



### Poland vs Alberta Canada Geography



**Poland**  
312,843 km<sup>2</sup>  
N-S = 876 km  
W-E = 689 km

**Alberta**  
661,848 km<sup>2</sup>  
N-S = 1,206 km  
W-E = 660 km

### Poland vs Alberta Canada Population



**Poland**  
Population 38 million

**Alberta**  
Population 3,8 million



## Comparative Effectiveness

### Definitions of Comparative Effectiveness

- ❑ *Center for Medical Technology Policy*: "...a set of analytic tools that allow for the comparison of one treatment – drug, device, or procedure - to another treatment on the basis of risks, benefits, and potentially, cost."
- ❑ *Institute of Medicine*: Primary comparative effectiveness research involves the direct generation of clinical information on the relative merits or outcomes of one intervention in comparison to one or more others. Secondary comparative effectiveness research involves the synthesis of primary studies (usually multiple) to allow conclusions to be drawn.
- ❑ *American College of Physicians*: ... the evaluation of the relative (clinical) effectiveness, safety, and cost of two or more medical services, drugs, devices, therapies, or procedures used to treat the same condition.
- ❑ *Neumann(9)*: Comparative effectiveness generally means an analysis based on clinical not economic grounds. That is, it addresses whether drug A offers more clinical benefit than drug B not whether its extra health benefits are worth its extra costs. At its heart, it is still about obtaining better value: not paying for care that does not work. However, it says nothing about whether drug A's added clinical benefits are worthwhile.

### Common features of Comparative Effectiveness

- ❑ **Direct comparisons –not with placebo not indirect comparisons**
- ❑ **All types of interventions;** pharmaceuticals, biotechnology, medical devices, equipment, medical and surgical procedures, organization, delivery, management, financing
- ❑ **Effectiveness –not only efficacy**
- ❑ **Real health care outcomes;** morbidity, mortality, quality of life, adverse events, and symptoms -surrogates or other intermediate endpoints



## Some other characteristics of Comparative Effectiveness

- ❑ Primary data collection, preferably head-to-head RCTs
- ❑ Observational studies, including registries, claims data, epidemiological data
- ❑ Systematic reviews, which may include meta-analyses of head-to-head comparisons
- ❑ Meta-analyses
- ❑ Modeling
- ❑ No consensus as yet about incorporation of costing studies or cost-effectiveness analysis

## ARRA 2009 statements

“Nothing in this section shall be construed to permit the Council to mandate coverage, reimbursement, or other policies for any public or private payer.”

“None of the reports submitted under this section or recommendations made by the Council shall be construed as mandates or clinical guidelines for payment, coverage, or treatment.”

## Examples of priority topics in comparative effectiveness research

- ❑ Compare the effectiveness of treatment strategies for atrial fibrillation including surgery, catheter ablation, and pharmacologic treatment.
- ❑ Compare the effectiveness of primary prevention methods, such as exercise and balance training, versus clinical treatments in preventing falls in older adults at varying degrees of risk.
- ❑ Compare the effectiveness of various screening, prophylaxis, and treatment interventions in eradicating MRSA in communities, institutions and hospitals.



## Examples of priority topics in comparative effectiveness research

- ❑ Compare the effectiveness of treatment strategies for unspecific low back pain
- ❑ Compare the effectiveness of pharmacologic and non-pharmacologic treatments in managing behavioral disorders in people with Alzheimer's disease and other dementias in home and institutional settings
- ❑ Compare the effectiveness of clinical interventions (e.g. prenatal care, nutritional counseling, smoking cessation, substance abuse treatment, and combinations of these) to reduce incidences of infant mortality, pre-term births, and low birth weights

## Relative Effectiveness

Excerpt of a statement from the G10 High-Level  
Group on innovation and provision of medicines  
in 2002

- ❑ The Commission should organise a European reflection to explore how Member States can improve ways of sharing information and data requirements...
- ❑ The objective is to foster the development of health technology assessment (HTA), including clinical and cost-effectiveness in the Member States and to improve the value of HTA....



## EMA 2004

- “The notion of the assessment of risk/benefit of a new product being informed by an active comparator is considered part of the assessment of efficacy and safety and fundamentally different from the concepts of placing the product in the therapeutic strategy.”
- It is also different from “...relative effectiveness which implies two components: 1) the added therapeutic value and 2) cost effectiveness. These two components go beyond the standards of marketing authorisation (quality, safety, efficacy).”

Source: European Medicines Agency. *Pre-authorization Evaluation of Medicines for Human Use*. EU Standard of Medicinal Product Registration: Clinical Evaluation of Risk/Benefit - The role of Comparator Studies. Doc. Ref: EMEA/119319/04. London, 21 October 2004.

## The High Level Pharmaceutical Forum 2007

- Assessment of Relative Effectiveness should include comparison with the most appropriate healthcare interventions.
- Such comparison should build on the results of active controlled clinical trials, where available.
- The aim of relative effectiveness assessment is to compare healthcare interventions in practice
- The first step in assessing relative effectiveness is an assessment of relative efficacy.



## Comparative Effectiveness

or

## Relative Effectiveness

### Comparative Effectiveness of treatments used in obesity

- Dietary counseling
- VLCD
- Carbohydrate-rich diets
- Protein-rich diets
- Lactovegetarian diets
- Dietary fiber supplements
- Starvation
- Behavior therapy
- Physical exercise
- Pharmacotherapy
- Surgery
- Acupuncture
- Aromatherapy
- Caffeine
- Hypnosis
- Cromium
- Vinegar

### Comparative Effectiveness of technologies used in diagnosing back pain

- Physical examination
- Mobility and muscle tests
- X-ray
- MRI
- CT-scanning
- Neurophysiologic tests including EMG
- Facet blocks
- Stress radiography
- Discography
- Nerve root infiltration
- Bone scintigraphy
- Termography
- Ultrasound



## Comparative Effectiveness of technologies used in treatment of non-specific back pain

Acupuncture	Health resorts	Neck support
Antidepressants	Heat	Paracetamol
Back exercises	Infrared light	Patient education
Back School	Injections in facet joints	Physical exercise
Behavioural therapy	Injections in ligaments	Rest/bed-rest
Biofeedback	Injections in trigger points	Shortwave diathermy
Colchicines	Laser therapy	Steroid injections
Cold	Manual therapy	Surgical procedures
Cold spray	Massage	TENS
Stretching	Multidisciplinary treatment	Traction
Continued activity	NSAIDs	Ultrasound
Corsets		
Cortisone		
Electromagnetic therapy		

## Comparative Effectiveness in treatment of alcohol and drug abuse -list of common but proven ineffective treatments\*

- |                                                      |                                 |
|------------------------------------------------------|---------------------------------|
| <input type="checkbox"/> Environment therapy         | • Psychodynamic insight therapy |
| <input type="checkbox"/> Self image therapy          | • General support therapy       |
| <input type="checkbox"/> Drama therapy               | • Therapeutic society model     |
| <input type="checkbox"/> Self identity therapy       | • Acupuncture                   |
| <input type="checkbox"/> Confrontative interventions | • Relaxation therapy            |
| <input type="checkbox"/> Self help courses           | • Biofeedback                   |