

Tobacco Use by Cancer Patients in Clinical Trials

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Formerly: Statistician, National Surgical Adjuvant Breast and Bowel Project (NSABP) and University of Pittsburgh Cancer Institute (1999-2011)

Purpose of today's presentation

- To inform CTAC of initiative
- To solicit early input

- Problem
- Scene
- Science
- Action
- Feedback

problem

scene

science

action

feedback

Problem (Clinical)

Cancer patients and survivors who smoke cigarettes have worse health outcomes (including higher all-cause and cancer-specific mortality, and risk of tobacco-related second primary cancer).

Smokers may have higher risk of recurrence, poorer response to treatment, and increased toxicity.

Clinical significance of smoking by cancer patients

- Relative risk of all-cause mortality*
 - Current smokers 1.5 (relative to never smokers)
 - Former smokers 1.3
- Relative risk of cancer-specific mortality**
 - Current smokers 1.6 (relative to never smokers)
 - Former smokers 1.05

* Phipps, 2011 (colorectal cancer)

** Kenfield, 2011 (prostate cancer)

Problem (Scientific)

There are many scientific questions related to tobacco use in the cancer patient population.

Current approaches to data collection:

- Not widely assessed in trials or practice
- Inconsistent tobacco use assessment methods
- Little follow-up during/after treatment

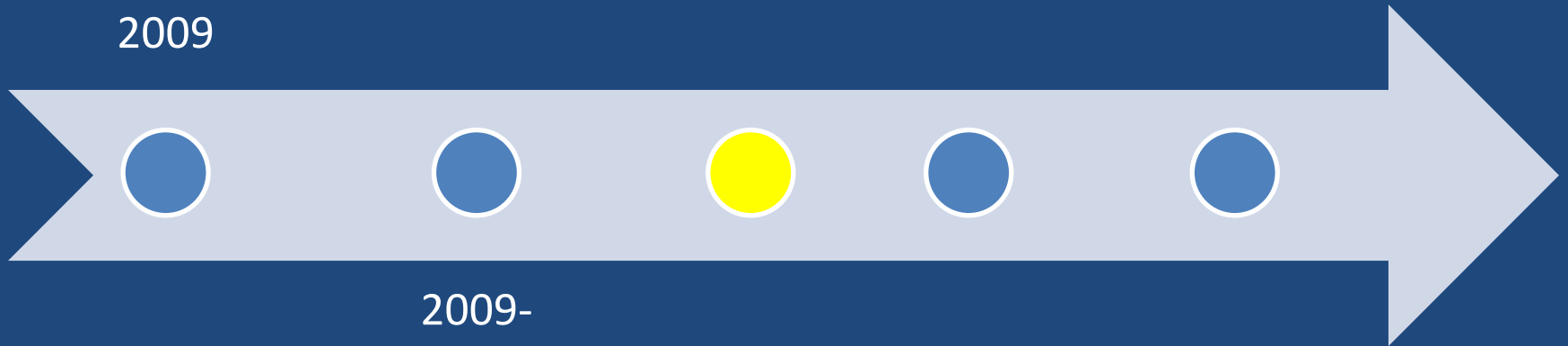
Current practice

- NCI-Designated Cancer Centers
 - < 50% include tobacco use as a vital sign in the medical record
- NCI-funded phase III Cooperative Group trials
 - 22% record cigarette smoking status at enrollment, and
 - 4% during follow-up.

Goldstein, NTR, 2012; Warren, IJC, 2012

Action Timeline

NCI
conference
2009



2009-
present

AACR,
ASCO, IOM,
JCO
activities

problem

scene

science

action

feedback

Recent action and dissemination

AACR American Association for Cancer Research

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SCIENTISTS

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Home > Scientists > Working Groups & Task Forces > Task Forces > Tobacco and Cancer

SCIENTISTS

- Pediatric Cancer Working Group
- Behavioral Science in Cancer Research Working Group
- Cancer Immunology Working Group
- Chemistry in Cancer Research Working Group
- Molecular Epidemiology Working Group
- Tumor Microenvironment Working Group
- Task Forces**
 - Aging and Cancer
 - Cancer Epigenome Task Force
 - Regulatory Science and Policy
 - Tobacco and Cancer
- AACR-FDA-NCI Cancer Biomarkers Collaborative

AACR Task Force on Tobacco and Cancer

The AACR Task Force on Tobacco and Cancer was convened in 2009 to foster science and policy initiatives to reduce the incidence of disease and mortality due to tobacco use.

Tobacco use is the leading preventable cause of premature mortality, killing more than five million people worldwide every year. It has a particularly profound impact on cancer incidence and mortality. Indeed, tobacco use is causally associated with 18 different types of cancer, including lung, head and neck, stomach, pancreas and cervical cancers, and alone tobacco accounts for 30 percent of all cancer deaths.

THE SCIENCE BEHIND TOBACCO CONTROL

How Research Informs Policy to Save Lives and Money

On June 12, the AACR sponsored a congressional briefing to highlight evidence that underscores the need for successful interventions both preventing the initiation of tobacco use and helping those who are addicted to quit.

Dr. Roy Herbst, chair of the AACR Task Force on Tobacco and Cancer, welcomes Sen. Richard Blumenthal (D-Conn.), a staunch tobacco control advocate

Action TO QUIT
Advancing Tobacco Control Policy

ABOUT | OUR WORK | COMMUNICATIONS | STATE PROJECTS | NEWS | POPULATIONS

Home > News > Study Recommends National Standards for Tobacco Use Treatment in Cancer Centers

Study Recommends National Standards for Tobacco Use Treatment in Cancer Centers

April 17, 2012 One in five National Cancer Institute (NCI)-designated Cancer Centers offer no tobacco use treatment services to their patients, while less than half report a

Land, JCO, 2012
Peters, JCO, 2012
Ganz, JCO, 2012
IOM, 2012

Warren, JOP, 2013
Warren, JTO, 2013
Toll, CCR, 2013
Hanna, JCO, 2013

ASCO
American Society of Clinical Oncology
Making a world of difference in cancer care

Tobacco Cessation Guide
For Oncology Providers

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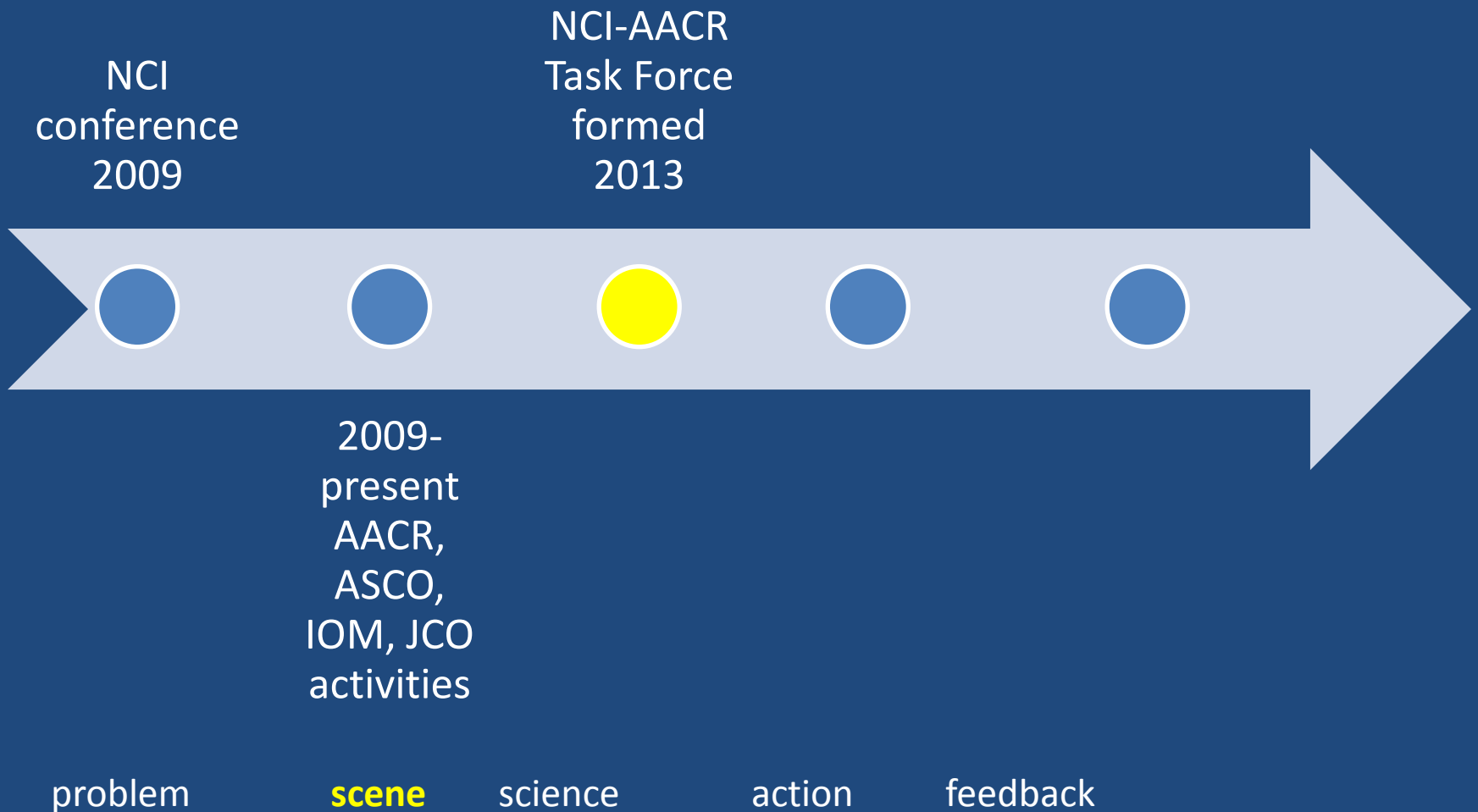
Stopping Tobacco Use After a Cancer Diagnosis
Resources and Guidance for Patients and Families

“In the oncology setting, tobacco use should be addressed at presentation and throughout treatment.”

“If tobacco use data are systematically collected and analyzed, the information would provide clinicians and regulatory agencies with the data needed to understand the impact of existing and new tobacco products.”

Hanna, et al, Tobacco Cessation and Control a Decade Later: American Society of Clinical Oncology Policy Statement Update, *JCO*, 2013

Action Timeline



Scope and Purpose of NCI-AACR Cancer Patient Tobacco Use Assessment Task Force

From the scientific and medical perspective,
develop recommendations for

- tobacco measures,
- timing of assessment,
- research agenda

Task Force Roster

Jeffrey S. Abrams, MD
Thomas H. Brandon, PhD
Jan C. Buckner, MD
Paul M. Cinciripini, PhD
K. Michael Cummings, PhD, MPH
Carolyn Dresler, MD, MPA,
Sonia A. Duffy, PhD, RN, FAAN
Michael C. Fiore, MD, MPH, MBA
Ellen R. Gritz, PhD
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Roy S. Herbst, MD, PhD
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Robert A. Schnoll, PhD
Peter Shields, MD
Benjamin Toll, PhD
K. (Vish) Viswanath, PhD
Graham Warren, MD, PhD

See handout for titles and affiliations.

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Cooperative Group
leadership and committee
membership

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ASCO leadership and
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Cancer centers

NCCTG Phase III Trial N0147 (Alliance)

- 2686 resected stage III colon cancer randomized
- FOLFOX ± cetuximab
- Statistical power 90% to detect DFS HR=0.75 cetuximab
- No DFS benefit with cetuximab (Alberts, JAMA, 2012)
- Baseline smoking assessment (n=1968):
 - Smoked ≥ 100 cigarettes in lifetime
 - Currently smoker
 - Age initiation
 - Age quit
 - Average number of cigarettes smoked per day

Associations between Cigarette Smoking Status and Colon Cancer Prognosis among Participants in NCCTG Phase III Trial N0147 (Alliance)

- Phipps, Shi, Newcomb, Nelson, Sargent, Alberts, Limburg for the Alliance for Clinical Trials in Oncology *JCO Jun 1, 2013*
- Land, SR: New Evidence of the Clinical Significance of Cigarette Smoking by Colon Cancer Patients [podcast] , *JCO*
- 3-year DFS **70%** for ever-smokers vs **74%** never-smokers
- Current vs never-smokers (DFS HR=1.47; 95% CI 1.04 to 2.09)
- Former vs never-smokers (DFS HR=1.20; 95% CI 0.99 to 1.46)
- Interaction with BRAF mutation (P=.03):
ever-smoking was associated with
 - shorter DFS in pts with BRAF wild-type (HR=1.36; 95% CI, 1.11 to 1.66)
 - not in BRAF mutated (HR=0.80; 95% CI, 0.50 to 1.29) colon cancer.

Scientific questions

- Cigarette smokers seem to have greater morbidity and poorer clinical outcomes, but:
 - Evidence needs to be strengthened
 - Is the association actually due to exposure history, use during cancer therapy, or continued accrual of risk after therapy?
 - What is the improvement in prognosis with cessation, for a given history of exposure?

Scientific questions (continued)

Does quitting smoking actually impact the outcome of cancer, or is the damage already done?

Peter Shields, Professor

The Ohio State University College of Medicine

Deputy Director, The Ohio State University Comprehensive Cancer Center (OSUCCC)

Scientific questions (continued)

Does tobacco use diminish treatment efficacy?

We need to understand the **mechanisms** by which tobacco could exacerbate the disease or dilute the efficacy of the treatment.

*Vish Viswanath, Associate Professor
Harvard School of Public Health
and Department of Medical Oncology
Dana-Farber Cancer Institute*

Scientific questions (continued)

“There are substantial opportunities to identify better cancer therapeutics, use smoking as a **model** of general therapeutic resistance, and assess methods to improve outcomes.”

*Graham Warren, Associate Professor
Vice Chairman for Research in Radiation Oncology
Dept of Cell and Molecular Pharmacology and Experimental
Therapeutics
Medical University of South Carolina
Alliance (Cooperative Group Prevention Committee)*

Scientific questions (continued)

“Why does smoking affect virtually all disease sites for most treatment modalities?

Do we know of any other exposure that has this effect?
If we can determine how tobacco causes these effects, we might have a spectacular opportunity to advance cancer treatment.

Costs of existing therapies are so high, maximizing the utility of these therapies could be a great investment.”

K. Michael Cummings

Professor, Department of Psychiatry & Behavioral Sciences

Medical University of South Carolina

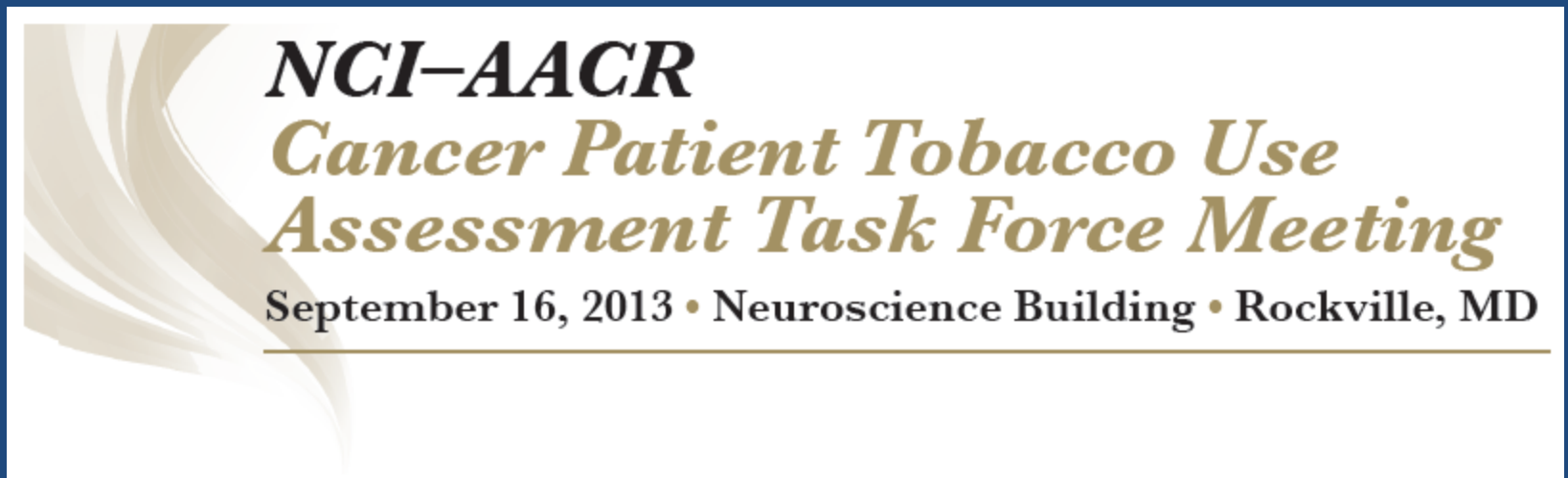
Scientific questions (continued)

- How does tobacco use affect tumor biology?
- Should cancer therapeutic agent dosing be modified for tobacco users?
- Optimal timing of cessation relative to therapy?
- What are the best approaches for cessation interventions in cancer patients?
- Can cessation improve adherence to cancer therapy?
- Can cessation improve quality of life?
- How does tobacco use interact with other behavioral and demographic factors?
- What is the clinical impact of other tobacco products?

Task Force Near Term Deliverables

- Recommended measures (online)
 - 3 tiers; Tier 1 is minimal set
- Protocol for tobacco use measurement (online)
 - Timing and procedures
- Research agenda (publication; see handout)

- June-present, 2013: Working groups and conference calls
- Sept 2013: In-person meeting facilitated by NCI Office of Science Planning and Assessment



Draft recommended measures

Tier 1 (minimal) paraphrased

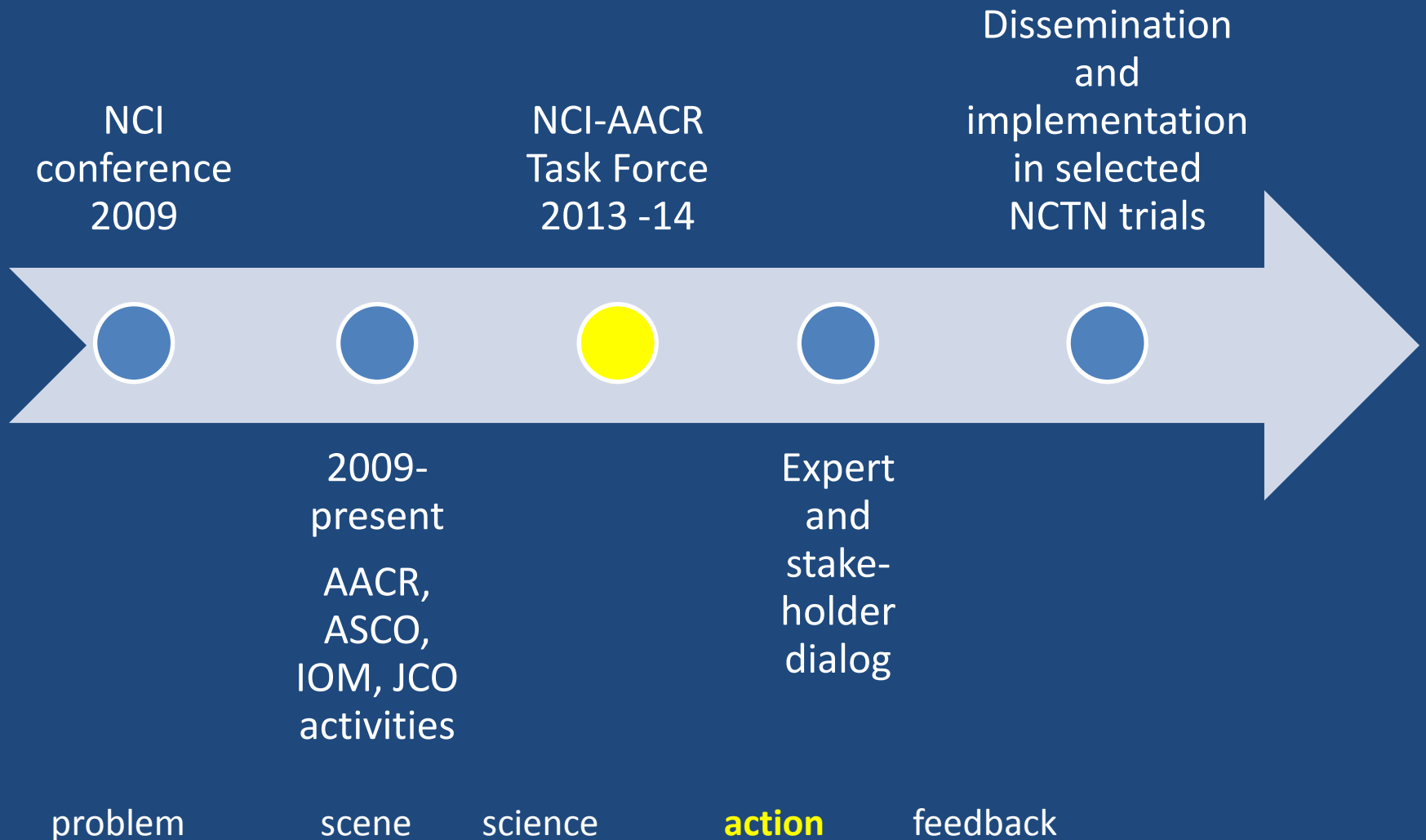
Baseline:

- Ever smoked 100+ cigarettes in lifetime?
- How long since smoked?
- How many years smoked?
- Average number of cigarettes per day?

Follow-up:

- How long since smoked?

Action Timeline



Next steps

- Finalize and promote measures and recommendations via scientific dialog
- Facilitate implementation of tobacco use assessment in National Clinical Trials Network
- Assessment in selected trials
- Develop NCI Guidance

Feedback

What are the barriers to incorporating tobacco use items in

- Selected clinical trials?
- All NCTN Phase III clinical trials?