THE IMPACT OF THE AFFORDABLE CARE ACT (ACA) ON CANCER RESEARCH, CARE, AND PREVENTION

William S. Dalton, PhD, MD

AACR
April 17, 2016
Designing a Federated Model To Support Research & Healthcare
Goals of the Patient Protection & Affordable Care Act of 2010

1. Expand access to health insurance coverage

2. Improve affordability & sustainability for those who have health care insurance

3. Control the rising costs of health care while improving quality
### Clinical Trials
- Prohibits insurers from dropping coverage because an individual chooses to participate in a clinical trial
- Prohibits insurers from denying coverage for routine care they would otherwise provide just because an individual is enrolled in a clinical trial
- Applies to all clinical trials that treat cancer or other life-threatening diseases
- Approved clinical trials are defined as those approved or funded by a government agency, such as the NIH
- Starts in 2014

### Comparative Effectiveness Research
- Establishes the Patient-Centered Outcomes Research Institute (PCORI) A private, nonprofit institute to identify national priorities and provide for research to compare the effectiveness of health treatments and strategies
- Mandatory funding stream through a trust fund
- Overseen by a board of governors with broad stakeholder involvement and assisted by expert advisory panels
- Cannot mandate coverage, reimbursement or other policies for payers
- CMS is restricted from using research data alone to deny coverage
- Methodology committee to develop a standard set of methods
- Requires that research take into account subpopulations, genetic and molecular subtypes, and the phase in the innovation cycle of the treatment modality
Patient Protection & Affordable Care Act: Cancer Provisions, Cont’d.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Provision</th>
</tr>
</thead>
</table>
| Translational        | • Establishes Cures Acceleration Network (CAN) at the NIH under the director's leadership  
| Research             | • Charged with speeding translation of basic scientific discoveries into treatments for patients  
|                      | • Establishes a 24-member board of diverse membership, including leaders in medicine, research and venture capitalism  
|                      | • Provides for grants of up to $15 million per year, per project, to both industry and academic researchers  
|                      | • Establishment dependent on appropriations  
|                      | • Provides the Therapeutic Discovery Project Credit, a 2-year temporary credit to encourage investments in new therapies to prevent, diagnose, and treat disease, including to significantly advance the goal of curing cancer |
| Prevention           | • Coverage of preventive services rated A or B in the current recommendations of the U.S. Preventive Services Task Force  
|                      | • Requires state Medicaid programs to cover tobacco cessation services for pregnant women  
|                      | • Establishes Prevention Fund for prevention, wellness, and public health activities, including prevention research. $15 billion over 10 years. |
That was the opportunity…. Where are we in 2016?

- Clinical Trials
- Comparative Effectiveness Research
- Translational Research
- Prevention
That was the opportunity....
Where are we in 2016?

Clinical Trials
Comparative Effectiveness Research
Translational Research
Prevention
Clinical Trials Coverage

• Health plans newly issued or renewed on or after January 1, 2014 must provide coverage for routine costs of care that would have normally been covered if a patient is not on a trial. This provision does not apply to “grandfathered” plans that existed on or before 1/1/14.

• Conditions of coverage include:
  • Patient must be eligible for the trial
  • Trial must be an approved clinical trial
  • Trial does not involve out-of-network doctors or hospitals, if out-of-network care is not part of the plan

• Approved clinical trials must be:
  • Federally funded (NIH, organizations funded by NIH or NCI, CDC, AHRQ, CMS, DoD, VA, Dept of Energy)
  • Have submitted an investigational new drug application to the FDA or be exempt from IND requirements

• Medicare and Medicaid coverage for clinical trials are not affected by the ACA and have slightly different rules

Source: Cancer.Net, NCI
“nearly 63% of cancer centers and organizations that responded to a recent survey reported insurance denials of routine care costs associated with patient involvement in clinical trials during 2014”

Still an Issue in 2016

The study also found that where prior insurance approval of a procedure, test, or medication is required, patients were three times more likely to experience denials than at sites without precertification requirements.

Reasons Given for Clinical Trial Coverage Denials

That was the opportunity….
Where are we in 2016?

Clinical Trials

Comparative Effectiveness Research

Translational Research

Prevention
Why The Patient-Centered Outcomes Research Institute Was Created

The purpose of the Institute is to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the health care interventions, protocols for treatment, care management, and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals (including drugs and biologicals), integrative health practices, and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury in, individuals.
PCORI Strategic Plan: Mission, Vision, Goals

**Mission**
PCORI helps people make informed health care decisions, and improves health care delivery and outcomes by producing and promoting high integrity, evidence-based information that comes from research guided by patients, caregivers and the broader health care community.

**Vision**
Patients and the public have information they can use to make decisions that reflect their desired health outcomes.

**Goals**
1. Substantially increase the quantity, quality, and timeliness of useful, trustworthy information available to support health decisions.
2. Speed the implementation and use of patient-centered outcomes research evidence.
3. Influence clinical and health care research funded by others to be more patient-centered.

PCORI, Strategic Plan, Cont’d

**STRATEGIC IMPERATIVES**

**Engagement**
Engage patients, caregivers, and all other stakeholders in our entire research process from topic generation to dissemination and implementation of results.

**Methods**
Develop and promote rigorous patient-centered outcomes research methods, standards, and best practices.

**Research**
Fund a comprehensive agenda of high quality patient-centered outcomes research and evaluate its impact.

**Dissemination**
Disseminate patient-centered outcomes research to all stakeholders and support its uptake and implementation.

**Infrastructure**
Promote and facilitate the development of a sustainable infrastructure for conducting patient-centered outcomes research.

**CORE VALUES**

**Usefulness**
We focus on funding research that provides actionable answers to questions that are important to patients and the healthcare community.

**Transparency**
We work in the open and facilitate public access to build trust, encourage participation, and promote implementation.

**Patient-Centeredness**
Patients are our true north: we rely on patient perspectives and values to guide and improve our work.

**Inclusiveness**
We study broad patient populations and seek to provide evidence that is tailored to patients’ demographic or clinical characteristics and their preferences.

**Evidence**
We consistently rely on the best available science and we evaluate our work to improve its reliability and utility.
Has PCORI Been Successful?

- Government Accounting Office performed a ACA mandated study in 2015 and 2018
- GAO examined:
  - Extent to which PCORI established priorities & processes for funding and disseminating CER — **Goal Met**
  - Status of PCORI’s efforts to fund CER — **Goal Met**
  - PCORI’s plans to evaluate the effectiveness of its work — **Goal Met**
- As of October 2014, PCORI has awarded 360 contracts, committing a total of $670.8M.
- Expect to commit $2.6B to research contracts out of $3.5B in estimated total spending.
- Early results related to primary outcome measures expected to begin in 2017 after first CER studies are completed; full evaluation will not be possible until 2020
That was the opportunity…. Where are we in 2016?

Clinical Trials

Comparative Effectiveness Research

Translational Research

Prevention
Cures Acceleration Network

Advancing Development of High-Need Cures & Reducing Barriers Between Research Discovery & Clinical Trials

- CAN was established in NIH, in the Office of the Director, not as an independent entity.
- The program was subsequently moved to National Center for Advancing Translational Research (NCATS)
- It had an authorized budget for fiscal year (FY) 2010 of $500 million
- CAN is the smallest of the four major programs and initiatives within NCATS—Clinical and Translational Science Activities, Rare Diseases Research and Therapeutics, Re-engineering Translational Sciences, and CAN.
- CAN gives NCATS new flexibilities in its funding authorities.
- Under CAN, NCATS may make large grant awards of up to $15 million per fiscal year, partnership awards that require 1:3 matching funds, and flexible research awards using the special funding mechanism called other transactions (OT), which allows projects to be actively and aggressively managed by using mechanisms similar to those used by the Defense Advanced Research Projects Agency at the U.S. Department of Defense. CAN investments are guided by the CAN Review Board.
- Typically, CAN supports projects through the following programs: *Discovering New Therapeutic Uses for Existing Molecules* and *Tissue Chip for Drug Screening*
Final Reflections on Ways to Maximize the Goals of CAN

Key Messages*

- CAN could break the status quo by supporting individuals and companies that are outside the mainstream.
- CAN's portfolio could focus not only on cures but on transforming the process that will lead to cures.
- Personal passion and a tolerance of failure will be important components of CAN's success.
- Possible ways to define success of CAN include
  - installation of NCATS staff with therapeutics development expertise;
  - implementation of milestone-based contracts and increased accountability;
  - establishment of greater collaboration and robust public–private partnerships;
  - advancement of regulatory science and tools for drug development tools; and
  - development of cures: new therapeutics and diagnostics.

* Identified by individual speakers.
The Cures Acceleration Network, an NIH initiative intended to help speed the translation and application of discoveries that have shown signs of success at the laboratory level but have not advanced far enough to attract significant investments from the private sector.
That was the opportunity…. Where are we in 2016?

- Clinical Trials
- Comparative Effectiveness Research
- Translational Research
- Prevention
Knowledge of and Attitudes Toward Evidence-Based Guidelines for and Against Clinical Preventive Services: Results from a National Survey

Authors
PAULA M. LANTZ, W. DOUGLAS EVANS, HOLLY MEAD, CARMEN ALVAREZ, LISA STEWART

Abstract

Policy Points:

- Both the underuse and overuse of clinical preventive services relative to evidence-based guidelines are a public health concern.
- Informed consumers are an important foundation of many components of the Affordable Care Act, including coverage mandates for proven clinical preventive services recommended by the US Preventive Services Task Force. Across sociodemographic groups, however, knowledge of and positive attitudes toward evidence-based guidelines for preventive care are extremely low.
- Given the demonstrated low levels of consumers’ knowledge of and trust in guidelines, coupled with their strong preference for involvement in preventive care decisions, better education and decision-making support for evidence-based preventive services are greatly needed.

Findings

While 36.4% of adults reported knowing that the Affordable Care Act requires insurance companies to cover proven preventive services without cost sharing, only 7.7% had heard of the USPSTF. Approximately 1 in 3 (32.6%) reported trusting that a government task force would make fair guidelines for preventive services, and 38.2% believed that the government uses guidelines to ration health care. Most of the respondents endorsed the notion that research/scientific evidence and expert medical opinion are important for the creation of guidelines and that clinicians should follow guidelines based on evidence. But when presented with patient vignettes in which a physician made a guideline-based recommendation against a cancer-screening test, less than 10% believed that this recommendation alone, without further dialogue and/or the patient’s own research, was sufficient to make such a decision.

Conclusions

Given these demonstrated low levels of knowledge and mistrust regarding guidelines, coupled with a strong preference for shared decision making, better consumer education and decision supports for evidence-based guidelines for clinical preventive services are greatly needed.
ACA Intent to Overcome Cost Barriers to Preventive Services

Under Section 2713 of the ACA, private health plans must provide coverage for a range of preventive services and may not impose cost-sharing (such as copayments, deductibles, or co-insurance) on patients receiving these services. These requirements apply to all private plans – including individual, small group, large group, and self-insured plans in which employers contract administrative services to a third party payer – with the exception of those plans that maintain “grandfathered” status.

Figure 1
Cost barriers to use of preventive services for women and men

<table>
<thead>
<tr>
<th>Share of women and men reporting they put off or postponed preventive services in past year due to cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
</tr>
<tr>
<td>Insured</td>
</tr>
<tr>
<td>Uninsured</td>
</tr>
<tr>
<td>Less than 200% FPL</td>
</tr>
<tr>
<td>200% FPL or greater</td>
</tr>
<tr>
<td>Women</td>
</tr>
<tr>
<td>20%</td>
</tr>
<tr>
<td>13%</td>
</tr>
<tr>
<td>52%*</td>
</tr>
<tr>
<td>35%*</td>
</tr>
<tr>
<td>13%</td>
</tr>
<tr>
<td>Men</td>
</tr>
<tr>
<td>16%</td>
</tr>
<tr>
<td>9%</td>
</tr>
<tr>
<td>42%*</td>
</tr>
<tr>
<td>31%*</td>
</tr>
<tr>
<td>11%</td>
</tr>
</tbody>
</table>

NOTE: Among women and men ages 18-64. Federal Poverty Level (FPL) was $19,530 for a family of three in 2013.*Indicates a statistically significant difference from insured and 200% FPL or greater, p<.05.
SOURCE: Kaiser Family Foundation, 2013 Kaiser Women’s Health Survey.

Source: http://kff.org/health-reform/fact-sheet/preventive-services-covered-by-private-health-plans/
Opportunities Presented by Novel Health Information Systems

“The opportunities for improving patient care, the quality of care and driving new healthcare innovation require the development of novel health information systems”

• Must overcome the information gaps within the health care continuum
• Must address lack of standardized nomenclatures, data standards, data quality
• Must overcome the technical capabilities of data management architecture
SPECIAL FEATURE

Improving U.S. Healthcare Symposium
Feature Editors: Drs. John R. Feussner, Eugene Oddone & Eugene Rich

The Promise of Information and Communication Technology in Healthcare: Extracting Value From the Chaos

Burke W. Mamlin, MD and William M. Tierney, MD

ABSTRACT

Healthcare is an information business with expanding use of information and communication technologies (ICTs). Current ICT tools are immature, but a brighter future looms. We examine 7 areas of ICT in healthcare: electronic health records (EHRs), health information exchange (HIE), patient portals, telemedicine, social media, mobile devices and wearable sensors and monitors, and privacy and security. In each of these areas, we examine the current status and future promise, highlighting how each might reach its promise.

Steps to better EHRs include a universal programming interface, universal patient identifiers, improved documentation and improved data analysis. HIEs require federal subsidies for sustainability and support from EHR vendors, targeting seamless sharing of EHR data. Patient portals must bring patients into the EHR with better design and training, greater provider engagement and leveraging HIEs. Telemedicine needs sustainable payment models, clear rules of engagement, quality measures and monitoring. Social media needs consensus on rules of engagement for providers, better data mining tools and approaches to counter disinformation. Mobile and wearable devices benefit from a universal programming interface, improved infrastructure, more rigorous research and integration with EHRs and HIEs. Laws for privacy and security need updating to match current technologies, and data stewards should share information on breaches and standardize best practices.

ICT tools are evolving quickly in healthcare and require a rational and well-funded national agenda for development, use and assessment.

Key Indexing Terms: Health information technologies; Electronic medical records; Telemedicine; Information management.
Reasons for Chaos

• The many different EHR systems serving U.S. healthcare have limited ability to share information.
• There are no secure connections between EHRs, no national identifiers to link patients ‘data and few existing standards for formatting, summarizing or displaying patient information.
• Mandates for billing, quality improvement and other initiatives have expanded documentation requirements whereas funding constraints have reduced clinician time. Consequently, clinicians use shortcuts (eg, templates and copy-and-paste) that often increase the amount of information recorded but decrease its readability.
• The amount of available information is constantly increasing; the tools to safely digest, summarize and empower the provider have not kept up.

Source: THE AMERICAN JOURNAL OF THE MEDICAL SCIENCES, VOLUME 351, NUMBER 1, January 2016
Reasons for Optimism

• Evolving EHRs,
• Health information exchange (HIE),
• Patient portals and personal health records (PHR),
• Telemedicine,
• Social media,
• Mobile devices and wearable sensors or monitors,
• Privacy and security

Source: THE AMERICAN JOURNAL OF THE MEDICAL SCIENCES, VOLUME 351, NUMBER 1, January 2016
“Information and Technology Tools are evolving quickly and require a rational and well-funded national agenda for development, use and assessment” Mamlin and Tierney; Amer J Med Sci 2016.