

Characteristics and Quality of Spontaneous ADR Reports Submitted via the WEB-RADR App

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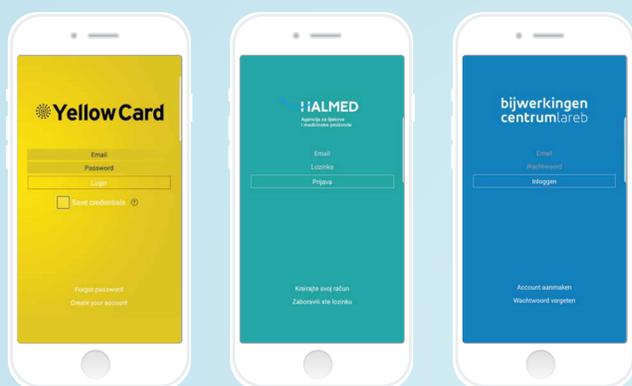
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Background

Spontaneous reporting of suspected ADRs is key for efficient post-marketing safety surveillance. However, existing reporting tools are sometimes perceived as complex or inaccessible. As a complement, the WEB-RADR consortium developed an app for mobile phones and tablets, based on a simplified reporting form. The app also allows you to subscribe to news regarding the medicines you use.

Objectives

To evaluate the characteristics and quality of reports submitted via the WEB-RADR app.



Methods

The app was launched in UK in July 2015, Croatia in May 2016, and Netherlands in January 2016. This study includes reports submitted up to September 2016 that

- were spontaneous,
- had a single notifier, and
- were submitted directly by a health care professional or patient.

The number of collected app reports was 144 for the UK, 37 for Croatia and 106 for the Netherlands. The app reports from each country, separately, were compared to a set of reference reports, submitted via conventional means during the same period, and meeting the inclusion criteria. The following report characteristics were analysed:

- Proportions of patient reports (Chi-squared test)
- Proportions of reports concerning females (Chi-squared test)
- The median patient age (Mann-Whitney U test)

In addition, a set of 100 app reports and 100 reference reports from each country (for Croatia 37 and 68 reports, respectively) was randomly sampled, stratified by the proportion of patient reports among the app reports. Blinded assessors scored the quality and clinical relevance of reports in this subset using a tool called ClinDoc [1], and the proportion of reports of at least moderate quality was compared (Chi-squared test).

References

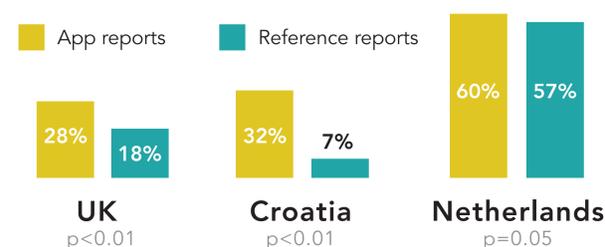
1. Oosterhuis I, et al. PDS. 2016;25(Suppl. 3):417.



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Results

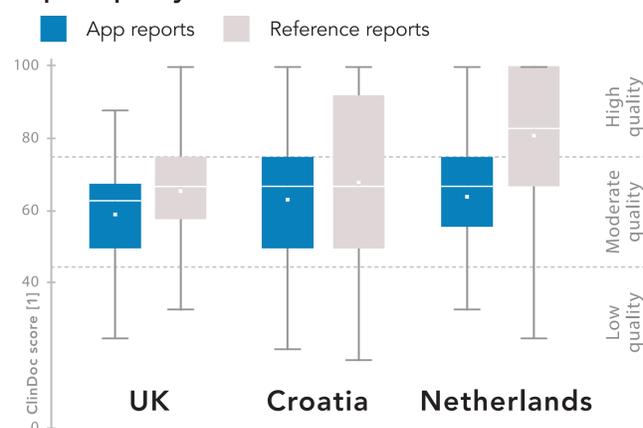
A significantly higher proportion of app reports from the UK and Croatia were submitted by patients



The proportion of female patients among app reports was relatively similar to the reference reports, in all countries: 53% vs 60% in the UK; 76% vs 66% in Croatia; and 59% vs 64% in the Netherlands (p>0.1 for all).

Median patient ages were also similar: 60 vs 55 years in UK; 56 vs 56 years in Croatia; and 48 vs 48 years in Netherlands (p>0.05 for all).

Report quality



The proportion of reports of at least moderate quality was high in both groups, for all countries, but relatively lower for app reports: 83% vs 92% in the UK (p=0.08); 78% vs 78% in Croatia (p=1.0); and 85% vs 98% in the Netherlands (p<0.01).

Conclusions

The WEB-RADR app offers a new complementary route of spontaneous reporting that has been shown to attract patients. Patient demographics are similar to conventional reporting routes, and report-quality is comparable to that from other reporting methods, despite a simplified form. This study shows that an app can be a valuable tool which increases the accessibility of reporting forms to patients and health care professionals.