Access to Innovative Medicines and Value: The Fine Balance

Tuesday, October 18, 2016

MaRS Discovery District, Toronto

This session was generously sponsored by Amgen Canada Inc.

CAPT ACTP

Meet the Panel

Moderator:

- Angela Rocchi (Athena Research)

Speakers:

- Sherry O'Quinn (PDCI Market Access Inc.)
- Glenn Monteith (Innovative Medicines Canada)
- Andrew Loblaw (Sunnybrook Health Sciences Centre)
- Rocco Rossi (Prostate Cancer Canada)

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Session Overview

Given the increasing demands for access to innovative medicines and increasing cost-pressures on a limited budget, payers are looking for more guidance on public listing (and thus patient access) based on cost. This session will explore how certain Canadian stakeholders determine value of innovative medicines while remaining objective during the HTA process and leaving the issue of affordability to the provincial payers.

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Access to Innovative Medicines and Value

The Fine Balance

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Introductions

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Discussion Question

Given the increasing demands for access to innovative medicines and increasing cost-pressures on a limited budget, how do Canadian stakeholders determine the "value" of innovative medicines?

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Public Payer Perspective

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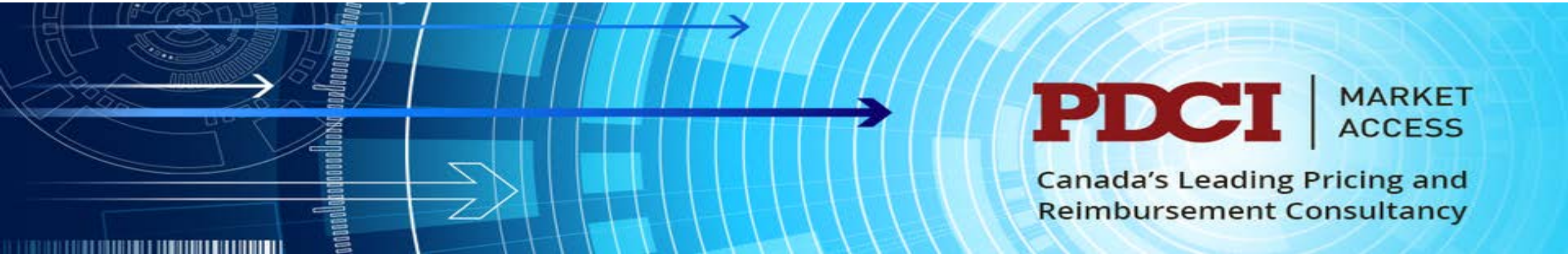
Innovation and Cost: the fine balance
(Ex) Public Drug Plan Payer Perspective

October 18, 2016
Sherry O'Quinn



Understanding the challenges of public drug plans

- Budgets are set for them
- Forecasts far exceed budgets they will receive from the government
- Significant stakeholder pressure to fund most drugs
  - Manufacturers
  - Patients
  - Patient groups
  - Clinicians
  - Media
  - Political
- Increasing volume of workload: new launches, negotiations, re-evaluation
- Resources: time & people

Their dilemma: how to manage their current budgets within their constrained system now?

Focus is on strategies that can be implemented quickly

Value varies by stakeholder and their lens: Public Payer

Value is not placed on the fact that a drug is an “innovation” or is new.

Value to payers consists of many factors, most notably:

- Provides **significant** improvement in clinically meaningful outcomes for patients (morbidity, mortality, QOL, safety)
- **Demonstrates** value to the health care system overall
- Replaces existing therapies (cost-offsets) versus additive

A “cost-effective” drug typically results in budget impact to the drug plan. In a world of fixed budgets, there comes a breaking point…a cost effective and clinically relevant drug can be unaffordable.

Payers now also placing greater emphasis on the following question: Is the drug affordable?

Stakeholders have different value assessments based on the same evidence

Canadian environment & approach appears to be shifting

2006: Bill 102 – Reforms in Ontario

- With a major focus on **improving patient access** to drugs, ensuring better value for money, **rewarding innovations** and strengthening transparency and accountability
- Approach: Value-based pricing and decision making

Now: Environment and approach appear to be shifting

- Major media attention globally on pharmaceutical pricing
- Sustainability and Affordability is now at the centre in every public forum
- "Approaching a crossroad: can't expect to be able to afford **everything**."
- Approach: Best possible deals for the public plans = affordability-driven

Genuine apprehension that current approach no longer works given the shifting fiscal environment

Move to Affordability, Sustainability, "Fair Price" Lens?

World Health Organization:

- An 'affordable and fair price' is one that can reasonably be funded by patients and health budgets and simultaneously sustains research and development, production and distribution within a country
- Countries should make their pricing policies, processes and decisions transparent

BMJ Article[1] 2016 asks the question: Can we find a "just" price for drugs?

- Although a thriving drug industry may be an economic and financial benefit to governments, the triumphs of pharmaceutical innovation are hollow victories if they cripple health systems and generate massive inequities.

[1]Ghinea N, Lipworth W, Kerridge I. Propaganda or the cost of innovation? Challenging the high price of new drugs. BMJ 2016; 352

What could the future hold?

- Drug plan managers have been discussing how to manage their challenges in public forums:
  - Disinvestment
  - Saying “no” to more drugs
  - Therapeutic re-negotiations
  - Prioritization

- None of these approaches are ideal for any party, including government
- Without some assistance from other stakeholders, governments will likely make decisions to manage their budgets through these types of policy and decision mechanisms

Drug Plan “Solutions” will be imposed unless other alternatives are presented

Industry Perspective

The Value of Innovation: Value vs. Cost

Presented by Glenn Monteith
Vice President, Innovation & Health Sustainability

October 2016

INNOVATIVE MEDICINES CANADA
MÉDICAMENTS NOVATEURS CANADA

THE VALUE CHALLENGE

- **Increasing entry of new innovations (drugs, but also technologies e.g.: diagnostics, etc.)**
- **Increasing focus on managing fiscal resources**
- **Value for the investments made are increasingly important**
- **Value for whom?**

Value Concepts

Value in health - what is goal of patient care?	**Achieve best health outcomes or health gain for the patient**
How to achieve the goal?	Timely access and delivery of the best standard of care, ***the first time around***
Decision makers' perspective matters	Narrow Drug plan/ Cancer agency perspective? *or* Patient's perspective? *or* Health System perspective? *or* Societal/Holistic perspective?

Challenges for different decision-makers

Decision-maker	Decision Role	Challenges
Regulator (Health Canada)	Market authorization based on safety, efficacy and quality (Proof of concept)	Increasing complexity of science and need to modernize and be more efficient
PMPRB	Determine Non-excessive price	Pressure by the payers and consumers to demonstrate its relevance
HTA	Comparative effectiveness assessment Value for money assessment	Young discipline, evolving but rooted in quantitative evidence based assessments Need for evidence and value based decision making processes- better engagement with patients and clinicians
Payers	Reimbursement or funding decisions, provide equitable and timely access to their beneficiaries	Budget allocation and management strategies not fit for purpose, price and cost driven decision making processes instead of value based decisions, lack of appropriate data infrastructure or capacity to enable pay for performance strategies
Patients	Participation in clinical studies, informed decision making for their treatment	Patient input being sought by many in the process but the influence of their input on decision making processes not clear
HCPs	Prescribe and deliver the care in best interest of the patient	Optimal involvement in clinical trials to gain experience with novel medicines, rapidly changing treatment protocols, not part of the final decision making process
Innovative bio-pharma Industry	Innovate, develop, manufacture and supply medicines that improve upon the current standard of care, or provide choice	High attrition rate in the discovery and development phase, increasing cost of innovation and drug development Increasing barriers to adoption of innovation Increasing timelines to listing decisions due to multiple sequential process steps

Who can help the decision-makers in determination of value?

Who	What information would help in determination of value?
Patients	Lived experience with disease and patient values Active participation through the continuum of care
Health care providers	Help define the current standard of care, unmet clinical need, experience with the new drugs and interventions, place in therapy
Industry (Developers, Manufacturers and Suppliers)	Human drug development data (positive as well as negative data) On-market data (real world) development Patient support programs and their value Investments to foster innovation in the country (new innovation support models) Global price dynamics and willingness to negotiate under pre-agreed and predictable frameworks
Health Canada	Proof of concept (clinical efficacy, safety and quality of data assessment) Clear description of the indication and clinical use, and precautions required Guidance on real world evidence development in the Canadian context
PMPRB	Set non-excessive price in consumer interest
Data systems	Real World/ On-market data Measuring health outcomes (effectiveness and safety) in the real world Facilitate outcomes based value discussion
HTA experts	Comparative effectiveness and value for money assessment Willingness to pay thresholds
Public and politicians	What balance do we want to achieve as a nation and what is our aspiration?

Are we prepared for the future of oncology therapeutics?

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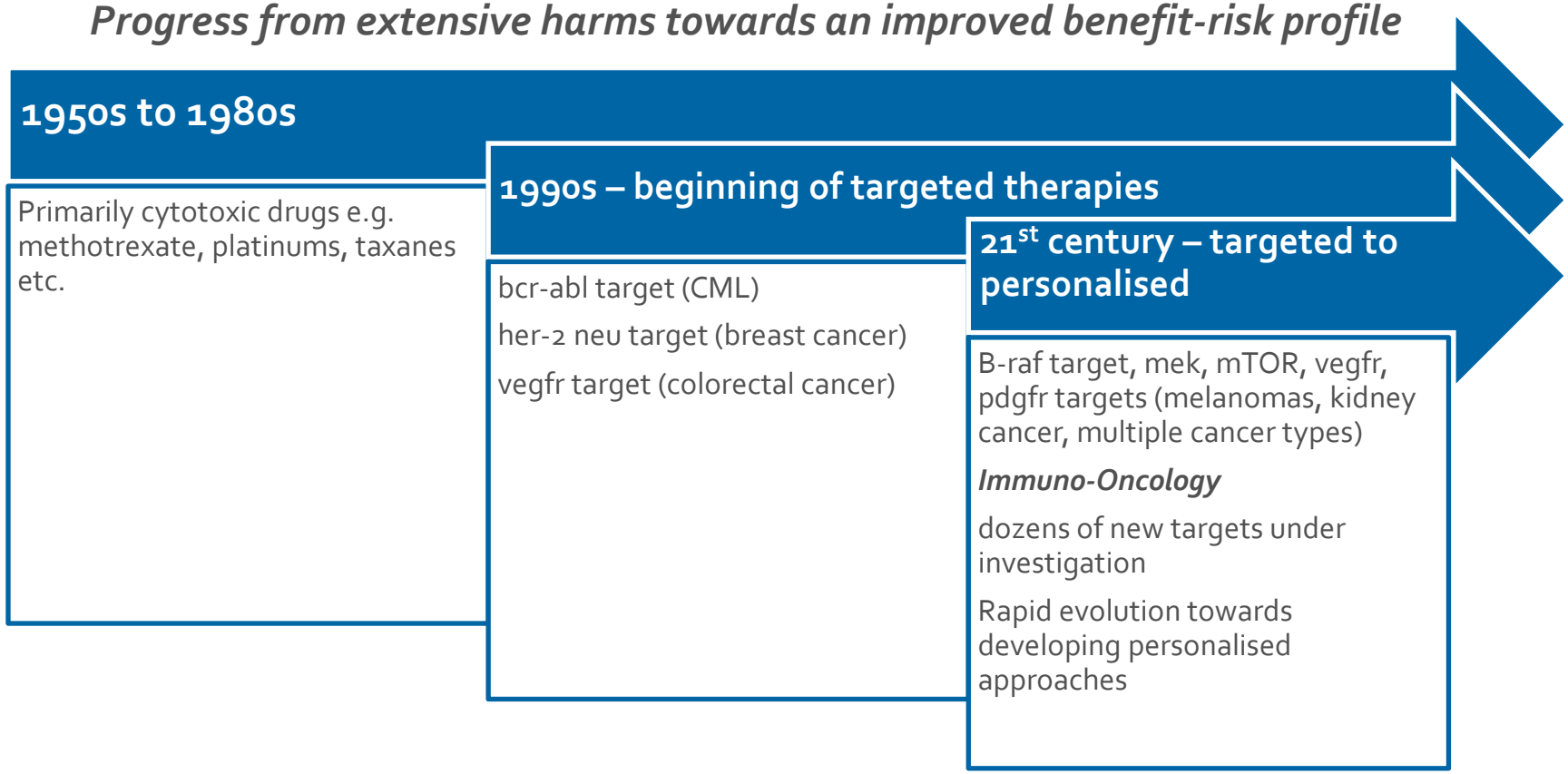
Evolution of pharmacotherapies in Oncology

Multidisciplinary progress made to change cancer from a death sentence to chronic treatment in many cases

Progress from extensive harms towards an improved benefit-risk profile



Oncology specific challenges and opportunities

Challenges	Opportunities
Market entry based on surrogate outcomes (e.g. progression free survival, disease free survival)	Early access of innovative therapies for patients On-market data development to capture longer term health outcomes and enable pay for performance schemes
Disruption of existing treatment protocols as a result of introduction of new drug (s)	Work closely with the clinical experts to identify the best place in therapy
Focus on price/cost of treatment Challenge in measuring value of innovation	Create better data systems to enable Pay for performance or Outcomes based negotiation frameworks
Companion diagnostics	Integrated access decision frameworks to ensure timely and accurate diagnosis Optimal patient selection
Cost of not adopting innovation	E.g. Oral treatments (health system perspective), better productivity for patients and caregivers

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Clinician Perspective

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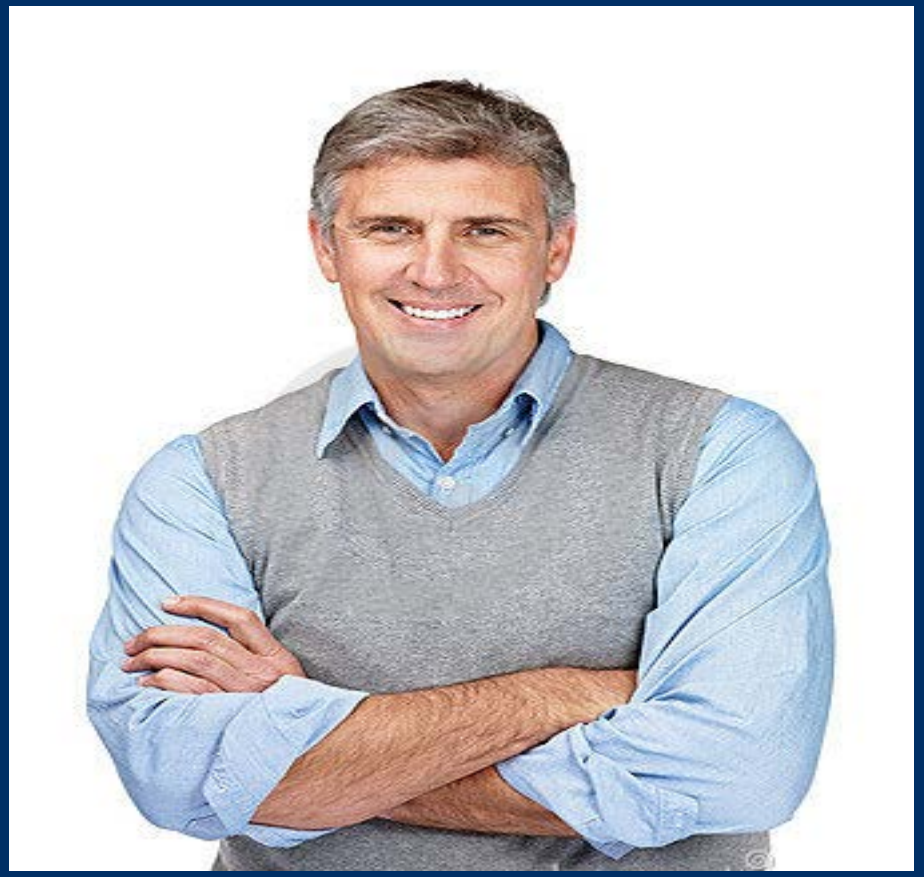
Prostate Cancer Treatment
A Health Policy Incubator?

Radiation Oncology
UNIVERSITY OF TORONTO

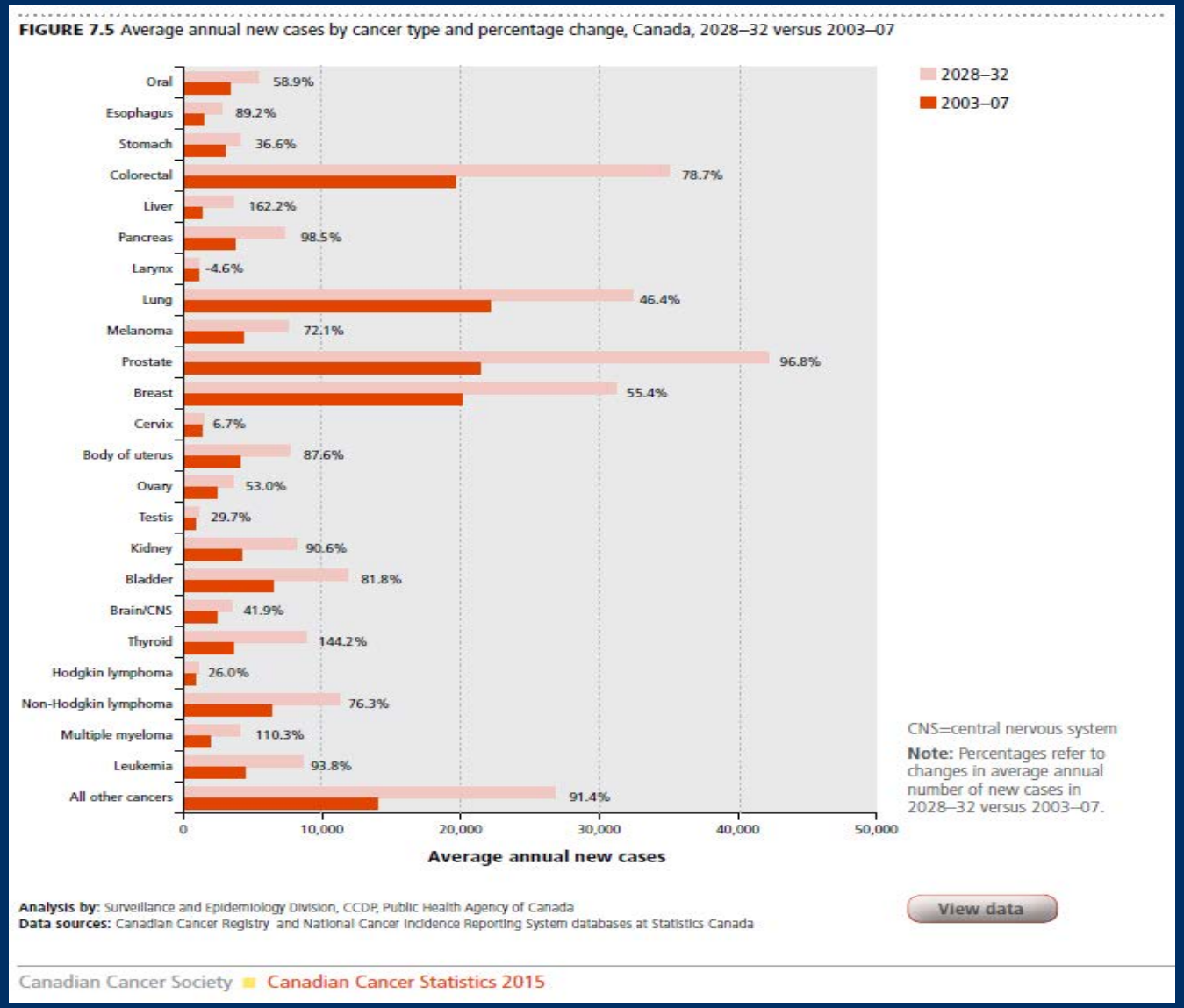
Sunnybrook
HEALTH SCIENCES CENTRE

Prostate Cancer

- Most common (non-cutaneous) in North American men
  - 1 in 8 will be diagnosed during their lifetime
  - 24,000 men will be diagnosed in Canada in 2015
  - 4,100 will die of prostate cancer
  - Highly curable (therefore long-term quality of life critical!)

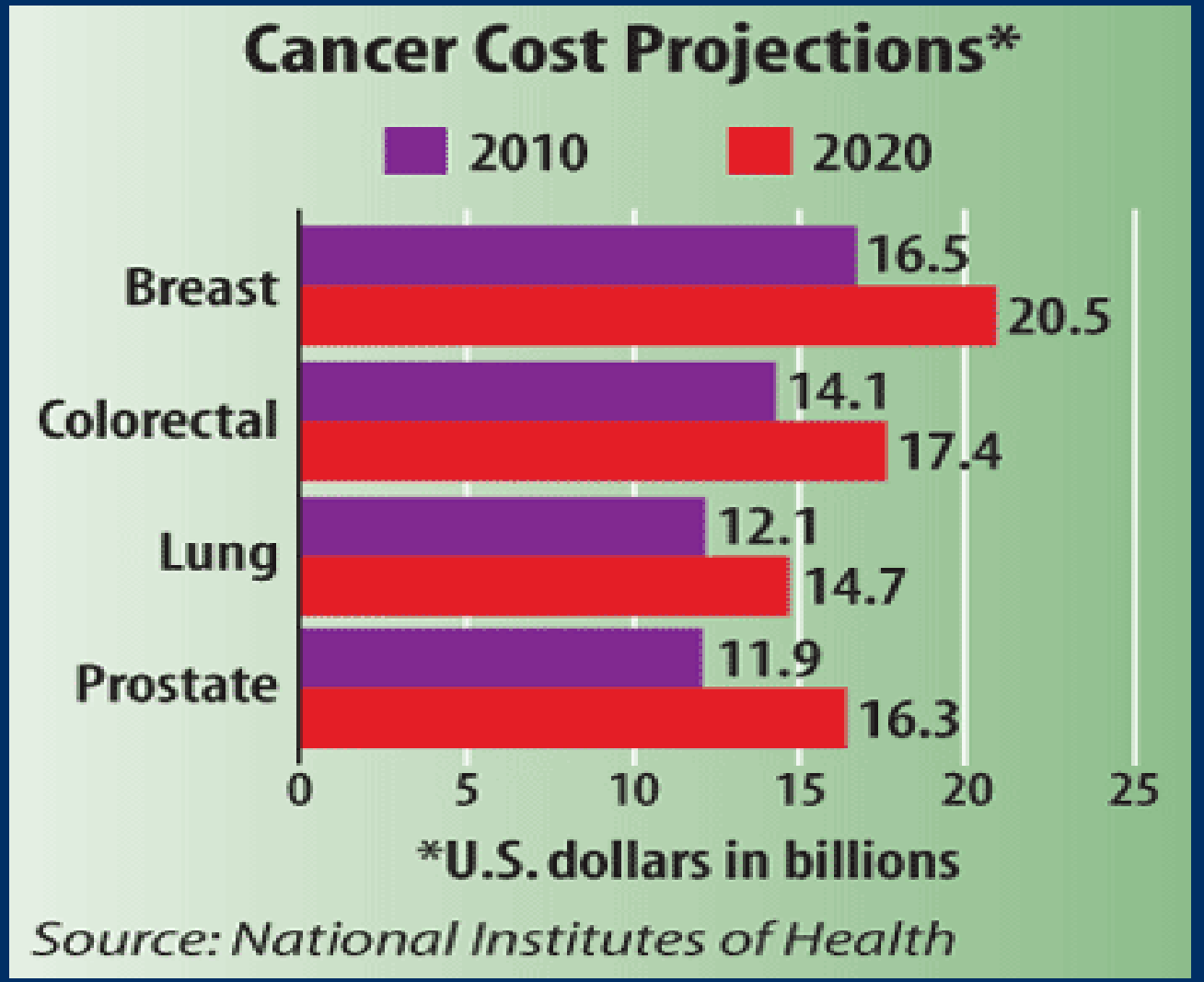


Why is this Important?



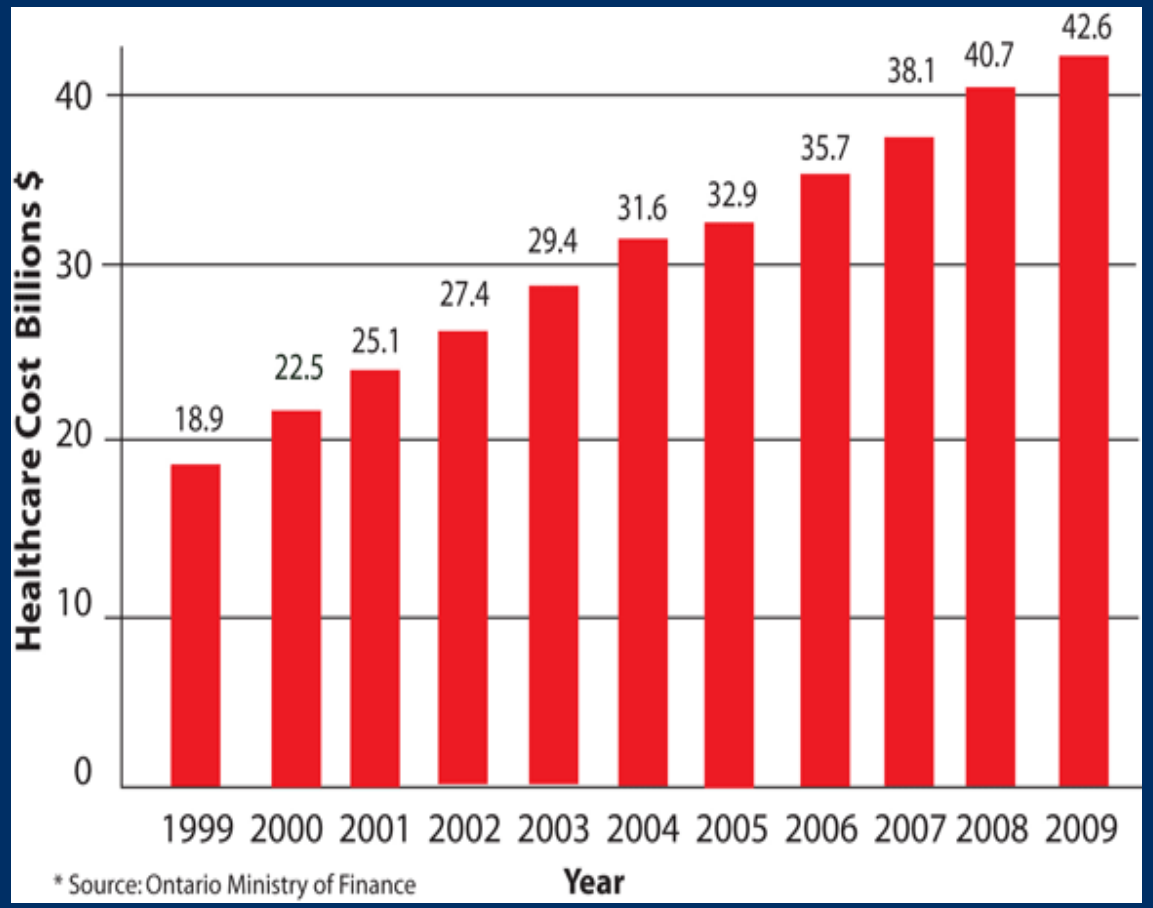
42,000 men

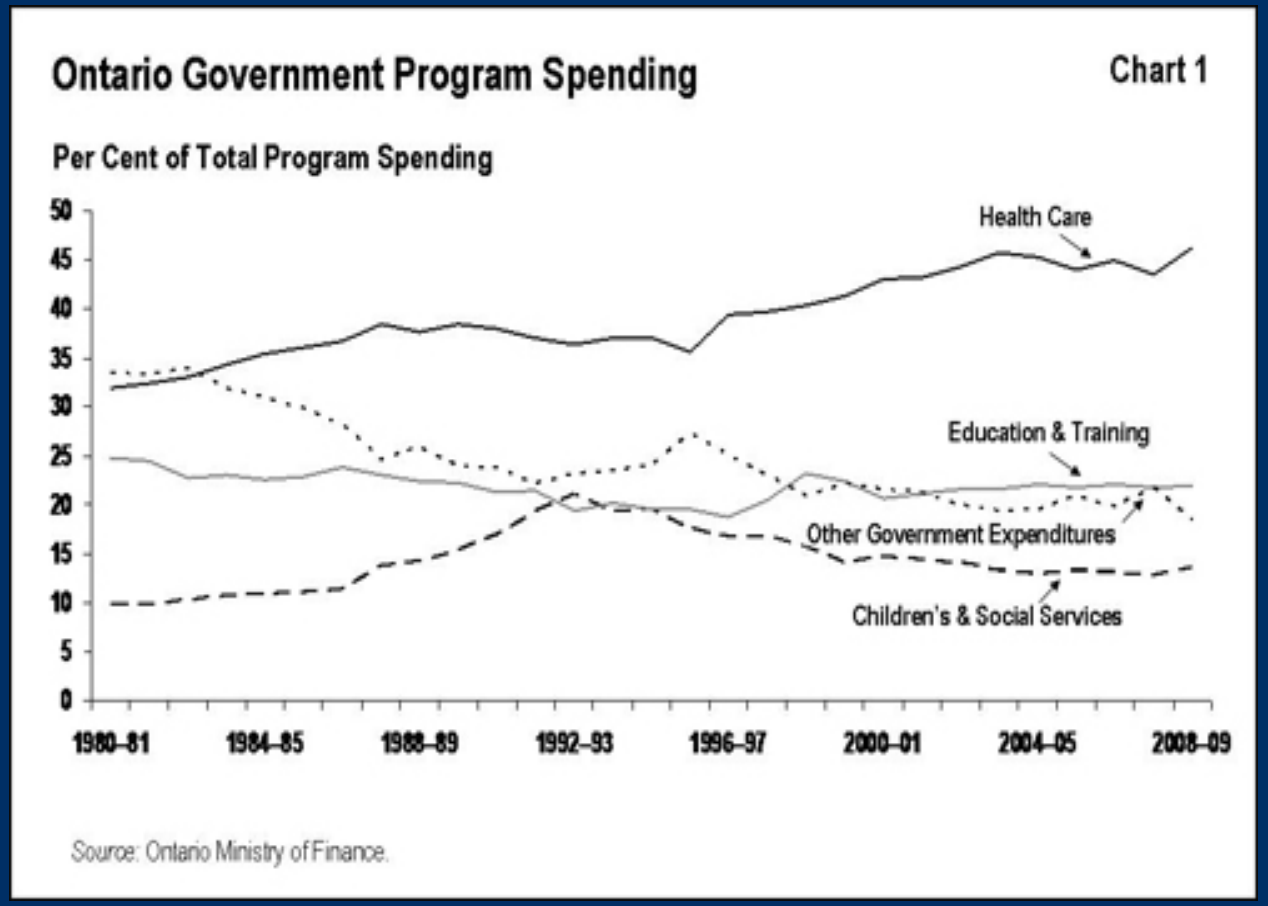
Prostate Cancer: Largest Increase in Cost



37% increase!

Public Healthcare Not Sustainable





2015 Healthcare Budget $50.8M

2014 Healthcare Proportion 41%

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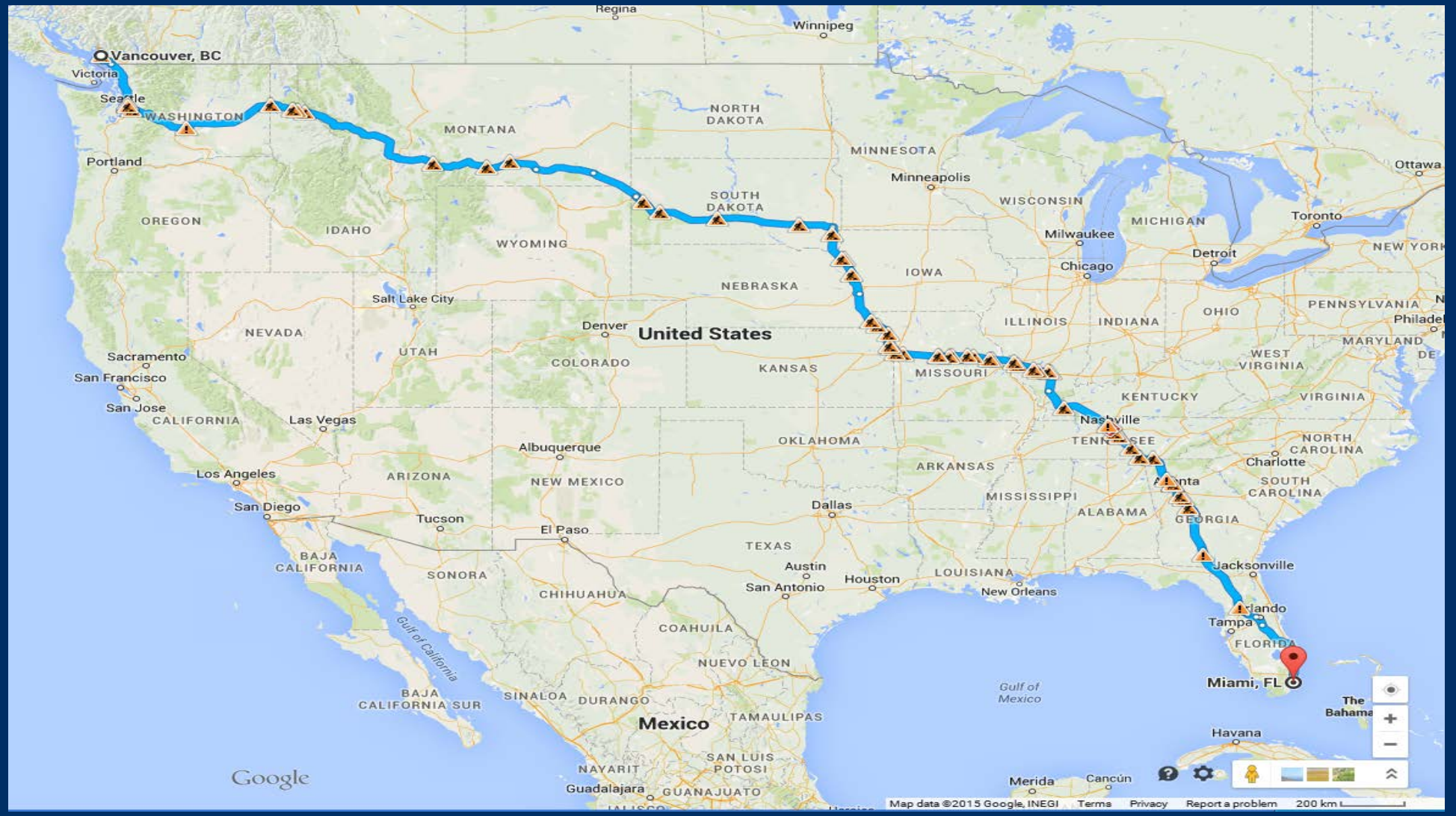
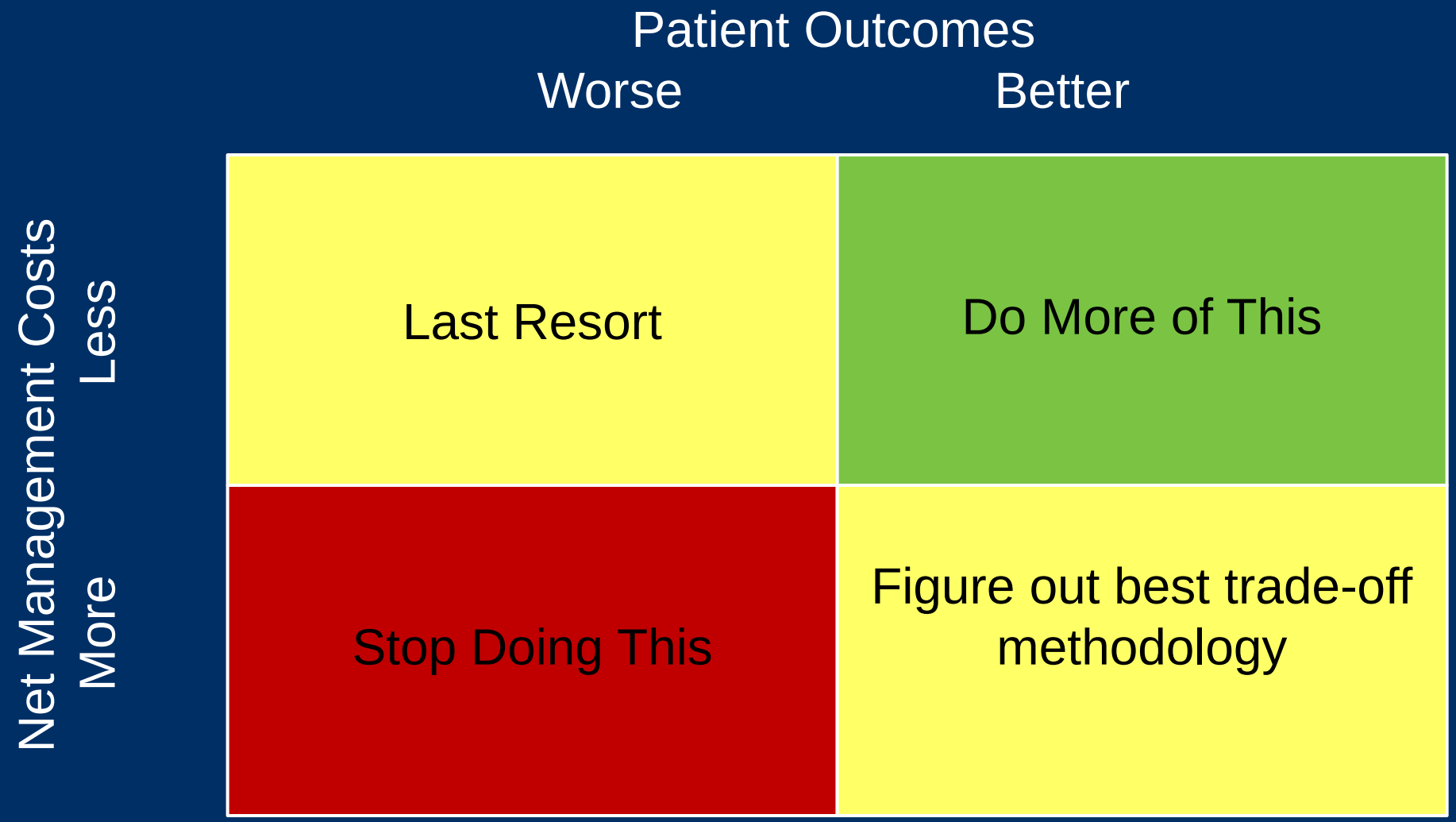
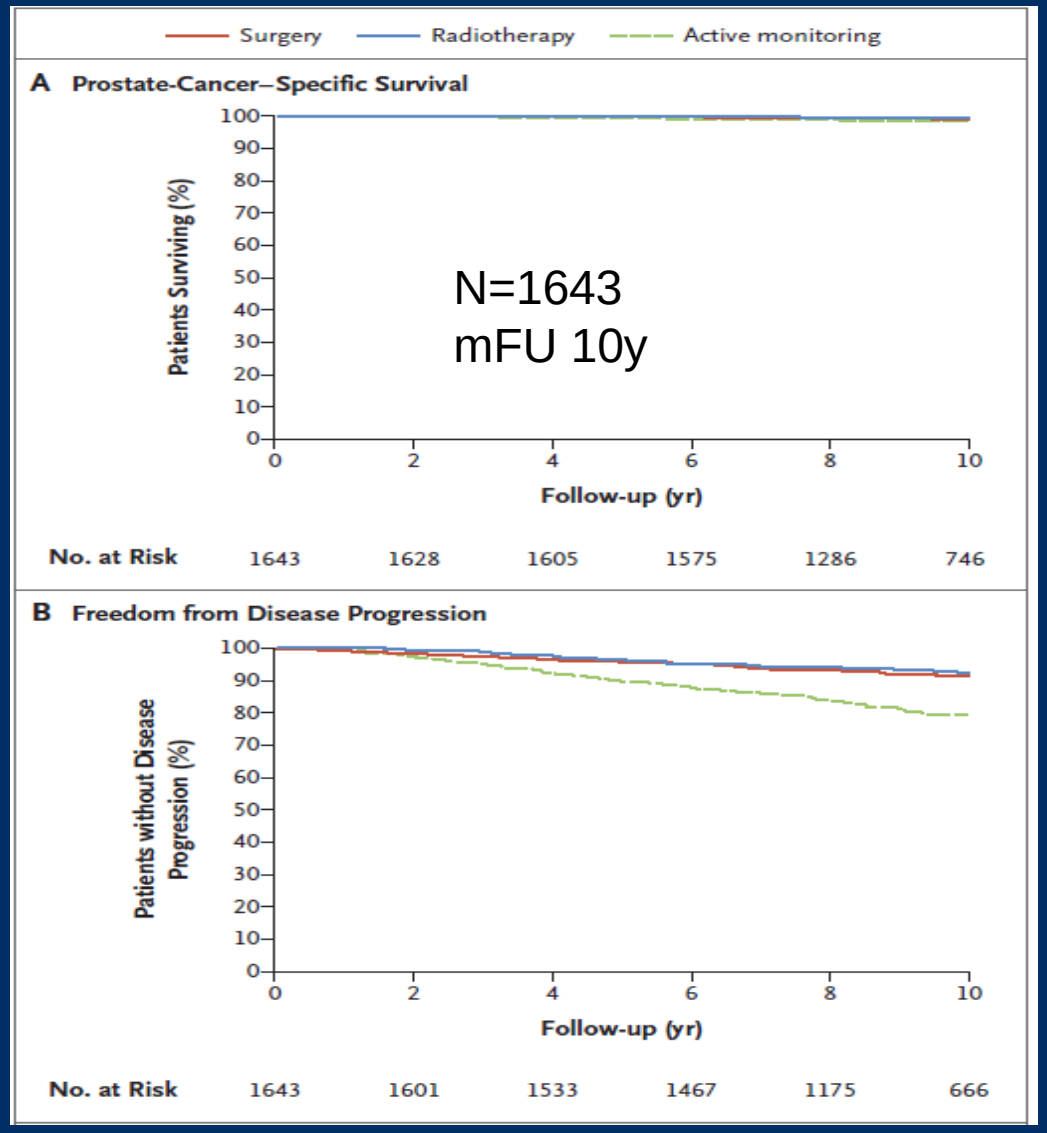
Vancouver to Miami

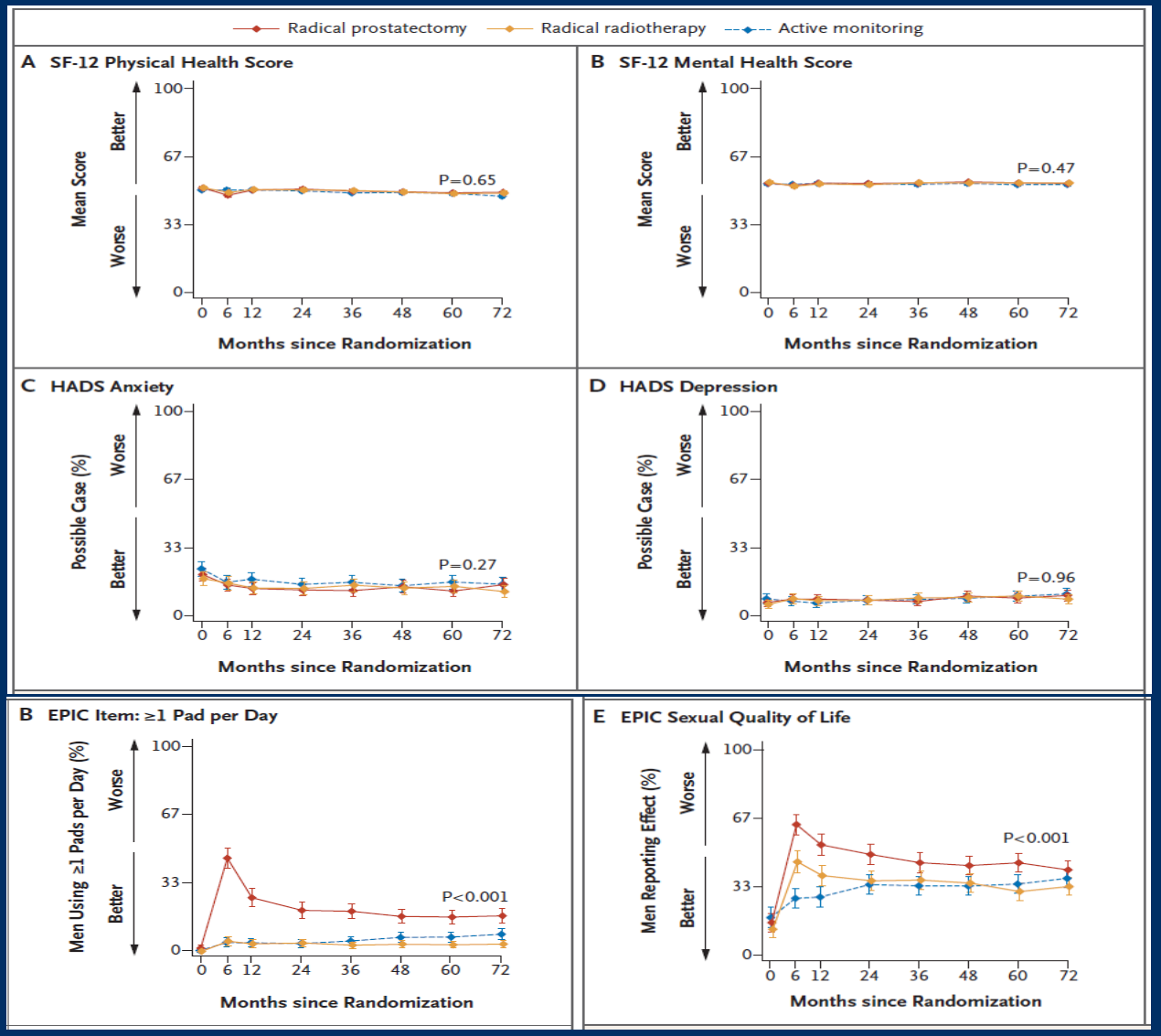


The Litmus Test of Public Healthcare



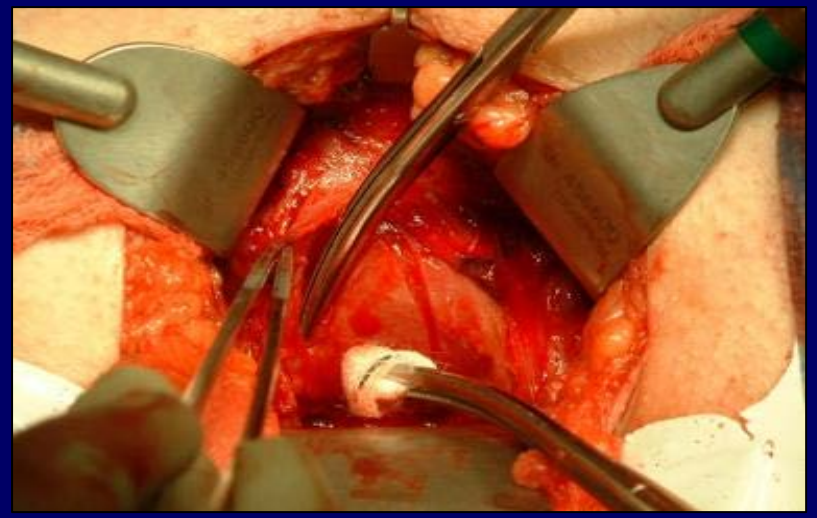
PROTECT Study





Hamdy F et al., NEJM 2016; Donovan JL et al., NEJM 2016

Surgery



2-3 day hospital stay
8-12 week recovery
60% success rate
>50% erectile problems
5% diaper rate

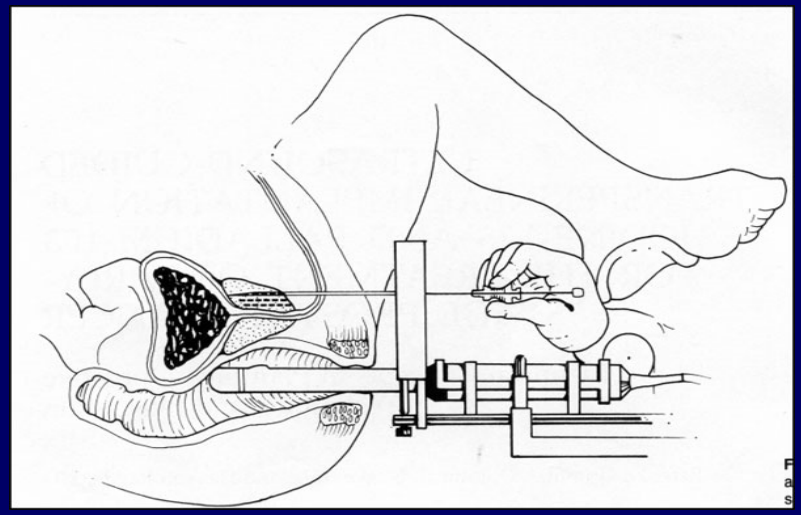
$7080
$11873

External Radiation

Up to 39 daily visits
No recovery required
70% success rate
25% erectile problems
0% diaper rate

$2985 - $5254
$3055 - $5324

Brachytherapy



2 hour hospital stay
1 day recovery
95% success rate
25% erectile problems
0% diaper rate

$4202 – 4540
$4272 - $4610

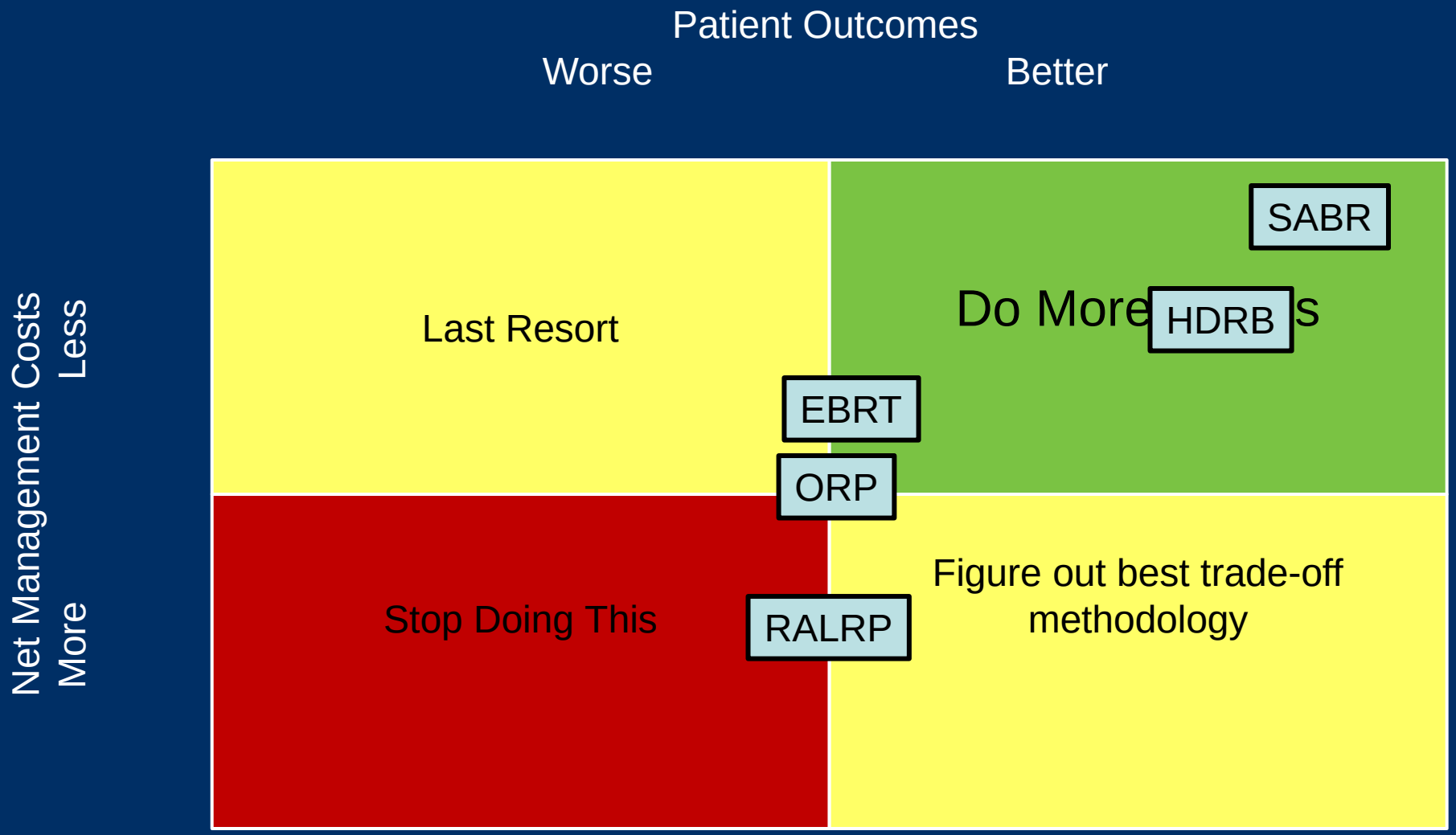
Comparative RT Costs

Treatment	Cost		
	1 phase	2 phase	2 phase long
HDR	$ 1,919	$4,246	$5,322
LDR	$ 1,408		
EBRT 39f	$ 5,435	$5,675	
EBRT 33f	$ 4,793	$4,913	
EBRT 20f	$ 3,082	$3,322	
SABR 25f	$ 4,685		
SABR 5f	$ 1,749		
SABR 2f	$ 1,389		

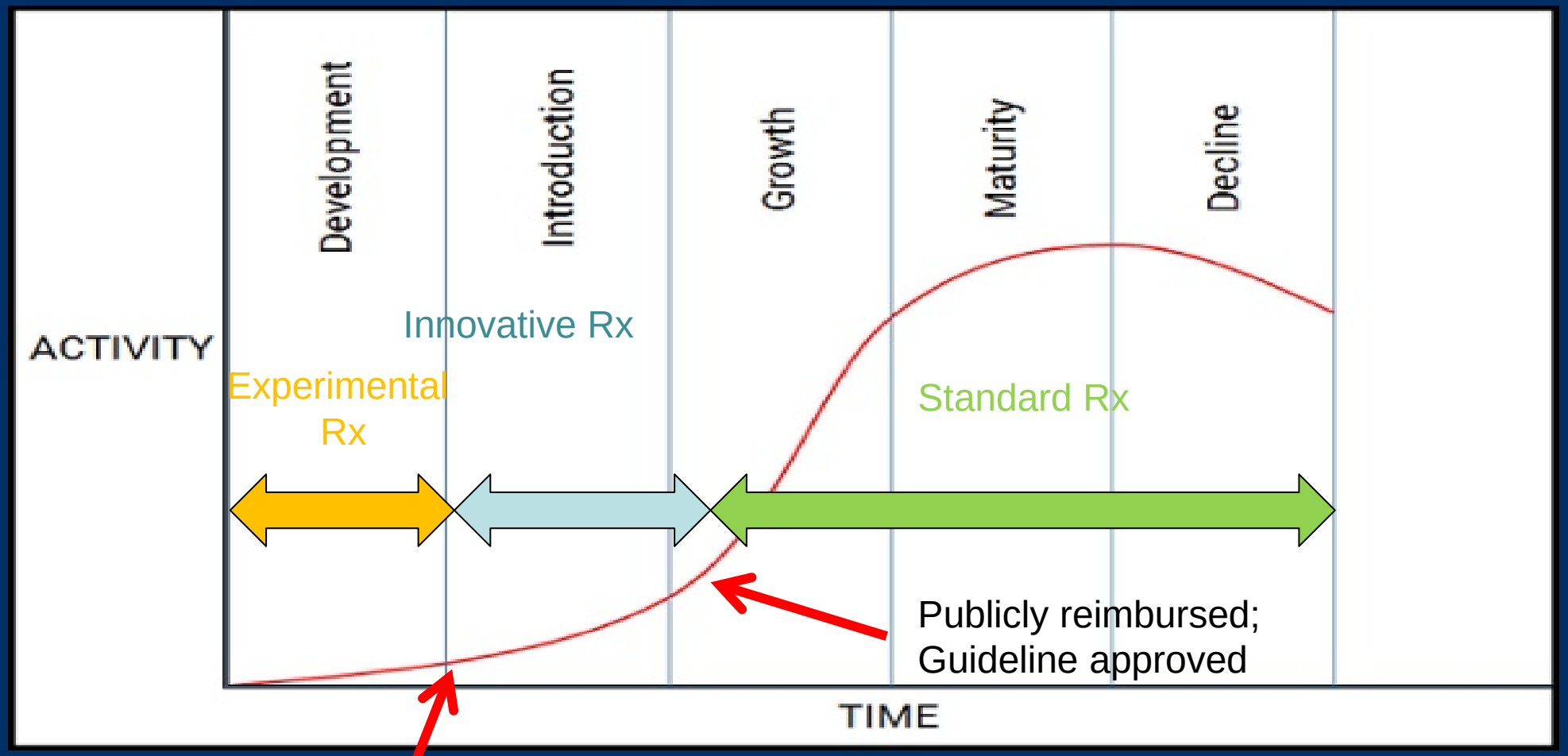
Comparative Prostate Costs

Treatment	Cost		
	1 phase	2 phase	2 phase long
HDR	$ 1,919	$4,246	$5,322
LDR	$ 1,408		
EBRT 39f	$ 5,435	$5,675	
EBRT 33f	$ 4,793	$4,913	
EBRT 20f	$ 3,082	$3,322	
SABR 25f	$ 4,685		
SABR 5f	$ 1,749		
SABR 2f	$ 1,389		
RP	$ 7,080		
EBRT 33f	$ 4,793		
TOTAL	$ 11,873		

The Litmus Test of Public Healthcare

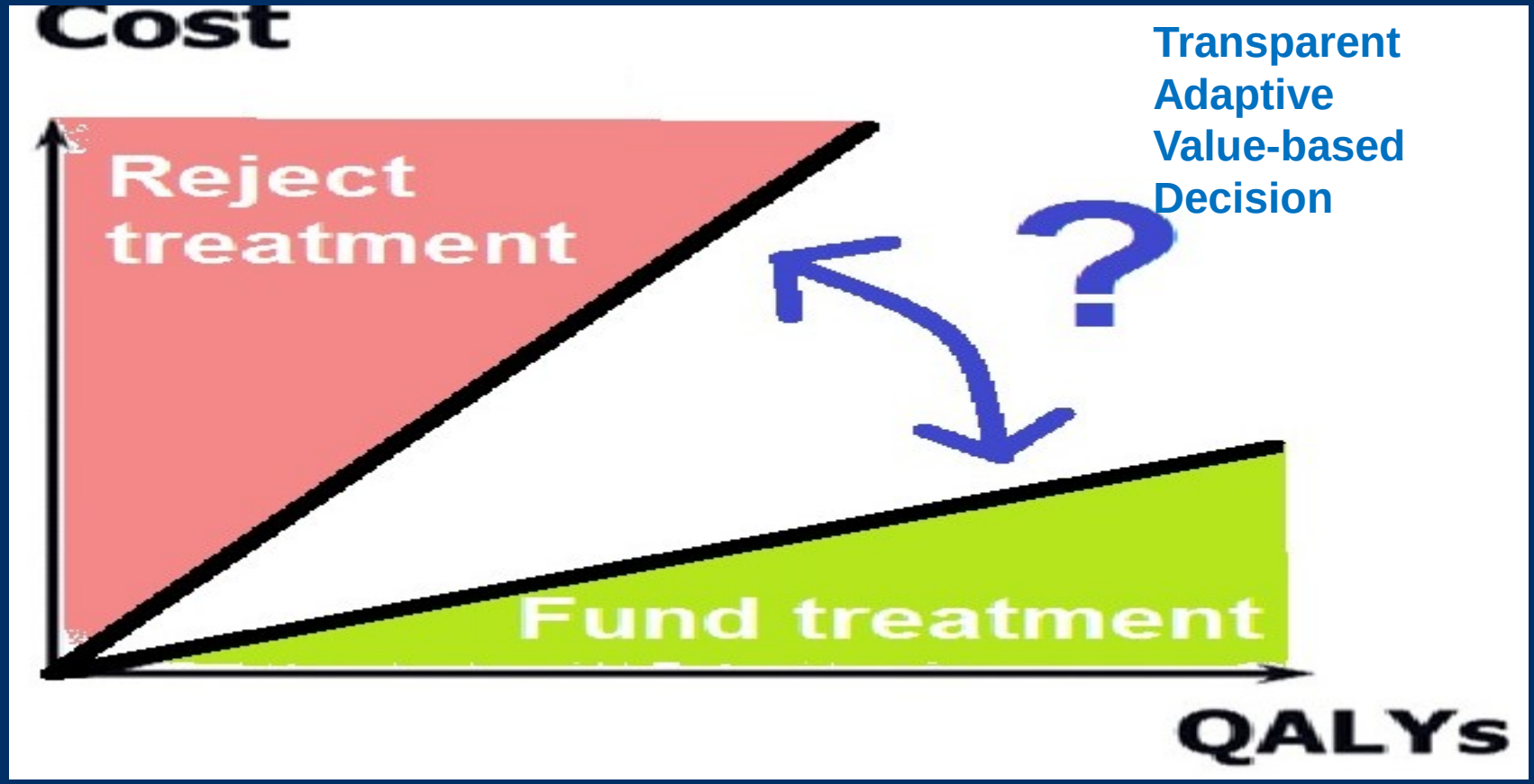


Innovation Definition



Phase 1/2 study published; Health Canada NOA

Value Perspective



Transparent
Adaptive
Value-based
Decision

Patient Perspective

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Prostate Cancer Canada

Presentation for

CAPT Conference 2016

October 17 – 18, 2016

Session 7. Innovation and Cost: the fine balance

Rocco Rossi
President & CEO, Prostate Cancer Canada
@roccorossiTO
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Promoting Equal Access & Incorporation of New Medicines in the Health Care System

- The Patient Perspective
- Health Systems: Disparities
  - PSA test coverage
  - Receptiveness to Innovative Medicines
    - Drug Approval and Coverage
- Closing Remarks

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Patients' Perspective & Value of Patient Input

- Patients and PCC are concerned with:
  - Having treatments equally available across the country
  - How the health care system is positioned to incorporate new medicines
- Disease affects entire family, not just the patients.
  - Patients, families and caregivers are **ALL** bearing costs
- Inclusion of patients' and caregivers' concerns, opinions, and experiences in decision-making process is crucial as they are the ones most directly affected by any decisions and/or recommendations
  - Ex. Patient input in pCODR process

Prostate Cancer Canada

Health systems: Disparities

- As treatments and advancements near clinical readiness, differences between health systems across Canada will mean differences in access to care

  - **Example:** PSA testing is **NOT** covered in BC and ON

PSA tests are covered for men in eight out of ten provinces. Patients want equal and fair access to PSA testing in ON and BC.

- In BC, early diagnosis of 580 men who died of prostate cancer could have resulted in up to $10M in savings (2014)

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Receptiveness to Innovative Medicines

- Lack of receptiveness and flexibility towards new innovations within health system's drug review process is the limiting step
- As a result, approval and coverage of treatments varies throughout provinces (as with many other drugs), thus denying patients the positive results that research is yielding
- Need health systems and processes that allow for integration of different drugs that deviate from what is deemed currently in place

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Discovery to Finished Product

- As PCC research gets closer to clinical readiness, a parallel push needs to occur to get health systems on the same page to make sure that:
  - Research findings are put into practice as soon as possible, **NOT** hold up progress and **NOT** be the limiting step
  - Health care is made available equally to men
- Flexibility and synchrony amongst provincial health systems are key

Prostate Cancer Canada

Prostate Cancer Canada

Thank you!

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Panel Questions

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Question #1

"Current relationships appear more strained than ever. ***How can we collaborate in this environment?*** *for example, to evolve risk-sharing, or on other solutions?"*

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Question #2

"To make room for the 'new', we may need to delist significant therapies. ***How do we make the decision to stop funding A in order to allocate funds to B, and how do we manage that challenge?"***

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Question #3

"Innovation is not equally distributed across disease. ***What can we do to assure equitable and sustainable funding across diverse diseases?***

What is our responsibility to achieve ***equity between provinces****?"*

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Question #4

"The oncology world has greater control of prescriber behaviour through institution-mandated treatment guidelines.

Is this a sustainability answer? Can we extrapolate this to the non-oncology world?"

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Question #5

*"Are there **any learnings from other countries** that we can examine?"*

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Audience Questions

Summary


Спасибо
Gracias
شكرا
Obrigado
Спасибо
Dank U
Grazie
Ευχαριστώ
Danke
Ευχαριστώ
Merci
Obrigado
Diolch
Thank You
Ngiyabonga
Dank U
Thank You
Ngiyabonga
Tack
Merci
Ευχαριστώ
Dzięki
Danke
Grazie
תודה
Dank U
Diolch
Dzięki
Terima Kasih
Grazie
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