

# Alzheimer's Disease: A Rapid-Learning System

Lynn Etheredge  
National Advisory Council on Alzheimer's Research, Care, and  
Services  
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## Fundamental Challenge

- Create a rapid learning health system to advance and deliver much better prevention and treatment for each patient
  - Health sector: 315 M; 17 % of GDP; complex, variable, dynamic, pluralist & public-private; many therapies that aren't very effective; underused IT
  - Learning (now): limited #s of patients & researchers, data poor, slow, expensive, RCT-focused, with many gaps; slow delivery-system learning/use of best practices

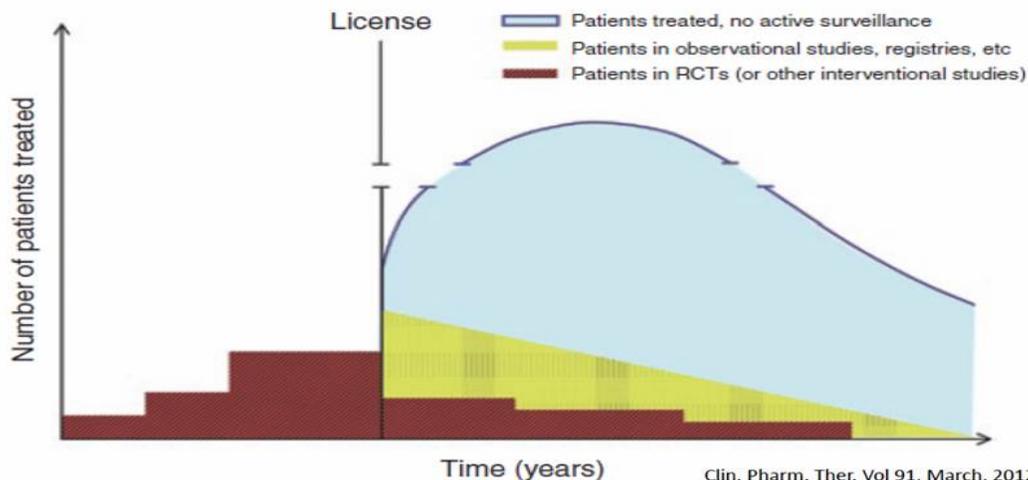
# Toward A Rapid-Learning Health System

- HIT-EHRs, big data, and learning networks are starting to change every aspect of healthcare.
- Accelerating biomedical research
  - NIH: Biobanks w/EHRs & genomics, 20-30M patient research networks, BD2K. VA: Million veterans biobank
- Learning what works
  - FDA: Sentinel (125 M patients). PCORI: national CER system & databases
- Delivering better care
  - EHRs national use, CMS \$10 B innovation center & ACOs, large health plans

# A Rapid Learning Model

- Research: Faster progress in biomedical research, prevention, and treatment requires large-scale databases (millions of patients), data-sharing, and research collaboration
  - Cancer research has shifted to genetics, pathways, & “precision medicine”. Most cancers involve 2-8 sequential alterations over 20-30 yrs, a dozen signaling pathways (Vogelstein 2013). Likely similarities for many chronic conditions, e.g. Alzheimer’s
  - Recent NIH large data initiatives include: Cancer Genome Atlas, 3 open science “data clouds”, international data-sharing agreement; 20-30M patient data registry network
- An enormous potential for learning much more, much more rapidly – from *national data strategies that are now possible*

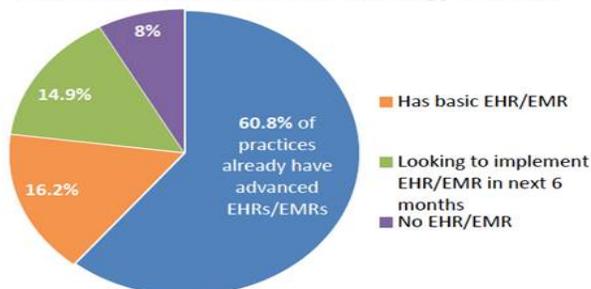
## Data from 97% of Cancer Care is Lost



## Health Information Technology Revolution

- Widespread adoption of EHRs by physicians and hospitals
- Improved data processing and storage capacities
- Rapid analysis tools
- Advances in natural language processing

2012: EHR/EMR Use in U.S. Oncology Practices



Source: Forte, GJ, et al. "American Society of Clinical Oncology National Census of Oncology Practices: Preliminary Report." JOP January 2013 vol. 9 no. 19-19



## A Rapid-Learning Model

- Assessment: Much faster learning will be possible about what works best for individual patients
  - 1,000 targeted cancer drugs now in development
  - For new targeted cancer therapies that show persuasive evidence of effectiveness (e.g. 30%-60%), FDA is considering reducing or eliminating Phase 3 RCTs
  - FDA Sentinel system: 24 hour studies (125 M patients) vs. 5 yrs +

## A Rapid-Learning Model

- Implementation: A rapid-learning system involves *researchers, biotech, physicians, patients, families, delivery systems, and payers*
  - ASCO's rapid-learning cancer system (CancerLinQ database for all cancer patients + IBM's Watson)
  - CMS \$10B Innovation Center for national rollout of best practices (patient safety (60,000 lives), million hearts, strong start; 40+ models)

# #1. Alzheimer's: Rapid-Learning

- **Build an international Alzheimer's Disease learning network with large research databases.**
  - US RL data infrastructure (current):
    - VA (8 M, age 65+), HMO Research Network (14M); NIH databases & research studies; FDA's clinical data repository; Medicare Chronic Disease Warehouse (32 M, 1999-2011); United-Optum & Wellpoint (30M+ enrollees each); FDA Sentinel (125M); PCORI registries
    - Alzheimer's registries and networks (e.g. NIA), CAMD pharmaceutical industry initiative
- **Many technical and policy/administrative issues will need to be identified and resolved. A collaborative effort, with data-sharing.**

## A Case For Data-Sharing

- **If 10 institutions each share 100 cases**
  - Database = 1,000 cases
  - *Every* institution gets 900 added cases for a contribution of 100 = 9:1
- **If 100 institutions each share 1,000 cases**
  - Database = 100,000 cases
  - *Every* institution gets 99,000 added cases for a contribution of 1,000 = 99:1
- **Data-sharing is a high pay-off strategy. More data-sharing multiplies benefits.**

## #2. Alzheimer's: Rapid-Learning

- Build the Alzheimer's data system as part of a national EHR-HIT strategy
- Develop a downloadable EHR "App" (or module) for patients with Alzheimer's and dementia
  - Supports standardized data collection and reporting to national Alzheimer's research registries
  - Supports two-way communications to physicians about best practices, practice guidelines, decision support
  - Includes patient & family reported data, information and involvement
  - One-click access to key resources, e.g. MedlinePlus, Alzheimer's Association, support networks for physicians and patients
  - Could be used to demonstrate adherence to requirement for test of cognitive impairment, quality reporting & new payment incentives
- Federal requirement: all HHS-supported EHRs accept and work with this App

## #3. Alzheimer's: Rapid Learning

- Develop and advance "best practices" models for Alzheimer's disease
  - Project ECHO (New Mexico)
- Use CMS's innovation authorities and \$10 B funding to roll these out nationwide for Medicare and Medicaid patients
  - Home and community-based care

## Summary

- #1. A large international learning and data-sharing network
- #2. An EHR-Apps initiative
- #3. National rollout of best practices

“How much faster can we learn?” is now a question to which new answers can evolve for Alzheimer’s Disease.