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

Henric Taavola[1], Ola Caster[1,2], Phil M. Tregunno[3], Petar Mas[4], Ingrid Oosterhuis[5], Sara Gama[6], Linda Härmark[5]

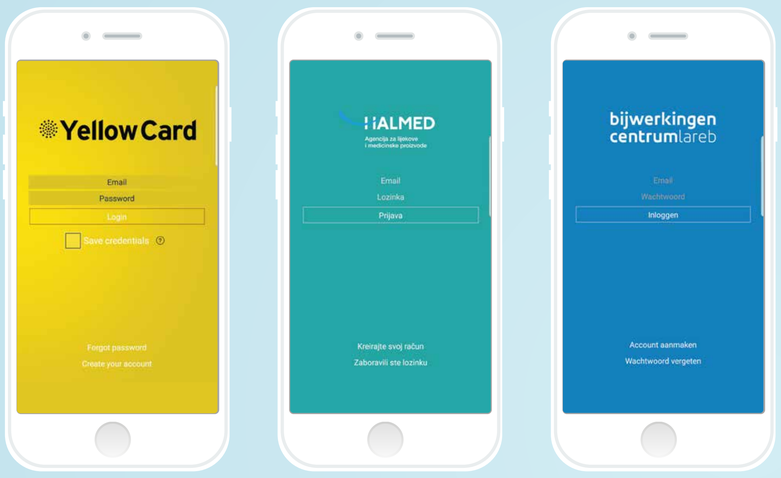
1. Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring, Uppsala, Sweden 2. Department of Computer and Systems Sciences, Stockholm University, Kista, Sweden 3. Vigilance and Risk Management of Medicines Division, Medicines and Healthcare Products Regulatory Agency, London, UK 4. Agency for Medicinal Products and Medical Devices, Zagreb, Croatia 5. Netherlands Pharmacovigilance Centre Lareb, 's-Hertogenbosch, the Netherlands 6. Novartis Pharma AG, Basel, Switzerland

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.

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.

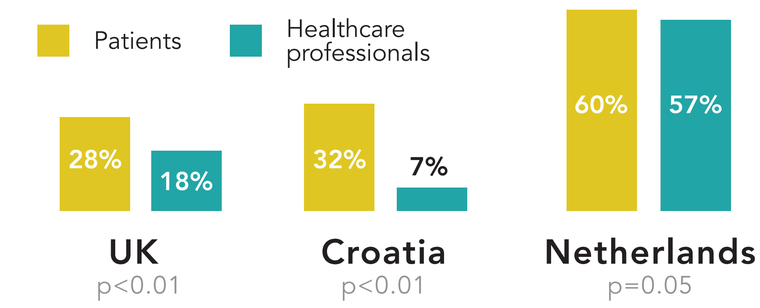
For each country separately, the app reports were compared to a set of reference reports, submitted via conventional means during the same period, and meeting the inclusion criteria. The following report characteristics were analysed:

- 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 (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).

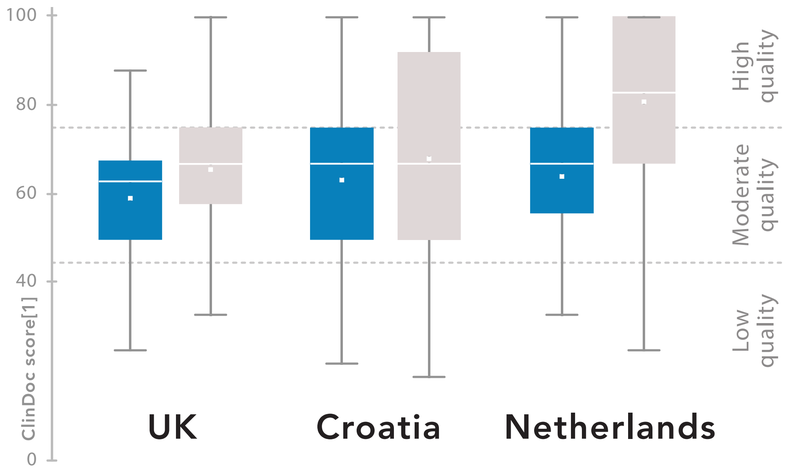
Results

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 and that could become an important tool in the future. Patient demographics are similar to conventional reporting routes, and report quality is sufficient despite a simplified reporting form.

References

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

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Uppsala Monitoring Centre | WHO Collaborating Centre for International Drug Monitoring

Uppsala Monitoring Centre (UMC)
Box 1051, SE-751 40 Uppsala, Sweden
+46 18 65 60 60 www.who-umc.org