Sorting Out the Translational Spectrum of Biomedical Research

Sainath Suryanarayanan, Noelia Sayavedra, Linda Scholl, D. Paul Moberg

November 2, 2018

UW Institute for Clinical and Translational Research

UW ICTR

Background

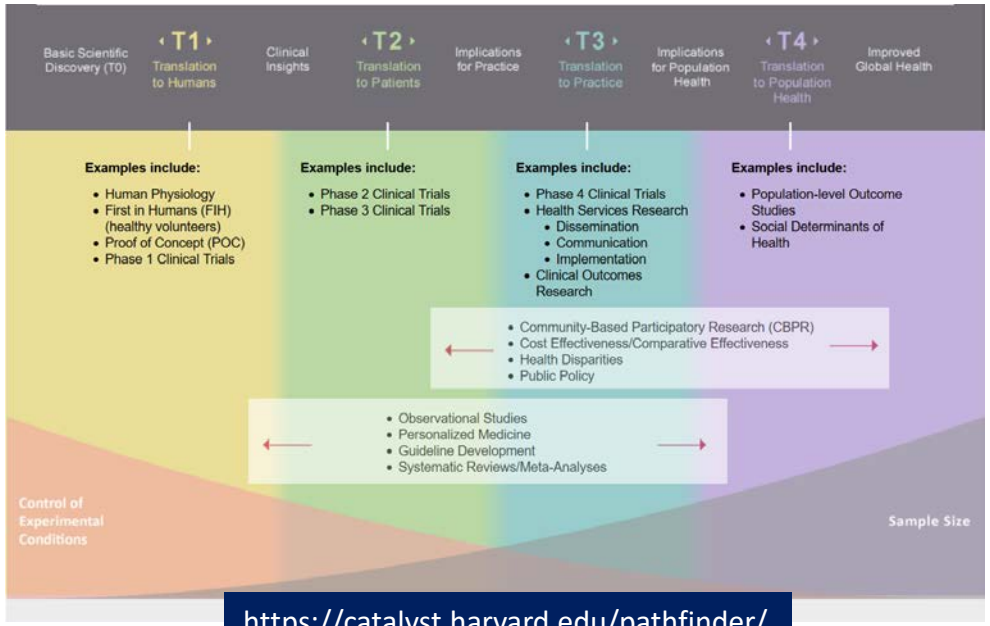
The Clinical and Translational Science Awards (CTSA) program established in 2006

- **Recommendation 3:** Build on the strengths of individual CTSAs across the spectrum of clinical and translational research (IOM, 2013).

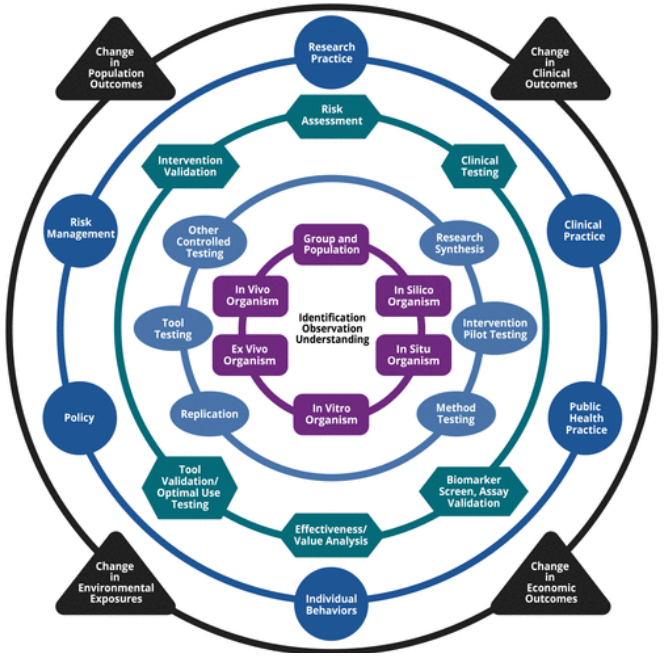
Evaluation Question

Are the CTSAs actually supporting research distributed across the translational spectrum?

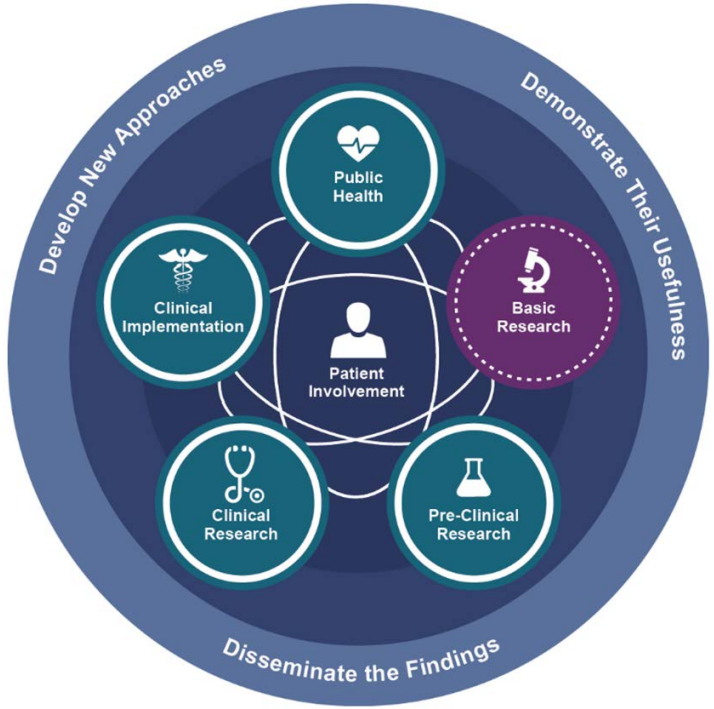
Visual models of the translational research spectrum



https://catalyst.harvard.edu/pathfinder/



Pettibone et al. 2018



https://ncats.nih.gov/translation/spectrum

Our Initial Approach

- Bibliometric analysis of publications has the potential to contribute to a more in-depth understanding of how CTSA support moves research across the translational spectrum

- Surkis A, Hogle JA, DiazGranados D, Hunt JD, Mazmanian PE, Connors E, Westaby K, Whipple EC, Adamus T, Mueller M, Aphinyanaphongs Y. Classifying publications from the clinical and translational science award program along the translational research spectrum: a machine learning approach. *J Transl Med*. 2016 Aug 5;14(1):235.

Our Initial Approach

A CTSA cross-hub collaboration led by NYU with significant contributions from UW-Madison's ICTR Evaluation group developed:

1) a set of definitions in the form of a checklist, vetted by a group of investigators and stakeholders;
2) a machine-learning algorithm that could automatically code publications using those definitions

Surkis et al. 2016 *J Transl Med*

Definitions for each translational phase

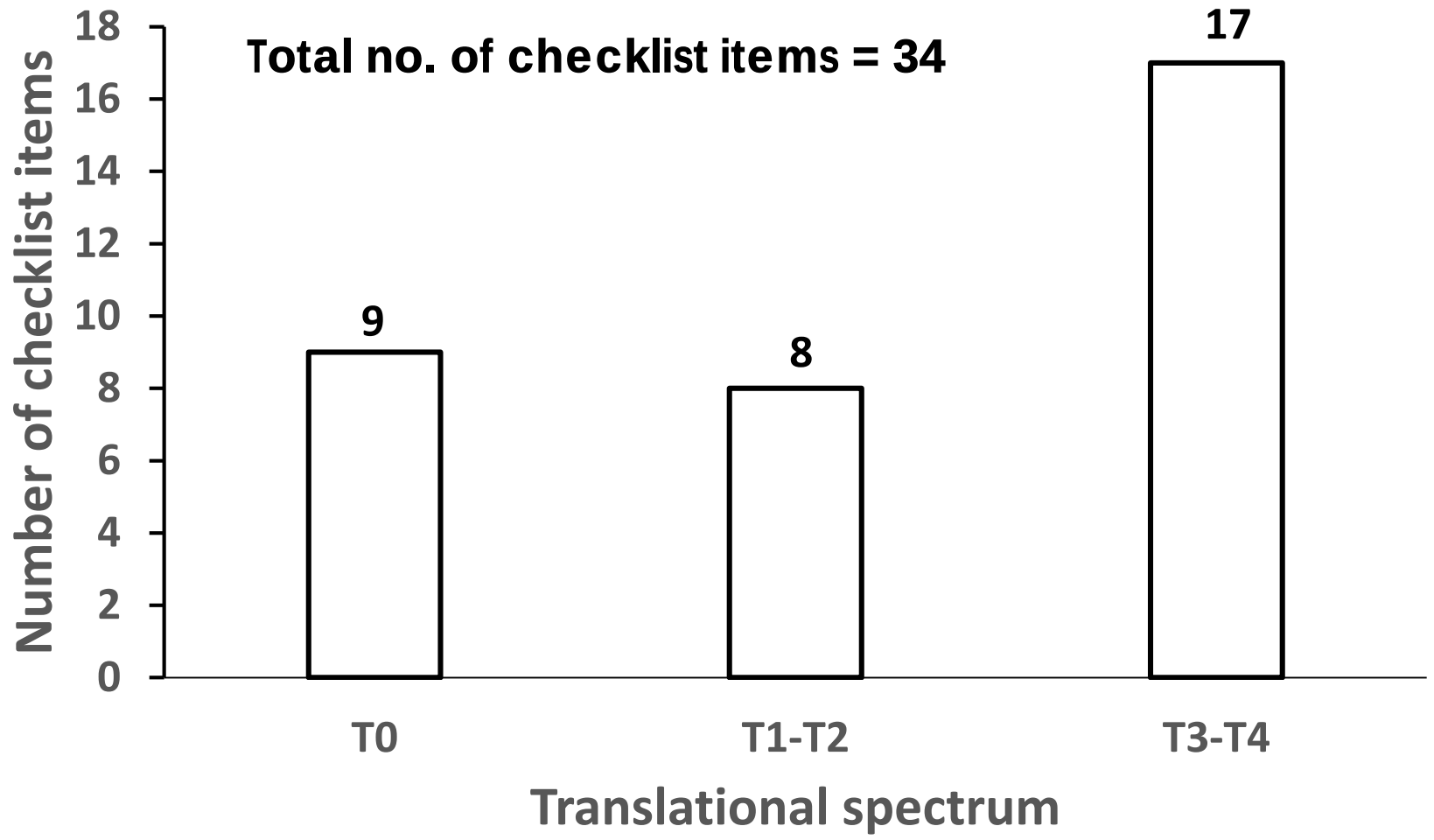
T0	BASIC BIOMEDICAL RESEARCH Identification of opportunities and approaches to health problems. Includes: preclinical and animal studies; GWAS studies; studies of cells, proteins, and DNA; studies on humans or existing datasets that focus on understanding biological, social and behavioral mechanisms that underlie health or disease
T1	TRANSLATION TO HUMANS Seeks to move fundamental discovery into health application; provide clinical insights Includes: Proof of Concept studies; phase 1 clinical trials; studies testing feasibility or safety of a new method of diagnosis, treatment, or prevention
T2	TRANSLATION TO PATIENTS Health application to implications for evidence-based practice guidelines. Includes: Phase 2/3 clinical trials; studies to test efficacy of interventions in highly controlled settings
T3	TRANSLATION TO PRACTICE Practice guidelines to health practices. Includes: Phase 4 clinical trials, comparative effectiveness research, community based participatory research, dissemination and implementation research, clinical outcomes research, health services research, meta-analyses/systematic reviews of interventions, development/implementation of guidelines
T4	TRANSLATION TO COMMUNITIES: Health practice to population health impact, providing communities with the optimal intervention Includes: population-level outcomes research; wider implementation and dissemination; policy impacts; disease prevention through lifestyle/behavior modifications; real-world health outcomes; true benefit to society

Surkis et al. 2016 *J Transl Med*

What we did

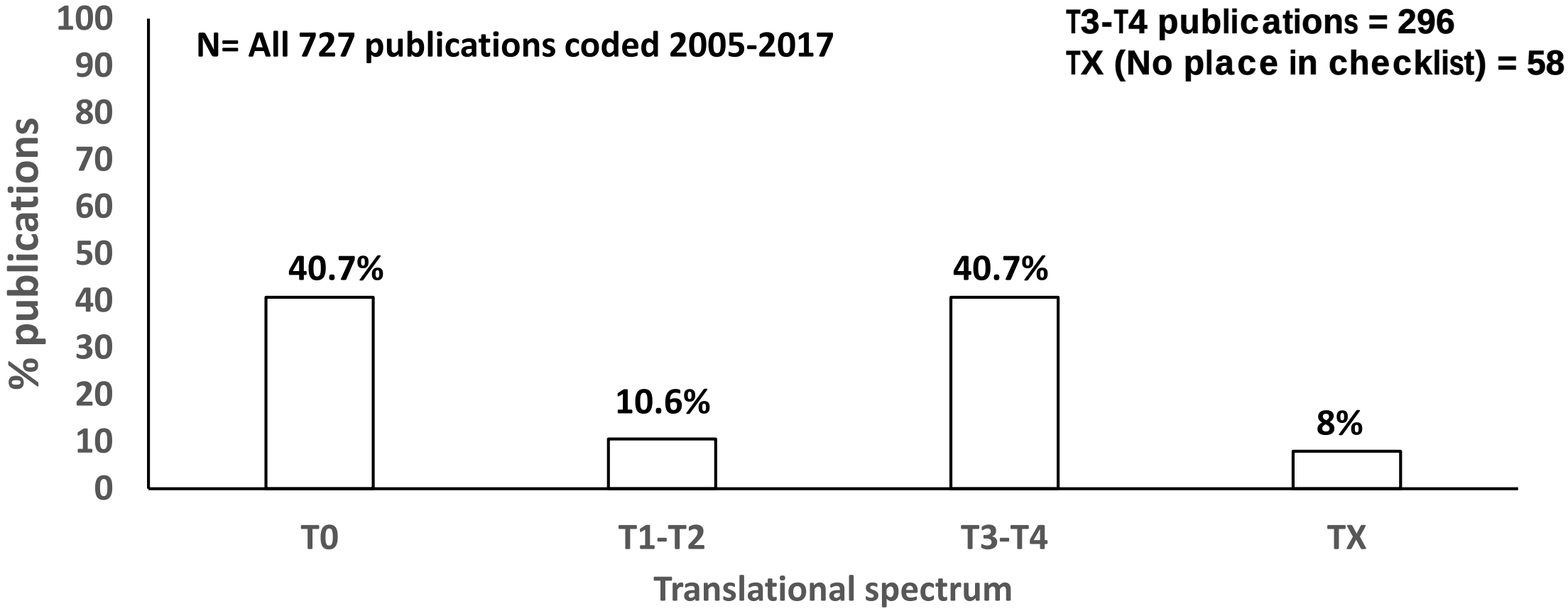
- Manually coded **727 publications** published by ICTR between **years 2005 and 2017**
- Consensus process between 3 evaluators
- Mean **inter-rater reliability** for 2018 rating sessions= 76.2% (N= 207 papers)
- Documented a number of ambiguities and gaps in the set of definitions of translational stages which result in coding challenges
- **116 publications or ~16%** either difficult to code (50%) or did not conform to any checklist item and so labeled as TX (50%)

Uneven distribution of checklist items

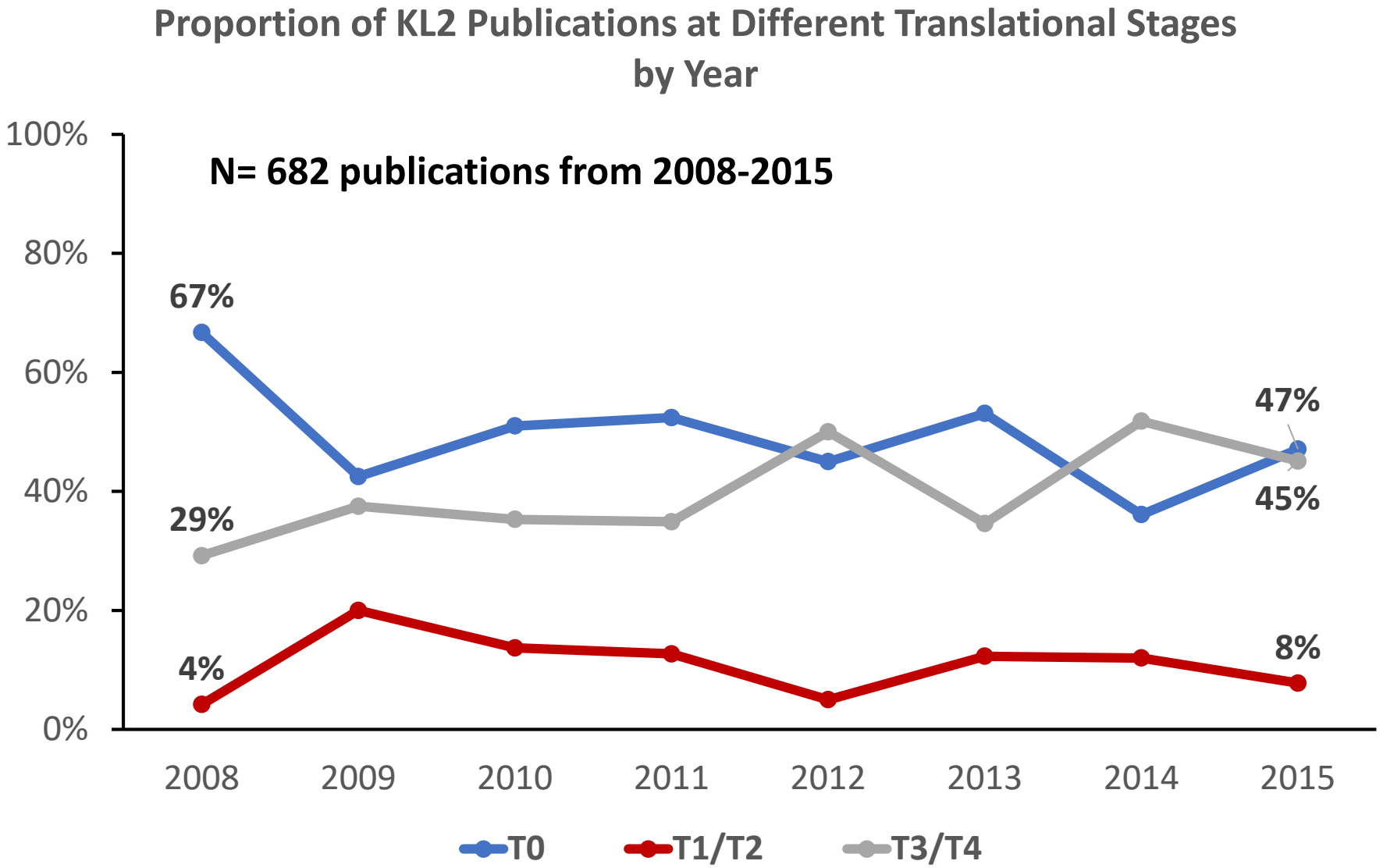


Distribution of T-codes in Publications

T0 publications = 296
T1-T2 publications = 77
T3-T4 publications = 296
TX (No place in checklist) = 58



Application of T-coding to ICTR



Recurring Themes in T-Coding Challenges

TX (Missing in Checklist)	Characteristics
Study Type	Scale-validation studies; Feasibility Studies; Veterinary research; Association studies in T3-T4; Labor force and Race/ethnicity/gender; Calibration of radiological images for diagnostic purposes; Predictive algorithms to determine how likely individuals with certain biomarkers are to develop particular conditions
Publication type	Case Report; Comment; Letters to Editor

Recurring Themes in T-Coding Challenges

Other coding challenges	Characteristics
Definitional issues	What counts as “population”; “new”; “large”?
Study Type	Epidemiological studies with T0/T4 split; Health services research; Framework development; Program development informed by community input/stakeholders

A CTSA-wide Problem

The biomedical research community lacks:

- consistent, specific, and operationalized definitions of translational stages
- reliable, efficient, and scalable methods to analyze and classify the specific products of research, such as publications, by their translational stage.

Manually coding publications: extremely time-consuming

Our Proposal: A Delphi Process

How can we address the ambiguities and gaps in the checklist definitions we developed to come up with a more robust and reliable set of operational definitions to classify research across the translational spectrum?

After the Delphi, conduct a new machine learning process to develop automated scoring algorithm

More Information:

Sainath Suryanarayanan, PhD
ssuryanaraya@wisc.edu

Noelia Sayavedra, MS
nsayavedra@wisc.edu

Linda Scholl, PhD
linda.scholl@wisc.edu

D. Paul Moberg, PhD
dpmoberg@wisc.edu

Institute for Clinical & Translational Research
School of Medicine and Public Health
University of Wisconsin -- Madison
https://ictr.wisc.edu

This project was supported by the Clinical and Translational Science Award (CTSA) program, through the NIH National Center for Advancing Translational Sciences (NCATS), grant **UL1TR000427**. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.