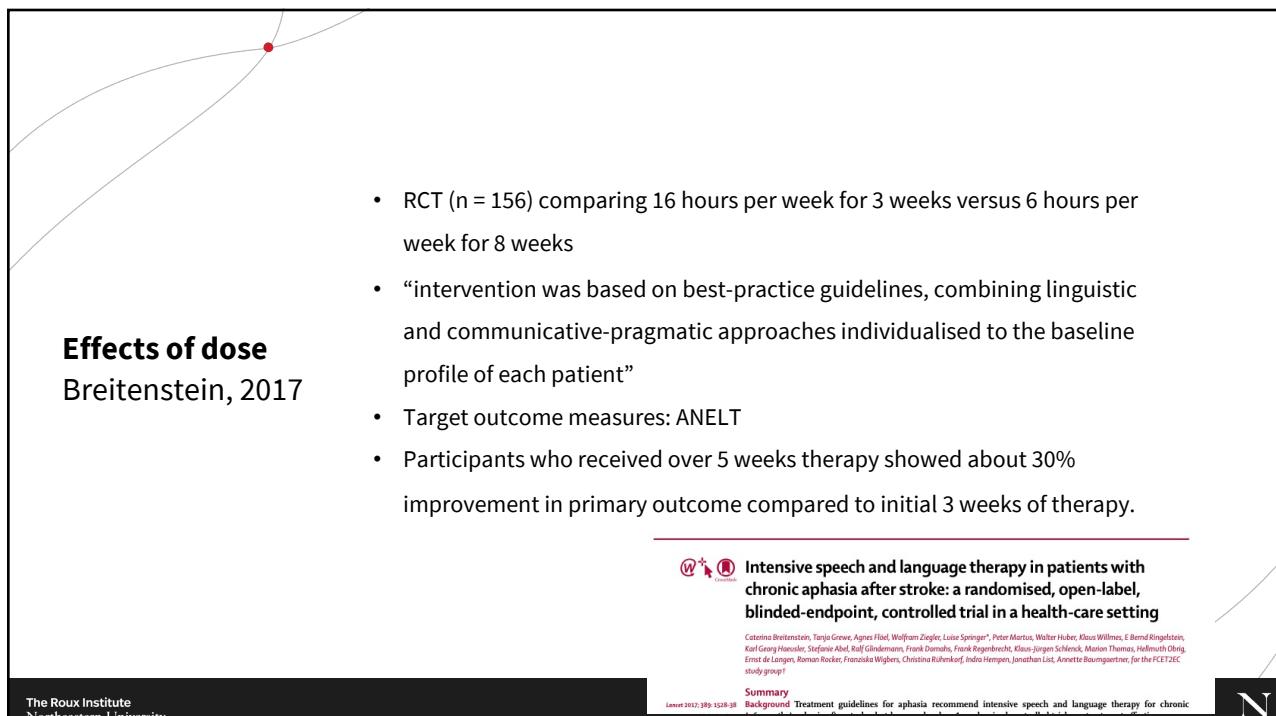
- Most treatment studies report dosage in terms of therapy minutes / hours
~25% report dosage in terms of therapeutic elements delivered
- Many studies report the prescribed schedule but not the amount of treatment participants actually receive
- Home practice time rarely included or tracked

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: ANELT
- Participants who received over 5 weeks therapy showed about 30% improvement in primary outcome compared to initial 3 weeks of therapy.

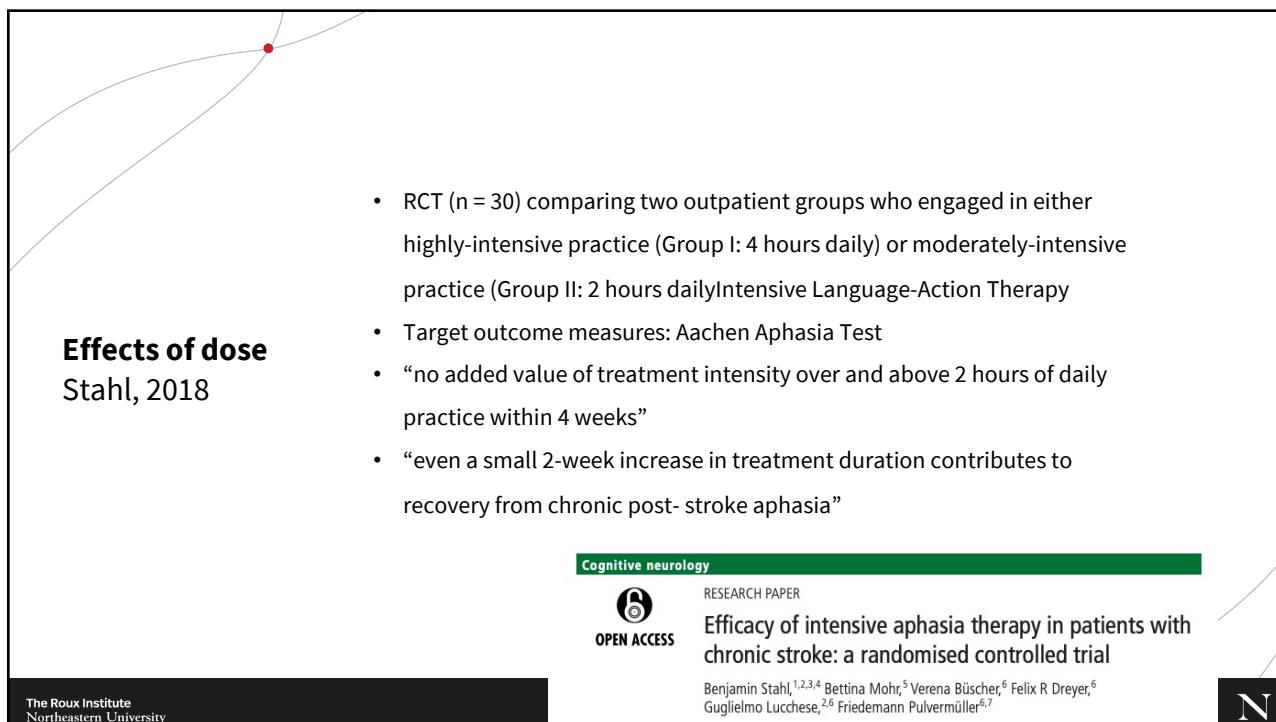
Intensive speech and language therapy in patients with chronic aphasia after stroke: a randomised, open-label, blinded-endpoint, controlled trial in a health-care setting

Caterina Breitenstein, Tanja Greve, Annet Fiedl, Wolfgang Ziegler, Loes Springer*, Peter Martus, Walter Huber, Klaus Willmes, E Bernd Roedel, Karl Georg Haeseler, Stefanie Abel, Rolf Glendemann, Frank Domahs, Frank Regenbrecht, Klaus-Jürgen Schmeck, Marion Thome, Ingrid Münch-Dörsch, Erich da Cunha, Konstanze Kucke, Barbara Wiegert, Christiane Küller, Ingrid Hempel, Jonathan Liss, Annette Baumgärtner, for the PCE72C study group*

Summary | Background | Treatment guidelines for aphasia recommend intensive speech and language therapy for chronic study group?

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Effects of dose
Stahl, 2018

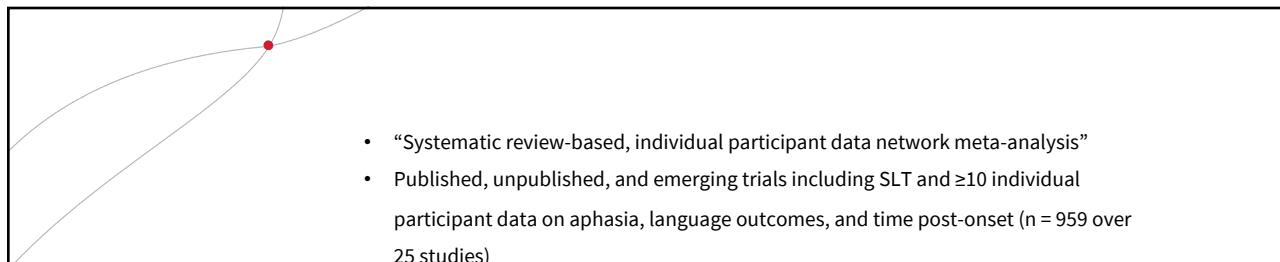
- RCT (n = 30) comparing two outpatient groups who engaged in either highly-intensive practice (Group I: 4 hours daily) or moderately-intensive practice (Group II: 2 hours daily)
- Intensive Language-Action Therapy
- Target outcome measures: Aachen Aphasia Test
- “no added value of treatment intensity 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,^{1,2,3,4} Bettina Mohr,⁵ Verena Büscher,⁶ Felix R Dreyer,⁶ Guglielmo Lucchese,^{2,6} Friedemann Pulvermüller^{6,7}

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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 ≥ 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

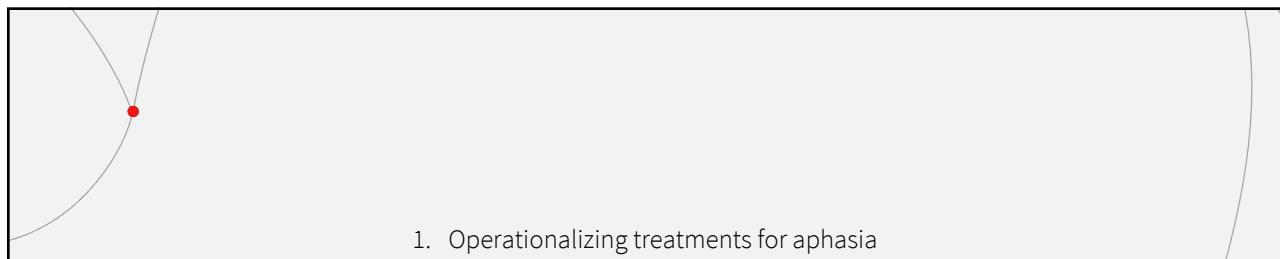
Dosage, Intensity, and Frequency of Language Therapy for Aphasia: A Systematic Review-Based, Individual Participant Data Network Meta-Analysis

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

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Outline

1. Operationalizing treatments for aphasia
2. Conceptualizing dose in aphasia treatment
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4. *Comparing to dosage in ‘real-world’ clinical practice settings*
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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?

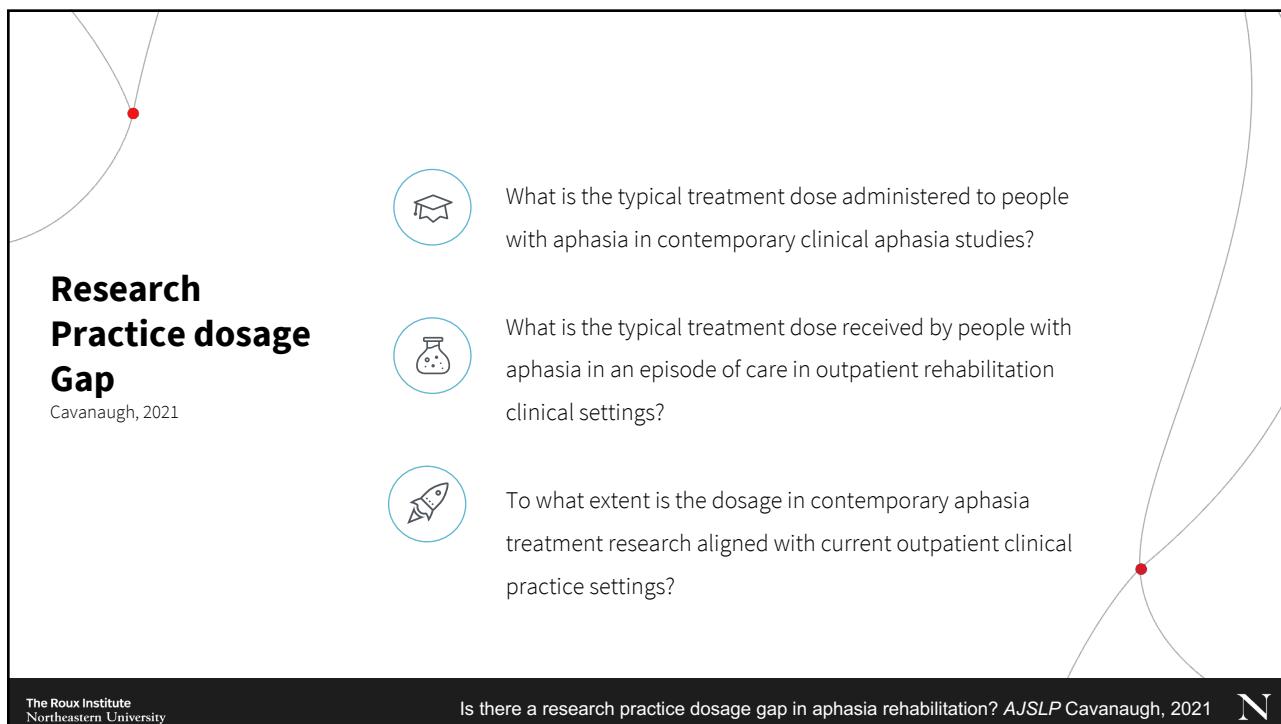
A: Voltage Drop
Reduced treatment fidelity in clinical settings → Poorer treatment effectiveness/outcomes in clinical practice

AJSLP
Research Article
Is There a Research–Practice Dosage Gap in Aphasia Rehabilitation?
Robert Cavanaugh,^{a,*} Christina Kravetz,^b Lillian Jarold,^{a,c} Yina Quique,^a Rose Turner,^a and William S. Evans^a

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Research Practice dosage Gap
Cavanaugh, 2021

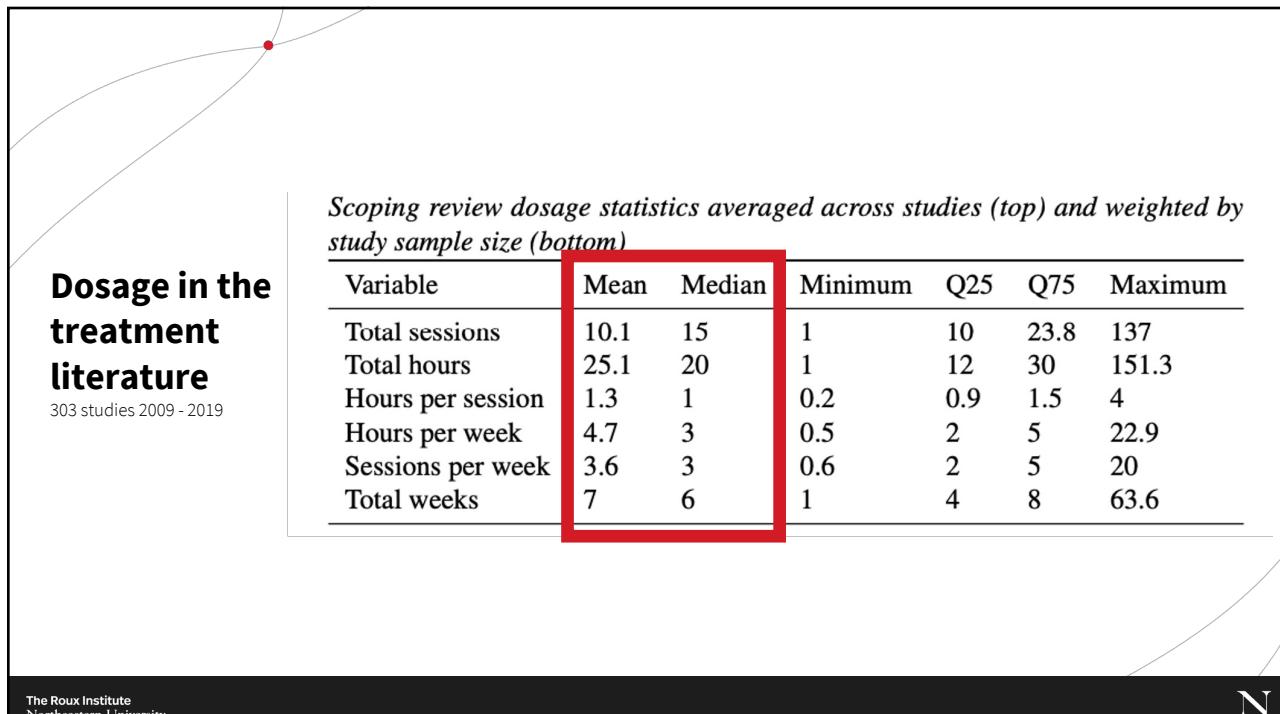
-  What is the typical treatment dose administered to people with aphasia in contemporary clinical aphasia studies?
-  What is the typical treatment dose received by people with aphasia in an episode of care in outpatient rehabilitation clinical settings?
-  To what extent is the dosage in contemporary 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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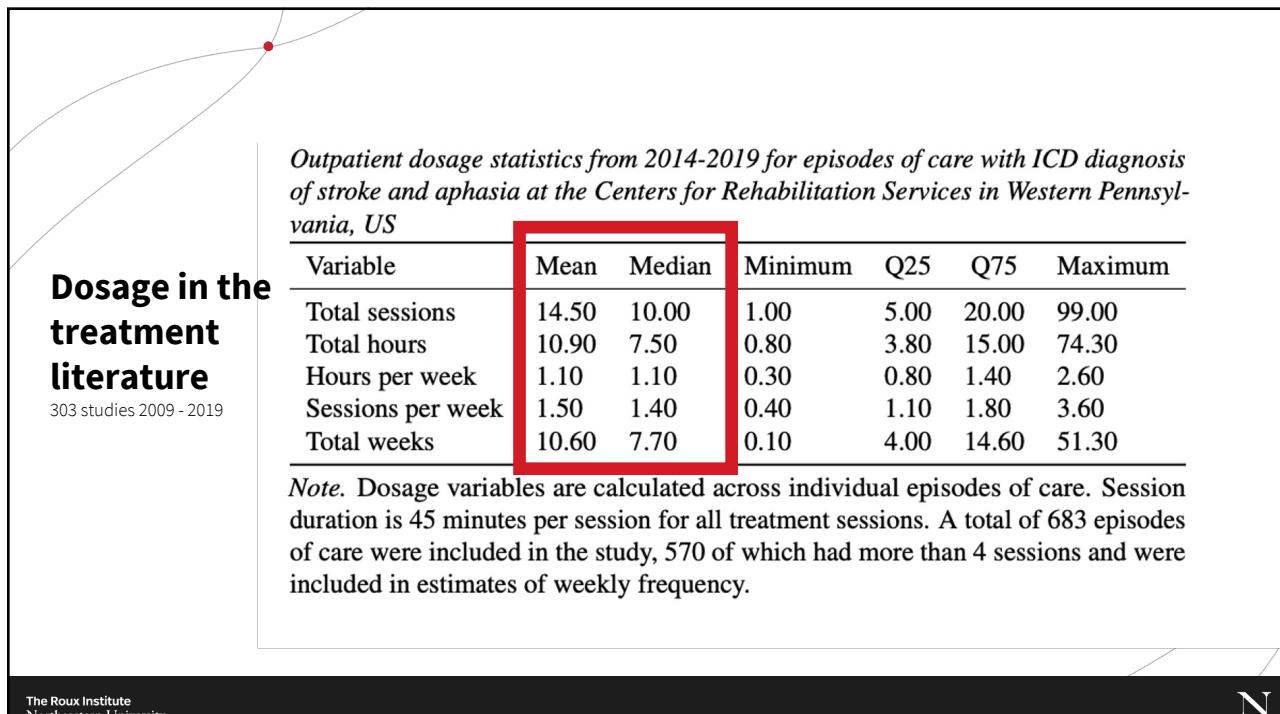
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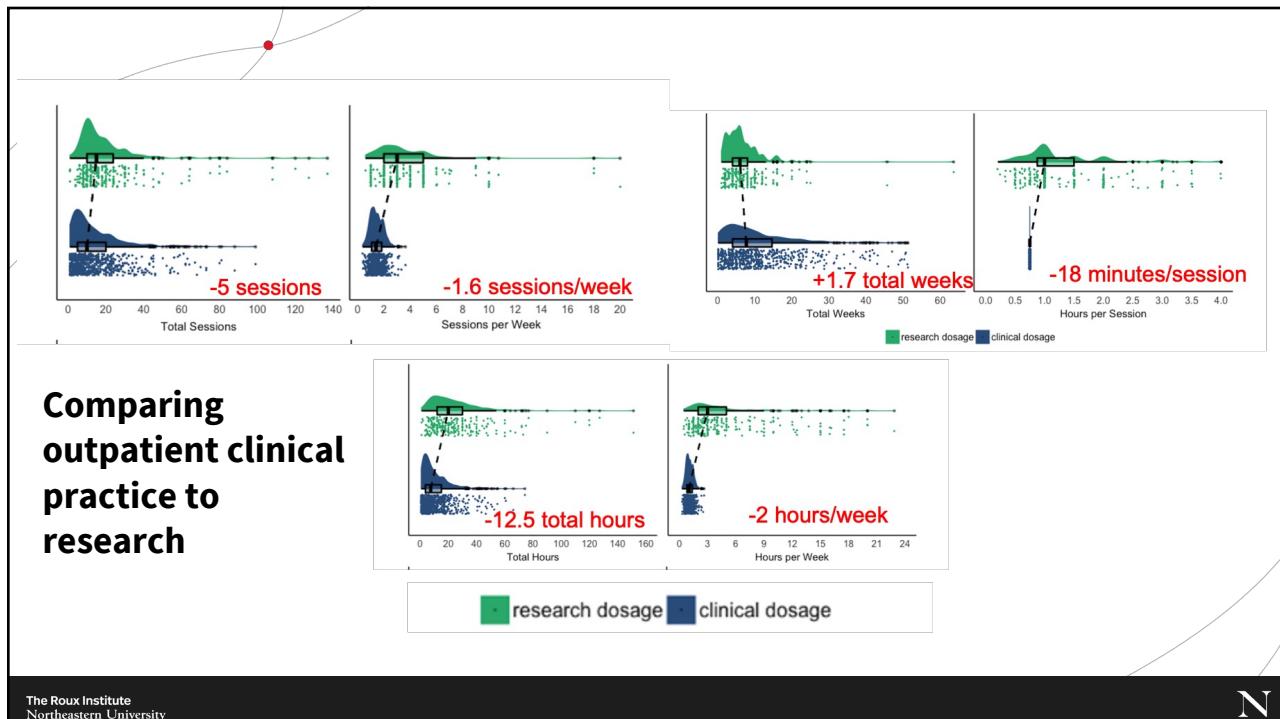
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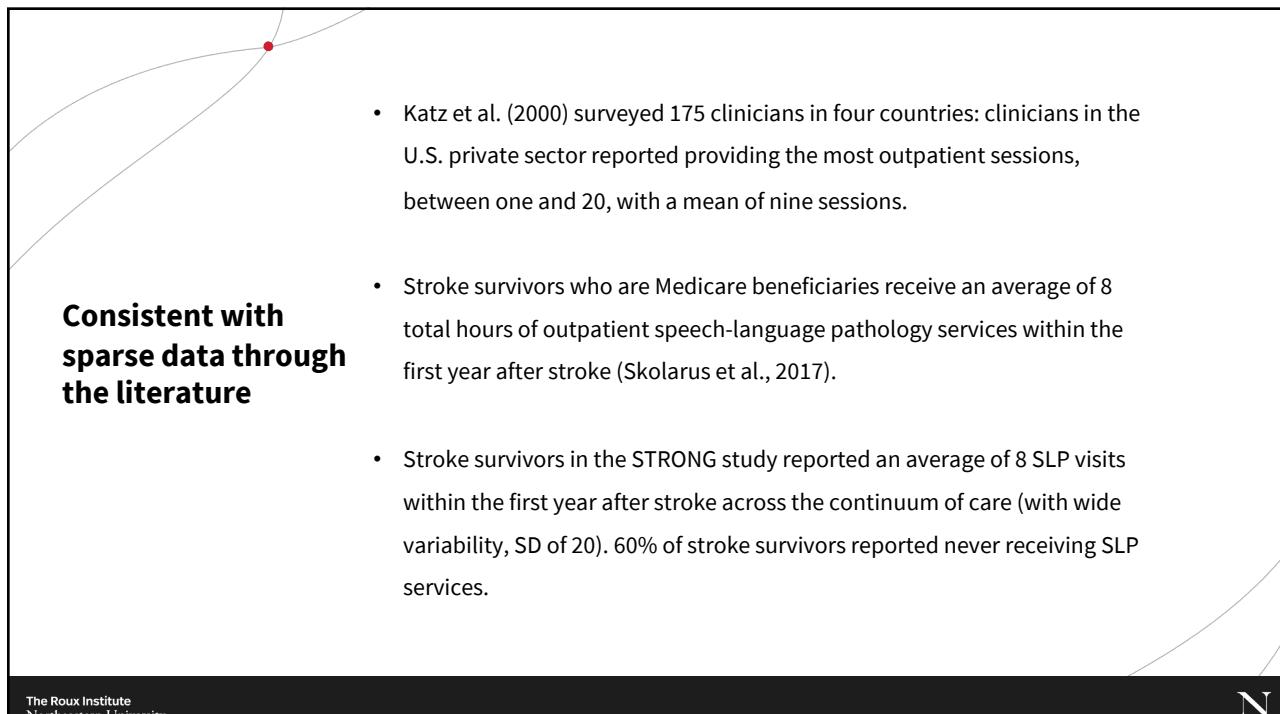
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Dose in aphasia clinical settings

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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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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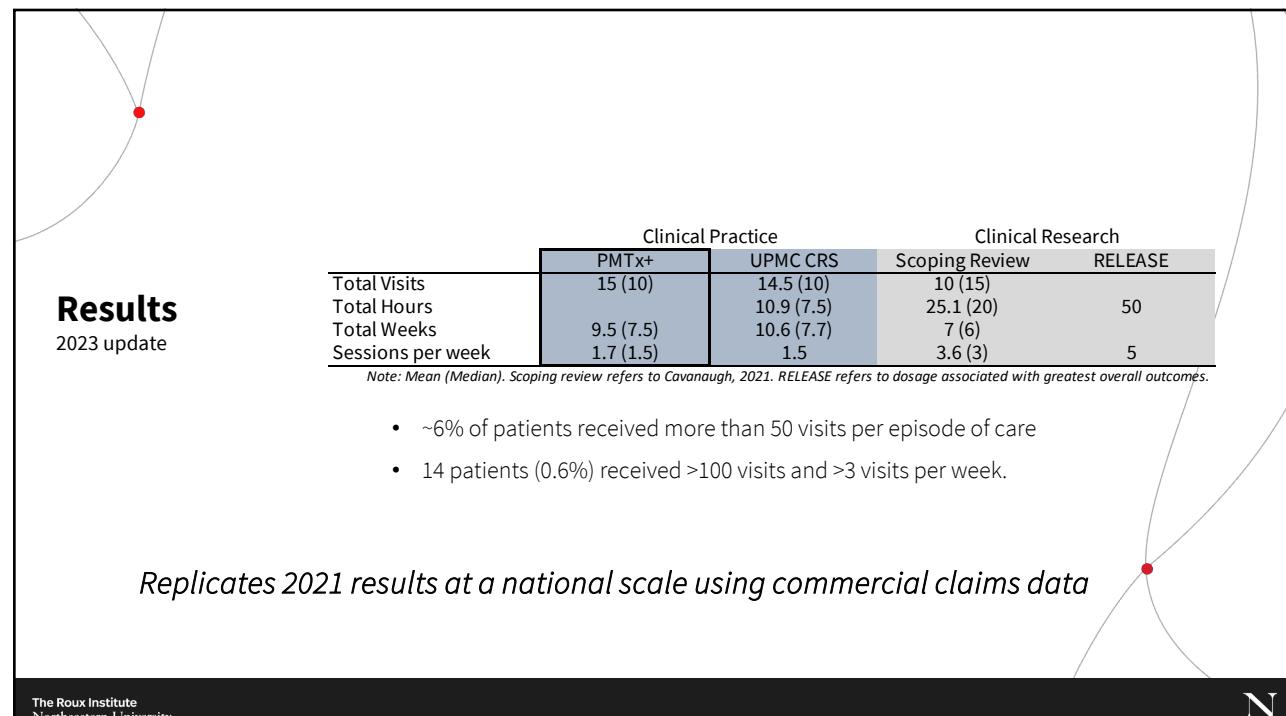
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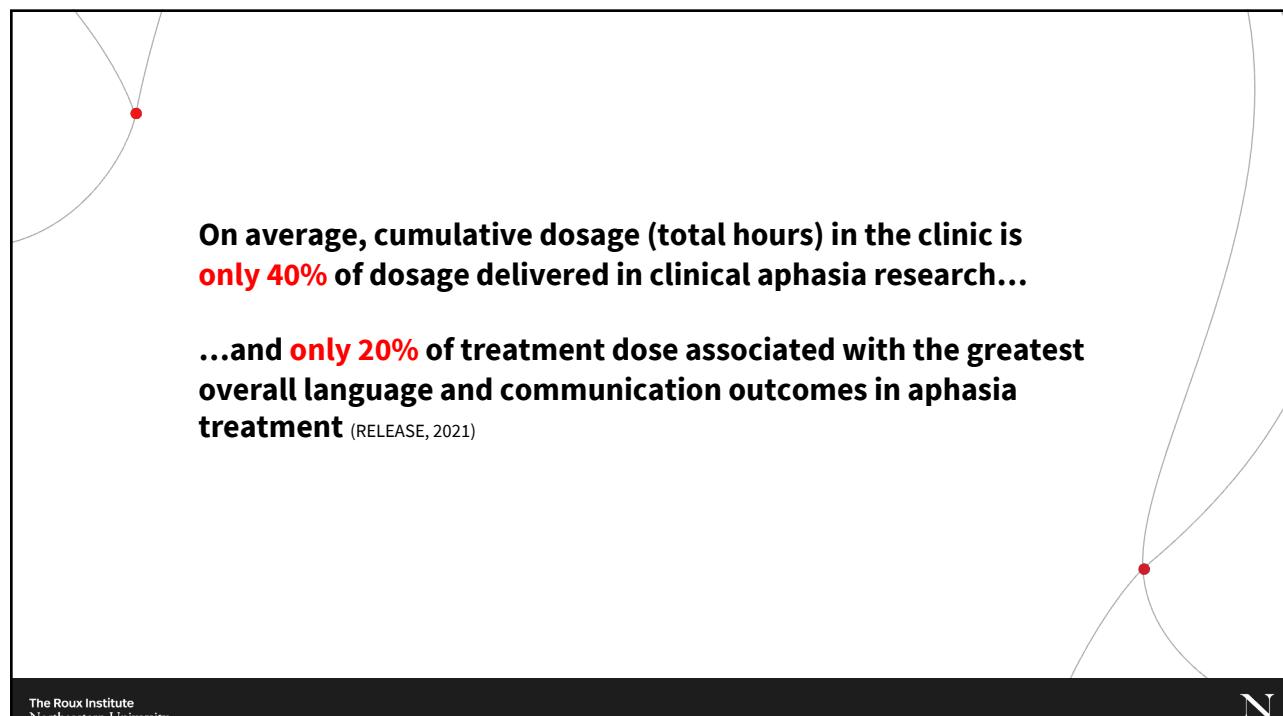
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Factors that might influence real-world dose

- 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 diagram illustrates the framework across four main domains:

- Outer Setting:**
 - Critical incidents
 - Values and beliefs
 - Organizational characteristics
 - Politics and laws
 - Partnerships and collaborations
 - Financing
 - External pressure
- Inner Setting:**
 - Structural characteristics
 - Administrative characteristics
 - Communication
 - Leadership
 - Tension for change
 - Comparability
 - Relative priority
 - Implementation barriers
 - Widespread implementation
 - Access to knowledge about the innovation
- Individuals:**
 - Opinion leaders
 - High-level leaders
 - Implementation facilitators
 - Implementation barriers
 - Implementation team members
 - Other implementation agents
- The WID (Innovation):**
 - Source
 - Evidence base
 - Implementation strategy
 - Adequacy
 - Usability
 - Complexity
 - Cost

Process: Training, Assessing Needs, Assessing Current Capabilities, Talking Strategically, Doing, Learning & Evaluating, Adapting.

CFIR 2.0

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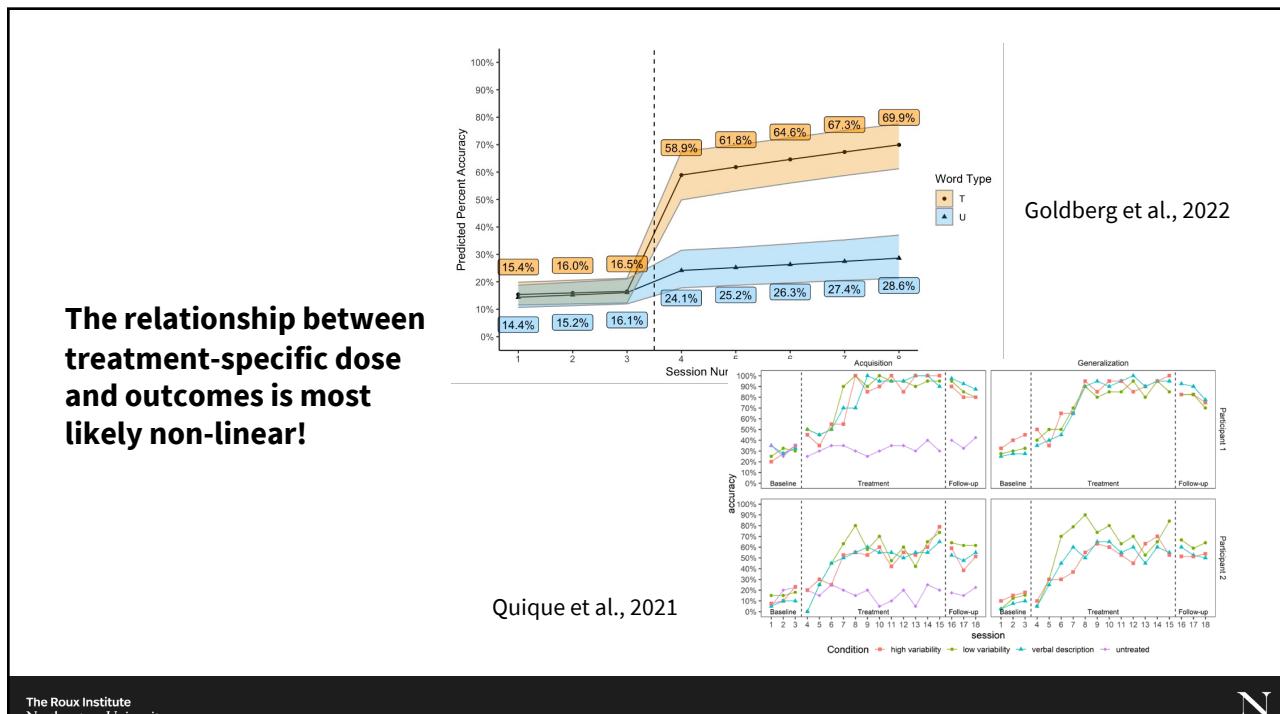
Clinical Reflections & Recommendations

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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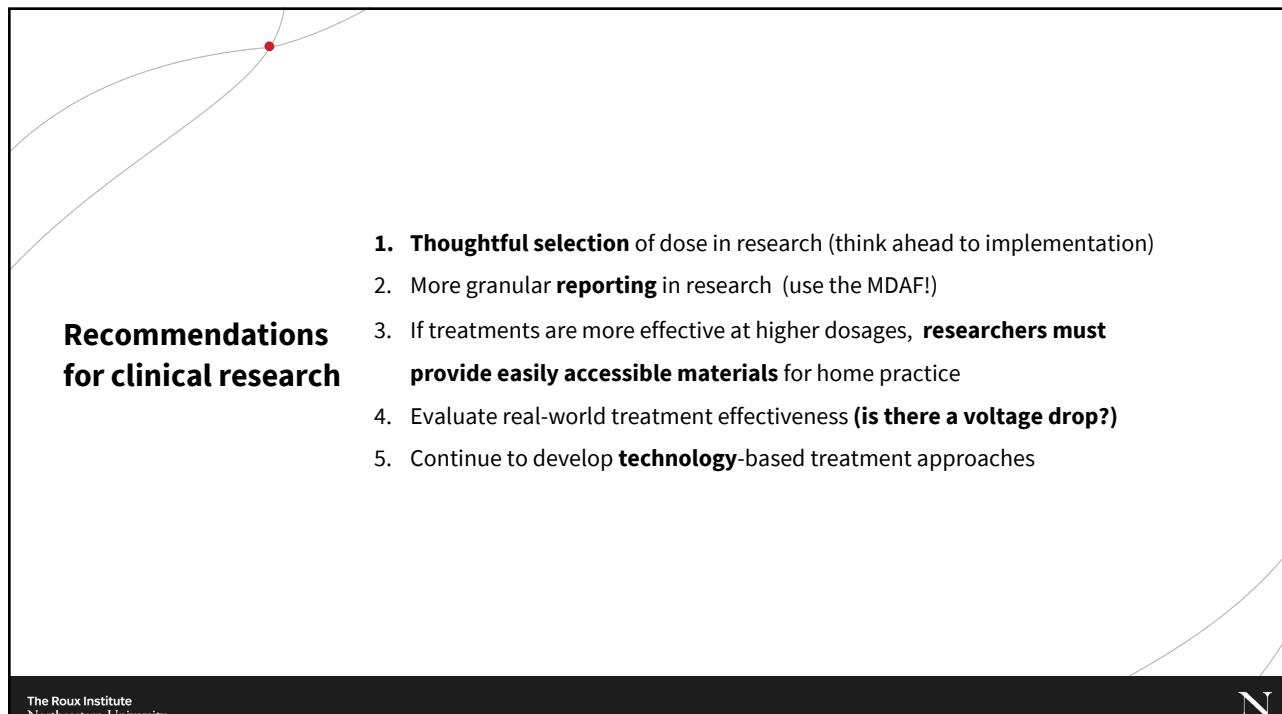
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Ways forward for aphasia rehabilitation
Strengthening the case for more comprehensive aphasia services

- Strengthen the web of evidence around dose to align clinical reimbursement with the evidence base and what we believe individuals with aphasia should receive.
- Tie clinical services to key outcomes (patient-reported outcomes, quality of life, readmissions, total cost, medication adherence, return to work, long-term disability)
- Build the case for reimbursable chronic-care models for aphasia rehabilitation (Advocacy!)

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Roadmap for RWE in Aphasia, CSD, and Rehabilitation

- Validate phenotypes for communication disorders such as aphasia to increase confidence in diagnosis codes (Rao, 2023)
- Develop rehabilitation-specific standardized vocabularies for real-world evidence generation in rehabilitation
- Increase uptake of data from rehabilitation provider notes, imaging data, through the data vendors and into national databases

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