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RESEARCH LETTER

Insight into the Severity of Adverse Drug Reactions as Experienced by Patients

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Dear Editor,

Experiencing adverse drug reactions (ADRs) may have a great impact on the patient's well-being, attitudes and beliefs regarding medicines [1–3]. In the regulatory setting, serious ADRs are often prioritised, for example those leading to hospitalization. Medical seriousness can, however, differ from patients' views on what constitutes a serious problem [4]. Insight into how patients experience the severity of ADRs may help healthcare professionals to understand how patients feel [1, 5]. It can also help to better assess for what type of ADRs patients need more information. Systematically gathering data about the severity of ADRs by pharmacovigilance centres is still uncommon. Following previous research by Lareb [6], the question 'How severe was the ADR?'—with a 5-point Likert scale answer option ranging from 'none at all' to 'extremely'—was added to the existing patient reporting form.

We explored data collected in the first year this 'severity question' was in place on the reporting form in order to get an impression about differences in experienced severity for ADRs. We retrospectively analysed the severity scores of all serious versus non-serious ADRs reported to Lareb by patients between 10 July 2017 and 10 July 2018. Analysis was based on ADR (Higher Level Term, minimal 20 reports), outcome of the ADR (recovered vs. not recovered) and the action taken on the suspected drug (continued vs. discontinued). The dataset included 2969 ADR reports, including 7769 drug–ADR associations, of which 205 (2.6%) were serious ADRs and 7564 (97.3%) non-serious ADRs.

Serious ADRs had an average severity score of 4.7 versus 3.4 for non-serious ADRs (Fig. 1; Pearson's Chi-squared test $p < 0.001$). For an in-depth analysis we focused on non-serious ADRs as, compared with medically serious ADRs, less is known about the impact of non-serious ADRs.

Behaviour and socialisation disturbances (e.g. aggression) had the highest severity grading (4.7), followed by *suicidal and self-injurious behaviour* (4.6). ADRs with the lowest severity grading were *injection-site reactions* (2.9) and *vulvovaginal disorders* (3.0).

Patients who did not recover from the ADR more often reported the categories 'slightly' (9.3% vs. 4.4%; $p < 0.001$), 'moderately' (27.2% vs. 16.8%; $p < 0.001$), and 'very' (29.1% vs. 27.2%; $p = 0.011$). The category 'extremely' was more often reported by patients who recovered from the ADR (51.3% vs. 34.1%; $p < 0.001$). This may imply that patients who did not recover accepted the burden of the ADR. Another possible explanation for this difference could be a difference in motive for reporting.

Figure 2 demonstrates the severity based on the action taken on the drug use and the outcome of the ADR. The action taken on the drug can, for example, be use is continued, the dose is decreased or the drug use is discontinued. In this analysis we included the actions 'continued with drug use' and 'discontinued with drug use'. We compared this with the outcomes of the ADR 'the ADR recovered' and 'the ADR did not recover'. Patients who continued the drug use more often reported the categories 'none at all' (0.5% vs. 0.2%; $p < 0.001$), 'slightly' (20.8% vs. 13.5%; $p < 0.001$) and 'moderately' (32.4% vs. 15.1%; $p < 0.001$). The category 'extremely' was more often reported by patients who discontinued the drug (54.3% vs. 24.8%; $p < 0.001$).

Our analysis shows that patients' experiences can differ from what is considered medically important. Also, non-serious ADRs can have a severe burden for the patient. We believe information about the severity can be useful for

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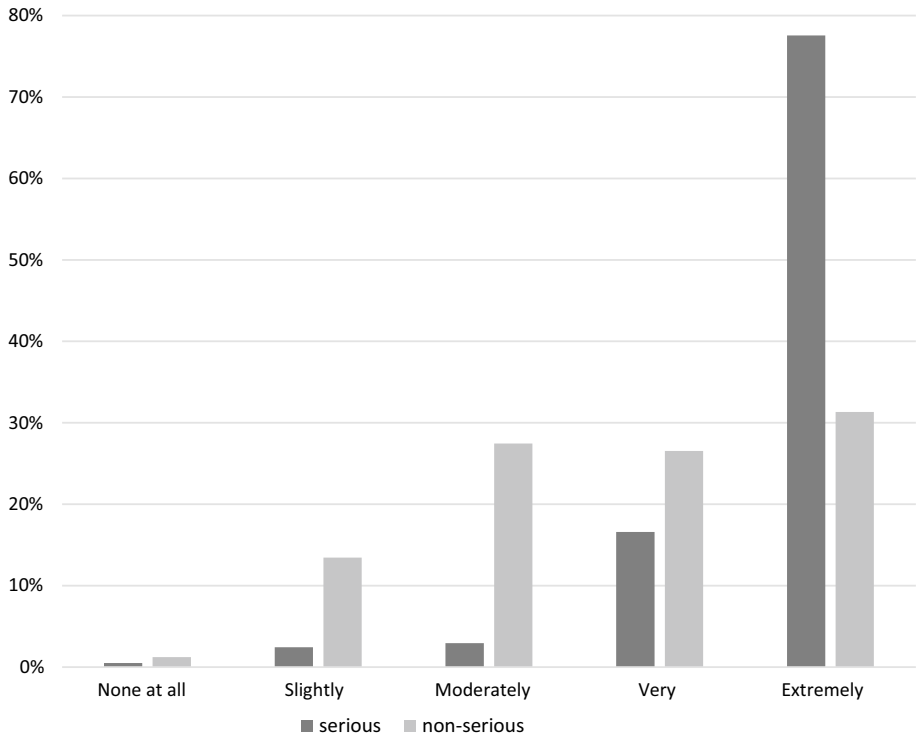

Fig. 1 Severity of serious versus non-serious adverse drug reactions (ADRs)

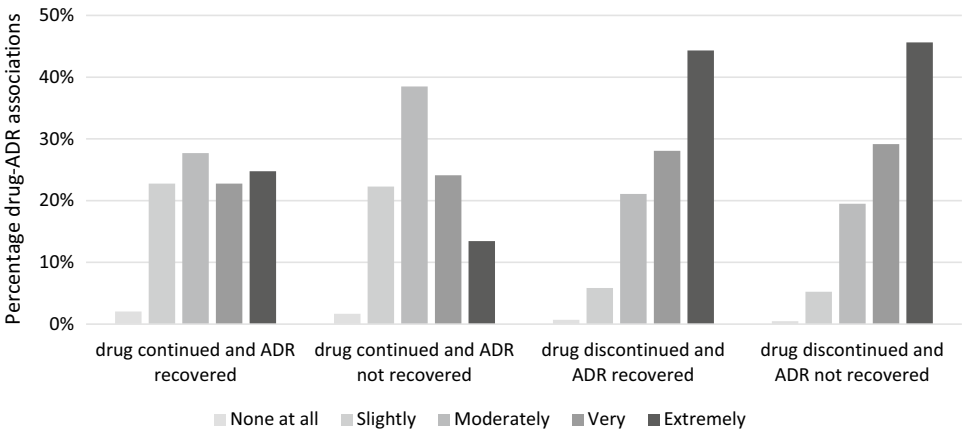

Fig. 2 Severity based on the action taken on the drug use and the outcome of the adverse drug reaction (ADR)

signal management, for example for prioritising for what type of ADRs patients need more information. It would be beneficial to have an objective standardised measure developed that could be used by pharmacovigilance centres across the world. But before such a standard is developed and in place, we would like to stimulate others to engage in generating knowledge about the severity of ADRs since this is not yet common practice. Thereafter, initial steps would be to explore how to use this information for signal management purposes, and to identify the ADRs with the largest burden for patients.

Compliance with Ethical Standards

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Conflict of interest Leàn Rolfes, Michelle Haaksman, Florence van Hunsel and Eugène van Puijenbroek declare that they have no conflicts of interest that are directly relevant to the content of this study.

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