

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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Brand & Model		Ratings and Test results													
		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"/>	Hitachi DS18DMR  Tougher job drill/drivers	85											6	18	
<input checked="" type="checkbox"/>	Makita LXT BDF451  Tougher job drill/drivers	82											4.9	18	
<input checked="" type="checkbox"/>	Milwaukee 0824-24  Tougher job drill/drivers	81											6.2	18	
<input checked="" type="checkbox"/>	Panasonic EY6432GQKW  General use drill/drivers	80											4.8	15.6	
<input checked="" type="checkbox"/>	Bosch 33618-2G  Tougher job drill/drivers	80											5.9	18	
<input checked="" type="checkbox"/>	Makita 6347DWDE  Tougher job drill/drivers	79											5.4	18	
<input checked="" type="checkbox"/>	Ryobi P813  General use drill/drivers	77											4.8	18	
<input checked="" type="checkbox"/>	Makita 6980FDWDE  Cordless impact drivers	75											3.6	12	
<input checked="" type="checkbox"/>	Ryobi P230C  Cordless impact drivers	74											4.6	18	