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Short Communication

A Breif Note on Vigimed

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INTRODUCTION

In brief, routine pharmacovigilance is, from the regulatory perspective, concerned with the detection of adverse effects, drug interactions and other drug-related problems and with restricting drug-related risks through regulatory interventions. The registration conditions may need to be changed regarding, for example, the instructions for use, indications and warnings and the information in the approved product information. Little is documented about the daily practices and experiences of pharmacovigilance specialists, both at drug regulatory agencies and national pharmacovigilance centres (NPCs) [1]. We lack information about the drugs involved, adverse events and other problems, and how matters are handled and solved. Only when major findings require immediate and drastic measures, such as sus pension or termination of a marketing license, is this information overtly communicated to the medical pharmaceutical community and the media. Many data sheet changes, on the other hand, take place without further notice [2].

The importance of pharmacovigilance is now widely recognised and there is also increased inter in the improvement of procedures and practices and in further development of the underlying science. In this context, a better understanding of the processes involved in current pharmacovigilance would be helpful [3].

The WHO set up its International Drug Monitoring Programme following the thalidomide disaster, and since 1978 the Programme has been carried out by the Uppsala Monitoring Centre (UMC) in Swe- den. One of the channels used by the UMC and national NPCs for communication and risk management is their e-mail discussion group Vigimed [4].

ABOUT VIGIMED

Vigimed is a worldwide e-mail discussion group
maintained by the UMC. It has been in place since -1997, uses e-mail and related technology, and aims to improve and accelerate the sharing between its users of information regarding drug-related problems to aid problem solving and decision making [5]. Vigimed allows rapid exchange of information and opinions on drug safety matters between NPCs around the world as well as the UMC. Membership is restricted to persons connected to NPCs or drug regulatory agencies in participating countries, including 'associate member countries'. Some of the UMC and WHO-headquarters staff is also on the list of Vigimed members. At the time of the study, there were 71 countries collaborating in the Vigimed. System In each country, one or more persons have access to Vigimed [6]. It is the only e-mail discussion group connecting all NPCs participating in the international pharmacovigilance programme. The e-mail messages mostly concern announcements or questions and the subsequent answers [7]. The message flow is not moderated; in other words, there is no manual filter between the submission of a message and the distribution to list members. Thanks to complete storage of all messages in the Vigimed system, it can also be used as a unique source of information regarding factual daily practice of governmental pharmacovigilance and the procedures and discussions in problem solving and decision making.

In addition to the pre-registration assessment of new medicines, regulators have devoted more and more time in recent years to the evaluation of their safety after approval [8]. The use of medicines can, directly or indirectly, lead to a wide variety of problems. Compared with drug development and clinical trials, the theory and practice of the post- approval study of drugs are in an earlier phase of development. There is still a lot to be learned and improved. Vigimed is a forum where colleagues may dis- cuss problems. It is a complementary tool, in addition to other sources of information and activities at NPCs. Our review shows that Vigimed has been well received and has rapidly found a place in inter- national pharmacovigilance routines.

In addition to assessing how it has been performing quantitatively in the past few years, our interest was to evaluate the nature of the matters discussed in order to increase our understanding of what pharmacovigilance is about in practice [9], to learn more about the problems that are encountered (the drugs, the ADRs and other possible experiences) and to get an idea of how such problems are dealt with. Vigimed is used on a daily basis, new members are signing up to the discussion group regularly and new drug problems arise continuously; therefore, an analysis of the exchange of information made during a different time period may show a different result.

The countries using Vigimed (asking as well as answering questions) are heterogeneous, in various phases of development and from all parts of the world. The contributions per country were higher if more persons per centre had access to Vigimed [10]. A possible

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reason for non-activity of some members, on the other hand, may have been difficulty communicating in English. It is known that pharmacovigilance experts in some countries do not feel confident expressing themselves in English. Consequently, drug problems of concern in such countries may be under-represented in the present study.

The majority (approximately 70%) of the questions concerned the regulatory status of a drug and/ or a safety problem, in particular ADRs. Most questions were of substantial public health importance. Although the category 'regulatory status' may sound somewhat administrative or bureaucratic, this was mostly not the case. Many of the questions that were classified into this category described problems that were serious, realistic and linked to drug safety matters. Many of the matters in the questions were preliminary, i.e. somewhere between suspicion and fact, between 'smoke and fire'. A few examples of questions were included in the Results section to illustrate this point [11].

As many as 90% of the questions raised in the Vigimed discussion group concerned established drugs, i.e. drugs that have already been on the market for 7 years. This finding is of interest in light of the relaxation of the legal obligations in the EU regarding pharmacovigilance to pharmaceutical companies 5 years after the approval of a medicine. Our study gives support to the view that pharma covigilance is continuously needed for all products on the market and should not be restricted to new ones only [12].

The review of the substances discussed by the email group showed that a few therapeutic groups (ATC codes) predominated, notably NSAIDs/anal- gesics, antibacterials, anti-obesity drugs, psychotropic drugs, antihistamines and vaccines. Obviously, these groups contain drugs that are heavily used around the world and may therefore be more likely to attract the attention of Vigimed members. NSAIDs, in particular, seem to constitute a complex challenge to regulators; there is a great demand for these drugs in society, by patients, prescribers and companies alike, while their benefit/risk profile is often controversial. Most of the questions (73%) concerned orthodox drugs, 9% herbals and 4% vaccines. On the other hand, novel biotechnology products, such as mononuclear antibodies, received little attention in the study period [13].

Once a question had been raised, the answers came quickly and most of them were appropriate, relevant and useful. The answers often described the situation in the responding person's country and often also contained advice for how to carry on with the issue in the question. Several of the questions where forwarded by Vigimed members to experts in different areas in their country. Many of the ques- tions were of a sensitive nature. The spontaneity of the asking and answering of these questions seems to have benefited much from Vigimed's guarantee of confidentiality. The presentation of the results of our study has been limited by this [14].

CONCLUSION

A distinctive pattern in problem raising and problem solving could be seen. In order to find out how satisfied Vigimed users are, what changes would likely improve the functioning and the use of the system, and to learn more about the details of the complex processes underlying problem solving and decision making, more active data collection and contacts with the NPCs, for example using questionnaires and interviews, would be needed.

REFERENCES

1. Johansson K, Olsson S, Hellman B, Meyboom RH. An analysis of Vigimed, a global e-mail system for the exchange of pharmacovigilance information. Drug safety. 2007 Oct;30(10):883-9.
2. Reason J. Understanding adverse events: human factors. BMJ Quality & Safety. 1995 Jun 1;4(2):80-9.
3. Almenoff J, Tonning JM, Gould AL, Szarfman A, Hauben M, et al. Perspectives on the use of data mining in pharmacovigilance. Drug safety. 2005 Nov;28(11):981-1007.
4. Ridings JE. The thalidomide disaster, lessons from the past. InTeratogenicity Testing 2013 (pp. 575-586). Humana Press, Totowa, NJ.
5. Olsson S. The role of the WHO programme on International Drug Monitoring in coordinating worldwide drug safety efforts. Drug safety. 1998 Jul;19(1):1-0.
6. Lindquist MA, Edwards IR. The WHO Programme for International Drug Monitoring, its database, and the technical support of the Uppsala Monitoring Center. The Journal of rheumatology. 2001 May 1;28(5):1180-7.
7. Kim S. Questioners' credibility judgments of answers in a social question and answer site. Information Research. 2010 Jun 1;15(2):15-2.
8. van't Veer AE, Giner-Sorolla R. Pre-registration in social psychology—A discussion and suggested template. Journal of Experimental Social Psychology. 2016 Nov 1;67:2-12.
9. Poluzzi E, Raschi E, Piccinni C, De Ponti F. Data mining techniques in pharmacovigilance: analysis of the publicly accessible FDA adverse event reporting system (AERS). InData mining applications in engineering and medicine 2012 Aug 29. IntechOpen.
10. Herdeiro MT. Improving Adverse Drug Reaction Reporting in Portuguese Health Professional: case-control studies and cluster-randomized trial. Departamento de Psiquiatría, Radioloxía e Saude Pública, Faculdade de Medicina e Odontoloxía, Universidade de Santiago de Compostela. 2005.
11. Letourneau MA. Improving global monitoring of vaccine safety: an evaluation of the World Health Organization Programme for International Drug Monitoring and Adverse Reactions Database on how they serve the needs of vaccine safety (Doctoral dissertation, University of Ottawa (Canada)).
12. van Puijenbroek EP, van Grootheest K. Monitoring adverse events of the vaccination campaign against influenza A (H1N1) in the Netherlands. Drug safety. 2010 Dec;33(12):1097-108.
13. Tsioulias GJ, Go MF, Rigas B. NSAIDs and colorectal cancer control: promise and challenges. Current pharmacology reports. 2015 Oct;1(5):295-301.
14. Isen AM, Daubman KA, Nowicki GP. Positive affect facilitates creative problem solving. Journal of personality and social psychology. 1987 Jun;52(6):1122.