New Oral Hepatitis C Medications: Are They Living up to Their Expectations in a Real-World Setting?

Kevin Wilson, Saskatchewan Ministry of Health
CADTH Symposium 2017
Disclosure

I have no actual or potential conflict of interest in relation to this topic or presentation.

Note: Gilead Sciences Inc. and AbbVie Corporation provided funds to support analysis of data collected by the Ministry. The companies were not involved in determining what would be analyzed or in the analysis itself.
New HCV Drugs - Real World Effectiveness?

• Listing new HCV drugs represents a significant investment by the province.

• Provides an opportunity to monitor outcomes and engage prescribers.

• Would the high rates of Sustained Virologic Response (SVR) observed in clinical trials (90% or greater) be similar in a real world setting?
BACKGROUND - New Hepatitis C Oral Medications Listed on the SK Formulary

1st step --- National collaboration
  • CADTH review of clinical and cost effectiveness of new agents; and
  • Negotiations with manufacturers via the pan-Canadian Pharmaceutical Alliance.

2nd step --- Provincial listing
  • New hepatitis C medications listed on the Saskatchewan Formulary in 2015 (Sovaldi™, Harvoni™, and Holkira Pak™). Criteria focuses coverage to patients with more severe disease.
Saskatchewan Approach
(post national review and pricing negotiations)

• Consultations with local public health experts and key prescribers led to:
  – prescriber agreements (includes a requirement to provide info on patient SVRs at end of therapy).
  – support for patients (adherence and accountability).

• Consent to collect data on individual patients who were approved for coverage and completed therapy.
Adherence and Accountability

• Measures taken to position SK Drug Plan patients and prescribers for successful treatment include:
  – patient commitment by signing application form
  – daily pharmacist observed therapy (in certain situations)
  – drug dispenses in limited quantities

• Rationale: more patients are cured, tax $ are put to good use, and ↓ resistance to therapy.
Initial Results

• So far, data has been collected on 88 patients
  – overall SVR rate: 92.3% (PP); 86.4% (ITT)
    • those with fibrosis stage F3: 100%
    • majority of non-responders: fibrosis stage F4
  – most common genotype: GT1
    • SVR rate: 94.2% (PP) and 86.7% (ITT)
SVR Response - Overall

Response
No Response
n/a

ITT PP

%
SVR Response – by Genotype

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Response (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 1</td>
<td>86.7</td>
</tr>
<tr>
<td>Genotype 2</td>
<td>100</td>
</tr>
<tr>
<td>Genotype 3</td>
<td>77.8</td>
</tr>
</tbody>
</table>

Legend:
- Response
- No Response
- n/a
SVR Rate by Fibrosis Stage: F2 to F4

![Bar chart showing SVR rate by fibrosis stage.]
HIV+ Co-infection

• n=<5
  – Genotype 1a
  – Treatment-naïve
  – Non-cirrhotic

• Fibrosis stage: F2, F3

• Positive response (patients achieved SVR)
Summary

• Small number of patients followed to date, but RWE seems to align with predicted efficacy.
• Prescriber agreements continue with the additional HCV medications listed in April 2017.
• Learnings will be shared with the Drug Advisory Committee of Saskatchewan and prescribers.
• Provides a model for future collaborative outcomes based agreements with prescribers.