NIA IMPACT
COLLABORATORY
TRANSFORMING DEMENTIA CARE

National Institute on Aging (NIA) IMbedded Pragmatic Alzheimer's Disease (AD) and AD-Related Dementias (AD/ADRD) Clinical Trials (IMPACT) Collaboratory (NIA U54AG063546)

"FINDING PRAGMATIC AND RELEVANT OUTCOMES FOR AD/ADRD ePCTS"

Laura C. Hanson, MD, MPH & Sheryl Zimmerman, PhD

June 18, 2020

Housekeeping

- All participants will be muted
- Enter **all questions** in the Zoom **chat box** and send to everyone
- Moderator will review questions from chat box and ask them at the end
- Want to continue the discussion? Look for the associated podcast released about 2 weeks after Grand Rounds.
- Visit impactcollaboratory.org
- Follow us on Twitter: **@IMPACTcollab1**

What we'll cover

- Outcomes relevant for people living with dementia and their caregivers
- Applying the Alzheimer's Association conceptual framework to link care interventions to outcomes
- Selecting outcome measures for AD/ADRD ePCTs

IMPACT PCRO Core members

Core Lead: Laura C. Hanson, MD, MPH

Executive Committee:

- Antonia Bennett, PhD
- Amy Kelley, MD, MSHS
- Christine Ritchie, MD, MSPH
- Deborah Saliba, MD, MPH
- Joan Teno, MD, MS
- Sheryl Zimmerman, PhD

Core Support:

- Mattias Jonsson
- Stacey Gabriel
- Kathryn Wessell

IMPACT PCRO Core Aims

- Create a **library of Clinical Outcome Assessments (COAs)** relevant to ePCTs enrolling people with AD/ADRD and caregivers
- Define and disseminate **best practices for collecting COAs**
- Provide **guidance and consultation to investigators** on measuring outcomes in the design and conduct AD/ADRD ePCTs

NIH Stage Model for Behavioral Interventions

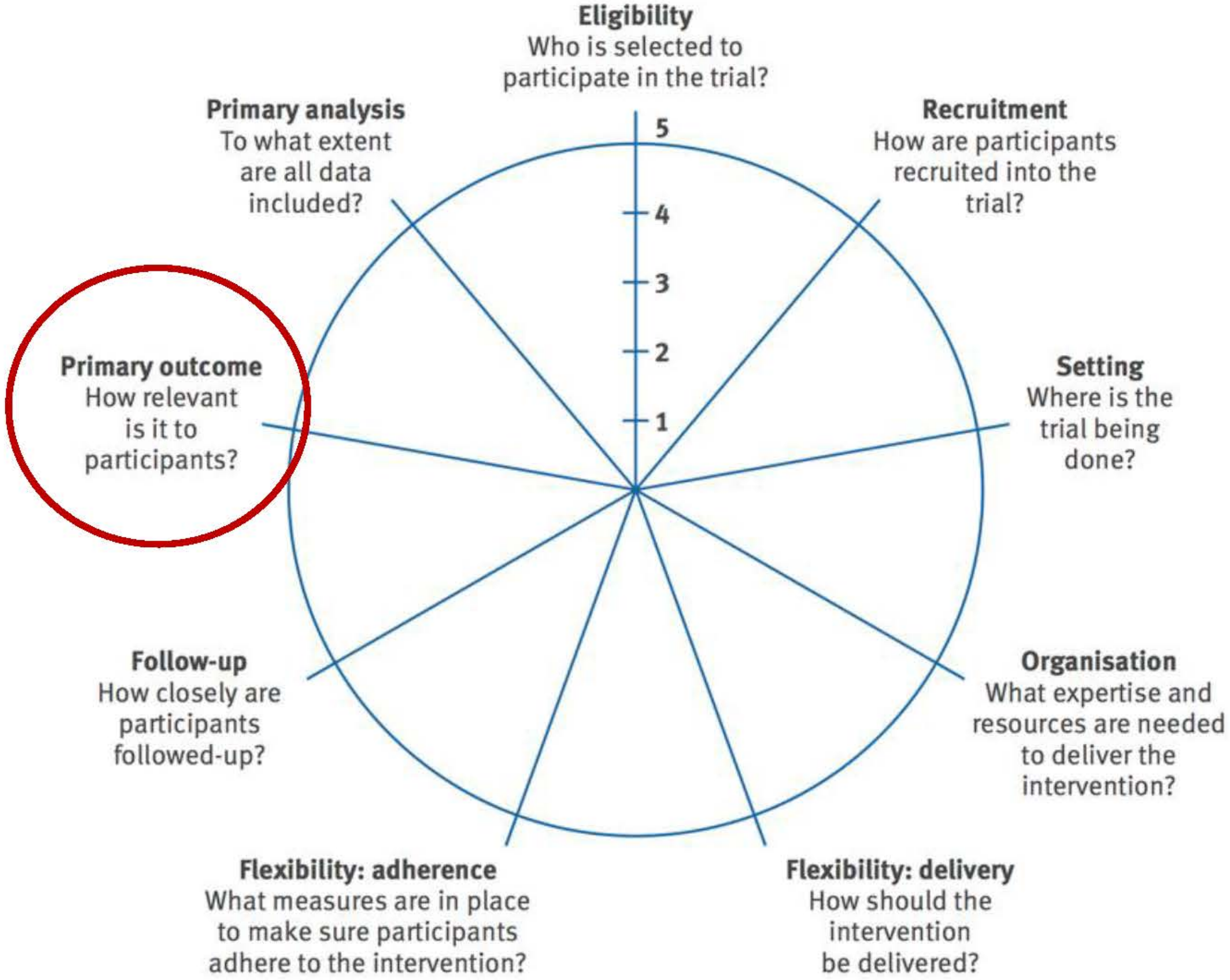
In a single site efficacy trial (Stage II), investigators find that a transitional care intervention tailored for AD/ADRD improves multiple patient- and caregiver-reported outcomes

- *QOL, neuropsychiatric symptoms, caregiver burden, ED transfers*

Are there pragmatic outcomes that are also relevant for people living with dementia and their caregivers?

Onken L et al, Clin Psych Sci 2014

PRECIS-2



Eligibility
Who is selected to participate in the trial?

Recruitment
How are participants recruited into the trial?

Setting
Where is the trial being done?

Organisation
What expertise and resources are needed to deliver the intervention?

Flexibility: delivery
How should the intervention be delivered?

Flexibility: adherence
What measures are in place to make sure participants adhere to the intervention?

Follow-up
How closely are participants followed-up?

Primary outcome
How relevant is it to participants?

Primary analysis
To what extent are all data included?

RAPT Model


Implementation protocol
Is the protocol sufficiently detailed to be replicated?

Evidence
To what extent does the evidence base support efficacy?

Risk
Do we know how safe the intervention is?

Feasibility
To what extent can the intervention be implemented under existing conditions?

Measurement
To what extent can outcomes be captured?

Cost
How likely is the intervention to be economically viable?

Acceptability
How willing are providers likely to be to adopt the intervention?

Alignment
To what extent does the intervention align with external stakeholders' priorities?

Impact
How useful will the outcomes be?

Person-centered outcome domains

- Survival
- Function
- Cognitive function
- Symptoms
- Neuropsychiatric distress
- Quality of life
- Quality of communication
- Quality of care

Zimmerman S, JPSM 2015; Ersek M, Pain Med 2010

Caregiver-centered outcome domains

Caregiver health / well-being

- Quality of life
- Physical / psychological health

Caregiving experience

- Burden / strain / benefit
- Time in caregiving
- Loss of employment
- Healthcare decision-making
- Care coordination
- Preparedness

Challenge: Gaps in Existing Measures

- Are based on a medical model; focus on deficits
- Were largely not provided with input from PWD
- May not be relevant as the disease progresses
- Do not exist for numerous domains
- Are not oriented toward quality improvement
- Lack validation for diverse populations

Challenge: Data Capture for Existing Measures

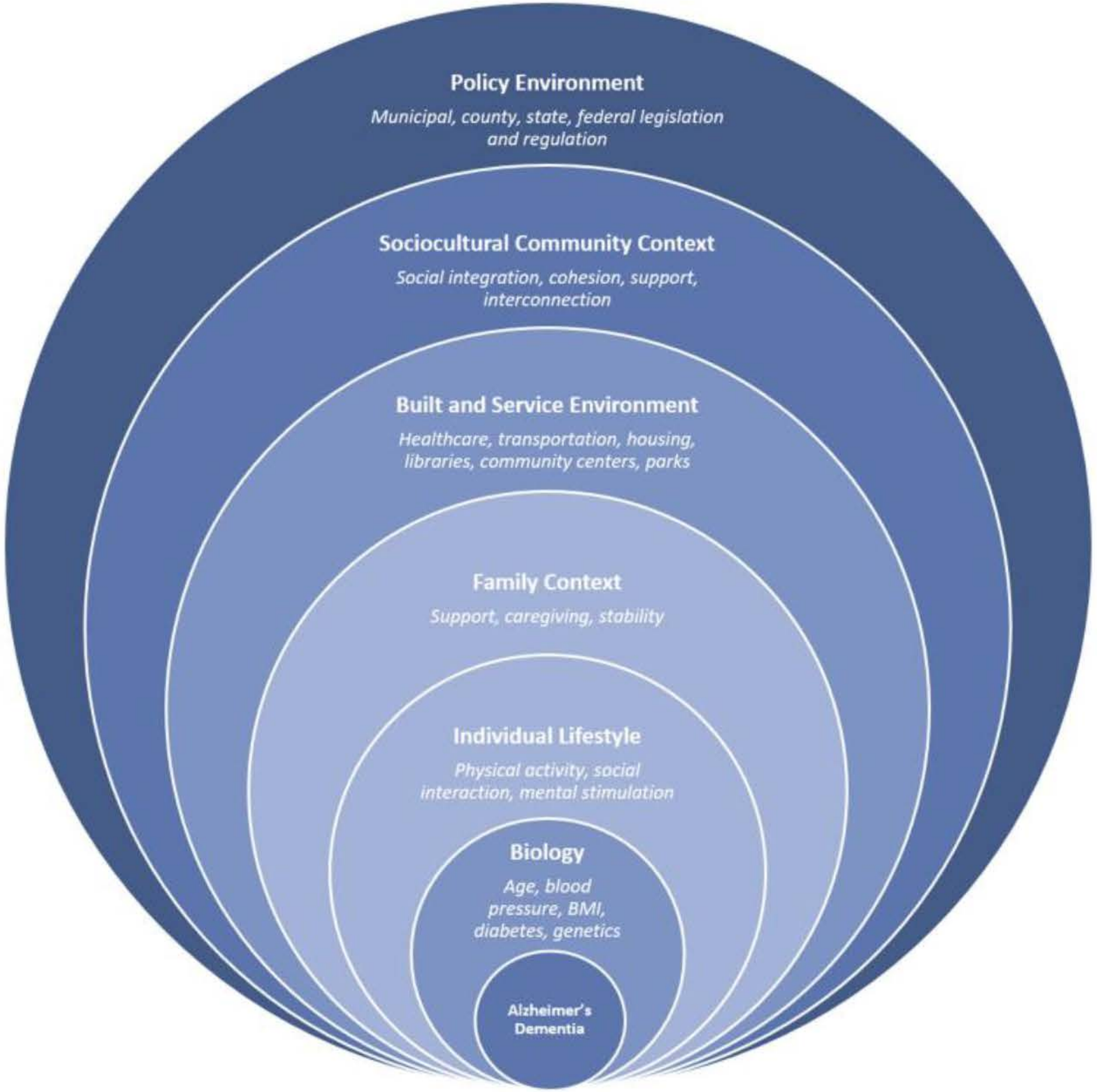
- Require time-intensive informant reporting
- Lack consistent approaches for person vs proxy reporting
- Rarely embedded in routine and systematic clinical data sources
- Do not cross all care settings

Conceptual framework

Systems Perspective

The experience of ADRD is imbedded within ….

- Biology
- Individual lifestyle
- Family context
- Built and service environment
- Sociocultural community context
- Policy environment



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Reconsidering Frameworks of Alzheimer's Dementia When Assessing Psychosocial Outcomes
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6708985/

Defining Quality Dementia Care

Alzheimer's Association: 1992-2009

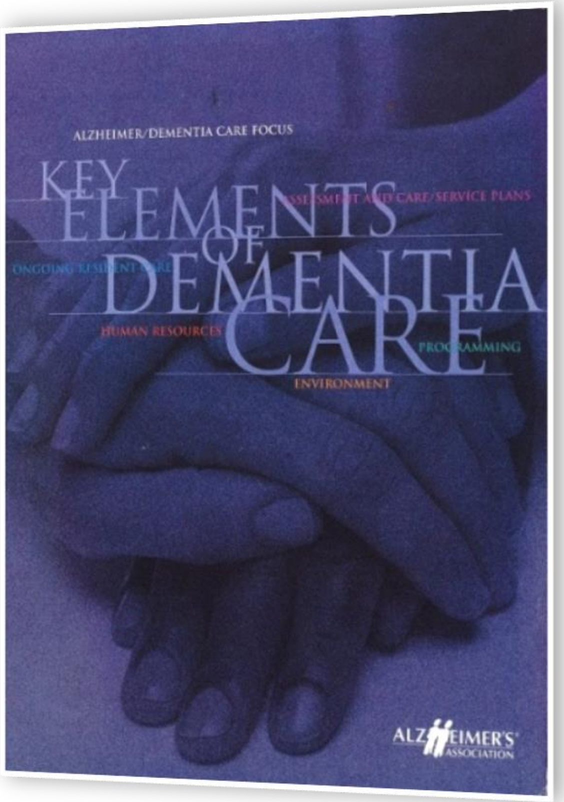
Guidelines for Dignity:

Goals of Specialized Alzheimer / Dementia Care
in Residential Settings

"A Wave" by Helen

July 1992

ALZHEIMER'S
Someone to Stand By You



ALZHEIMER/DEMENTIA CARE FOCUS

KEY ELEMENTS OF DEMENTIA CARE

ASSESSMENT AND CARE/SERVICE PLANS

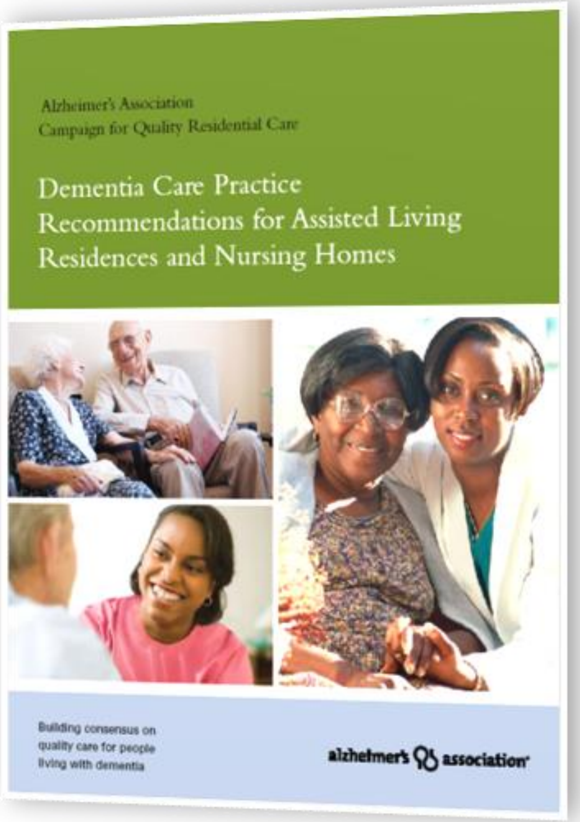
ONGOING RESIDENT CARE

HUMAN RESOURCES

PROGRAMMING

ENVIRONMENT

ALZHEIMER'S ASSOCIATION



Alzheimer's Association
Campaign for Quality Residential Care

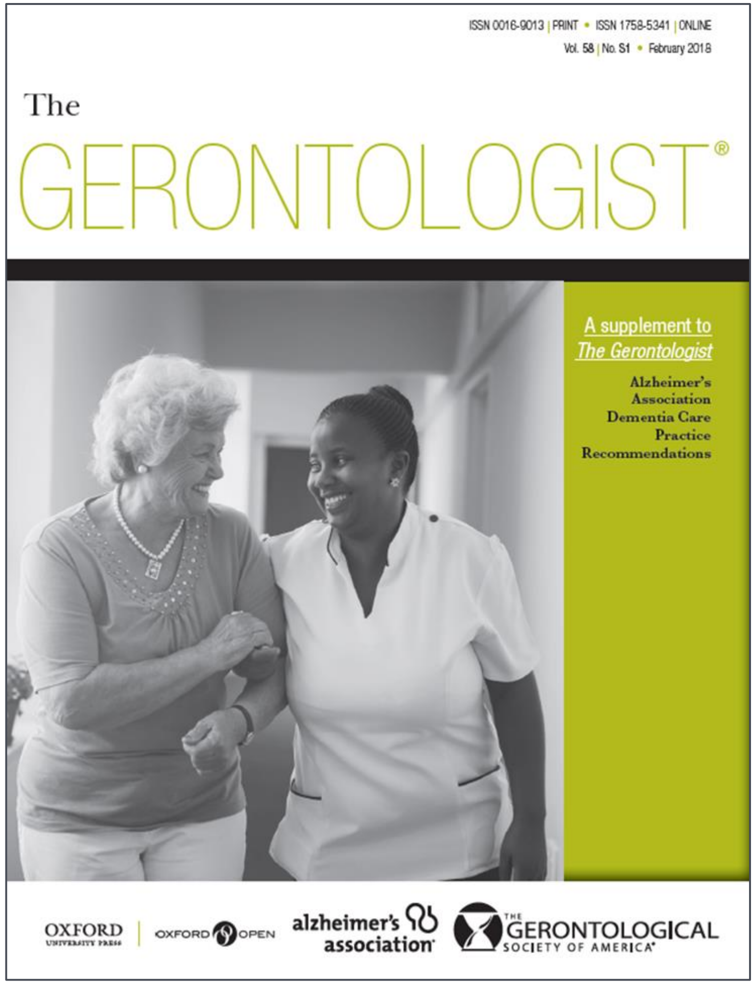
Dementia Care Practice
Recommendations for Assisted Living
Residences and Nursing Homes

Building consensus on
quality care for people
living with dementia

alzheimer's association

2018:Dementia Care Practice Recommendations

- Evidence-based practices
- 56 recommendations by 27 expert authors
- Applicable to any care settings and throughout the disease continuum
- Published as a supplement to the February 2018 issue of *The Gerontologist*
- Foundation for quality person-centered care



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The
GERONTOLOGIST®

A supplement to
The Gerontologist

Alzheimer's Association Dementia Care Practice Recommendations

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alzheimer's association
THE GERONTOLOGICAL SOCIETY OF AMERICA

Practice Recommendations: Conceptual Framework

Person-Centered Focus

Detection and Diagnosis

Assessment and Care Planning

Medical Management

Information, Education and Support

Dementia-Related Behaviors

Activities of Daily Living

Workforce

Supportive and Therapeutic Environment

Transition and Coordination of Services

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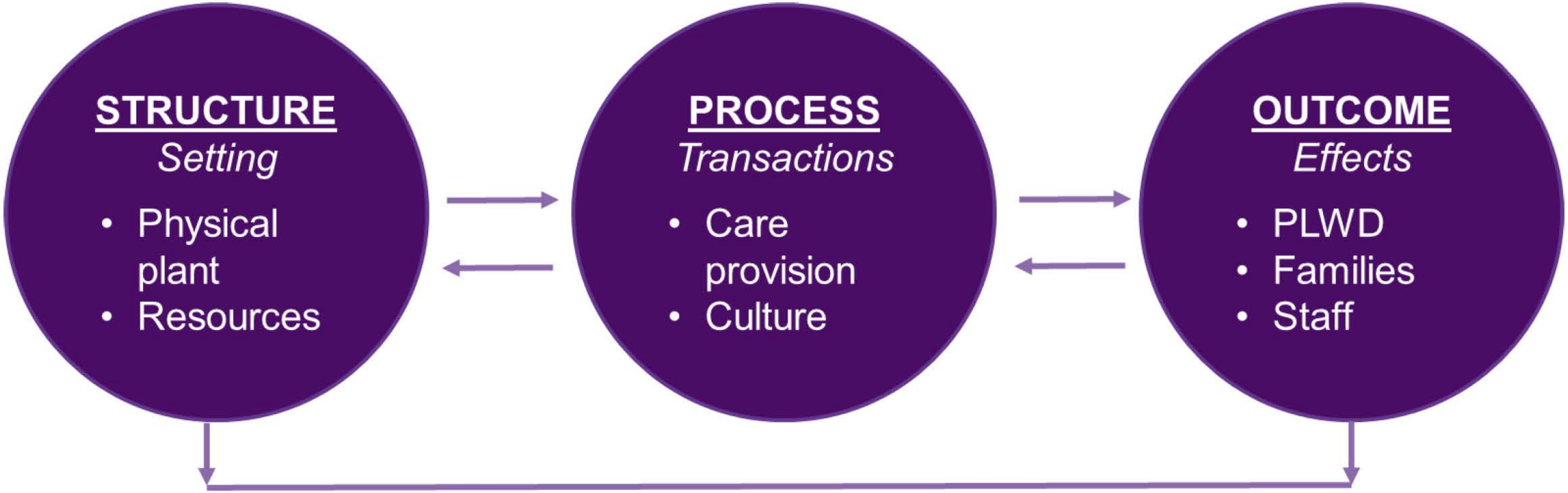
Alzheimer's Association. Dementia Care Practice Recommendations.
https://alz.org/professionals/professional-providers/dementia_care_practice_recommendations

Select Evidence-Based Care Recommendations

- Detection and diagnosis: Assessment and referral
- Assessment and care planning: Advance planning
- Medical management: Person-centered planning for crises
- Information, education, and support: Culturally sensitive programs
- Ongoing care for ADLs: Functional support
- Dementia-related behaviors: Non-pharmacological practices
- Workforce: Collaboration, leadership
- Supportive and therapeutic environment: Meaningful engagement
- Transitions and coordination of services: Communication

Donabedian Model of Health Care Quality

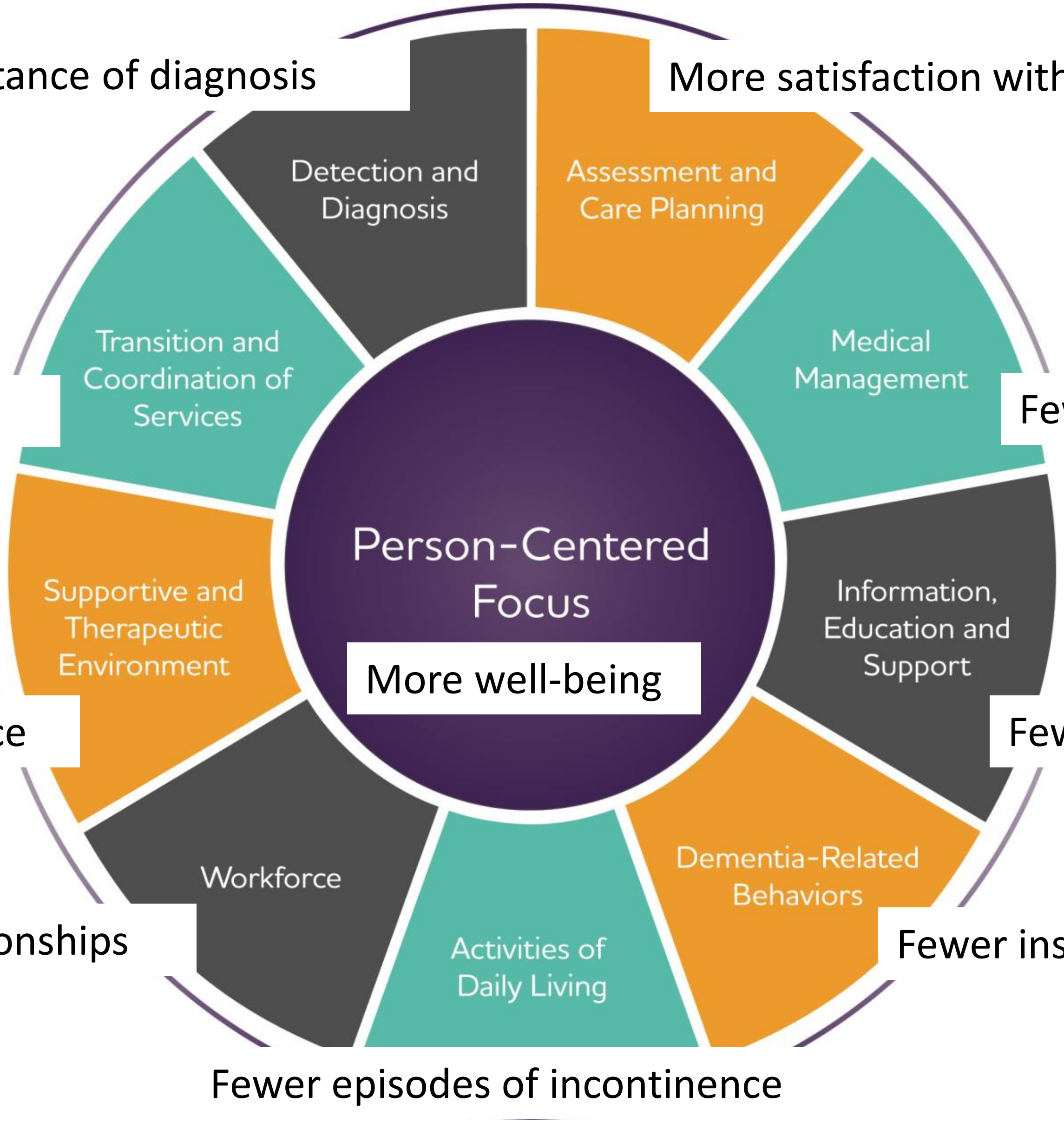


STRUCTURE
Setting
- Physical plant
- Resources

PROCESS
Transactions
- Care provision
- Culture

OUTCOME
Effects
- PLWD
- Families
- Staff

Domain-Targeted Measures: “Well-Being”



Easier acceptance of diagnosis

More satisfaction with care choices

More readiness for death

Fewer medical events

More well-being

More feeling of choice

Fewer crises over time

More satisfactory relationships

Fewer instances of agitation

Fewer episodes of incontinence

Behavioral and Social Research Network

LINC-AD

Leveraging an **In**terdisciplinary **C**onsortium to

Improve Care and Outcomes

for Persons Living with **A**lzheimer's and **D**ementia

Funded by the National Institute on Aging (R24AG065185)

Overarching Goal of LINC-AD

- Broaden interdisciplinary interest in measuring person-centered outcomes that …
  - Foster a constructive balance between strengths and deficits assessment
  - Add a new emphasis on evidence-based tools to guide structures and processes of care
  - Provide a novel conceptual framework to inform measurement and care

Aims and Opportunities of LINC-AD

1. **Critique existing outcome measures and care tools within each of the nine domains of the dementia care practice recommendations, and identify gaps.**
    - Publication in *Alzheimer's & Dementia: Translational Research & Clinical Interventions*

2. **Promote the development of new outcome measures and care tools to fill identified gaps.**
    - Call for papers for *Alzheimer's & Dementia: Translational Research & Clinical Interventions*
    - Alzheimer’s Association International Grant Program competitive seed grants

3. **Facilitate the dissemination, adoption, implementation and sustained use of existing and new outcome measures and care tools, aligning with the nine domains of the DCPR.**
    - Online repository of recommended measures and care tools – linked with IMPACT
    - Corresponding data-sharing database – linked with IMPACT

LINC-AD Members

Leadership Team

- Sam Fazio, PhD (sfazio@alz.org)
- Sheryl Zimmerman, PhD (Sheryl_Zimmerman@unc.edu)
- Joanne Pike, DrPH, Heather Snyder PhD, Maria Carrillo, PhD

Research Advisors

Research Steering Committee

Care and Support Advisors

Initial Measurement Recommendations

- Adopt a unifying lexicon
- Include domain-specific and overarching measures
- Bring a diversity lens to measurement
- Evaluate sufficiently important/meaningful differences
- Consider emerging/latent areas of measurement
- Assure measures are applicable across the diversity of settings
- Avoid stigma in measurement
- Focus on pragmatic measures

Outcomes for AD/ADRD ePCTs

Challenge: relevant outcomes for AD/ADRD ePCTs

Outcomes are **relevant** when they reflect an important dimension of the lived experience of AD/ADRD

- Person / caregiver reported outcomes

Outcomes are **pragmatic** when data capture uses existing data sources embedded in clinical settings

- Electronic health record
- Administrative data sources

Outcome data capture methods

PCROs

- Person-reported outcomes
- Caregiver-reported outcomes
  - Proxy respondent for the person with dementia
    - Throughout research study
    - When person loses capacity
  - Research participant
    - Primary focus of study

Existing data sources

- Federally administered datasets
- Electronic health records
- Administrative data

Person / caregiver-reported outcomes

Questionnaires for self-report of the lived experience of dementia and dementia caregiving

- STRENGTH - Values voice of the person
- STRENGTH – Instruments with established psychometrics
  - Validity, reliability, responsiveness
- CONSIDER - Instruments are valid for context
  - Adaptation for proxy reporting (observable phenomena)
  - Adaptation from original validation
  - Cultural appropriateness and language

Person / caregiver-reported outcomes

- CONSIDER mode(s) of administration – in-person, telephone, written, electronic
  - Self-administered
  - Support for completion
- ADDRESS burden on respondents – number of items, time required
- ADDRESS costs to administer and track

Consensus-Based Standards for the Selection of Health Measurement Instruments (COSMIN). http://www.cosmin.nl/index.php

Person / caregiver-reported outcomes

SUCCESS for person with ADRD / caregiver

- Survey content is highly relevant to lived experience
- Research staff establish rapport with respondent
- Surveys are easy to complete (embedded administration, burden)

SUCCESS for the research team

- Clinical relevance and psychometric strengths of outcome
- Protocol for data capture is rigorous
- Health system buy-in
- Adequate staff time

Outcomes from existing data sources

Federally administered datasets

- Minimum Data Set (nursing home)
- Hospice Item Set (hospice)
- Hospice CAHPS (hospice)
- OASIS (home health) – cognitive function
- Electronic health record (hospital +/- nursing home)

Not available

- Home caregiving
- Assisted living
- Adult day care

Outcomes from existing data sources

Data captured for clinical or administrative purposes, available for use as outcome measures in embedded clinical trials

- STRENGTH – uniformly collected
- STRENGTH – data completeness
- STRENGTH – low burden, low cost; pragmatic
- CONSIDER – timing relative to clinical trial intervention
- CONSIDER – “match” between intervention and measure
- ADDRESS – need to validate against PCRO

Outcomes from existing data sources

SUCCESS for person with ADRD / caregiver

- Burden is minimal
- Reflection of highly relevant aspects of healthcare experience

SUCCESS for the research team

- Data capture is more complete
- Data capture is more uniform across multiple sites
- Costs and burden are low

Example Clinical Outcome Measures for ePCTs

Outcome Domain	Clinical Outcome Tool	Measure Type	Methods for Data Capture
Detection and diagnosis	Brief Interview for Mental Status (BIMS)	Person-reported outcome	Embedded in Minimum Data Set
Assessment and care planning	Preference Assessment Tool (PAT)	Person-reported outcome	Embedded in Minimum Data Set
Medical management	Pain Assessment in Advanced Dementia (PAIN-AD)[57]	Clinician-reported outcome	Brief clinician observational tool with 5 items for pain behaviors; suitable for embedding in EHR
Information, education and support	Short-form Zarit Caregiver Burden Interview[58]	Caregiver-reported outcome	Brief survey in formats ranging from 1-6 items, suitable for embedding in EHR
Dementia related behaviors	Confusion Assessment Method (CAM)	Clinician-reported outcome	Embedded in Minimum Data Set[49]; suitable for embedding in EHR
Activities of daily living	Short Functional Survey	Clinician-reported outcome	Embedded in Minimum Data Set; suitable for embedding in EHR
Workforce	Staff hours in direct caregiving	Utilization outcome	Administrative data sources
Supportive and therapeutic environment	Caregiver report of quality of hospice care	Caregiver-reported outcome	CAHPS Hospice survey
Transition and coordination of services	Hospital transfers	Utilization outcome	Administrative data sources or EHR
Person centered	Dementia Quality of Life – Care Home (DEMQOL-CH)[59]	Clinician-reported outcome	Staff survey with items suitable for embedding in EHR; subsets of items capture engagement, function, positive emotion or negative emotion

RETURN to example / story

In a single site efficacy trial, investigators find that a transitional care intervention tailored for AD/ADRD improves multiple patient- and caregiver-reported outcomes

- *QOL, neuropsychiatric symptoms, caregiver burden, ED transfers*

To prepare for a multi-site ePCT, investigators

- Operationalize ED transfers (primary outcome) in administrative data
- Establish association between QOL PRO and ED transfers
- Affirm health system will embed brief caregiver measure in EHR

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QUESTIONS?