

“Caring for Every Patient, Learning from Every Patient”

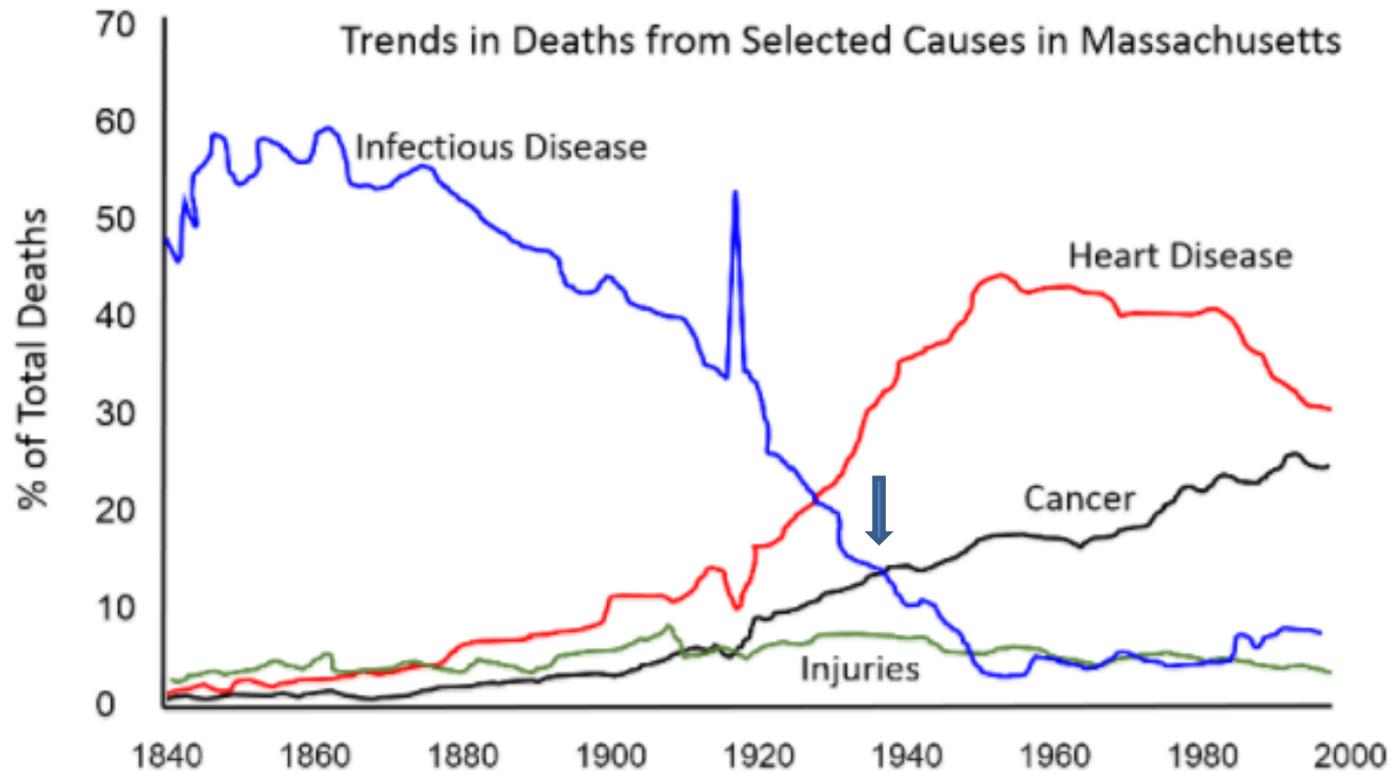
Building a Learning Health Care System



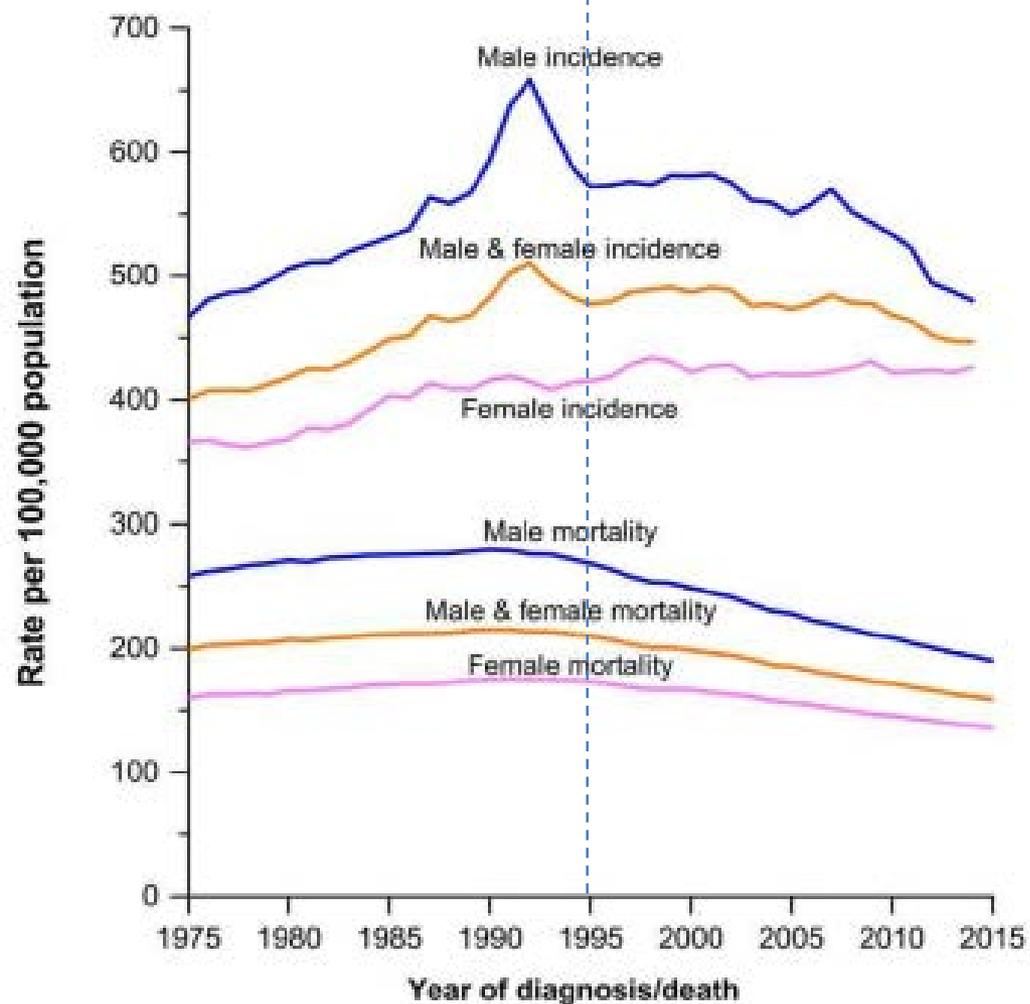
Monica M. Bertagnolli, MD
President, American Society of Clinical Oncology

Disclosures

- Research funding to the Alliance for Clinical Trials in Oncology Foundation
 - AbbVie
 - Agenus
 - Astellas
 - AstraZeneca
 - Baxalta
 - Bayer HealthCare
 - Breast Cancer Research Foundation
 - Bristol-Myers Squibb
 - Celgene
 - Complion
 - Czarnowski
 - Derse, Inc.
 - Eisai
 - Exelixis
 - Genentech
 - GHI
 - Gilead Sciences
 - GSK Total
 - Incyte Corporation
 - Janssen
 - Jazz Pharma
 - Leidos
 - Lexicon Pharma
 - Lilly
 - Maltrex
 - Merck
 - Millennium
 - Novartis
 - Pfizer
 - Pharmacyclics
 - Robert Wood Johnson Foundation
 - Roche/Genentech
 - Sagerock Advisors
 - Sanofi
 - STO
 - Taiho Oncology
 - Takeda
 - Tesaro
 - Teva

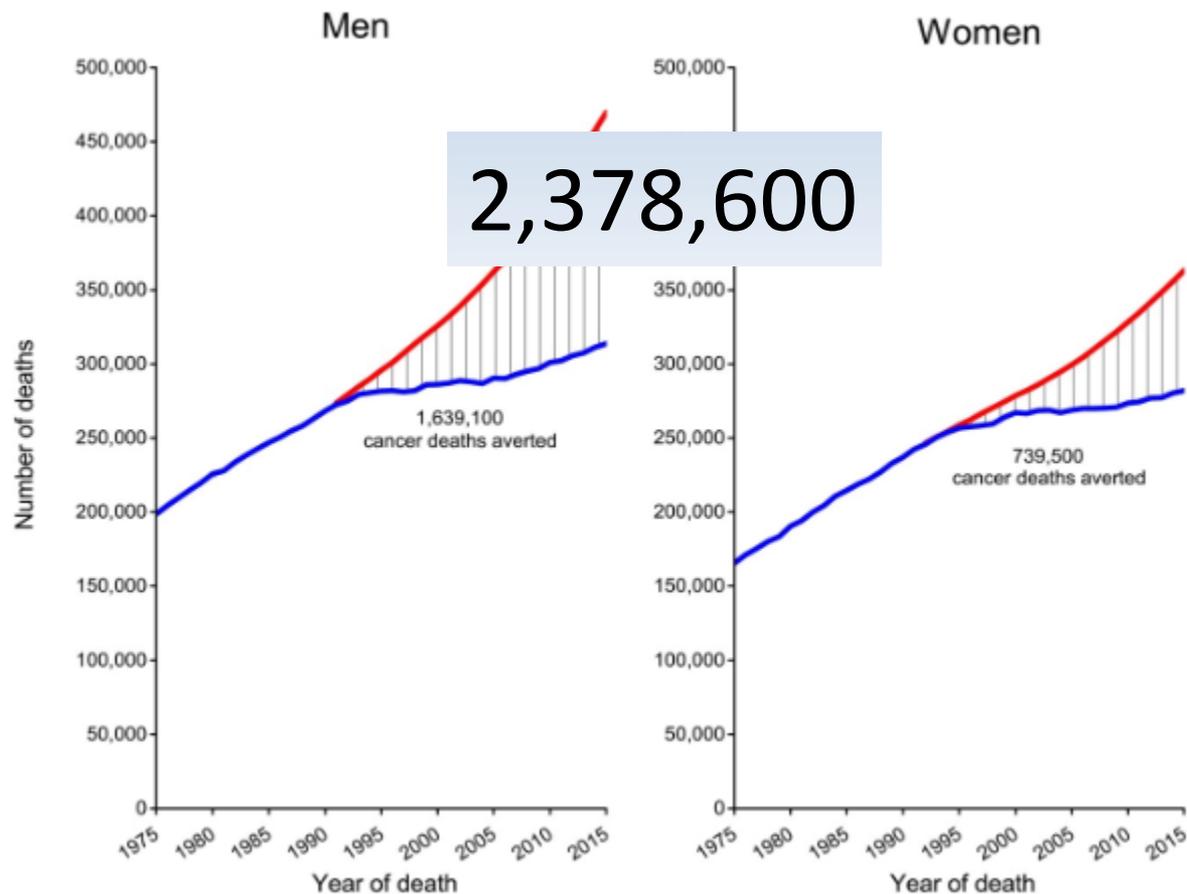


National Cancer Act, 1937
National Cancer Institute



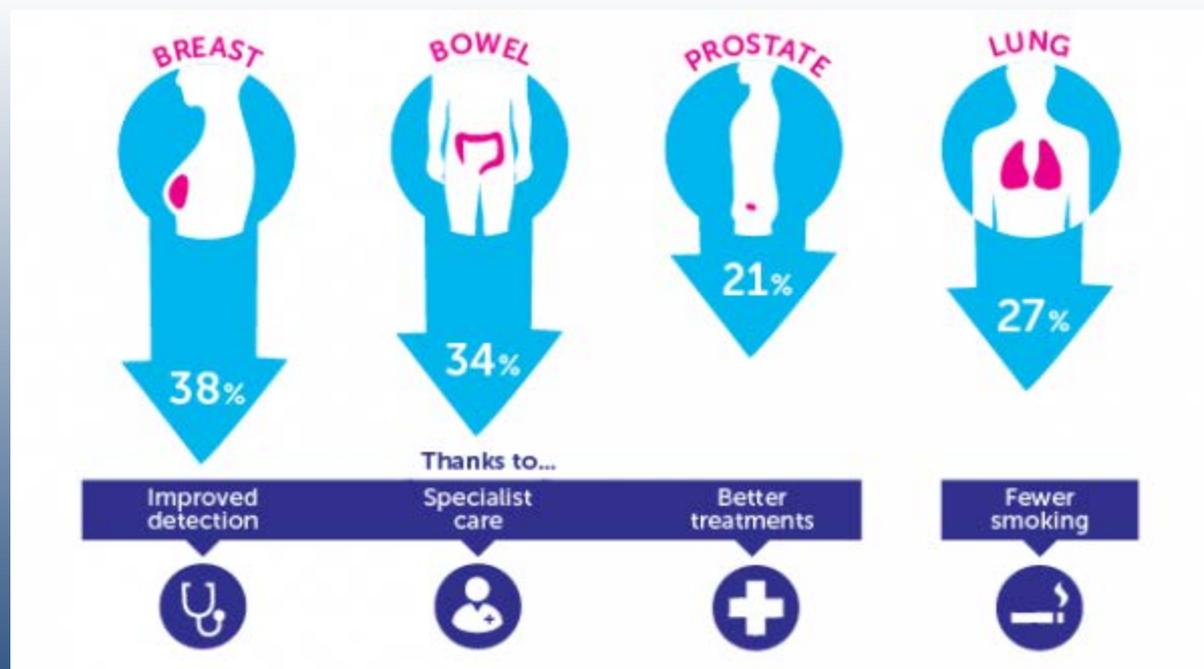
Cancer statistics, 2018

Rebecca L. Siegel MPH, Kimberly D. Miller MPH, Ahmedin Jemal DVM, PhD



What bent the curve?

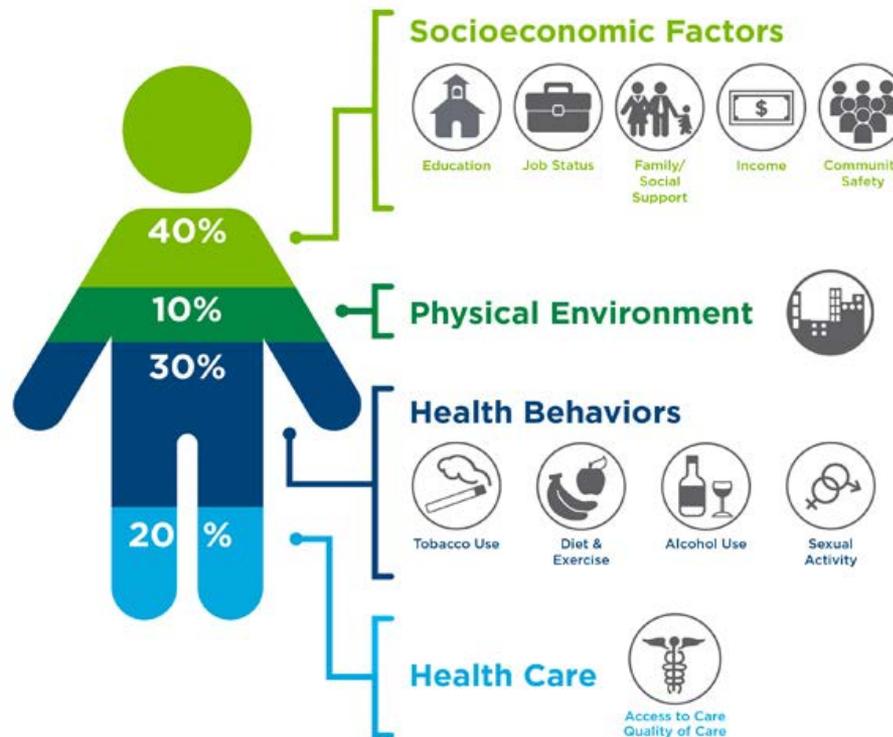
- Surgery, radiation therapy: safer, less morbidity
- Earlier detection - mammography
- Prevention – colonoscopy, smoking cessation, vaccines, anti-viral therapy
- Hormone therapy/chemotherapy



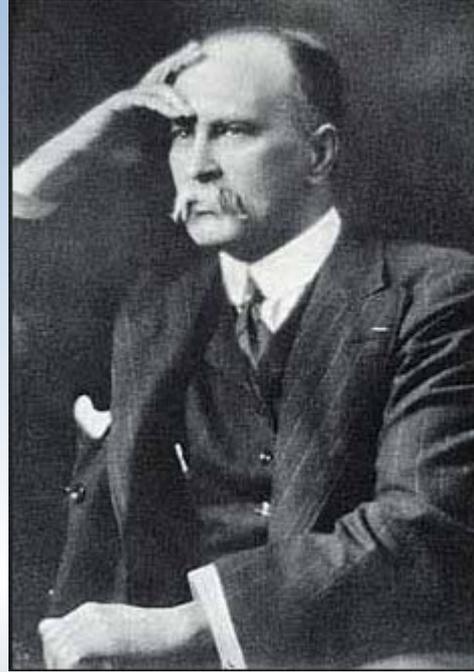
Cancer clinical research:

Developing and disseminating the tools to overcome cancer

What Goes Into Your Health?



Source: Institute for Clinical Systems Improvement, Going Beyond Clinical Walls: Solving Complex Problems (October 2014)



Medicine is a science of
uncertainty and an art
of probability

William Osler

CLINICAL RESEARCH CHANGING PATIENT CARE



↑
Case series with
careful follow-up

Individual Institution
Surgeon
Radiation Therapist
Pathologist

CLINICAL RESEARCH CHANGING PATIENT CARE



Randomized Controlled Trials;
Prospective Longitudinal Cohort Studies

Multi-Institutional Consortia
Surgeon
Radiation Therapist
Pathologist
Medical Oncologist
Statistician

CLINICAL RESEARCH CHANGING PATIENT CARE



Marker-Driven Adaptive Designs
Comparative Effectiveness Research
Molecularly-Defined Disease Cohorts

Real World
Data

Multiinstitutional Research Consortia
Academic-Community

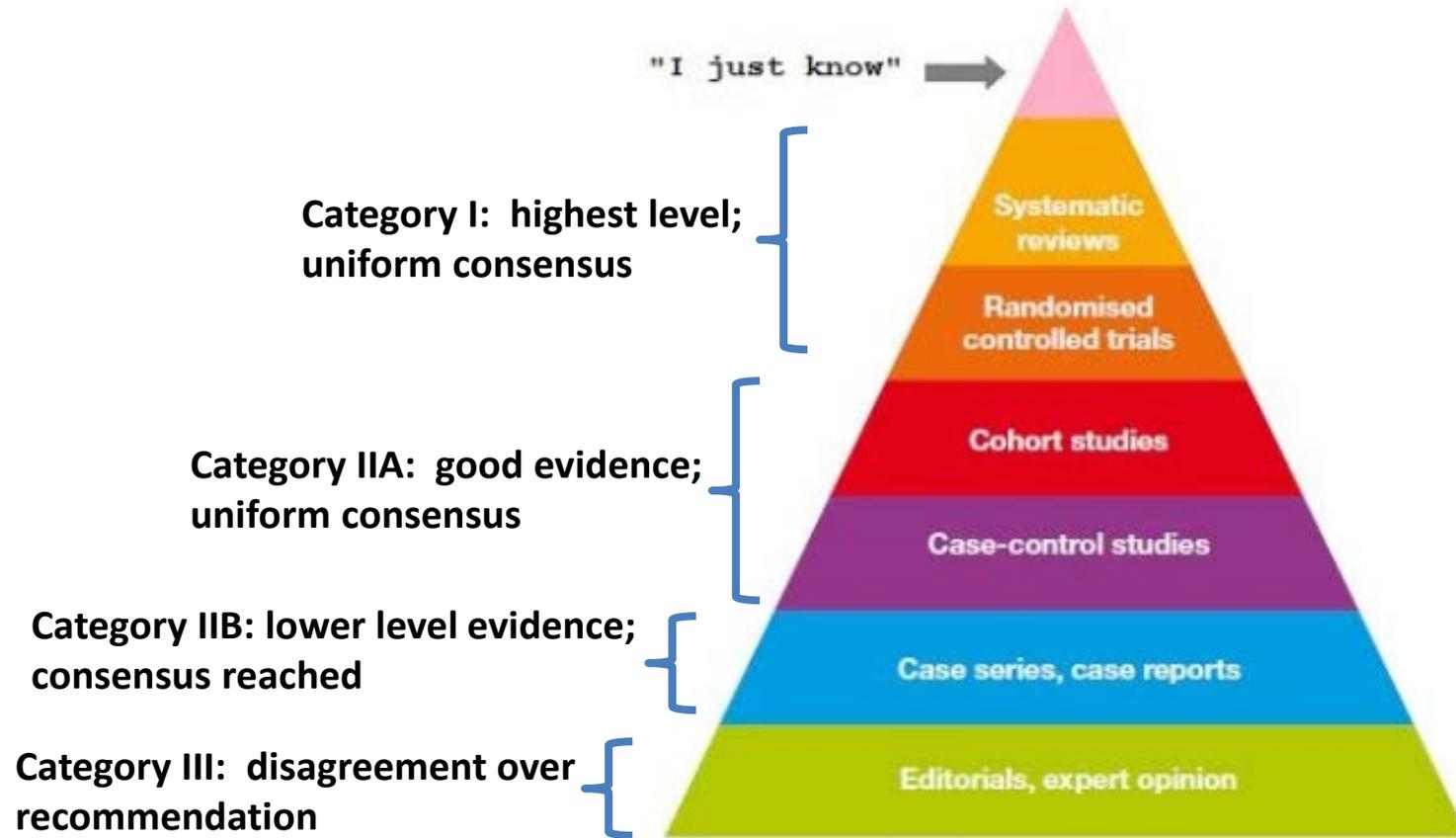
Surgeon
Radiation Therapist
Pathologist
Medical Oncologist
Biostatistician

Basic Scientist
Bioinformatician
Imaging Researcher
Molecular Geneticist
Patient Advocates

Laboratory Medicine Specialist
Outcomes Researcher
Information Systems Expert
Regulatory Affairs Specialist
Database Developer

“Evidence-based medicine”

David M. Eddy, 1987 Council of Medical Specialty Societies
Methods for designing clinical practice guidelines



Levels of Evidence

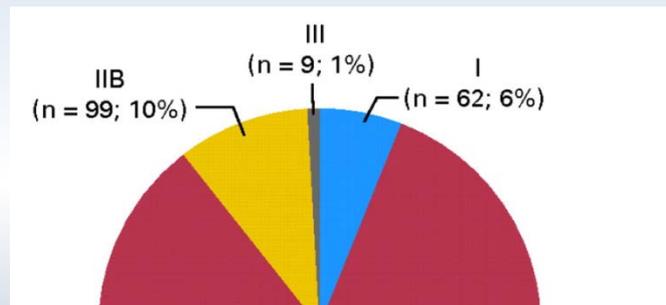
Level of Scientific Evidence Underlying Recommendations Arising From the National Comprehensive Cancer Network Clinical Practice Guidelines

Thejaswi K. Poonacha and Ronald S. Go

JCO 2011: 10 most common cancers

Recommendations for staging, initial and salvage therapy, surveillance

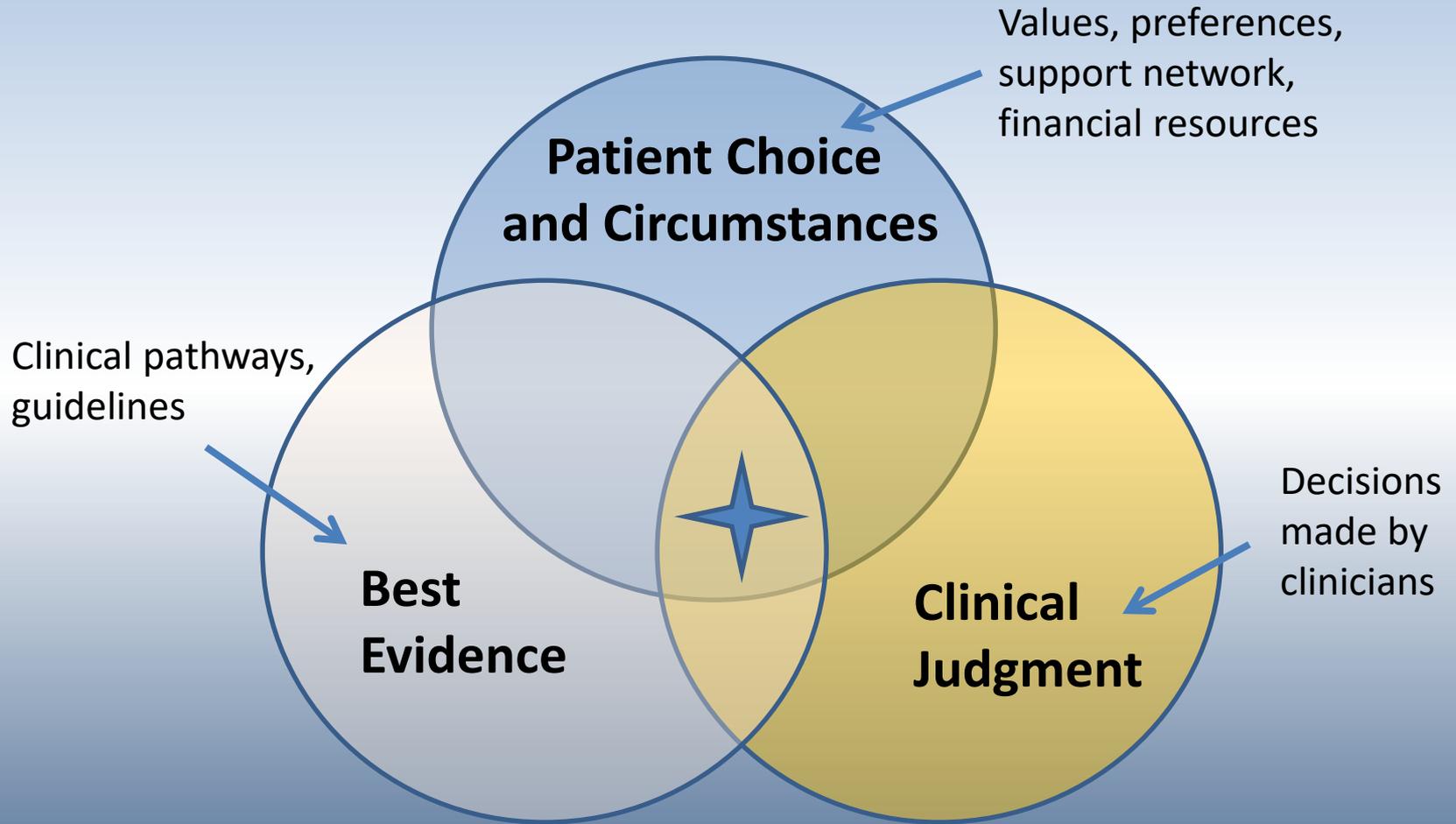
1,023 recommendations in the 10 guidelines

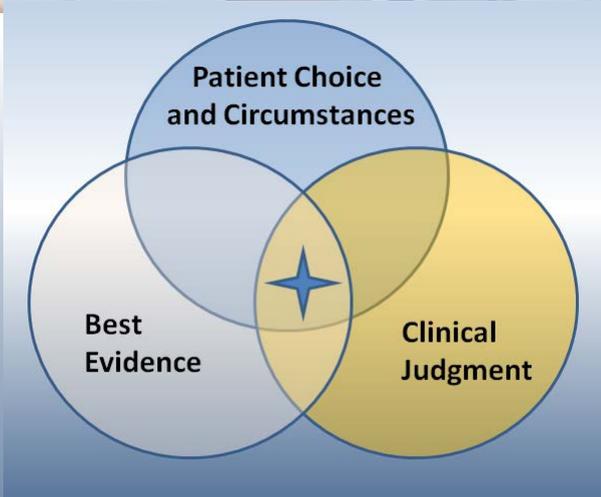


Urinary bladder and uterine cancer:
no level I guidelines



We can't deliver data-driven cancer care without data....





chal·lenge

/ˈCHalənj/ 

noun

plural noun: **challenges**

1. a call to take part in a contest or competition, especially a duel.

"he accepted the challenge"

synonyms: dare, provocation; summons

"he accepted the challenge"

Increasing complexity and cost of health care delivery

Fragmentation of health care delivery

Non-uniform access to care

Patients bear the burden of navigating the system

Stress, financial toxicity

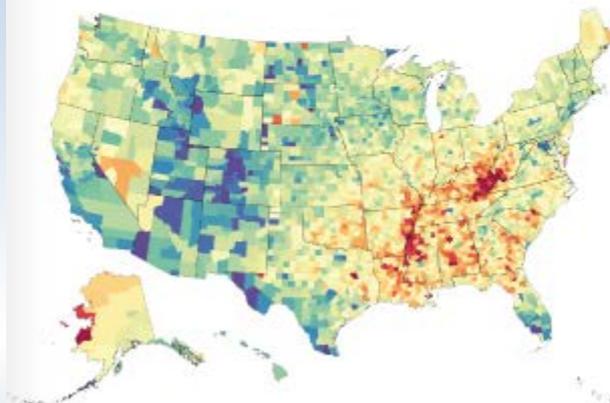
Lack of information to drive value-based care

CANCER MORTALITY RATES

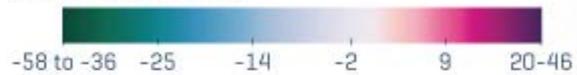
DEATHS PER 100,000 POPULATION



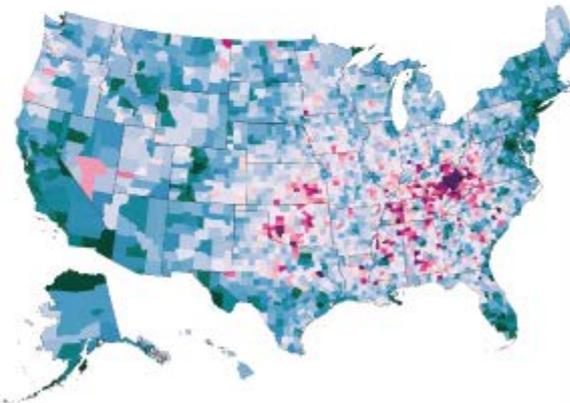
Age-standardized mortality rate from neoplasms (cancer), both sexes, 2014



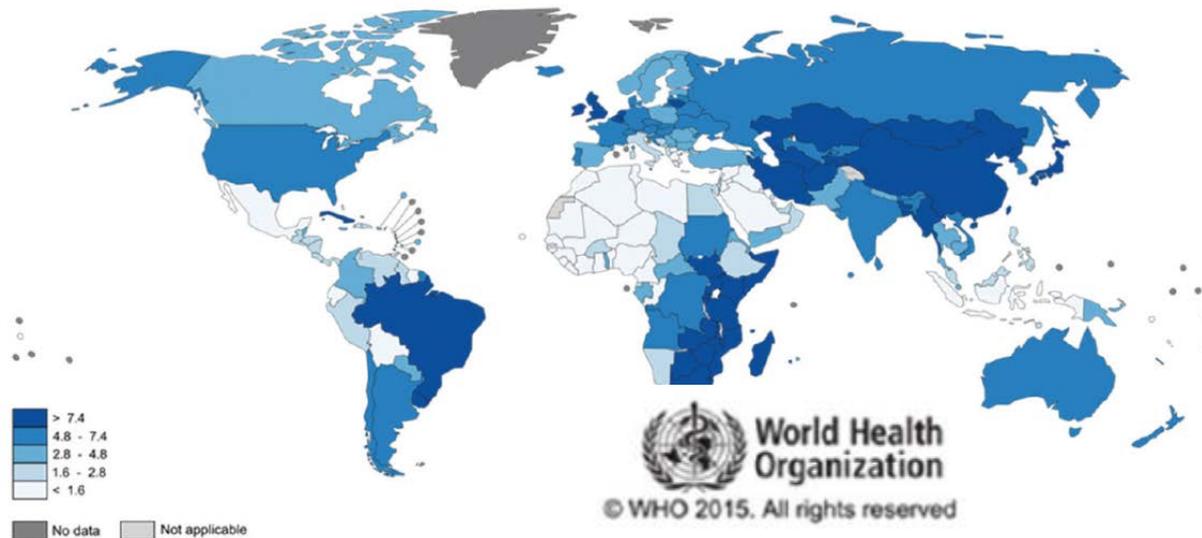
PERCENT CHANGE



Percent change in age-standardized mortality rate from neoplasms (cancer), both sexes, 1980-2014



Source: JAMA



chal·lenge

/ˈCHalənj/ 

noun

plural noun: **challenges**

1. a call to take part in a contest or competition, especially a duel.

"he accepted the challenge"

synonyms: dare, provocation; summons

"he accepted the challenge"

Increasing complexity and cost of clinical research

Low participation of adult patients in clinical trials

Precision Medicine challenges

Rising drug development costs

Limits to federal funding for research

Data silos

Only 3% of adult cancer patients participate in clinical trials



Understudied populations

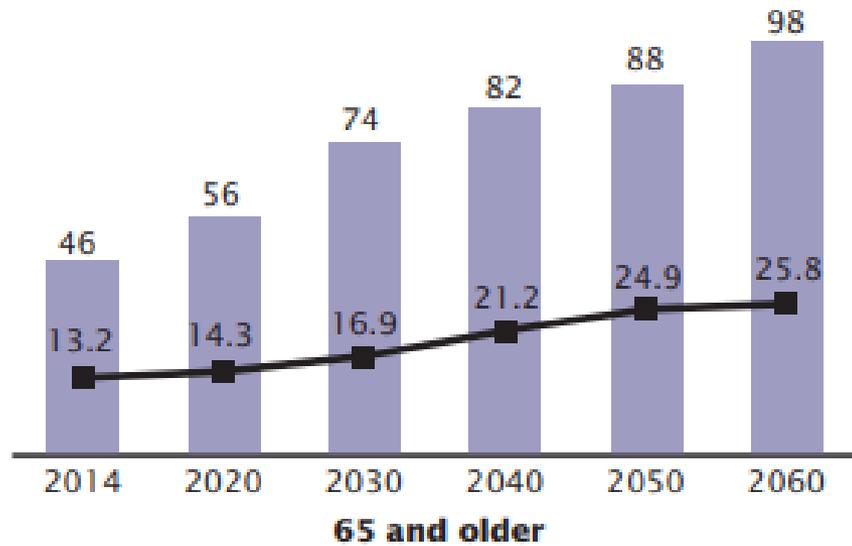
- Age 15-19 and > 65
- Underrepresented minorities
- Residents of rural communities
- Patients with co-morbid conditions
- Uninsured patients

Projections of the Size and Composition of the U.S. Population: 2014 to 2060

Population Estimates and Projections

Current Population Reports

By Sandra L. Colby and Jennifer M. Ortman
Issued March 2015

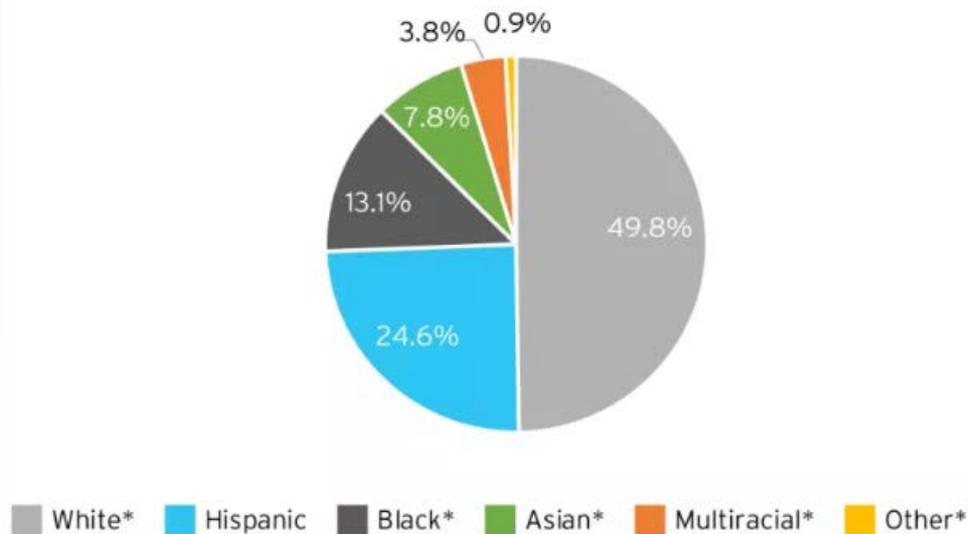




THE AVENUE

The U.S. will become “minority white” in 2045, Census projects

Racial profile of U.S. population, 2045



* Non-Hispanic members of race

Source: William H Frey analysis of U.S. Census population projections released March 13, 2018



Metropolitan Policy Program
at BROOKINGS

op·por·tu·ni·ty

/,äpär't(y)oonədē/ 

noun

plural noun: **opportunities**

a set of circumstances that makes it possible to do something.

"we may see increased **opportunities** for export"

synonyms: chance, lucky chance, favorable time/occasion/moment, time, right set of circumstances, occasion, moment, opening, option, window (of opportunity), turn, go, possibility;

Recognized need to reduce cost without sacrificing quality

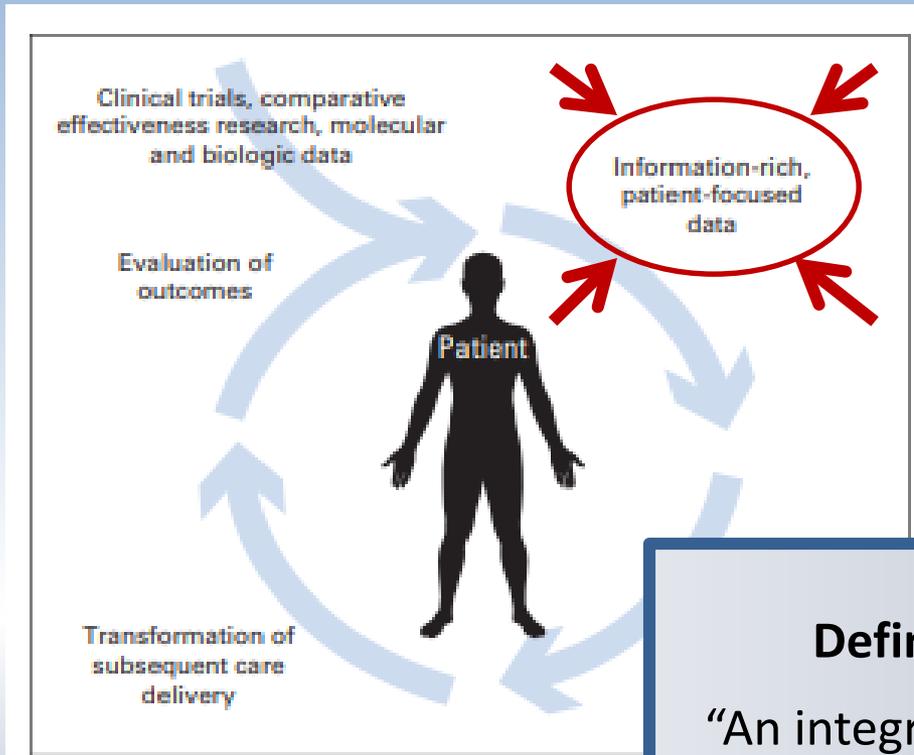
Recognized need to broaden access to care

Adoption of quality care metrics

Emergence of “real world” evidence

Value-based care models

Increasing consolidation of provider practices



Definition: Learning Health System

“An integrated health system which harnesses the power of data and analytics to learn from every patient and feed the knowledge of what works best back to clinicians, health professionals, patients and other stakeholders to create cycles of continuous improvement.”

Friedman CP et al, 2010; Sci Trans Med 2:57

ASCO[®]

AMERICAN SOCIETY OF CLINICAL ONCOLOGY

Research



Combined strength of data from ASCO members powers research that improves quality of care and health care resource utilization

Education



ASCO members receive education specific to their own clinical practice patterns and environment that enables positive change

Quality



Quality of care is optimized by both knowledge generation and direct feedback of relevant information to ASCO members

Data-Driven Improvements in Clinical Care

Clinical Research:

- Randomized Clinical Trials
- Pragmatic Trials
- Comparative Effectiveness Research
- Observational Research: Longitudinal Cohorts, Registries



Quality Improvement:

- Quality Metrics
- Clinical Pathways/Decision Support



Economic Factors:

- Health Care Resource Utilization



***Current state of data accumulation:
Fragmented, Siloed, Expensive, Inefficient***

Quality Oncology Practice Initiative

ASCO QOPI[®]

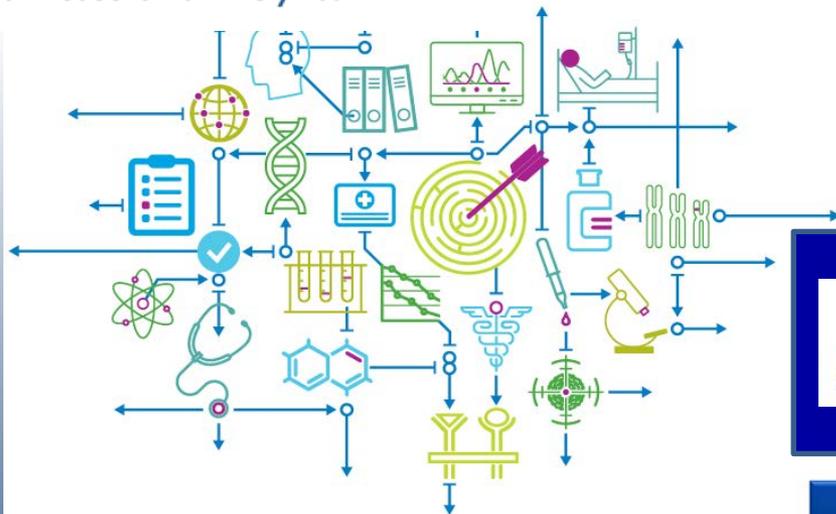
Quality Oncology Practice Initiative

ASCO[®]
Guidelines



ASCO[®] CENTRA

Center for Research & Analytics

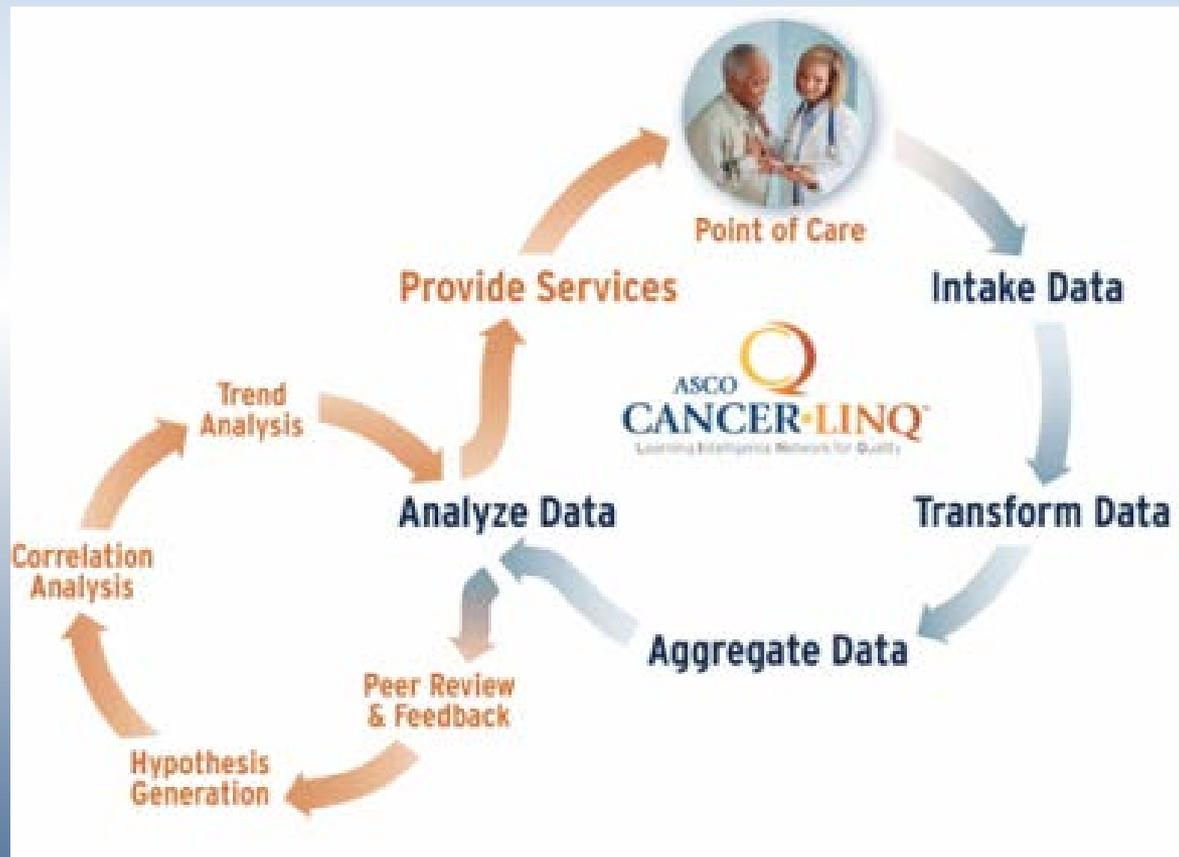


ASCO VALUE FRAMEWORK

Clinical benefit

Toxicity

Cost



Desired Future State

Clinical Research:

Enhanced ability to gather data on “real world” clinical practice

Improved ability to gather data on important populations not currently participating in clinical research: e.g. elderly, underrepresented minorities, patients with co-morbid conditions, those living in rural locations

Reduced cost and duration of clinical research is achieved by EHR-based collection of research data

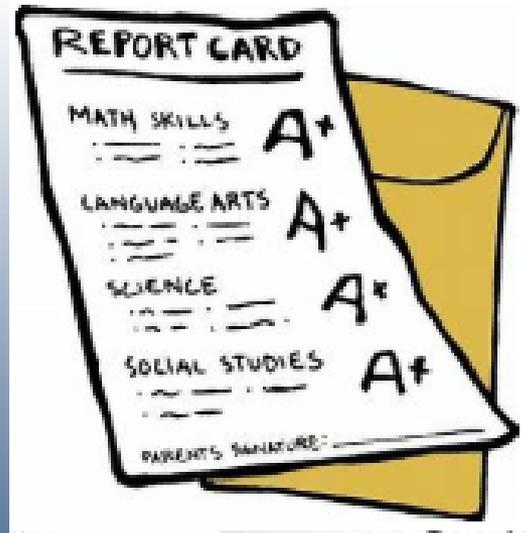


Desired Future State

Quality Improvement:

Quality metrics are assessed and analyzed across many clinical care sites to enable benchmarking

Clinicians receive data specific to their own clinical practice patterns and environment that enables positive change

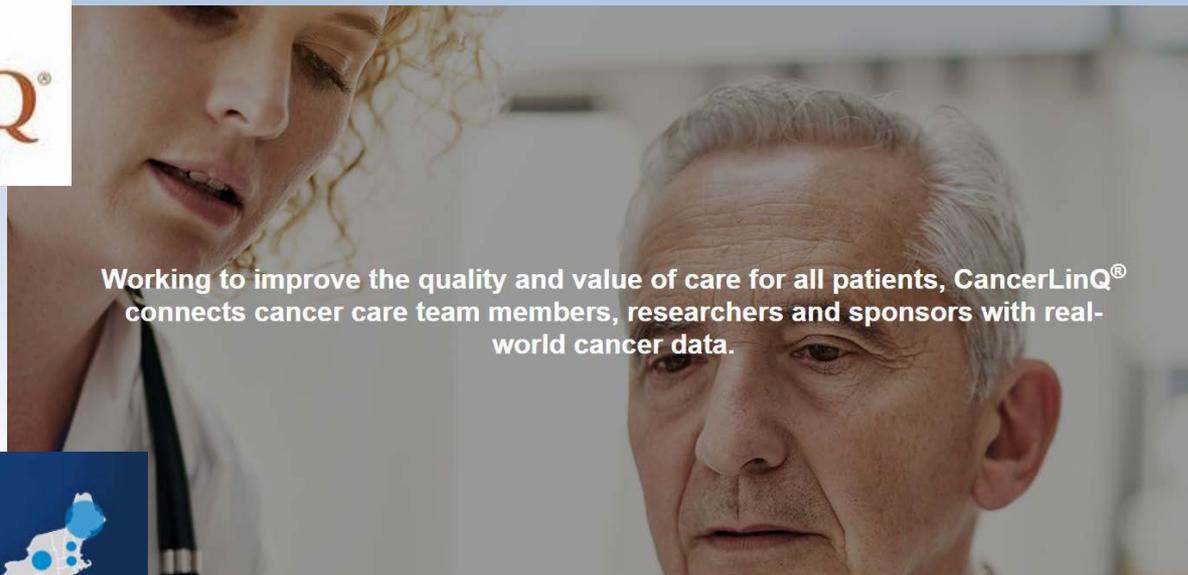


Desired Future State

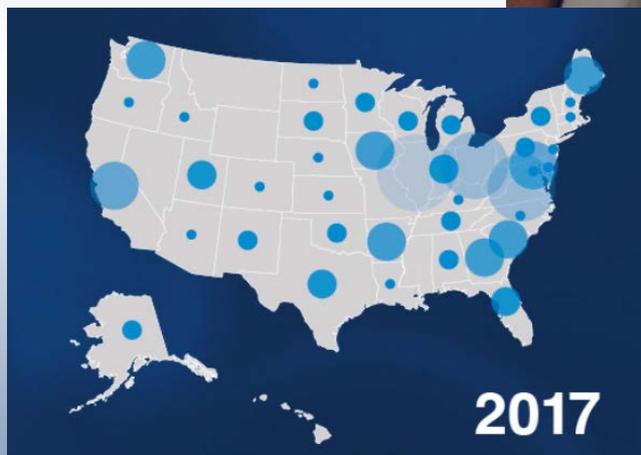
Health Care Resource Utilization:

Linking resource utilization to clinical outcomes enables adoption of value-based care approaches





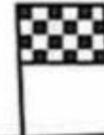
Working to improve the quality and value of care for all patients, CancerLinQ® connects cancer care team members, researchers and sponsors with real-world cancer data.



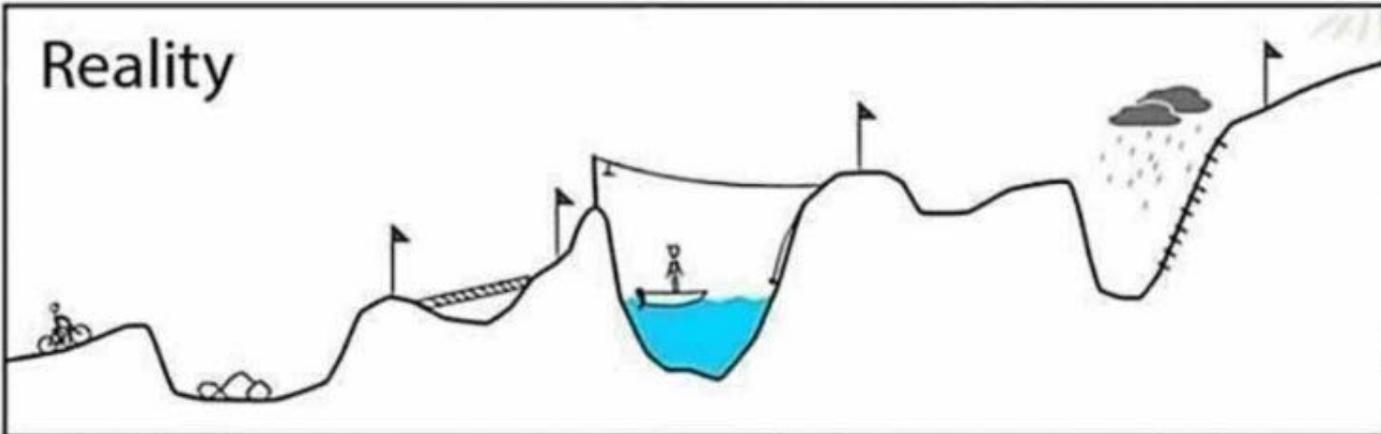
- 0 ✓ Clinical site participation
- 0 ✓ Technology for data transfer
- 0 ✓ Engagement of patients
- 0 ✓ Data analysis expertise
- 0 ✓ Structure for data access

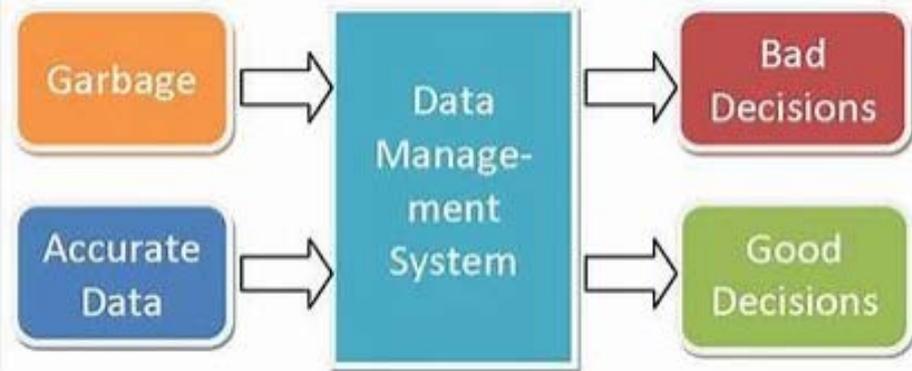
Lung CA slides

Your plan

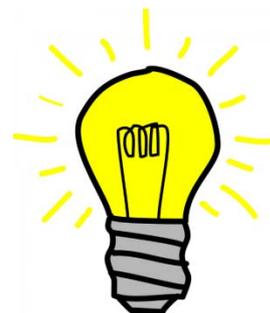
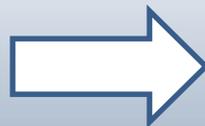


Reality





> ** patient records curated



We need better data!

“Caring for Every Patient, Learning from Every Patient”

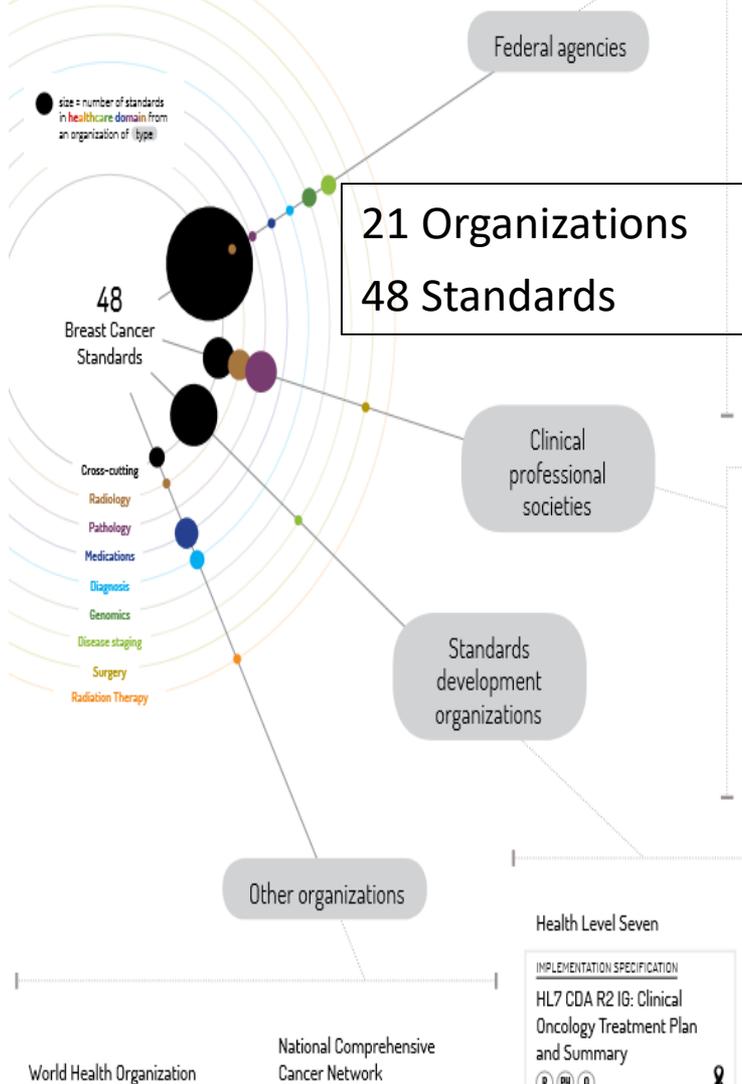


Harness the capabilities of the Electronic Health Record to implement a Learning HealthCare System



Who develops what standards for Oncology and Breast Oncology?

How are these standards used in the oncology care continuum?



Centers for Disease Control and Prevention

VALUE SET REPOSITORY

Public Health Information Network Vocabulary Access and Distribution System

(PH)

National Institutes of Health

DATA ELEMENT REPOSITORY

NIH Common Data Elements Repository

(R)

National Human Genome Research Institute

DATA ELEMENT REPOSITORY

PhenX Toolkit - Cancer Domain

(R)

CDC National Program of Cancer Registries

APPLICATION

Registry Plus

(PH)

API

NPCR TNM 7th Edition Staging API

(PH)

APPLICATION

NPCR TNM 7th Edition Staging Batch Calculation Tool

(PH)

National Cancer for Biotechnology Information

DATA REPOSITORY

ClinVar

(R)

NCI Surveillance, Epidemiology, and End Results Program

DATA DICTIONARY

Surveillance, Epidemiology and End Results (SEER) Program Coding and Staging Manual

(R)

(PH)

VALUE SET REPOSITORY

SEER Case Finding Lists

(R)

(PH)

VOCABULARY

SEER*Rx - Interactive Antineoplastic Drugs Database

(R)

(PH)

National Libraries of Medicine

VALUE SET REPOSITORY

Value Set Authority Center

(CP)

(Q)

National Cancer Institute

DATA REPOSITORY

NIH Cancer Data Access System

(R)

DATA ELEMENT REPOSITORY

CaDSR Common Data Elements Browser

(R)

ONTOLOGY

NCI Thesaurus

(R)

(CP)

META-VOCABULARY

NCI Metathesaurus

(R)

(CP)

DATA REPOSITORY & API

Cancer Imaging Archive

(R)

TERMINOLOGY BROWSER

NCI Term Browser - Terminologies

(R)

(CP)

VALUE SET REPOSITORY

NCI Term Browser - Value Sets

(R)

(CP)

DATA REPOSITORY & API

Genomic Data Commons

(R)

College of American Pathologists

DOCUMENT TEMPLATE

CAP Breast Biomarker Reporting Templates

(CP)

(PH)

DOCUMENT TEMPLATE

CAP Breast Cancer Protocols

(CP)

(PH)

(A)

DOCUMENT TEMPLATE

CAP Electronic Cancer Checklists

(CP)

(PH)

(A)

DOCUMENT TEMPLATE

CAP Structured Data Capture Cancer Templates

(CP)

(PH)

(A)

American College of Radiology

DATA DICTIONARY

National Mammography Database Data Dictionary

(Q)

TERMINOLOGY

Breast Imaging Reporting and Data System

(CP)

(Q)

American Society of Clinical Breast Surgeons

WEB TOOL

Mastery of Breast Surgery

(CP)

Radiological Society of North America

ONTOLOGY

RSNA RadLex

(R)

(CP)

(Q)

DATA ELEMENT REPOSITORY & API

Common Data Elements for Radiology

(R)

(CP)

(Q)

Key

TYPE OF STANDARD

Standard Name

(R)

(CP)

(Q)

Usage - see What are these standards used for? above for key.

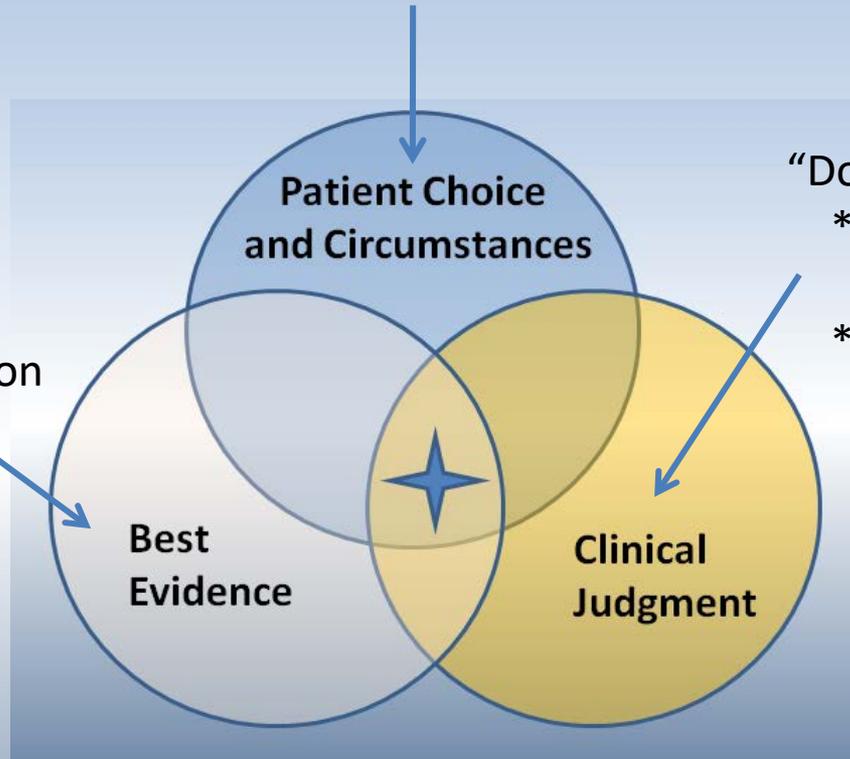
This standard has restricted access and/or use

Filled background: used in production
White background: trial use

Black ribbon: standard is specific to oncology
Pink ribbon: specific to breast oncology

Patient-Reported Outcomes
Socio-economic status, "zip code"

Demographics
Disease Characterization
Treatment
Clinical tests
(labs, imaging, etc.)

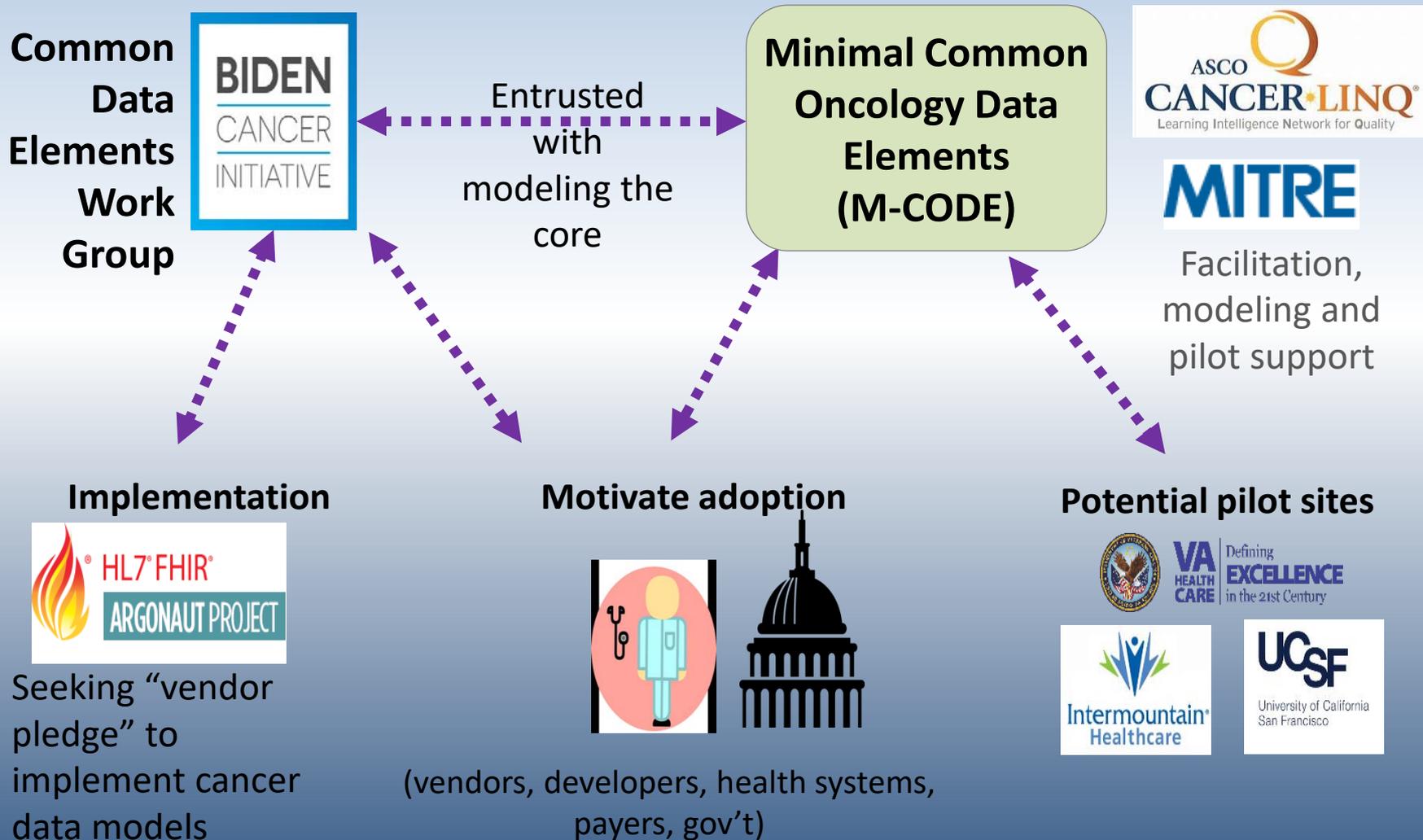


"Doctor Decision" Questions
*Is the patient responding to treatment?
*Is there an adverse event that requires a change in treatment?

Partner Organizations



Coming together now: A concept for broad collaboration around a common, core cancer data model



ASCO's Integrated Learning Health System

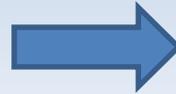
ASCO Members/Users



ASCO/CancerLinQ

ASCO's Integrated Learning Health System

ASCO Members/Users



ASCO/CancerLinQ

- **Certify data standards in collaboration with many stakeholders**

ASCO's Integrated Learning Health System

ASCO Members/Users



ASCO/CancerLinQ

- Certify data standards in collaboration with many stakeholders
- **Provide a vehicle to deliver data from quality improvement programs (QOPI, pathways)**

ASCO's Integrated Learning Health System

ASCO Members/Users

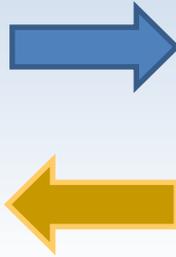


ASCO/CancerLinQ

- Certify data standards in collaboration with many stakeholders
- Provide a vehicle to deliver data from quality improvement programs (QOPI, pathways)
- **Assemble/analyze patient-level data across multiple clinical sites**

ASCO's Integrated Learning Health System

ASCO Members/Users



ASCO/CancerLinQ

- Certify data standards in collaboration with many stakeholders
- Provide a vehicle to deliver data from quality improvement programs (QOPI, pathways)
- Assemble/analyze patient-level data across multiple clinical sites
- **Integrate member-contributed data with relevant data from other sources (SEER registries, clinical trials, etc.)**

ASCO's Integrated Learning Health System

ASCO Members/Users



ASCO/CancerLinQ

- Certify data standards in collaboration with many stakeholders
- Provide a vehicle to deliver data from quality improvement programs (QOPI, pathways)
- Assemble/analyze patient-level data across multiple clinical sites
- Integrate member-contributed data with relevant data from other sources (SEER registries, clinical trials, etc.)
- **Facilitate research using large clinical datasets**

ASCO's Integrated Learning Health System

ASCO Members/Users



ASCO/CancerLinQ

- Certify data standards in collaboration with many stakeholders
- Provide a vehicle to deliver data from quality improvement programs (QOPI, pathways)
- Assemble/analyze patient-level data across multiple clinical sites
- Integrate member-contributed data with relevant data from other sources (SEER registries, clinical trials, etc.)
- Facilitate research using large clinical datasets
- **Provide recommendations and feedback back to sites (benchmarking quality metrics, research results, etc.)**

ASCO's Integrated Learning Health System

ASCO Members/Users

- Provide patient-level data adhering to CLQ-certified data standards



ASCO/CancerLinQ

- Certify data standards in collaboration with many stakeholders
- Provide a vehicle to deliver data from quality improvement programs (QOPI, pathways)
- Assemble/analyze patient-level data across multiple clinical sites
- Integrate member-contributed data with relevant data from other sources (SEER registries, clinical trials, etc.)
- Facilitate research using large clinical datasets
- Provide recommendations and feedback back to sites (benchmarking quality metrics, research results, etc.)

ASCO's Integrated Learning Health System

ASCO Members/Users

- Provide patient-level data adhering to CLQ-certified data standards
- **Implement data-driven quality improvement programs (QOPI, pathways)**



ASCO/CancerLinQ

- Certify data standards in collaboration with many stakeholders
- Provide a vehicle to deliver data from quality improvement programs (QOPI, pathways)
- Assemble/analyze patient-level data across multiple clinical sites
- Integrate member-contributed data with relevant data from other sources (SEER registries, clinical trials, etc.)
- Facilitate research using large clinical datasets
- Provide recommendations and feedback back to sites (benchmarking quality metrics, research results, etc.)

ASCO's Integrated Learning Health System

ASCO Members/Users

- Provide patient-level data adhering to CLQ-certified data standards
- Implement data-driven quality improvement programs (QOPI, pathways)
- **Modify clinical practice based upon summary results (e.g. quality benchmarking or research) provided from CLQ**



ASCO/CancerLinQ

- Certify data standards in collaboration with many stakeholders
- Provide a vehicle to deliver data from quality improvement programs (QOPI, pathways)
- Assemble/analyze patient-level data across multiple clinical sites
- Integrate member-contributed data with relevant data from other sources (SEER registries, clinical trials, etc.)
- Facilitate research using large clinical datasets
- Provide recommendations and feedback back to sites (benchmarking quality metrics, research results, etc.)

ASCO's Integrated Learning Health System

ASCO Members/Users

- Provide patient-level data adhering to CLQ-certified data standards
- Implement data-driven quality improvement programs (QOPI, pathways)
- Modify clinical practice based upon summary results (e.g. quality benchmarking or research) provided from CLQ
- **Participate in research driven by CLQ tools**



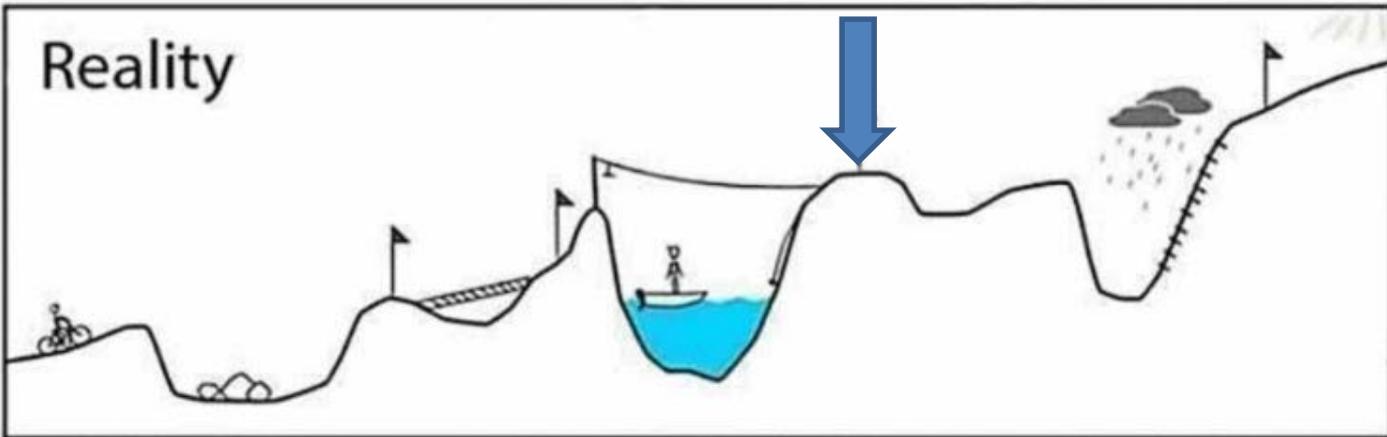
ASCO/CancerLinQ

- Certify data standards in collaboration with many stakeholders
- Provide a vehicle to deliver data from quality improvement programs (QOPI, pathways)
- Assemble/analyze patient-level data across multiple clinical sites
- Integrate member-contributed data with relevant data from other sources (SEER registries, clinical trials, etc.)
- Facilitate research using large clinical datasets
- Provide recommendations and feedback back to sites (benchmarking quality metrics, research results, etc.)

Your plan



Reality



Caring for Every Patient, Learning from Every Patient



Data-driven treatment
recommendations

Patient demographics
Disease characteristics
Specific treatment administered
Outcome of treatment



Data aggregation and analysis



THANK YOU!

