Significant Uptake of Truvada for Pre-exposure Prophylaxis (PrEP) Utilization in the US in Late 2014 – 1Q2015

IAPAC Treatment, Prevention, and Adherence Conference (June 28-30)

Bush, Staci; Ng, Leslie; Magnuson, David; Piontkowsky, David; Mera Giler, Robertino

Gilead Sciences
Background: Timeline of PrEP Community activation

- July 2012: FDA Approves Truvada for PrEP
- Summer 2014: Advocate Response
  - #Truvada"Whores"
- Sept. 2014: CDC High-Impact HIV Prevention Funding $210 mil
- May 2014: USPHS/CDC Guidelines
- Feb 2015: CROI Data
Method

- The objective of this study is to explore the increase of PrEP utilization between January 1, 2012 and March 31, 2015.

- An estimated 39% of TVD Prescriptions were analyzed from a national prescription database. An algorithm was used to identify TVD for PrEP use in this sample.

- De-identified patient data included:
  - Prescription refills
  - Medical claims
  - Patient demographics
Gilead’s Algorithm for PrEP Indication

Unique PrEP users were identified by excluding ICD-9 codes of TVD use for HIV treatment, HBV, and Post-Exposure Prophylaxis (PEP).

<table>
<thead>
<tr>
<th>HIV</th>
<th>HBV</th>
<th>PEP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Exclude</strong> a prior diagnosis of HIV disease</td>
<td><strong>Exclude</strong> a prior diagnosis of chronic hepatitis B infection</td>
<td><strong>Exclude</strong> specific codes contaminated needle stick and/or prophylaxis.</td>
</tr>
<tr>
<td><strong>Exclude</strong> all concomitant use of any other antiretroviral treatment.</td>
<td><strong>Exclude</strong> anti Chronic Hepatitis B specific treatment</td>
<td></td>
</tr>
<tr>
<td><strong>Exclude</strong> a prior diagnosis of an opportunistic infection</td>
<td></td>
<td></td>
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</tbody>
</table>
New PrEP Starts per Quarter

Total Unique Individuals = 8,512

IMS National Prescription Database accounts for approx. 39% of all TVD prescriptions

Bush, S. et al; IAPAC Prevention 2015; #74
New PrEP Starts per Quarter

<table>
<thead>
<tr>
<th>Year</th>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q4</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>293</td>
<td>317</td>
<td>389</td>
<td>321</td>
</tr>
<tr>
<td>2013</td>
<td>365</td>
<td>336</td>
<td>378</td>
<td>432</td>
</tr>
<tr>
<td>2014</td>
<td>530</td>
<td>753</td>
<td>1242</td>
<td>1395</td>
</tr>
<tr>
<td>2015</td>
<td>1761</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total Unique Individuals = 8,512

IMS National Prescription Database accounts for approx. 39% of all TVD prescriptions

Bush, S. et al; IAPAC Prevention 2015; #74
New PrEP Starts by Gender

Total Unique Individuals = 8,512

IMS National Prescription Database accounts for approx. 39% of all TVD prescriptions

Bush, S. et al; IAPAC Prevention 2015; #74
The proportion of new PrEP starts under 24 y/o are lower than other age groups at all time points.
No regional differences among individuals receiving PrEP determined by age

N = 45 subjects did not have region information
PrEP Growth Trend

IMS National Prescription Database accounts for approx. 39% of all TVD prescriptions

Bush, S. et al; IAPAC Prevention 2015; #74
**PrEP Growth Trend**

![PrEP Growth Trend Graph](image)

- **Unique individuals in IMS**
  - 2012: 1,320
  - 2013: 1,511
  - 2014: 3,920
  - 2015: 5,283

- **First Quarter**
  - 2015: 1,761

- **2015 Projection at same rate**
- **Individuals Starting PrEP**

**IMSS National Prescription Database** accounts for approx. 39% of all TVD prescriptions

Bush, S. et al; IAPAC Prevention 2015; #74
PrEP Growth Trend

Unique individuals in IMS

<table>
<thead>
<tr>
<th>Year</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
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<tbody>
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<td></td>
<td>7,044</td>
<td>1,761</td>
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Projected Unique Individuals Through 2015 = 13,895

IM National Prescription Database accounts for approx. 39% of all TVD prescriptions

Bush, S. et al; IAPAC Prevention 2015; #74
Limitations:

- The inability to track all prescriptions
- The lack of specific ICD codes for PrEP
- Possible projection errors
- Exclusion of patients with HBV from the data set who may be receiving TVD for both PrEP and off-label HBV treatment
Conclusion

Using a National Prescription Database that accounts for 39% of all Truvada prescriptions:

- The latest uptake data on Truvada for PrEP show that comparing 1Q 2014 to 1Q 2015, the incident usage in the US increased 332%, from 529 to 1,761 individuals, in that time period.
- In the same data base, there were 8,512 unique PrEP Individuals from January 2012 to March 2015.
- The gender of PrEP users in the US nationally appears to be shifting. The number of males initiating PrEP increased, while the number of females has remained static.
Thank you.

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BACKGROUND
Gilead’s Algorithm for PrEP Indication

Since there is no diagnosis code for PrEP, this involved examining all diagnosis codes where Truvada was prescribed, and excluding diagnosis codes for other possible Truvada uses.

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<tbody>
<tr>
<td><strong>Exclude</strong> all concomitant use of any other antiretroviral treatment.</td>
</tr>
<tr>
<td><strong>Exclude</strong> a prior diagnosis of HIV disease (ICD9 = 042); asymptomatic HIV infection (V08); HIV-2 infection (079.53) or nonspecific serologic evidence of HIV (795.71)</td>
</tr>
<tr>
<td><strong>Exclude</strong> a prior diagnosis of opportunistic infection:</td>
</tr>
<tr>
<td>(Candidiasis of bronchi, trachea, esophagus 112.84, or lungs 112.4, Toxoplasmosis 130.X, Coccidioidomycosis 114, Cryptococcosis 117.5, Cryptosporidiosis 007.4, CMV retinitis 078.5, Kaposi's sarcoma 176.0, Mycobacterium avium complex 031.2 031.0, Pneumocystis carinii pneumonia 136.3)</td>
</tr>
</tbody>
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<tbody>
<tr>
<td><strong>Exclude</strong> anti Chronic Hepatitis B specific treatment</td>
</tr>
<tr>
<td><strong>Exclude</strong> a prior diagnosis of chronic hepatitis B infection (70.22, 70.23, 70.32, 70.33).</td>
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<table>
<thead>
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<tr>
<td><strong>Exclude</strong> specific codes of E920.5 (contaminated needle stick) and /or V078 V079 (prophylaxis).</td>
</tr>
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</table>
A total of 77% of TVD pharmacy shipments are tracked to retail or mail order pharmacies.

77% of shipments to pharmacies contributed claims data:
- 59% to retail pharmacies;
- 18% to mail order pharmacies;
- 23% unable to be tracked: hospitals, clinics, prisons, universities, long term care, or ADAP programs.