Comparative Effectiveness Research

Opportunities in older persons with multiple conditions

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Comparative Effectiveness Research

"To improve the quality, effectiveness and efficiency of health care delivered through Medicare, Medicaid and the S-CHIP programs." (per MMA)

Premise

Since the majority of Medicare beneficiaries have at least two co-existing conditions, CER must address multimorbidity

Background

The average 80 year old person has 3-4 chronic diseases PLUS 3 health related conditions, such as insomnia, pain and loss of appetite.

Most of the patients with any common index condition HAVE multiple coexisting conditions (eg DM, CHF, COPD, OA)

Among persons aged 70 and older, 60% take 5-9 medications and 20% take over 10 medications

Persons aged 65 and older who have 2 or more conditions consume about 80% of Medicare costs

The Challenge

Older persons with multiple diseases and conditions receive the most medications, and use the most health resources BUT…

We have almost no evidence base for the the effectiveness (and harms) of their care

Why is there so little evidence?

Older adults with multiple conditions are generally excluded from clinical trials.

Even when research studies do include older persons with multiple conditions,

- outcome assessments prioritize a focused set of diseases
- The monitored spectrum of other treatment effects may be limited

Representation: Age distribution of common conditions and age of trial participants

disease	% disease in population 65+	% 65+ in trials	Data source
Cancer	61%	25%	Lewis JCO 2003
Surgery for stress UI	50%+	<10%	More AN Ob Gyn 2004
AMI	40% (75+)	10%	Lee PY JAMA 2001
Parkinsons	50% (75+)	6%	Mitchell S Arch Neurol 1997
Dementia	80%+ (75+)	<50%	Gill SS Can J Clin Pharm 2004

What is the best treatment for patients with multimorbidity?

Dilemma

Treatments have not been systematically assessed in the patient with other conditions

Treatments that benefit an index condition may be harmful for other conditions (eg CHF and renal insufficiency, androgen blockade and osteoporosis)

Solution

- Multimorbidity as a focus of comparative effectiveness research

An Agenda for Comparative Effectiveness Research in older adults with multimorbidity

General principles

Approach to defining multimorbidity
- Disease pairs
- Multiple diseases

Methodological issues

Priority areas

General Principles

What to compare? Eg "usual care", disease guideline care, treatment intensity

Include benefits and harms (net benefit vs. harm)

Identify key subgroups (by total disease burden)

rationale: Affects rate and magnitude of benefit and harm

analysis: Can stratify to examine benefit and harm

Define, assess and compare universal outcomes across treatments

What is a universal outcome?

Final common pathway affected by ALL disease-specific outcomes

Valued by patients and families

Can be assessed across all diseases and conditions

Can use to compare treatments
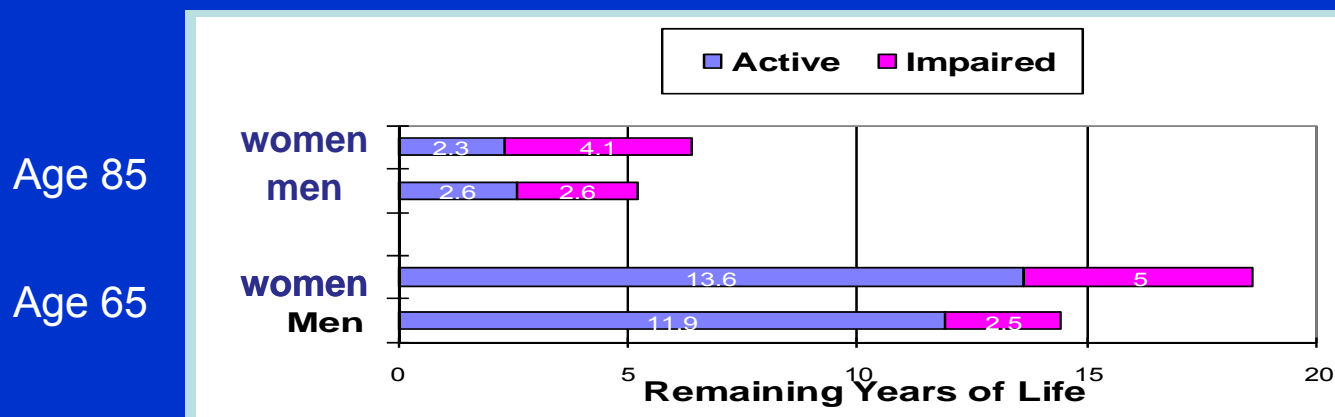
Universal Outcomes

Symptoms: dyspnea, fatigue, anorexia, pain

Impairments: physical and cognitive performance, wasting/weight loss

Function: disability, restricted activity

Health Care Use: hospitalization, services, caregiving

Active Life Expectancy

| | Active | Impaired |

Age 85
- women: 2.3 | 4.1
- men: 2.6 | 2.6

Age 65
- women: 13.6 | 5
- Men: 11.9 | 2.5

Remaining Years of Life

0 5 10 15 20

How to define multiple morbidity? Common Disease Pairs

- **Pairs with risk of therapeutic competition** (treatment of one disease may worsen another, eg hypertension and osteoporosis)

- **Goal of CER**: Determine optimal treatment target by balanced benefit to both elements of disease pair plus universal outcomes

HTN + osteop — meds

↓↓BP → CV | UO | FX

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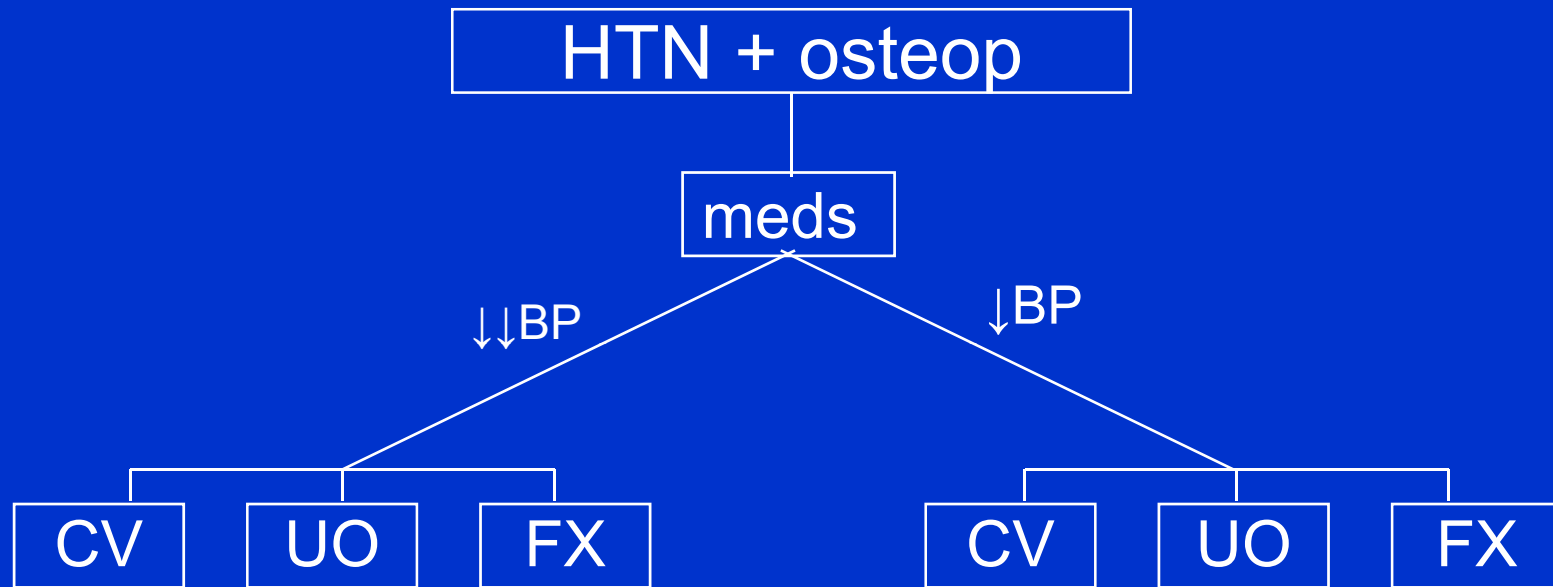
CV (MI, stroke, etc.); FX (hip, other fracture); Universal (fatigue, weakness, physical performance, ADLs, death)

The case of multiple coexisting diseases

Compare set of disease guidelines or usual care with…

Innovative models of care (e.g. chronic care model, self management, medical home)

Priority-driven treatment algorithms

Single intervention that benefits multiple diseases (e.g. exercise for BP, CAD, CHF, sarcopenia)

Example: Guided care (Boult)

- RN performs standard comprehensive assessment of diseases, function, etc.
- Collaboration among 1º MD, RN, patient, care givers →
  - Care guide for provider
  - Action plan for patient, family
- RN coordinates care across providers and transitions, monitors chronic conditions

Vs. disease-guideline driven care

- Each specialist prescribes according to evidence-based disease guideline

- Patient expected to adhere

- No coordination across providers, transitions

- Focus on disease-specific outcomes

Comparative effectiveness: Guided care vs. disease-guideline care

- Compare:
  - universal outcomes (symptoms, function, survival)
  - Health care utilization and costs
  - Patient and care giver satisfaction
  - Adverse treatment effects

Priority-driven treatment algorithms

- Priority-driven care:

  Older adults with multi-morbidity differ in universal outcome of greatest priority

  Able to map patients' disease-specific priorities (e.g. stroke, MI, COPD) unto universal outcomes (e.g. symptoms, function, survival)

  Care focused on maximixing outcome of greatest priority to the individual

Priority-driven treatment algorithms

- **Step 1**: Ascertain outcome priorities

- **Step 2**: Determine which condition(s) most affecting outcome

- **Step 3**: Of these, which most amenable to intervention

- **Step 4**: Implement treatment strategy based on Step 3

Comparative effectiveness: Priority algorithm vs. disease-guideline care

- Compare:

  % participants who met their outcome priority

  Health care utilization and costs

  Patient and care giver satisfaction

  Adverse treatment effects

  Universal outcomes

Methodologic issues in CER for older adults with multimorbidity

Observational or RCT

Requires innovative methodologies due to

      Heterogeneity

      Multiple outcomes

      Universal plus disease-specific outcomes

      Varying 1º outcomes if driven by patient priorities

Methodologic issues

- Samples:

  Large, representative, multiple conditions

  Can use ongoing large, longitudinal national samples eg MCBS

  Might use electronic health records but key universal variables such as function often not included (?Some Medicare HMOS, VA)

Methodologic issues

Data:

Baseline descriptive and prognostic (for risk stratified subgroups)

Disease-specific and universal outcomes (longitudinal)

Treatment characteristics

Priorities in CER for older adults with multimorbidity

- **Key subgroups** – total morbidity burden
- **Key outcome(s)** –disease- specific plus universal (symptoms, function, survival)
- **Key comparisons**
  - Treatment intensity
  - Treatment sequences eg behavioral followed by or combined with drugs
  - Coordination models vs. disease-guideline

SUMMARY
Comparative effectiveness for older adults with multimorbidity

Complex multimorbid health states have been avoided in research due to methodological challenges

The bulk of care is provided to older persons with complex multimorbid health states

Novel approaches to study design, variables and interventions can increase the feasibility and yield of research in this population