Multimedia Appendix 3

Literature review on quality of reports in spontaneous reporting system

We searched MEDLINE database for recent studies on spontaneous reporting system (SRS) data quality between 2014 and February 2021. The following search terms were used: ("spontaneous report*" OR "adverse drug reaction report*" OR "ADR report*" OR "adverse event report*" OR "AE report*" OR "Individual Case Safety Report" OR "ICSR" OR "pharmacovigilance") AND ("quality" OR "completeness"). The search was limited to English language studies and full-text availability. Of the 6,257 studies, abstracts were screened for relevance to the topic. Furthermore, a reference list search and a cited reference search were carried out based on full-text papers meeting the study selection criteria. Studies that reported only completeness score or well-documented rate without discussing factors that may contribute were excluded. As a result, 25 studies were reviewed in total.

Among the 25 studies reviewed, 18 examined reports recorded in the national or regional databases [1-18], six evaluated VigiBase reports [19-24], and one studied the global safety databases of pharmaceutical companies [25]. While most were descriptive cross-sectional studies, there were two quasi-experimental studies that evaluated the impact of pharmacovigilance assessors [1] and the new consumer reporting form in plain language [2]. Most studies employed a single method to evaluate report quality, whereas some used multiple — vigiGrade was used in six studies [19-24] and adapted in seven [3-8, 25], clinical documentation tool (ClinDoc) in three [2, 9, 24], WHO documentation grading in two [7, 10], while the other studies employed different scoring methods. It is, however, important to note that studies applying vigiGrade in different data sources other than VigiBase may have found different completeness score, as they did not take into account for possible transmission errors [19] or the study datasets may not have contained all granularity of E2B format [26] to reproduce the multiplicative scoring method. Compared to studies that evaluated reporting
rates, the significant methodological heterogeneity of studies on reporting quality makes comparing their overall completeness difficult.

Diverse findings pertaining to factors associated with report completeness have been observed among different countries and stakeholders, depending on the existence of regulations, practices, resources, and cultures of reporting. Factors frequently reported were included sender type (e.g., medical institutions versus pharmaceutical companies) [4-6, 10-15, 19, 21], reporter qualification [6, 8, 10, 13-15, 18, 19, 21, 23], means of reporting (e.g., app reporting, plain-language forms) [2, 3, 12, 19, 21, 24], case seriousness or outcome [12-14, 16, 17], report type (e.g., study reports, program-specific reports) [7, 22, 25], patient age group [15, 17], patient sex [15], and causality [15]. Importantly, most included studies performed simple univariable analysis to examine the relationships among subcategories of a single variable and report completeness, whilst three have used multivariable logistic regression to study factors associated with well-documented reports [15, 16] or completeness of specific information [18]. Probably owing to the complex data structure in E2B format (as one report may contain multiple drugs and reactions), Toki and Ono [18] assessed only factors related to primary suspect drugs. Another two multivariable models did not study the relationships between characteristics of suspect drugs or reactions and report quality [15, 16].

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