Real World Cost-Effectiveness of Cancer Drugs

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Canadian Centre for Applied Research in Cancer Control

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CADTH
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Outline

Overview & Objectives

Rituximab Study
- Background
- Cohort Selection
- Survival
- Toxicity
- Costs
- Cost-effectiveness

Conclusion
Background

- Maximizing investment in healthcare involves making good choices about which drugs we choose to fund;

- Ontario’s HTA process for drugs involves careful scrutiny of cancer drugs before they are funded:
  - Pan Canadian Oncology Drug Review
  - Committee to Evaluate Drugs
  - Ministry of Health and Long Term Care (MOHLTC)
Why is this not enough?

- Data required to make confident decisions are typically not available;
- Clinical trials are often conducted in "ideal" scientific settings with subgroups;
- Pharmacoeconomic analyses use models based on assumptions; creating huge uncertainty
Why real-world analysis?

- Accurate information about true healthcare costs and patient outcomes only available after the drug is funded
- “phase-IV”; “post-market evaluation”

- Provide an accurate assessment of value for money and accountability for spending on cancer medicines in Ontario
Our study

- First study in Ontario that evaluates population-based post-market effectiveness and cost-effectiveness of cancer drugs (New Drug Funding Program)

- First study in Canada incorporating recently developed statistical methods for analyzing incomplete costs and cost-effectiveness of cancer treatments
Overall Objectives

- To determine whether it is feasible to conduct post-market evaluation of cancer drugs using Ontario’s administrative databases.

- To establish a robust template that links datasets across the province, applies rigorous methods for analyzing costs and cost-effectiveness and generates outcomes.

- To compare survival benefits and costs from the real-world to what is being reported in RCTs and economic models.
How is this done?

1. Chose 5 cancer drugs (6 indications) based on policy-relevance and data availability.
2. Linked administrative data from Cancer Care Ontario and Institute for Clinical Evaluative Sciences (ICES).
3. Worked closely with clinical and method experts to develop analytical framework.

Population-based retrospective analysis of cancer drugs

Patterns of Care:
Who used these drugs and how?

Clinical Outcomes:
Did the drugs improve survival? Were they safe?

Real World Outcomes

Direct Costs:
How much did Ontario spend?

Cost-effectiveness:
What was the real added value for each extra dollar spent?
Cancer drugs of interest

- Rituximab for diffuse-large-B-cell lymphoma
- Oxaliplatin for metastatic colorectal cancer
- Bortezomib for relapsed multiple myeloma
- Rituximab for follicular lymphoma
- Trastuzumab for breast cancer
- Docetaxel for hormone refractory prostate cancer
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Diffuse-large-B-cell lymphoma

- 3000 new cases of non-Hodgkin lymphoma in Ontario in 2010
- 1300 deaths attributed to the disease
- Diffuse-large-B-cell lymphoma is the most common form, represents approx. 25% of new cases
Evidence around Rituximab

- Randomized trials: addition of Rituximab (R) to CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) improved 3 to 5-year survival by 10-13%
  - Very elderly groups (80+) were under-represented or explicitly excluded

- Published economic evaluations used RCT results; showed RCHOP to be either a dominant strategy or cost-effective

- Post-market reports cited increased rates of complications
  - hepatitis reactivation, interstitial lung disease, bowel perforation or obstruction and progressive multifocal encephalopathy
In Ontario

- Approved for funding via the New Drug Funding Program in Ontario:
  - Jan 10\textsuperscript{th}, 2001 – 60-80 years old
  - April 2\textsuperscript{nd}, 2001 – ≥80 years old
  - July 1\textsuperscript{st}, 2004 – <60 years old

- Based on efficacy results from out-of-province trials and theoretical economic models
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Historical cohort selection

Pre-era CHOP

Jan, 2001

July, 2004

<60

≥80

60-80

Post-era RCHOP

Mar 31, 2009

Dec 31, 2007

Jan 1, 1997

Jan, 2001

April, 2001

June, 2001

Mar 31, 2009

<60

≥80

60-80
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*ACG – adjusted clinical group scores

- Hard-matched on age group
- Propensity score-matched on:
  - Sex
  - Adjusted clinical group (ACG) score
  - Income quintile
  - Treatment intensity
  - Primary histology diagnosis code
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Kaplan-Meier Survival Curves

(a) Survival Curves before matching

(b) Survival Curves after matching

3-year: 4%↑
5-year: 3%↑

3-year: 10%↑
5-year: 8%↑
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## Toxicity

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<td>HIV</td>
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<td>4%</td>
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<td>CHF</td>
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<td>Angina</td>
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### Hospitalization within one year

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Cost analysis

- Cost components
- Adjusting for censoring
- Fixed time-frames: 3-year and 5-year
- Effect of discounting
Costing Components

- Hospitalization
- Outpatient laboratory/Imaging Services
- Physician Services
- Emergency Room Visits/Same Day Surgery
- Prescription Drugs (≥65 or low income group)
- Chemotherapy (Physician & drug costs)
- Radiation Treatment
- Home Care Services
- Complex Continuing Care
Estimating mean cost by adjusting for censoring

- Complete cost data not available
  - Not enough observation time – “censoring”

- Severely biased estimates can arise without appropriately adjusting for censoring

- A number of methods have been proposed
Estimating mean cost by adjusting for censoring

- Lin’s Kaplan-Meier sample average (KMSA) estimator (1997)
  \[
  \hat{\mu}_{KMSA} = \sum_{j=1}^{K+1} \hat{S}_j \hat{E}_j
  \]

- Bang and Tsiatis’ estimator (2000)
  \[
  \hat{\mu}_{Bang} = \frac{1}{n} \sum_{i=1}^{n} \sum_{j=1}^{K} \frac{\Delta_i^j M_{ij}}{\hat{R}_j}
  \]

- Basu’s two-part estimator (2010)
  \[
  \hat{\mu}_{Basu} = \sum_{j=1}^{K} \hat{S}_j \left[ \hat{h}_j \hat{E}_j^{\text{dead}} + (1 - \hat{h}_j) \hat{E}_j^{\text{alive}} \right]
  \]
Adjusted 5-year costs

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Unadjusted</th>
<th>Bang</th>
<th>Lin</th>
<th>Basu</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHOP</td>
<td>$71,639</td>
<td>$71,640</td>
<td>$71,640</td>
<td>$79,668</td>
</tr>
<tr>
<td>RCHOP</td>
<td>$88,536</td>
<td>$88,536</td>
<td>$88,536</td>
<td>$88,536</td>
</tr>
</tbody>
</table>
Cost drivers
Outline

Overview & Objectives

Rituximab Study
- Background
- Cohort Selection
- Survival
- Toxicity
- Costs
- Cost-effectiveness

Conclusion
## Incremental Cost-effectiveness Ratios

<table>
<thead>
<tr>
<th></th>
<th>no discounting</th>
<th>3% discounted</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Censor adjusted incremental cost (CAD$)</td>
<td>Censor adjusted incremental survival (Years)</td>
</tr>
<tr>
<td>3 year</td>
<td>14,923</td>
<td>0.16</td>
</tr>
<tr>
<td>5 year</td>
<td>16,896</td>
<td>0.35</td>
</tr>
</tbody>
</table>
Scatter Plot from Bootstrapping

- ICER $96,764/LYG
  (95%CI: 36,667; 139,273)

- ICER $51,687/LYG
  (95%CI: 19,769; 59,738)
Cost-effectiveness acceptability curve

Bootstrap ICERs vs WTP

Willingness-to-pay ($/LYG)

Percentage

3 Year 5 Year

92% 99.7% 91%

23%
Outline

Overview & Objectives

Rituximab Study
- Background
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- Costs
- Cost-effectiveness

Conclusion
How do we compare?

2-year Absolute Survival Benefit

- **Our study**: 8
- **Europe GELA Trial**: 13
- **BC observational study**: 26
How do we compare?

5-yr Incremental Cost

- **Our study**: 16785
- **US model**: 12740
- **BC microsimulation**: 7900-9700

Cost ($)

0 5000 10000 15000 20000
Overall Conclusions

- It is feasible to perform real-world cost-effectiveness analysis with Ontario’s administrative data.

- Cost-effectiveness results in a real-world analysis differ from those from clinical trials and economic models.

- Decision-makers should be cautious about conclusions from results of trials/models.
Key findings

- Using appropriate methods to adjust for confounding variables is important

- Adjusting for incomplete cost data is essential

- Selection of timeframe has a big effect of cost-effectiveness results
  - “coverage with evidence”
  - “only in research”
Future steps & recommendations

- Compare results to Canadian economic models submitted to the Ministry of Health by the drug company
  - Help evaluate assumptions made in original model and improve methods used

- Post-market analyses be incorporated in the standard evaluation of funded cancer drugs
  - As a decision tool to help calibrate policies (re-evaluate/ calibrate decisions)
  - As a foundation for accountability and sustainability
Thank you

- Contact us:

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Email: sara.khor@cancercare.on.ca

Websites:
http://healtheconomics.utoronto.ca
http://www.cc-arcc.ca
Extra slides
Limitations

- Data availability – relying on existing administrative databases (completeness, data variables)
- Historical cohort design – temporal changes over time might not be adjusted for
- Missing quality of life information