Social Impact of Adverse Drug Reactions in the Canadian Spontaneous Reporting Database

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BACKGROUND

• Social impact is defined as the effect on the society of a person’s impairment of interpersonal and occupational (job/academic) functions and social roles, directly caused by an adverse drug reaction (ADR) (Ref. 1-4).
• Within spontaneous reporting systems, there is no systematic documentation of the impact of ADRs on patients’ social functioning.
• Some ADRs may have an important impact on work or academic productivity and/or social behavior. Although they do not meet regulatory criteria for seriousness, such ADRs could have important consequences for patients.

OBJECTIVES

Main: To characterize ADRs with social impact in the Canada Vigilance Program (CVP) spontaneous reporting database.
Specific:
1) To determine the proportion and types of ADRs with social impact in the CVP database;
2) To compare seriousness of ADRs with and without social impact;
3) To evaluate trend over time in the proportion of ADRs with social impact;
4) To identify health products most frequently associated with ADRs with social impact.

METHODS

Study design: Descriptive analysis of spontaneous reports.
Data source: Canada Vigilance Program Adverse Reaction Online Database.
Eligibility criteria: All reports registered in the CVP databases from 1st January 1965 to 31st December 2015, with the exception of: i) health products for veterinary use; ii) reports with no suspected drug; iii) no MedDRA term recorded or iv) missing initial received date.
Study outcomes:
• Primary: Broad category of ADRs with social impact.
• Secondary: Individual types of social impact and seriousness of ADRs.
Coverables:
• Reporter (consumer or other non-health professional, health professional, market authorization holder, other);
• Suspected health product (ATC category);
• Year of reporting;
• Patient characteristics (gender, age);
• Seriousness according to regulatory criteria (i.e., hospitalization, life-threatening, disability, death);
• Reported outcomes (recovered/resolved, recovering/resolving, resolved/recovered with sequelae, not recovered/not resolved or death).

MedDRA Preferred Terms (PT) and Social Impact

Two clinicians independently reviewed a total of 22,210 PTs included in MedDRA version 19.1, in order to identify those that have a direct social impact using the definition above.

Examples of MedDRA PTs indicative of social impact
- Activities of daily living impaired
- Impaired work ability
- Aggression
- Impisonment
- Antisocial behavior
- Legal problem
- Crime
- Loss of employment
- Delinquency
- Marital problem
- Disturbance in attention
- Physical assault
- Divorced
- School refusal
- Educational problem
- Social fear
- Fight in school
- Theft
- Homicide
- Verbal abuse

RESULTS

Number of ADRs With Social Impact by Year

Distribution of ADRs With Social Impact According to Type

- Personality disorders and disturbances in behaviour
- Neurological disorders
- Nec
- Lifestyle issues
- Mental impairment disorders
- Others

Most Frequent Nervous System Drugs in ADRs With Social Impact

- Natural opioid analgesics (19.5%)
- Oxycodone
- Hydroxomorphine
- Morphine
- Methadoninate

- Drugs used in nicotine dependence (19.3%)
- Varenicline
- Bupropion
- Paroxetine

- Other antidepressants in ATC (10.0%)
- Venlaxine
- Bupropion
- Paroxetine

- Selective serotonin reuptake inhibitors (8.0%)
- Venlaxine
- Bupropion
- Paroxetine

- Antineoplastic and immunomodulating agents

Most Frequent Antineoplastic and Immuno-Modulating Agents in ADRs With Social Impact

- Adalimumab
- Infliximab
- Etanercept
- Leflunomide
- Tolctinib
- Abatacept
- Rituximab
- Bevacizumab

CONCLUSION

• An important proportion of serious ADRs have a social impact (80.5%). For this reason, it may be important to include a subsection in the Canadian Federal Adverse Reaction Reporting Form to document social impact. This would certainly increase the sensitivity of signal detection methods for these types of events.

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