The Student-run pharmacovigilance program
A win-win venture for medical students and the Netherlands pharmacovigilance centre Lareb.

Michael Reumerman, MD
PhD-student, Internal Medicine – section Pharmacotherapy, VU University medical center Amsterdam, The Netherlands.
Faculty Disclosure

X No, nothing to disclose
Background

• Adverse drug reactions (ADRs) cause major harm.\(^1\)

• Healthcare students are inadequately prepared for their role pharmacovigilance.\(^2-4\)

• Few interventions have proven effective (theoretical basis). [poster]

Aims

• Develop and evaluate a student-run pharmacovigilance program.

---

Method

• Collaboration since May-2014:
  o Learner-centered student-run clinic VUmc
  o Netherlands pharmacovigilance centre Lareb

• Student-run + learning by doing.
  o Maximal responsibility
  o Teamwork
  o Real and legitimate clinical tasks
Netherlands pharmacovigilance centre Lareb

Student-run pharmacovigilance program, student coordinators

Student-run pharmacovigilance team

Patiënts or healthcare professionals

\[ \text{Check Substantiation} \]
\[ \text{Check Useful} \]
\[ \text{Check Complete} \]
\[ \text{Check Accurate} \]
\[ \text{Check Time} \]
\[ \text{Check Overall score} \]
Results

• May 2014 – January 2015:
  o Three reports weekly (100 ADR-reports)
  o 115 drugs with 148 different symptoms

• Student participation (n=43)
• Student coordinators (n=3)
• Pharmacovigilance centre staff (n=3)
Assessment rating

<table>
<thead>
<tr>
<th></th>
<th>Pilot score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Useful assessment</td>
<td>93%</td>
</tr>
<tr>
<td>Scientifically substantiated</td>
<td>90%</td>
</tr>
<tr>
<td>Complete</td>
<td>92%</td>
</tr>
<tr>
<td>Accurate</td>
<td>92%</td>
</tr>
<tr>
<td>Overall mark (1-10 min/max)</td>
<td>8.28 (SD 1.15)</td>
</tr>
</tbody>
</table>

Time to verify student ADR assessment.

- Less time: 11%
- Neutral: 56%
- More time: 33%
Student outcome [zoom in on awareness]

- "I know where to report an ADR": Pre-test 60%, Post-test 100%
- "I know which essential information is needed for a qualitatively good ADR-report": Pre-test 40%, Post-test 80%
- "I know why ADRs should be reported to the Dutch pharmacovigilance center Lareb": Pre-test 30%, Post-test 100%

* indicates statistical significance.
Current situation [June-2017]

• Continuing program (434 assessments)
• Student participation (n=168)
• 3 reports weekly (48 weeks a year)
• Weekly student coordinator sessions.
• Collaboration with Rijks Universiteit Groningen (RUG).
  o Pharmacy students
## Latest results [June-2017]

<table>
<thead>
<tr>
<th></th>
<th>Jun-2017</th>
<th>Pilot score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Useful assessment</td>
<td>87%</td>
<td>93%</td>
</tr>
<tr>
<td>Scientifically substantiated</td>
<td>91%</td>
<td>90%</td>
</tr>
<tr>
<td>Complete</td>
<td>91%</td>
<td>92%</td>
</tr>
<tr>
<td>Accurate</td>
<td>88%</td>
<td>92%</td>
</tr>
<tr>
<td>Overall mark (1-10 min/max)</td>
<td>7.95 (SD 0.93)</td>
<td>8.28 (SD 1.15)</td>
</tr>
</tbody>
</table>

Time to verify student ADR assessment:

- 15% Less time
- 23% Neutral
- 62% More time
Conclusion

• The Student-run pharmacovigilance program is a win-win venture:
  o Continuous high-quality student assessments
  o No extra time expenditure
  o Creates awareness in future healthcare professionals
  o Valuable “pharmacovigilance experience”

• Future
  o Determine the value of this intervention in healthcare curricula.
  o Evaluate the long-term and clinical value of educational interventions.
  o Pilot patient related educational interventions in pharmacovigilance.
The team!

Internal medicine VUmc
Drs. T. Schutte
Dr. J. Tichelaar
Dr. M. Richir
Dr. M. van Agtmael

Pharmacovigilance program, student coordinators:
Pilot: Mrs. S. Groenland, Mrs. S. de Boer and Mrs. L. van Gastel
Current: Mrs. Y. Civil, Mrs. M. Kockx, Mrs. N. Hollander and Dhr. D. Baron

Student chairman: Dhr. E. Donker

Pharmacovigilance center Lareb
Prof. Dr. E van Puijenbroek
Drs. R. van Eekeren,
Mrs. L. Rolfes, Msc
Drs. E. Ederveen

All LC-SRC coordinators and participating students!
Questions

www.VUmc.com/RECIPE

www.lareb.nl