Yellow Card Scheme reaches 50

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In response to the thalidomide disaster, the Yellow Card Scheme (YCS) was introduced in 1964 to help the government monitor the safety of medicines and all medical devices in the UK. It allows health professionals and, more recently, patients and carers, to report side-effects to medicines (also known as adverse drug reactions, ADRs), medical device adverse incidents, defective medicines (those that are not of an acceptable quality) and counterfeit or fake medicines or medical devices. In 2014 alone the YCS received 1920 reports on fatal adverse drug reactions. It is clear that the YCS has been successful and has obvious benefits, but there is still room for improvement. A recent conference celebrated the success of the YCS, but also focused on presenting a road map for the future of the scheme. Some highlights of this are discussed below.

Increasing reporting to the Yellow Card Scheme

In spite of the success of the YCS, it is widely known that on average 94 per cent of ADRs are not reported. Given the importance of spontaneous reporting of ADRs, this clearly demonstrates the need to encourage higher levels of reporting. Recent attempts have been made to overcome underreporting by allowing patients and carers to report to the scheme, but while this is helpful, still only six per cent of reports to the YCS come from patients and carers. Nevertheless, patients and carers could help reduce the current gap in reporting. Patients not only provide a different perspective, but also report different drug reaction types compared with health professionals and are more likely to report the symptoms and impact of an adverse drug reaction. In fact, reporting ADRs can help to empower patients, and generate signals earlier than if reports from health professionals alone are relied upon. One of the ways to encourage more reporting from both health professionals and patients is to improve feedback to reporters.

Improving the use of data from the scheme

While the YCS has been a valuable source of information and a prevention tool, data from the scheme are underutilised. In particular it has been noted that the optimisation of signal detection is essential. It was also recognised that other sources of data could be used to enhance available information, such as the Clinical Practice Research Datalink (CRPD), but with the recognition that there might be some overlap between the various sources of data. There was also discussion around the need to encourage spontaneous reporting and share data more widely internationally. The WHO pharmacovigilance system currently includes 120 countries, but the majority of data comes from the USA and UK, with relatively little reporting from lower and middle income countries. There is clearly a need to encourage these countries to report more, as issues they experience may well be very different from the USA and UK, which they are currently relying on.

In addition, the use of YCS data for research purposes is not being exploited. A number of ways the data could be used have been identified. In particular, they could be used to identify patients for genetic studies by identifying those with genetic predisposing factors to ADRs and eventually help to develop predictive genetic tests. The creation of a YCS “biobank” may help to address this.

Using social media

Social media is now recognised as a potentially valuable source of information about ADRs, and may provide some of the missing data from patients, who currently report very little to spontaneous reporting schemes. Some work in the USA has looked at both Facebook and Twitter as a potential source of data, and was able to identify ADRs after using a data cleaning and filtering system. It was recognised that data from social media has limitations; it suffers from typos and inaccuracies, and patients are not always able to assess causality. It is worth exploring the use of these data further and developing systems to be able to interrogate them in a more efficient and timely manner.

Conclusion

What does the future hold for the YCS and reporting of ADRs?

Clearly the YCS has a reason to celebrate. It has captured extremely important data in a systematic way, which has been used to inform the development of medicines, the reaction to any serious incidents and the future direction of pharmacovigilance on an international scale. There is however room for improvement. In particular, there is a need to encourage patient reporting to the scheme, as patients can provide a different and valuable perspective. The use of data for research purposes also needs to be further exploited through the creation of a YCS research “biobank”. Finally, the use of social media as a potential source of information on ADRs needs to be further explored and refined.

References


Declaration of interests

None to declare.

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