WORLD HEALTH ORGANIZATION COLLABORATING CENTRE

GOVERNANCE, ACCOUNTABILITY & TRANSPARENCY IN THE PHARMACEUTICAL SECTOR

Activities Report
October 2015 to January 2018

Director
Dr. Jillian C. Kohler

COPYRIGHT © 2018
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABOUT US</td>
<td>3</td>
</tr>
<tr>
<td>WHO WE ARE</td>
<td>4</td>
</tr>
<tr>
<td>DIRECTORS</td>
<td>4</td>
</tr>
<tr>
<td>RESEARCH FELLOWS AT UNIVERSITY OF TORONTO</td>
<td>4</td>
</tr>
<tr>
<td>GLOBAL RESEARCH FELLOWS</td>
<td>5</td>
</tr>
<tr>
<td>WORKSHOPS, SYMPOSIAUMS, COURSES &amp; INTELLECTUAL SALONS</td>
<td>6</td>
</tr>
<tr>
<td>PUBLICATIONS &amp; KNOWLEDGE DISSEMINATION</td>
<td>9</td>
</tr>
<tr>
<td>SUMMARY</td>
<td>22</td>
</tr>
<tr>
<td>FUTURE DIRECTIONS</td>
<td>22</td>
</tr>
</tbody>
</table>
ABOUT US

The World Health Organization (WHO) Collaborating Centre for Governance, Accountability and Transparency in the Pharmaceutical Sector was convened in 2015 and is currently led by Dr. Jillian C. Kohler, at the Leslie Dan Faculty of Pharmacy (University of Toronto).

*Our mission is to conduct research, analysis and training on critical issues related to good governance and transparency in medicines.*

The Collaborating Centre has three objectives:

- To use existing research facilities at the University of Toronto for pharmaceutical policy research, analysis, and training on critical issues related to good governance and transparency in medicines, in collaboration with the WHO.

- To ensure global dissemination of knowledge on the issues related to good governance and transparency by establishing a global network of researchers, policy makers, and advocates in coordination with the WHO.

- To support collaboration and help intensify the work of the WHO in areas related to good governance and transparency in medicines.

TERMS OF REFERENCE

The WHO Collaborating Centre for Governance, Accountability and Transparency in the Pharmaceutical Sector (WHO CCGAT) conducts the following activities:

- Policy Workshops, Symposia and Seminars
- Undergraduate and Graduate Courses
- Information Dissemination and Media

These activities and their outputs are further described throughout the report.
Who We Are

This WHO Collaborating Centre (WHO CC) involves the following multidisciplinary team of directors, faculty members, research fellows and global collaborators:

Directors

<table>
<thead>
<tr>
<th>DR. JILLIAN C. KOHLER</th>
<th>DEIDRE DIMANCESCO</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Director</strong></td>
<td><strong>Technical Director</strong></td>
</tr>
<tr>
<td><em>Leslie Dan Faculty of Pharmacy</em></td>
<td><em>Medicines Policy, Access &amp; Rational Use</em></td>
</tr>
<tr>
<td><em>University of Toronto</em></td>
<td><em>World Health Organization</em></td>
</tr>
</tbody>
</table>

Research Fellows at University of Toronto

<table>
<thead>
<tr>
<th>DR. ZUBIN AUSTIN</th>
<th>DR. SUZANNE CADARETTE</th>
<th>DR. JOHN FARRELL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Professor</strong></td>
<td><strong>Associate Professor</strong></td>
<td><strong>Executive Director</strong></td>
</tr>
<tr>
<td><em>Leslie Dan Faculty of Pharmacy</em></td>
<td><em>Leslie Dan Faculty of Pharmacy</em></td>
<td><em>Centre for Practice Excellence</em></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DR. SARAH GUILCHER</th>
<th>DR. PAUL GROOTENDORST</th>
<th>DR. ALISON THOMPSON</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Associate Professor</strong></td>
<td><strong>Associate Professor</strong></td>
<td><strong>Associate Professor</strong></td>
</tr>
<tr>
<td><em>Leslie Dan Faculty of Pharmacy</em></td>
<td><em>Leslie Dan Faculty of Pharmacy</em></td>
<td><em>Leslie Dan Faculty of Pharmacy</em></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DR. ERICA DIRUGGIERO</th>
<th>DR. LISA FORMAN</th>
<th>DR. ANITA MCGAHAN</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Associate Professor</strong></td>
<td><strong>Associate Professor</strong></td>
<td><strong>Professor</strong></td>
</tr>
<tr>
<td><em>Dalla Lana School of Public Health</em></td>
<td><em>Dalla Lana School of Public Health</em></td>
<td><em>Munk School of Global Affairs</em></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DR. JOSEPH WONG</th>
<th>DR. JOEL LEXCHIN</th>
<th>DR. TRUDO LEMMENS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Professor</strong></td>
<td><strong>Associate Professor</strong></td>
<td><strong>Associate Professor</strong></td>
</tr>
<tr>
<td><em>Munk School of Global Affairs</em></td>
<td><em>Faculty of Medicine</em></td>
<td><em>Faculty of Law</em></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DR. NAV PERSAUD</th>
<th>DR. MARIANA PRADO</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Associate Scientist</strong></td>
<td><strong>Associate Professor</strong></td>
</tr>
<tr>
<td><em>Li Ka Sing Knowledge Institute</em></td>
<td><em>Faculty of Law</em></td>
</tr>
</tbody>
</table>
## Global Research Fellows

<table>
<thead>
<tr>
<th><strong>DR. TIM K. MACKEY</strong></th>
<th><strong>DR. MARC-ANDRÉ GAGNON</strong></th>
<th><strong>DR. VARUN GAURI</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Assistant Professor</td>
<td>Associate Professor</td>
<td>Head &amp; Senior Economist</td>
</tr>
<tr>
<td>Anesthesiology and Global Public Health (University of California)</td>
<td>School of Public Policy &amp; Administration (Carleton University)</td>
<td>Global Insights Initiative (Development Research Group)</td>
</tr>
</tbody>
</table>

**DR. MATTHEW HERDER**

Associate Professor  
Faculty of Medicine  
(Dalhousie University)

---

**Contact Us:**

Leslie Dan Faculty of Pharmacy  
University of Toronto  
144 College Street  
Toronto, Ontario, M5S3M2  
Tel: 416-946-8708 | Fax: 416-978-1833  
Email: jillian.kohler@utoronto.ca  
Website: [http://www.pharmacy.utoronto.ca/whoc](http://www.pharmacy.utoronto.ca/whoc)
Workshops, Symposia, Courses & Intellectual Salons

2017-2018

January 18, 2018
Health Law, Ethics & Policy Seminar Series: The Benefit and Risks of Expedited Development and Regulatory Approval of New Drugs

Along with the Faculty of Law, University of Toronto, the WHO CC sponsored a lunchtime seminar on the topic of expedited drug approval processes. The key speaker was Dr. Aaron Kesselheim and the commentator was Dr. Megan Bettle from Health Canada.


Outcomes:
Professionals, community members and students were able to engage in a stimulating discussion on relevant and topical issues related to drug approval processes in North America. Attendees learned about streamlined drug development processes in the US, their implications and how they compare to Canada.

January 17, 2018
Idea Salon with Dr. Aaron Kesselheim: Expedited Development & Regulatory Approval of New Drugs

A dinner with experts from the Ontario and Federal Governments, academia and the non-governmental organization (NGO) community was hosted at the University of Toronto’s Faculty Club, in advance of Dr. Kesselheim’s seminar presentation to discuss related issues in a smaller, off-the-record setting.

Outcomes:
Experts were able to meaningfully share ideas and engage in a small-group discussion on this topic. Attendees also raised critical thoughts on related and relevant issues. This salon successfully connected leading-thinkers from NGOs, academic institutions, as well as federal and Ontario governments.

September 29, 2017
Governance of Pharmaceuticals Policy Workshop

Internationally renowned experts gathered for this workshop to discuss the impacts of corruption and lack of good governance on the pharmaceutical sector. This one-day course was offered to researchers, policy makers, the private sector, and undergraduate and graduate students at the University of Toronto.

(Link: http://www.pharmacy.utoronto.ca/sites/default/files/upload//who_cc/sept17-workshop/Sept%202017%20Workshop%20Agenda.pdf)

Outcomes:
Participants learned about how corruption and a lack of good governance can have an impact on the pharmaceutical sector. Participants also learned about strategies and tactics for countering vulnerabilities in this sector. Learning materials are available online on our WHO CC website.
September 28, 2017
*Tackling corruption in procurement: how open contracting improved healthcare in Nigeria, Ukraine and Honduras*

This workshop was presented by Lucas Amin (Transparency International, UK).

**Outcomes:**
A presentation on the challenges with drug procurement was delivered to an audience of graduate students in the Department of Pharmaceutical Sciences.

---

May 24, 2017
*Processes for Developing and Updating an Essential Medicines List in Canada?*

This policy meeting was led by a WHO CCCGAT Research Fellow, Dr. Nav Persaud.

**Outcomes:**
This workshop led to important discussions with several policymakers, including representatives from the Ontario Ministry of Health and Long-Term Care, Alberta Health, the Newfoundland and Labrador Department of Health and Community Services, Manitoba Health, British Columbia Ministry of Health, Patented Medicine Prices Review Board, the Canadian Agency for Drugs and Technology in Health (CADTH), Canadian Institute for Health Information, and Health Canada.

---

May 23, 2017
*Should Canada Develop a List of Essential Medicines?*

This seminar was presented by the WHO Secretary of the Expert Committee on the Selection and Use of Essential Medicines, Dr. Nicola Magrini and Lars Gustaffson, a Professor in the Department of Laboratory Medicine at Karolinska University.
(Link: https://munkschool.utoronto.ca/event/23013/)

**Outcomes:**
A presentation on the benefits and challenges of creating an essential medicines list was delivered. The opinions and reactions of Canadian decision-makers were discussed, followed by an open public forum discussion to involve all participants.

---

February 2, 2017
*Access to Medicine – Benchmarking Pharmaceutical Companies in Weak Regulatory Environments*

This seminar was presented by Luca Genovese, a researcher with the Access to Medicine Foundation. This was co-hosted by the Leslie Dan Faculty of Pharmacy, Universite Sainte Anne, and Carleton University Faculty of Public Affairs and the WHO CCGAT. (Link: http://www.pharmacy.utoronto.ca/sites/default/files/upload/who_cc/Feb%202%20-%20Genovese.Kohler.pdf)

**Outcomes:**
A report from this symposium was published in the Canadian Medical Association Journal.
2015-2016

November 28, 2016
Symposium
**Governance and Corruption in the Pharmaceutical Sector: Causes and Consequences**

The keynote speaker for this symposium was Dr. Sidney Wolfe (Co-founder; Public Citizen’s Health Research Group). The event was co-hosted by the Leslie Dan Faculty of Pharmacy, Universite Sainte Anne, and Carleton University Faculty of Public Affairs and the WHO CCGAT.


**Outcomes:**

This was the first policy workshop of the 2016-2017 work program and led to a multidisciplinary discussion on legal, financial and ideological varieties of corruption.

April 29, 2016
**Taking the Pulse of Governance, Accountability and Transparency in the Pharmaceutical Sector: Diagnosing the Issues**

This policy workshop included a series of presentations led by multiple experts, researchers and students.

(Link: http://www.pharmacy.utoronto.ca/sites/default/files/upload/who_cc/Save%20the%20date%20WHO%20CC%20launch.pdf)

**Outcomes:**

A series of presentations were provided from research fellows and experts in the field. Notes and an overview from this workshop is available on our WHO CC website.

April 28, 2016
**Corruption and the Pharmaceutical & Healthcare Sector: Global Policy & Structural Issues**

This meeting was led by James Sale, a Project Officer from Transparency International (UK).

(Link: http://www.pharmacy.utoronto.ca/sites/default/files/upload/who_cc/SALE.James%20Apr%2028%20-%20Kohler.pdf)

**Outcomes:**

This seminar provided graduate students and attendees with knowledge on the topic of corruption.
Publications & Knowledge Dissemination

Presentations from Conferences (chronological order):

- **April 2016.** Panel at Consortium for Universities for Global Health – San Francisco:
  - Are Current Anti-Corruption Tools in the Health Sector Good Enough for Health Security?
    - Speakers – Josh Michaud, Kaiser Foundation, Jillian C Kohler (WHO CC and LDFP), Maureen Lewis (Georgetown University), Taryn Vian (Boston University), Tim Mackey (University of San Diego).
  - Corruption in Global Health: Scope, Diversity, Case Studies, Tools, and Legal Frameworks Tim Mackey, MAS, PhD, Assistant Professor, UC San Diego – School of Medicine.
  - Transparency and Accountability in Pharmaceutical Pricing and Procurement: Are Current Anti-Corruption Tools in the Health Sector Good Enough for Health Security? Jillian Clare Kohler, Associate Professor, Leslie Dan Faculty of Pharmacy, University of Toronto Director, WHO Collaborating Centre for Governance, Transparency and Accountability in the Pharmaceutical Sector.
  - An Evaluation of Accountability and Transparency in Brazil’s Pharmaceutical System (Abstract) Martinez MG (Leslie Dan Faculty of Pharmacy, University of Toronto), Kohler JC (Leslie Dan Faculty of Pharmacy, University of Toronto) (Winner of the 2016 Lancet-Consortium of Universities for Global Health Annual Meeting - Best Student Poster Track: Governance).

- **October 2016.** Workshop co-presenter, Beyond medicalization: an international view of MD roles in long term care, Ontario Long Term Care Clinicians, Toronto. Presenter: Lexchin, J.


- **October 18, 2016.** Twitter Analysis and Drug Abuse: Discussion About Data Collection, Methods, Analysis, and Recent Research. Mackey TK. UCSD Human Nature Group - Public Health, San Diego, CA Presenter: Mackey, TK.


- **November 2016.** Drug prices in the United States. Webinar for American Medical Students Association. Presenter: Lexchin, J.

December 1, 2016. SDGs, Anti-corruption and Equity: Leave No-one Behind to Deliver on the SDGs Mackey TK. 17th International Anti-Corruption Conference (IACC), Panama City, Panama. Presenter: Mackey, TK.


March 2017. Seminar on expedited drug approval programs in Canada and the United States, Centre for Healthcare Resilience and Implementation Science, Macquarie University, Sydney, Australia. Presenter: Lexchin, J.


March 22, 2017. Participation Panel on "The Opioid Crisis", event organized by the Health Law Club, Faculty of Law. Presenter: Lemmens, T.


• **May 2017.** Panelist, Seniors’ Housing as part of Housing Policy Forum Series sponsored by Social Planning Toronto, Wellesley Institute, Toronto Alliance to End Homelessness and City of Toronto, Toronto. Presenter: Lexchin, J.

• **May 2, 2017.** Curing Health Inequalities with Technology & Social Reform. Mackey TK. Health Technology Forum 2017, Stanford University, CA. Presenter: Mackey, TK.


• **May 9, 2017.** Educational Panelist: Webinar "Securing the Pharma Supply Chain with Blockchain", IEEE Standards Association. Presenter: Mackey, TK.

• **June 2017.** Myths and realities about why US drug prices are so high. PharmedOut Conference, Washington. Presenter: Lexchin, J.

• **June 2017.** Panelist, Ensuring safety, efficacy and access to medical products in the age of global deregulation. Yale Collaboration for Economic Integrity and Transparency and European Public Health Alliance, New Haven Connecticut. Presenter: Lexchin, J.

• **June 6, 2017.** The Last Mile: Design Elements that incentivize the Use of Blockchain Beyond Compliance. Mackey TK. IEEE Pharma Supply Blockchain Forum, Johns Hopkins University, Rockville, MD. Presenter: Mackey, TK.


• **August 2017.** The danger of imperfect regulation: how Purdue was allowed to push Oxycontin. Public lecture, Unitarian Church Vancouver. Presenter: Lexchin, J.


• **September 2017.** Where do we go from here: physicians, the medical profession and industry at Health Action International AGM, Berlin. Presenter: Lexchin, J.
• **September 2017.** Panelist, Beyond medicalization: an international view of MD roles in long-term care, Re-imagining Long-term Residential Care project, Toronto. Presenter: Lexchin, J.

• **September 7, 2017.** Carefully selected, Easily Accessible, at no charge Medications: CLEAN Meds Trial. Breezy Ridge, Muskoka, Ontario, Canada. Presenter(s): Persaud, N. PSI Graham Farquharson Knowledge Translation Fellows Retreat.

• **September 12, 2017.** Conflict of Interest Policy for Committee Members at Health Quality Ontario. Panel on Health Quality Ontario Board of Directors. 90 min lecture. Presenter(s): Persaud N, Patel R, Apkon M, Tunks E. Provincial talk at Health Quality Ontario.


• **September 26, 2017.** for the Pharma Supply Chain. Mackey, TK. Distributed Health 2017 Conference. Presenter: Mackey, TK.

• **September 29, 2017.** The Pharmaceutical Triple Aim: Policies to promote universal accessibility, appropriateness, and affordability of prescription drugs. Canadian Institutes of Health Research, Ottawa, Ontario, Canada. Presenter(s): Persaud, N. CIHR Best Brains Exchange.

• **September 29, 2017.** Speaker, Governance and corruption in the pharmaceutical sector: causes and consequences, WHO Collaborating Centre for Governance, Accountability and Transparency in the Pharmaceutical Sector, Toronto. Presenter: Mackey, TK.

• **September 29, 2017.** Leveraging the Sustainable Development Goals to Tackle Pharmaceutical Corruption. Mackey TK. World Health Organization Collaborating Centre on Pharmaceutical Governance, Accountability and Transparency, University of Toronto. Presenter: Mackey, TK.

Academic Publications (alphabetical order):


• Habibi, Roojin, Joel R. Lexchin, Barbara Mintzes, and Anne Holbrook. "Unwarranted claims of drug efficacy in pharmaceutical sales visits: are drugs approved on the basis of surrogate outcomes promoted appropriately?" *British Journal of Clinical Pharmacology* (2017).


• Lexchin, Joel R., Peter Doshi, Janice E. Graham, Matthew Herder, Tom Jefferson, Trudo Lemmens, Barbara Mintzes, and Nav Persaud. “Response to Health Canada discussion paper on Regulations Amending the Food and Drug Regulations (on safety reporting).” Health Canada (2017).


• Lexchin, Joel R. "Drug prices: How do we get to a better place?" Canadian Medical Association Journal 189, no. 23 (2017): E792-E793.


• Lexchin, Joel R. "Publication of confirmatory studies required by health Canada for drugs approved under a notice of compliance with conditions: a cohort study." CMAJ Open 5, no. 2 (2017): E295.


• Lexchin, Joel R. “Six myths about pharmacare.” Health Law in Canada (2017): 44-51.


• Menkes, David B., and Joel R. Lexchin. “Relationships with industry are undermined by unconscious bias.” *BMJ* (2017): 356.


• Persaud, Nav, Taehoon Lee, Haroon Ahmad, Winny Li, Michael Sergio Taglione, Yathavan Rajakulasingam, Norman Umali et al. "Protocol for a randomized controlled trial evaluating the effects of providing essential medicines at no charge: the Carefully selected and Easily Accessible at No Charge Medicines (CLEAN Meds) trial." *BMJ open* 7, no. 5 (2017): e015686.


**News Articles & Media Outputs (chronological order):**

• **October 2015**

• **November 2015**

• **December 2015**

• **April 2016**

• **June 2016**
• July 2016


• August 2016

• September 2016

• January 2017

• February 2017

• March 2017


• May 2017
- **June 2017**

- **July 2017**

- **August 2017**


- **September 2017**

Summary

2015 Activities

- The WHO CCGAT convened in October 2015. It is currently led by Dr. Jillian C. Kohler who works with a large multidisciplinary team of local and global research fellows. The expertise of said professionals informed the direction and planning for this research and training program.

2016 Activities

- Several workshops and symposiums were hosted in alignment with the program goals. Highlights (e.g. agendas and presentations) from these academic events are captured and further described on our WHO CC website.

2017 Activities

- Several workshops, symposiums and one summer course was hosted this past year in alignment with the program goals. Several publications (i.e. conferences, academic articles) were disseminated to reflect the current work of this WHO CC.

Future Directions

Moving forward, the WHO Collaborating Centre for Governance, Accountability and Transparency in the Pharmaceutical Sector aims to continue to provide a global venue for discussing and researching critical issues related to good governance in medicines.