

# Methodological Guidance for Comparing Health Interventions

## CONVERGENT STRATEGIES IN CER



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# FIFA World Cup

## Group C Final Standings

TEAM	GP	W	L	D	GF	GA	+/-	Pts
United States	3	1	0	2	4	3	+1	5
England	3	1	0	2	2	1	+1	5
Slovenia	3	1	1	1	3	3	0	4
Algeria	3	0	2	1	0	2	-2	1

### Next Games

- USA vs Ghana
- England vs Germany

# Radiation Therapy for Clinically Localized Prostate Cancer

Comparisons	Disease specific survival	Freedom from biochemical failure	GU/GI toxicity
RT vs NT	<i>insufficient</i>	<i>insufficient</i>	<i>insufficient</i>
SBRT vs EBRT	<i>insufficient</i>	<i>insufficient</i>	<i>insufficient</i>
SBRT vs HDBRT	<i>insufficient</i>	<i>insufficient</i>	<i>insufficient</i>
SBRT vs LDBRT	<i>insufficient</i>	<i>insufficient</i>	<i>insufficient</i>
EBRT vs HDBRT	<i>insufficient</i>	<i>insufficient</i>	<i>insufficient</i>
EBRT vs LDBRT	<i>insufficient</i>	<i>insufficient</i>	<i>insufficient</i>
HDBRT vs LDBRT	<i>insufficient</i>	<i>insufficient</i>	<i>insufficient</i>
Combined mod.	<i>insufficient</i>	<i>insufficient</i>	<i>insufficient</i>
Intra SBRT	<i>insufficient</i>	<i>insufficient</i>	<i>insufficient</i>
Intra EBRT	<i>insufficient</i>	<i>moderate</i>	<i>moderate</i>
Intra LDBRT	<i>insufficient</i>	<i>insufficient</i>	<i>insufficient</i>

# CMS Evidence Standards

- Coverage (“reasonable and necessary”)
  - “Adequate evidence to conclude that the item or service improves net health outcomes”
- Unique HCPCS code
  - “significant therapeutic distinction”
- New tech add-on payment
  - “Substantial clinical improvement”

# PCORI and CER methods

- “Within two years of enactment (with periodic updates) the methodology committee would determine a process to establish and maintain detailed methodological standards for comparative clinical effectiveness studies. The standards would provide criteria for study designs that balance generalizability, timeliness and other factors.”

# Methodological Guidance for CER

- “Effectiveness Guidance Documents”
- Analogous to FDA-guidance
- Recommendations for study design reflecting information needs of patients, clinicians, payers
- Targeted to product developers, clinical researchers
- Aligned with regulatory guidance
- Balance validity with relevance, feasibility, timeliness
- Objective is to provide “reasonable confidence of improved health outcomes”

# EGD Development Process

- Begin with systematic reviews, HTA, etc
- Content experts generate initial draft recommendations
- Technical working group refines draft recs
- Multi-stakeholder advisory group review
- Draft circulated for public comment
- CER methods symposium
- Revised recommendations posted

# Review Methods vs Methods Guidance

- EGAPP methods paper: “What was the relative importance of outcomes measured; which were pre-specified primary outcomes and which were secondary”
- EGD: “Acceptable outcomes for breast cancer prognosis include distant recurrence at 5 or 10 years, disease free survival, disease specific mortality, and overall survival”



# The Challenge of Methods Balance
































































- Including patients with hx of substance abuse in trials of anti-depressants
- Intensity of QA in radiation oncology studies
- Allowing clinicians to use any alternative to CCTA for dx of CAD
- Use of healing velocity rather than complete closure for wound healing trials

# CER Methods Guidance Underway

- Non-invasive cardiac imaging
  - Biomarkers for cardiovascular disease
  - Treatment for atrial fibrillation
  - Off-label indication for oncology drugs
  - Molecular diagnostics in oncology
  - Radiation therapy in oncology
  - Treatments for chronic wounds
  - Pragmatic phase III pharmaceutical trials
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		Overall score					Speed	Power	Run time	Charge time	Handling	Noise at ear	Weight (lbs.)	Volts	
		0	P	F	G	VG	E	100							
<input checked="" type="checkbox"/>	<b>Hitachi DS18DMR</b>  Tougher job drill/drivers	85											6	18	
<input checked="" type="checkbox"/>	<b>Makita LXT BDF451</b>  Tougher job drill/drivers	82											4.9	18	
<input checked="" type="checkbox"/>	<b>Milwaukee 0824-24</b>  Tougher job drill/drivers	81											6.2	18	
<input checked="" type="checkbox"/>	<b>Panasonic EY6432GQKW</b>  General use drill/drivers	80											4.8	15.6	
<input checked="" type="checkbox"/>	<b>Bosch 33618-2G</b>  Tougher job drill/drivers	80											5.9	18	
<input checked="" type="checkbox"/>	<b>Makita 6347DWDE</b>  Tougher job drill/drivers	79											5.4	18	
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