Spontaneous Reporting Data: A Global Comparison Using An Online Database Resource
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BACKGROUND
- Spontaneous reports (SR) of suspected adverse events associated with biopharmaceuticals / medical products are key sources for identifying potential adverse reactions (Spain).
- Date of last update
- Population size, Sample weights – Extrapolation factors
- Age, Gender, Date of birth (DOB, MOB or YOB)
- Gestation Period (for fetuses).
- MedDRA: LLT
- (4) Box 2.
- CIOMS

OBJECTIVE
To analyze SR databases and to characterize data elements useful for evaluating signals and for capturing different types of information.

METHODS
Box 1. We identified databases profiled in B.R.I.D.G.E. collecting SR data using two search criteria: "Database Type = Spontaneous reporting systems", and "Database Source = Spontaneous reports".

Box 2. Of the 75 data fields, 53 (71%) were frequently used among SR DBs: 21 (28%) were classified in Group 1 (G1) – consensus in use of field among the set Group 2 (G2) – use by ≤50% DBs.

Box 2. 20 of 209 profiles matched 21 criteria (Figure 2).

Box 3. The frequency of use of the 75 data fields (Table 1) used in B.R.I.D.G.E. structured profiles was compared among the 20 DBs.

Box 4. Based on use frequency, fields were categorized as:

- Group 1 (G1) – consensus in use of field among the set
- Group 2 (G2) – use by ≤50% DBs.
- Group 3 (G3) – use by <50% DBs.

RESULTS

- Of the 75 data fields, 53 (71%) were frequently used among SR DBs: 21 (28%) were classified in G1; 32 (43%) were classified in G2; 22 (29%) fields utilized less frequently comprised G3.
- Analysis of G1 revealed that a majority of SR DBs are funded by government agencies, capture OTC & prescription drug use in inpatient & outpatient settings; however, diagnosis data are heterogeneously coded.
- Of the 25 fields on the CIOMS reporting form, 13 corresponded to G1, 10 to G2, and 2 overlapped with G1 & G2.

LIMITATIONS
This analysis was done using DBs currently profiled within B.R.I.D.G.E. More profiles of data sources are continually being added to this resource.

CONCLUSION
In this analysis, B.R.I.D.G.E. TO DATA served as a tool to categorize data fields used in SR databases and to identify additional fields to complement the CIOMS effort (e.g., data on cost, procedures, environmental exposures). We believe that important capabilities such as access to medical records, cost data and DB linkages can enhance ad hoc pharmacoeconomic studies, yet are currently infrequently used in SRS. With increasing interest in SRS, it is likely that the use of these data fields will also increase, and the methods for collecting SR data may be instructive for database design.