PCORI, the ACA, and Cancer Comparative Effectiveness Research

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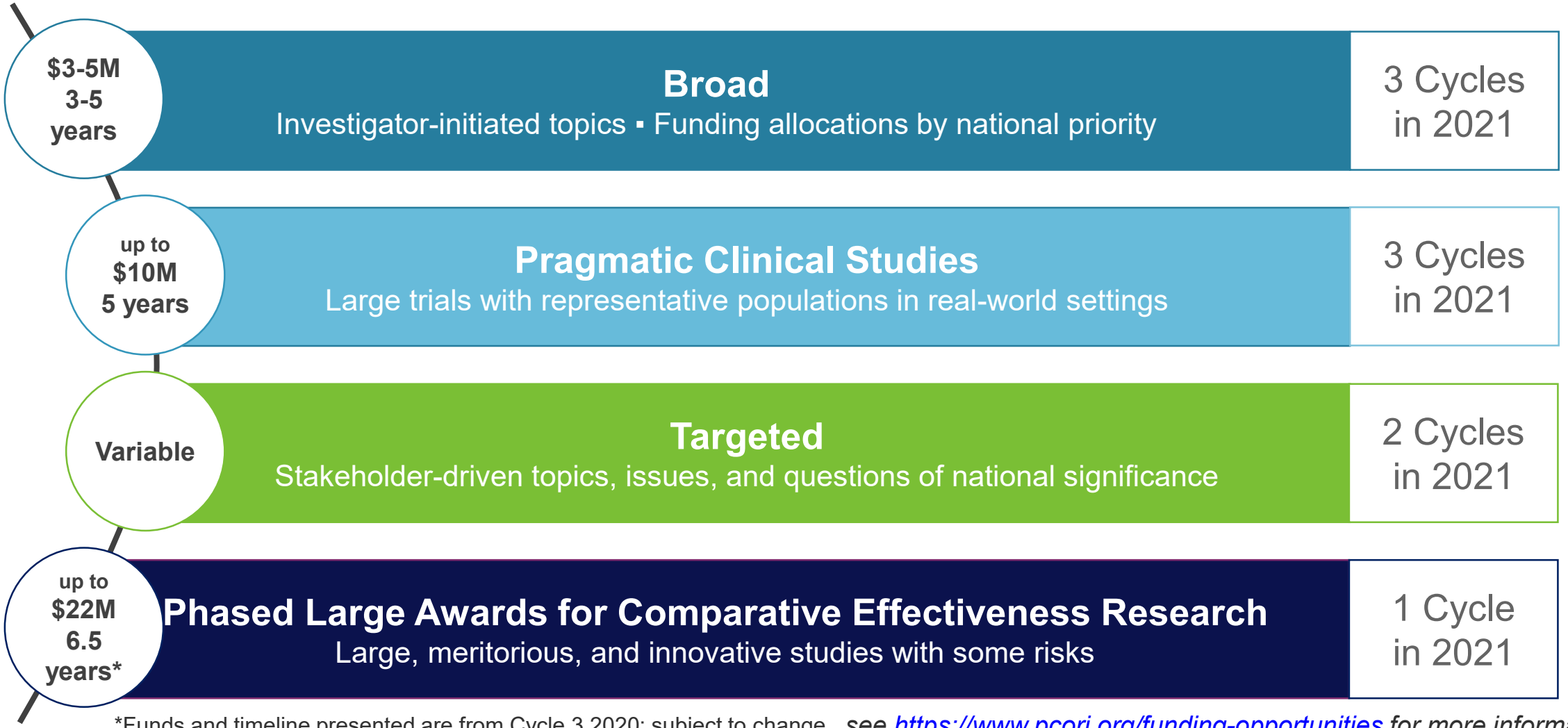
About PCORI

- PCORI is an independent research institute that as authorized by the ACA in 2010 for 10 years
  - Governed by a 21-member Board of Governors representing the entire healthcare community
  - Reauthorized by Congress in December 2019 for an additional 10 years (through September 30, 2029)
- Funds comparative clinical effectiveness research (CER) that
  engages patients and other stakeholders throughout the research process
- Seeks answers to real-world questions about what works best for patients based on their circumstances and concerns

PCORI's Funding Streams: Research Awards



*Funds and timeline presented are from Cycle 3 2020; subject to change *see https://www.pcori.org/funding-opportunities for more information.*

PCORI's Investment in Cancer Research

PCORI HAS AWARDED

$313 MILLION TO FUND **81** **CER studies**

on cancer, representing 17% of all PCORI CER awards

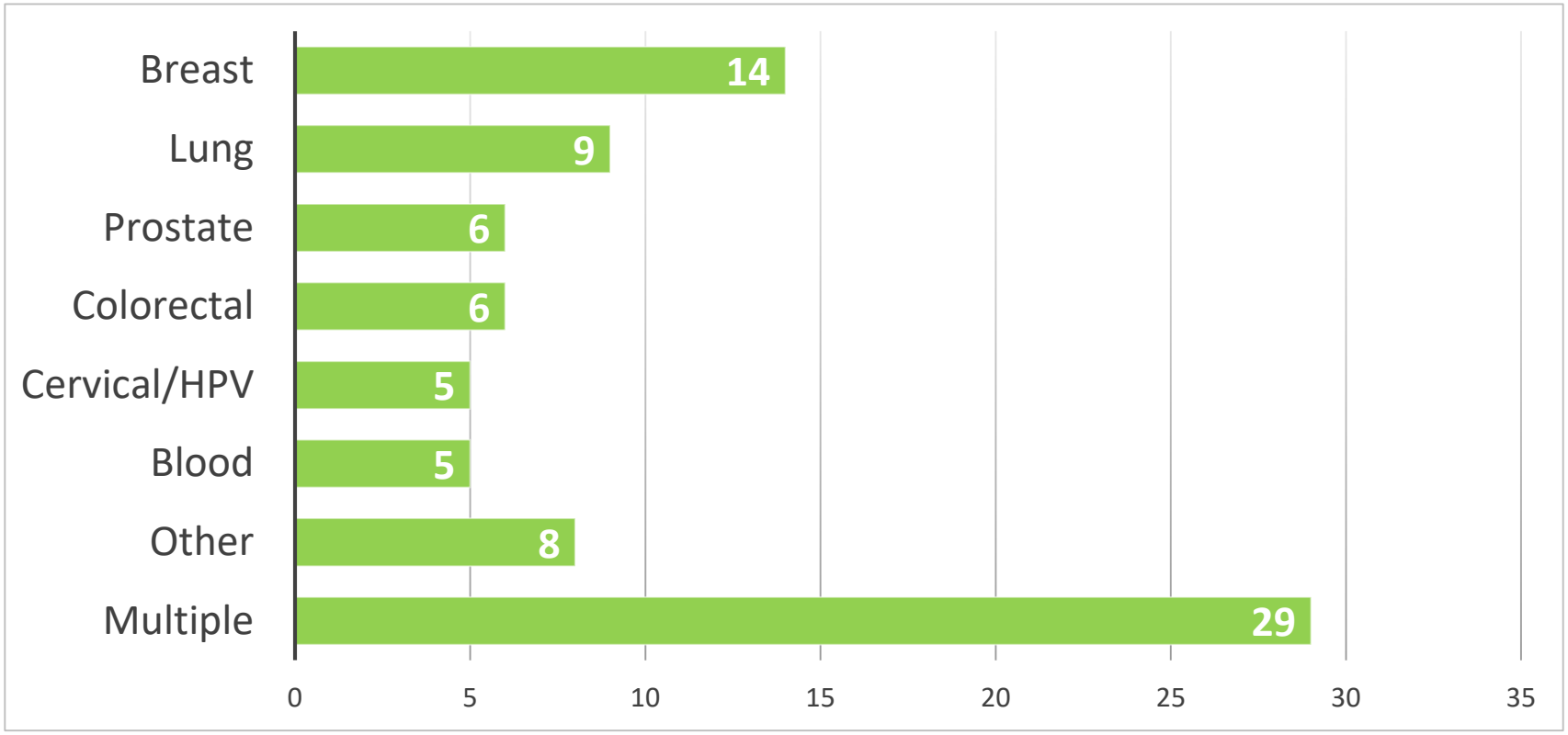
In addition, PCORI has also awarded:

- 45 Engagement Awards: $8.6M
- 3 Dissemination & Implementation Awards: $4.7M
- 1 PCORnet Rapid Research Award: $860,000
- 2 Systematic Reviews: $830,000

Current thru January 2020

The Research Portfolio Includes a Range of Cancer Types

Number of Research Studies by Cancer Type*



*Categories are not mutually exclusive

The Cancer Research Portfolio Includes a Range of Interventions

Clinical Interventions

- Primary Treatment Modalities (n=15)
  - Surgery, Radiation, Drugs
- Screening & Surveillance Protocols (n=8)
- Behavioral & Psychological (n=5)
- Complementary & Alternative Medicine (n=4)

Care Delivery/ Communication Strategies

- Models of Care (n=21)
- Decision Support Tools (n=16)
- Education & Communication (n=14)
- Telemedicine/mHealth (n=8)
- Patient Navigation (n=5)

Tailored Decision and Navigation Support Can Address Colorectal Screening Disparities

Ronald Myers, PhD (2013) - Thomas Jefferson University

Research Question	Does active decision support with a patient navigator improve colorectal cancer screening rates among Hispanic patients compared to mailed educational information?
What's New	Tailoring of decision and navigation support incorporating preferences for screening among Hispanic patients
Design	Randomized control trial at 5 primary care practices; n=400
Key Findings	Telephonic decision and navigation support increased colorectal screening (78%) compared to mailed information (44%).
References	Myers RE, Stello B, Daskalakis C, et al. Decision Support and Navigation to Increase Colorectal Cancer Screening Among Hispanic Patients. Cancer Epidemiol Biomarkers Prev. 2018 Oct 17. doi: 10.1158/1055-9965.EPI-18-0260. Myers RE, DiCarlo M, Romney M et al. Using a health system learning community strategy to address cancer disparities. Learn Health Sys. 2018;e10067. DOI: 10.1002/lrh2.10067

Long-Term Side Effects Remain After Treatment for Early-Stage Disease

David Penson, MD, MPH (2013) - Vanderbilt University Medical Center

Research Question	What are the side effects of treatments (surgery, radiation, and active surveillance) at 3 years for localized prostate cancer?
What's New	Comparison of modern prostate cancer treatments with active surveillance in a diverse population
Design	Prospective observational study; n=2550
Key Findings	• Men who had surgery reported a greater decline in sexual function and worse urinary incontinence compared to radiation or active surveillance at 3 years. • Men who had radiation reported worse bowel function at 6 months compared to surgery and active surveillance; no significant differences at 3 years.
Reference	Barocas DA, Alvarez J, Resnick MJ, et al. Association Between Radiation Therapy, Surgery, or Observation for Localized Prostate Cancer and Patient-Reported Outcomes After 3 Years. *JAMA*. 2017 Mar 21;317(11):1126-1140. doi: 10.1001/jama.2017.1704. PubMed PMID: 28324093.

Disseminating Findings from PCORI-Funded Research: PCORI Evidence Updates

Evidence Update for Clinicians:

Current Treatments for Localized Prostate Cancer and Symptom-Related Quality of Lif

Given the evidence of high 5- and 10-year survivorship rates for local treatment on symptom-related quality of life is an important consid treatment options. Two PCORI-funded studies published in the Marc impact of current treatments on symptom-related quality of life for r of life scores refer to symptoms, how much men were bothered by s studies looked at observed outcomes from a combined total of 3,60 following treatment. This evidence offers information that can help

Summary of the Evidence:

Sexual, urinary, and (to a lesser extent) bowel function were signi year for men receiving surgery or radiation compared with men i improve over 2 to 3 years, but differences may remain.

Surgery

(open or robotic assisted laparoscopy) was more likely to cause sexual dysfunction and urinary incontinence than radiotherapy or active surveillance.

- Sexual dysfunction was worse during the six months following surgery.
- While men who had full sexual function at study entry saw some improvement after one year, they continued to report sexual dysfunction at two and three years after surgery. In adjusted models at three years, men who had had surgery were more likely to report moderate or big problems with sexual function (44%) than those who had had radiotherapy (35%) or active surveillance (28%).
- Following initial declines, urinary function was more likely to improve after prostatectomy than sexual function, especially for men who had reduced urinary function at the time of treatmer For those men (who represent the majority), urinary incontinence symptoms initially got wor but improved by 12 months to baseline levels.
- Urinary irritation and obstruction scores were improved in patients who had a radical prostatectomy compared to those in active surveillance.

How Will Treating My Early-Stage Prostate Cancer **Affect My Quality of Life?**

Early-stage prostate cancer can be treated in different ways. The three main ways are active surveillance, surgery, and radiotherapy. Active surveillance means having your prostate checked every few months to make sure the cancer is not spreading. Surgery would take out the prostate, and radiotherapy uses high-energy rays to kill cancer cells in the prostate.

Two recent PCORI-funded studies compare the effects of these choices on the quality of life for men with early stage prostate cancer. These studies looked at three effects treatment might have on a man's quality of life. These are problems having sex, urinary problems, and bowel problems.

Prostate cancer grows very slowly, making the risk of dying from the cancer very low.

That gives you a chance to think about quality of life issues that matter most to you.

Here's what the new research says:

The different ways of treating early-stage prostate cancer (active surveillance, radiotherapy, or surgery) affect men differently. Men who have surgery or radiotherapy have more sexual, urinary, and bowel problems in the first year compared with men who were treated with active surveillance. After 2 to 3 years, most symptoms improve, but there may still be differences.

Surgery

Men who had surgery to remove the prostate (called a total prostatectomy) were:

- more likely to have problems with sex
- more likely to leak urine

than men who chose radiotherapy or active surveillance.

But men who had surgery had:

- less of a need to rush to the bathroom to pee
- less of a feeling that their pee was unable to come out

than men who chose radiotherapy or active surveillance.

What to expect after surgery:

- About four out of ten men who had surgery still had sexual problems 3 years after surgery.
- Problems leaking urine caused by surgery were more likely to improve than sexual problems. After one year, urinary leaking caused by surgery improved to what it had been before surgery.

Radiation

Men who had radiation to kill cancer cells in the prostate were:

- more likely to feel burning when peeing, more likely to feel that their pee won't come out, or a need to rush to the bathroom to pee
- more likely to feel the need to rush to the bathroom for a bowel movement. This was not as common as urinary problems or problems with sex.

What to expect after radiation:

- Urinary problems were more likely to get better by two years after treatment for men who had radiation from outside the body (external beam radiotherapy) than men who had radiation from pellets placed inside the body (brachytherapy).
- About 2 out of every 10 men who had radiation had sexual problems. These problems started a few months after men had radiation.

- **Dissemination activities** raise awareness, ability, and motivation to use evidence, targeting audiences who can use it to inform their healthcare or other health decisions.
- **PCORI Evidence Updates** distill main findings from one or more PCORI-funded studies or from systematic reviews, into accessible formats.
- **Cobranding organizations** are trusted sources of information for their membership.
- **Sample dissemination activities**: linking to websites; including in newsletters, blogs, or tweets; adding to resource libraries.

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