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## Assessing CPSP surveillance methodology for ADR reporting

December 2007 / January 2008

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A survey was conducted in December 2007 and January 2008, to assess the value of the CPSP in supporting increased recognition and reporting of serious and life-threatening adverse drug reactions (ADRs). Information was gathered on the ability of the CPSP to overcome the documented barriers to reporting associated with passive surveillance and the effectiveness of collaborative models in improving ADR reporting.

Information was collected via phone interviews, online questionnaire and mailed questionnaire. Phone interviews were conducted with eight Canadian Paediatric Society Board members. Over 700 survey responses were received, representing an approximate response rate of 28%.

Results clearly indicated that the CPSP has been instrumental in building and maintaining a culture of reporting amongst its members. It has simplified the reporting process and increased the likelihood of ADR reporting. Almost all (90%) respondents reported that they participate in the CPSP on a monthly basis, confirming the success of the program and highlighting the benefits of working with a national active surveillance program that promotes ongoing involvement and commitment of front-line members. When asked if serious and life-threatening ADRs were rare in children, 68% responded yes and 24% of respondents indicated that they had reported such an event during the study period.

Heavy workload, fear of legal liability and concerns with patient confidentiality are among the documented barriers associated with passive reporting systems. When asked about the barriers that impact the reporting of ADRs to the CPSP, heavy workload (51%), time to complete the detailed questionnaire (39%) and difficulty in determining whether the problem is associated with a drug versus a disease (53%) were identified as significant barriers. Comments provided suggested that even a simple questionnaire represents an increased workload and that defining priorities for reporting would help manage workload issues as would electronic reporting. Concerns about legal liability and fear of breaching patient confidentiality were not seen as barriers to the reporting of ADRs to the CPSP. This most likely reflects the awareness of CPSP participants that every study undergoes approval by an independent Canadian research ethics board and that the program is committed to the rights of individual privacy and professional confidentiality.

Meaningful and targeted feedback is a critical measure of value and instrumental in building motivation and buy-in with active surveillance. All reporters, regardless of the reporting program, are looking for meaningful feedback with information targeted to specific areas or issues having the most impact on building buy-in and support. Greater feedback (61%), Tips of the Month (60%), increased training (61%) and a simplified questionnaire (53%) were all seen as solutions to support increased reporting by CPSP participants.

In order to improve paediatric drug safety, different types of partnerships are needed to better understand and accommodate the needs of physicians practising across a variety of settings. However, in trying to increase reporting, we may be creating underreporting due to confusion. Competing interests must be minimized and synergies maximized. This evaluative survey has documented that collaboration with a national specialty active surveillance program is a very effective way to promote awareness and buy-in of participants to the ADR reporting process.

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