

Post-Approval Surveillance Systems



***HIV/AIDS Treatment Access
Advocacy Workshop Series***



Canadian Treatment Action Council



Conseil canadien de surveillance et d'accès aux traitements

Objectives

1. To define basic concepts & terms related to drug surveillance
2. To outline the current Canadian post-approval surveillance system
3. To examine the system's shortcomings
4. To briefly discuss CTAC's PASS Study



Canadian Treatment Action Council



Conseil canadien de surveillance et d'accès aux traitements

Workshop Overview

1. Introductions, terminology & basic concepts
2. Post-approval surveillance: the current Canadian system
3. Addressing systemic shortcomings
4. The CTAC PASS Study & future steps



Canadian Treatment Action Council



Conseil canadien de surveillance et d'accès aux traitements

Post-Approval Surveillance: The current Canadian system



Canadian Treatment Action Council



Conseil canadien de surveillance et d'accès aux traitements

Definitions: Adverse Drug Events

Unwanted, harmful, toxic reactions

- ADE: Adverse Drug Event
 - suspected connection to medication
- ADR: Adverse Drug Reaction
 - confirmed connection
- SAE: Serious Adverse Event
(also – Serious Adverse Reaction)



Canadian Treatment Action Council



Conseil canadien de surveillance et d'accès aux traitements

Definition of “Serious”

- A Serious Adverse Event / Serious Adverse Reaction...
 - requires hospitalization,
 - causes birth defects,
 - results in “persistent or significant disability or incapacity”,
 - is life-threatening or results in death
 - or requires “significant medical intervention to prevent one of these outcomes”



Canadian Treatment Action Council



Conseil canadien de surveillance et d'accès aux traitements

Reporting Mechanisms

- What reporting mechanisms are you aware of, *before* drug approval?
- What mechanisms are you aware of, *after* drug approval?
- What are the differences?

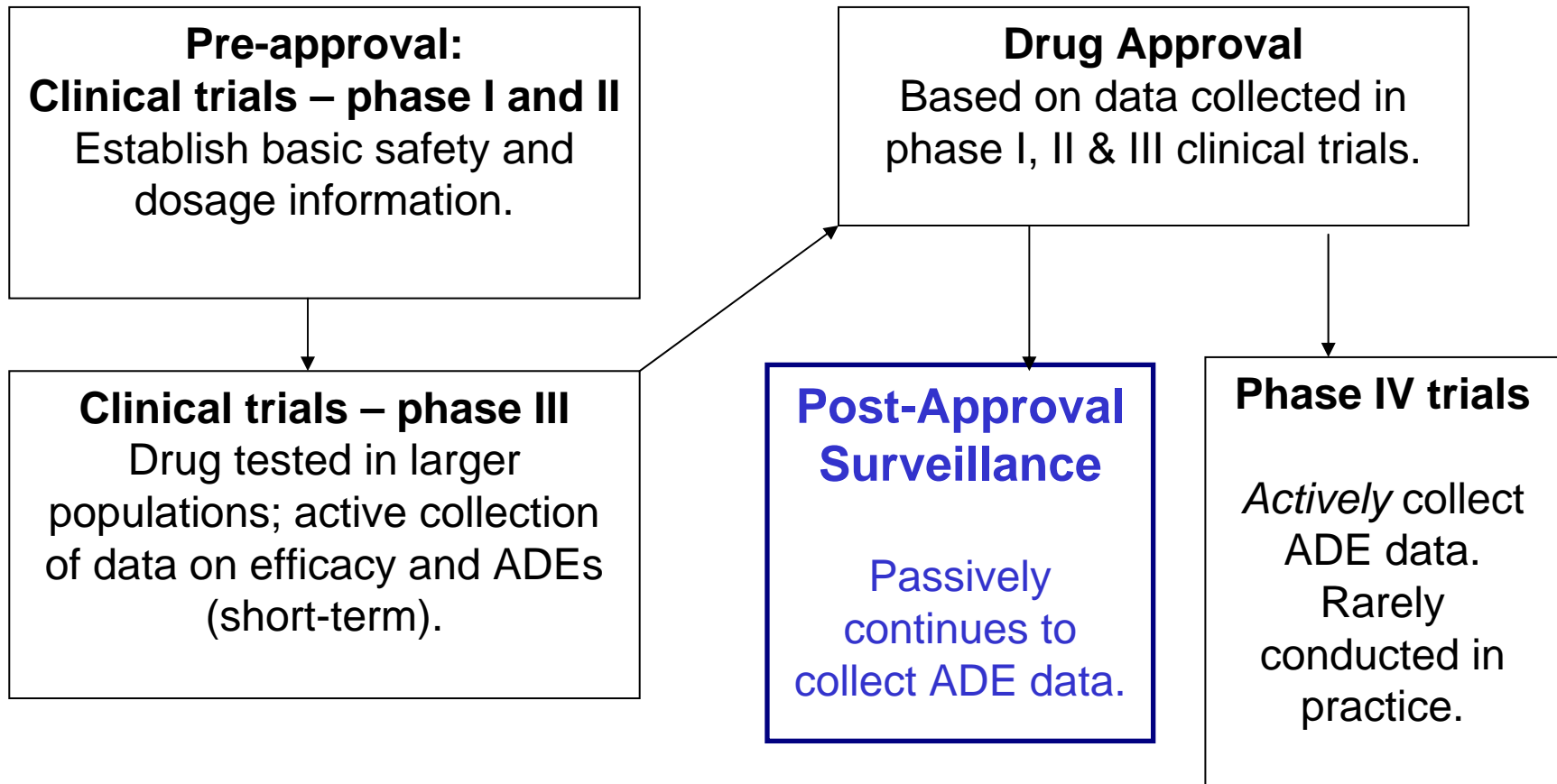


Canadian Treatment Action Council



Conseil canadien de surveillance et d'accès aux traitements

Drug Approval & ADE Monitoring



Current PASS system – Who's Responsible (Government)

- **CADRMP:**
Canadian Adverse Drug Reaction Monitoring Program
- Program of Health Canada
- One national office and 7 regional offices
(Regional Adverse Drug Reporting Centres)
- Receives reports of ADEs



Canadian Treatment Action Council



Conseil canadien de surveillance et d'accès aux traitements

Current PASS system – Who's Responsible (Consumers)

- Health care “consumers” can report ADEs:
 - to their doctor/health care professional
 - directly to Health Canada (or pharmaceutical co.)
- MedEffect
- Little-known, little-used
(but still relatively new)



Canadian Treatment Action Council



Conseil canadien de surveillance et d'accès aux traitements

Current PASS system – Who's Responsible (Industry & Health Care)

- Health care professionals: voluntary
- (although mandatory reporting is being discussed)
- Constraints: time, paperwork

- Pharmaceutical companies: mandatory reporting
- Any reports received *must* be forwarded to CADRMP



Canadian Treatment Action Council



Conseil canadien de surveillance et d'accès aux traitements

Current PASS system – MedEffect

12

- MedEffect: reporting system for consumers and health professionals (drugs, natural health products, and medical devices)
- includes existing Regional Adverse Drug Reporting Centres (contactable by phone/fax)
- adds centralized “online reporting”
- online component not fully functional yet



Canadian Treatment Action Council



Conseil canadien de surveillance et d'accès aux traitements

Then What?

- What happens to ADE information after it is collected?
 - National database
 - Canadian Adverse Drug Reaction Newsletter
 - Drugs & Health Products website



Canadian Treatment Action Council



Conseil canadien de surveillance et d'accès aux traitements

Current PASS system: shortcomings

- No consumer-centred PASS system in Canada
- Domain of health care providers and industry
- Consumers may report directly, but system is little-known and little-used
- Not all data is reported: limited to *serious* adverse events



Canadian Treatment Action Council



Conseil canadien de surveillance et d'accès aux traitements

Addressing The Issue



Canadian Treatment Action Council



Conseil canadien de surveillance et d'accès aux traitements

Improving on PASS: What has CTAC done?

16

- Multistakeholder committees: since 1998
- Position paper: “Improving Our Health: The Need To Enhance the Post-Approval Surveillance System for HIV/AIDS Drugs in Canada” – December 2000
- PASS Study: 2001-2004
- PASS Study Synthesis & Dissemination: 2005-2006



Canadian Treatment Action Council



Conseil canadien de surveillance et d'accès aux traitements

The PASS Study: Objectives & Methods

- **Main objectives:** To **pilot-test** and to **compare four community based methods** of data collection for antiretroviral side effects.
- **Mixed methodology:** *qualitative and quantitative.*



Canadian Treatment Action Council



Conseil canadien de surveillance et d'accès aux traitements

PASS Study: Community-based data collection methods

- 1. Face-to-face/one-on-one interviews**
- 2. A bilingual toll-free phone line**
- 3. A mail/fax-in option using standard 'Data Collection Forms'**
- 4. Four focus groups with Aboriginal people**



Canadian Treatment Action Council



Conseil canadien de surveillance et d'accès aux traitements

PASS Study - Main results

- 933.** Face-to-face interviews
- 97.** Mail/fax-in reports
- 40.** Telephone interviews
- 22.** Aboriginal focus group participants



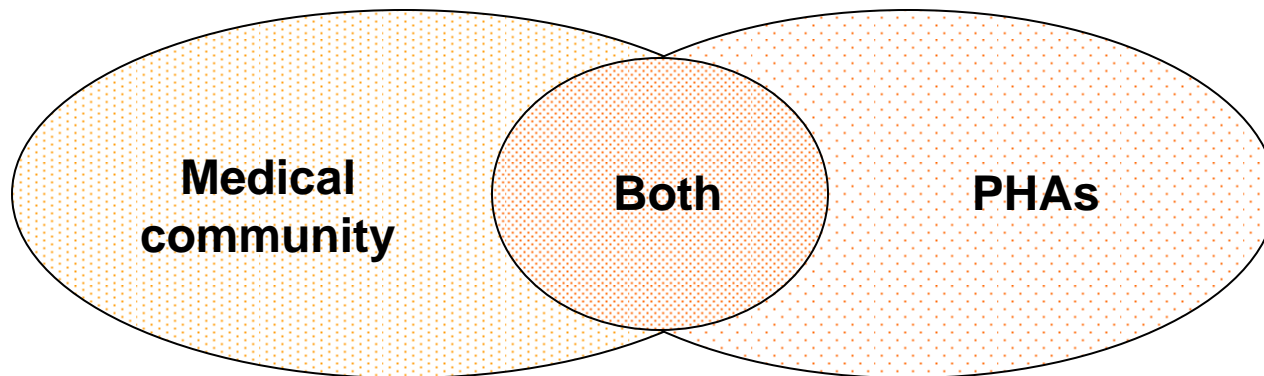
Canadian Treatment Action Council



Conseil canadien de surveillance et d'accès aux traitements

PASS Study Conclusions

- Typical ADE reporting focuses on identifiable medical problems.
- Overlap / Disparity: what is important to...



Canadian Treatment Action Council



Conseil canadien de surveillance et d'accès aux traitements

PASS Study Conclusions

- Treatment decision-making:
requires full information –
 - clinical info,
 - serious **and** less serious ADEs,
 - social impact
- Community-based, consumer-centred reporting system *can* work



Canadian Treatment Action Council



Conseil canadien de surveillance et d'accès aux traitements

Discussion

- What ADEs should be reported?
(kinds / levels of severity)
- Can we be community-based “sentinels”?
- Completing the circle: how do we advocate to make this information available?



Canadian Treatment Action Council



Conseil canadien de surveillance et d'accès aux traitements

Contact us:

23

Tools for Action: HIV/AIDS Treatment Advocacy Workshop Series

PO Box 116, Station "F"

Toronto, Ontario M4Y 2L4

Telephone & Fax: (416) 410-1369

Email: tfa@ctac.ca

Website: www.ctac.ca/tfa



Canadian Treatment Action Council



Conseil canadien de surveillance et d'accès aux traitements



THANK YOU!



Canadian Treatment Action Council



Conseil canadien de surveillance et d'accès aux traitements