



Health
Canada

Health Products
and Food Branch

Santé
Canada

Direction générale des produits
de santé et des aliments



Assessing CPSP Surveillance Methodology for Adverse Drug Reaction Reporting

1. Introduction

The case definition for serious and life-threatening Adverse Drug Reactions (ADRs) developed for the Canadian Paediatric Surveillance Program (CPSP) study is as follows (cited from *CPSP 2005 Results*, p. 24):

‘Serious and life-threatening adverse drug reactions in an infant or child 18 years or less, associated with the use of prescription, non-prescription, biological (immunoglobulin) products, complementary medicines (including herbals), and radio-pharmaceutical products have been defined as a noxious and unintended severe response to a drug, which occurs at any dose and results in emergency observation, hospitalisation, persistent or significant disability or death.

‘Exclusions: Reactions due to medical devices, blood products (platelets, red cells and single-donor plasma), vaccines, poisoning or self-administered overdoses.’

2. CPSP ADR Reporting

1. The CPSP ADR study definition describes a serious and life-threatening event.

Yes No

2. Serious and life-threatening ADRs are rare in children.

Yes No

3. Please indicate your understanding of a rare event – choose only one of the following.

1:1000
1:10,000
1:100,000
1:1,000,000

4. I report all serious and life-threatening ADRs.

Yes No

5. I only report serious and life-threatening ADRs that are rare or unexpected.

Yes No

6. I participate monthly in the program.

Yes No

7. I have reported ADRs to the CPSP during the study period. If no, why not?

Yes No Comments _____

8. The detailed questionnaire was...

	Yes	No
a. logical	<input type="radio"/>	<input type="radio"/>
b. easy to understand	<input type="radio"/>	<input type="radio"/>
c. easy to complete	<input type="radio"/>	<input type="radio"/>

9. The following components of the study provide me with meaningful information on ADRs in children and youth.

	Yes	No
a. Case definition & protocol	<input type="radio"/>	<input type="radio"/>
b. ADR Tips of the Month	<input type="radio"/>	<input type="radio"/>
c. Educational resources with accompanying quiz	<input type="radio"/>	<input type="radio"/>
d. CPSP Highlights with learning points in <i>Paediatric & Child Health</i> , Journal of the Canadian Paediatric Society	<input type="radio"/>	<input type="radio"/>
e. Annual CPSP Results	<input type="radio"/>	<input type="radio"/>
f. Study-related publications and oral and poster presentations	<input type="radio"/>	<input type="radio"/>
10. I report ADRs:	<input type="radio"/>	<input type="radio"/>
11. If yes, I report to:		
a. CPSP	<input type="radio"/>	<input type="radio"/>
b. Health Canada	<input type="radio"/>	<input type="radio"/>
c. Genotype-Specific Approaches to Therapy in Childhood (GATC)	<input type="radio"/>	<input type="radio"/>
d. Hospital	<input type="radio"/>	<input type="radio"/>
e. Manufacturer	<input type="radio"/>	<input type="radio"/>
f. Other. If yes, specify: _____	<input type="radio"/>	<input type="radio"/>

3. Barriers to CPSP ADR Reporting:

To what extent do the following barriers impact your ADR reporting?

	Very Significant	Significant	Of Little Significance	No Significance
12. Heavy workload	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. Time to complete the CPSP detailed questionnaire	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. Lack of confidence and knowledge in recognising ADRs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. Lack of understanding about the purpose and usefulness of ADR reporting	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. Concern about legal liability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17. Fear of breaching patient confidentiality	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18. Difficulty in determining whether the problem is associated with a disease versus a drug	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

4. Factors that negatively affect CPSP ADR Reporting:

To what extent do these factors negatively affect your ADR reporting?

	Very Significant	Significant	Of Little Significance	No Significance
19. Years of clinical experience	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
20. Practice setting	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
21. Location of practice	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

5. Solutions to increase CPSP ADR Reporting:

To what extent do/would the following strategies support your reporting of ADRs?

	Very Significant	Significant	Of Little Significance	No Significance
22. Tips of the month	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
23. Increased training in ADR reporting	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
24. Greater feedback	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
25. Simplify the detailed questionnaire	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

26. Other: Yes No

If yes, please provide comments: _____

27. Do you think that CPSP should continue to collect ADRs? Yes No

If no, please comment: _____

6. Tell us about yourself

28. Age:

- Less than 30
- 30-40
- 40-50
- 50-60
- Greater than 60

29. Gender: Male Female

30. Number of years in practice:

- Less than 10 years
- 10-20 years
- Greater than 20 years

31. Primary practice setting:

- Community
- Hospital
- Clinic
- Other, please specify: _____

32. Location of practice:

- Urban
- Rural
- Remote

33. Sub-specialty: _____

34. Any other comments:

THANK YOU!

Please return to the CPSP in the enclosed self-addressed envelope.