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How to Improve Communication for the Safe Use of Medicines?

Discussions on Social Marketing and Patient-Tailored Approaches at the Annual Meetings of the WHO Programme for International Drug Monitoring

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Abstract

Over the past decade, the annual meetings of national centres participating in the WHO Programme for International Drug Monitoring have increasingly included discussions on how to improve communication between national pharmacovigilance centres, patients, healthcare professionals, policy makers and the general public, with the aim of promoting the safe use of medicines. At the most recent meetings, working groups were dedicated to discuss possible applications and implementation of social marketing and patient-tailored approaches. This article provides the history and a summary of the recent discussions and recommendations to support progress in this respect at national and global level. Recommendations are made to investigate and pilot these approaches in small-scale projects at national pharmacovigilance centres. Applying elements from the social marketing and patient-tailored approaches to support behaviours of safe medicines use in patients and healthcare professionals should give the pharmacovigilance community new tools to achieve their goal to minimize risks with medicines and improve patient safety.

1. Background

The public expects that medicinal products, given their authorization by regulatory authorities, are safe, but at the same time patients generally know that medicines may bear risks. This may seem like a contradiction, but actually the key to safety lies in the concept of effective and safe use, i.e. aiming at maximizing benefits and minimizing risks whenever medicines are needed. This concept has been underpinned by the risk management approach introduced in pharmacovigilance.[1-5] Given the considerable rates of avoidable adverse reactions[6-15] as well as recurrent public concerns over specific product classes, the need to further improve information, communication and public awareness for the safe use of medicines is obvious. In view of this and in response to requests from their member states, the World Health Organization (WHO) has included communication-related topics with increasing priority on the agendas of the annual meetings of representatives of national centres participating in the WHO Programme for International Drug Monitoring[16] for almost a decade. This article intends to provide the history and summary of the latest discussions

at these meetings in order to support progress in the area of communication on the safe use of medicines at national and global level. Also, it gives insights into the working methodology of these meetings.

2. Discussions at Annual Meetings of the WHO Programme for International Drug Monitoring

Discussions initially looked at how to enhance communication between national pharmacovigilance centres and communicate feedback from centres to primary reporters of adverse reactions. One mechanism of providing feedback identified was publication of summaries of reported cases and the outcome of the related assessment in drug bulletins and medical journals. In 2006, an internal survey solicited views from national centres upon advocacy of pharmacovigilance targeted at patients, healthcare professionals, policy makers and the general public for promoting pharmacovigilance and the safe use of medicines. Its results formed the basis for a plenary session in 2007 on global awareness of pharmacovigilance, where the social marketing approach was identified as a tool for advocacy.

In parallel, the WHO Advisory Committee on Safety of Medicinal Products (ACSoMP) discussed, from a global policy perspective, this approach together with a proposed action plan for practical implementation (Hartigan-Go K., personal communication).

Since 2010, working groups dedicated to communication-related topics have been organized by WHO at the annual meetings of the WHO Programme for International Drug Monitoring: in 2010 on the topic of social marketing, and in 2011 on safety information to patients and their carers. In addition, a plenary session on social media was held in 2011, as recommended in the previous year.

Both working group topics attracted participants from all regions, working in national pharmacovigilance centres or international organizations, with the motivation to:

- reduce medicines-induced patient harm;
- empower patients for shared therapeutic decision-making;
- improve the reporting of suspected adverse reactions.

3. Working Group on Social Marketing in 2010

The working group at the 33rd annual meeting on 1–3 November 2010 in Accra, Ghana, was dedicated to the question "*How to improve awareness of drug safety issues – through social marketing of pharmacovigilance?*".

The participants exchanged experiences of major safety concerns over medicines linked with undesired behaviour in society, including the 'pill scare' of 1995 resulting in increased numbers of unintended pregnancies and abortions in the UK.[17] Other examples discussed included the worldwide overuse of anti-infectives accelerating resistance development, and the frequent use of substandard and falsified products, in particular in the developing world.

3.1 The Social Marketing Approach: Opportunities

Social marketing is the use of marketing principles and techniques to persuade a target audience to voluntarily change behaviour for the benefit of individuals or groups. Applying marketing tools in the public sector means to view services and information for the public as a product that is valuable and deserves advocacy, but also requires fulfilling the needs and expectations of the public, in order to achieve desirable general behaviours.[18] The participants saw possible applications of this approach in pharmacovigilance in:

- disseminating specific advice on how to use medicines safely;
- advocating for safety monitoring amongst healthcare professionals and patients;
- promoting mutual understanding of all parties involved with medicines;
- raising awareness of the need for and the benefits of pharmacovigilance to policy makers.

Succeeding in these four areas was identified as crucial to the overall success of pharmacovigilance with its goal to prevent adverse effects and other problems related to the use of medicines.[19]

A wider perspective of the safety of medicines was taken, to incorporate the benefits of medicines, treatment adherence and prevention of medical errors. It was agreed that messages should include positive aspects about medicines rather than focussing on risks only. The concept of benefit-risk balance could be conveyed to a wider audience to help promote the safe and appropriate use of medicines.

Also, hopes were expressed that the social marketing approach may help to correct misperceptions commonly experienced by the participants, such as 'no adverse reaction reports means there is no problem' or 'reporting adverse reactions is useless administrative work'.

There was consensus on the potential of a number of social marketing principles, namely that:

- interventions could be launched by national pharmacovigilance centres simultaneously to all target populations, i.e. patients, healthcare professionals and the general public, fulfilling their specific needs and expectations;
- additional subpopulations such as teenagers or the elderly could be targeted as necessary, with messages tailored in the appropriate language for the target (sub-)populations;
- possible interventions could include written materials, merchandising materials, radio and television spots, social media tools and school teaching modules, and be combined for comprehensive programmes promoting pharmacovigilance and the safe use of medicines;
- such programmes could be designed over longer time periods to achieve sustainable behaviour changes for the appropriate use of medicines.

For the practical application of this approach, however, it was considered useful to obtain advice from social marketing, communication and education specialists and to learn from other programmes, such as road safety training for children. Furthermore, patient groups as well as pharmacist and other healthcare professional organizations should be involved in the development of social marketing programmes for medicines safety. It was agreed that opportunities for individual patients to directly report suspected adverse reactions to national pharmacovigilance centres should be investigated further.

The success of social marketing efforts should of course be evaluated with a view to improvements and resource efficiency. Their effectiveness could be measured in the context of prescription data analysis, communication impact analysis, reviews of media coverage and surveys investigating behaviour changes. Expertise from the communication and social sciences should be sought to design meaningful effectiveness studies.

3.2 The Social Marketing Approach: Challenges

Despite much enthusiasm for the approach, the working group realistically looked at the challenges too. For example, how to deal with complex matters; how to have a broad reach across heterogenic populations and all medical disciplines; and, most importantly, how to avoid provoking – through the advocacy work for pharmacovigilance – unnecessary scares and negative outcomes, such as avoidance of medicine treatment or vaccination. These were important questions raised for future exploration.

4. Working Group on Patient-Tailored Information in 2011

The working group at the 34rd annual meeting on 31 October–2 November 2011 in Dubrovnik, Croatia, was dedicated to the question "*How to improve safety information to patients and their family and friends as carers?*". This topic was intended to follow-up the previous year's discussions where targeting subpopulations had been identified as crucial for communication interventions. The most fundamental question in this respect was raised by a participant right at the beginning of the discussion: how to study target populations?

In general, a target population is the audience certain communication interventions are intended for. Hence, targeting involves segmenting a given general population according to criteria (e.g. patients, healthcare professionals or further, e.g. the elderly, asthma patients, general practitioners), and tailoring information in order to meet their specific information needs, concerns and expectations.

Examples of relevant target subpopulations brought up during the discussion included the following: in Mauritius, illicit drug-dependent (ex-)prisoners have been included in a methadone programme. For these patients, their prison or probation officers often become their only trusted information source. The development of communication materials tailored for officers for their use in one-to-one communication settings has been chosen by the Mauritian authorities as the way to reach these patients. Another example presented by the participant from the Japanese regulatory authority related to varenicline (a smoking cessation medicine), for which communication between the healthcare professional and the patient is supported by visual materials with a cartoon picture warning against driving and machine operation. These materials are printable from the Internet for handing to the patient.[20] Having materials for the patient to take home was considered useful, as the patient may not remember everything the physician or pharmacist may have said. In addition, such materials could help the healthcare professional not to forget providing the patient with the key messages. Other examples where careful targeting was considered needed included communicating with paediatric nurses about dose calculations for children, and preparing with pharmacists and school nurses the switch of emergency contraception to availability without prescription in order to build up their skills to communicate with girls and women appropriately.

It became obvious that tailored communication for patients and their carers comprises addressing sub-segments of these populations directly as well as supporting healthcare professionals with communication materials they can use when discussing issues relating to medicines with patients and their carers.

4.1 Patient-Tailoring: Methods

Tailoring of communication requires analyses of and co-operation with the audience. Audience analysis includes audience segmentation into subpopulations and exploration of their health and medicines-related knowledge, beliefs, attitudes, emotions, values, priorities and behaviours as well as media preferences and trusted information sources. Audience analysis needs to take into account the cultural environments, preferred lifestyles in the respective society, and the given technical options and media access. Therefore, tailoring was viewed as a country or even region-specific exercise. A lot could be learned from journalists about how to tailor with impact. The working group discussed the following methods for audience analyses and co-operation which could be initiated by national pharmacovigilance centres:

- written consultations with the public, facilitated by, for example, web-based tools, in order to collect data about knowledge, attitudes, concerns, priorities, information needs and media preferences of subpopulations in relation to specific medicines;
- dialogue between regulators, patients and healthcare professionals in regulatory committees, where patients and healthcare professionals do not only provide input but more importantly serve as validating representatives of audiences to be convinced of regulatory decisions and the related proposed communication interventions;
- user testing of written communication materials at the level of subpopulations and populations with special needs, such as the visually impaired, non-native speakers of the local language and those with low literacy.

Public consultation was, for example, launched by the authorities in the UK to seek views on the regulation of nicotine-containing products for smoking cessation.[21]

Low literacy was discussed as a problem not only in low-income countries, but also in the high-income world. In the US, for example, about 50% of the population have only basic or below basic literacy skills[22] and may therefore not be reached by written materials. Despite the known challenges to agree meaningful and culturally acceptable pictograms at global level, a participant reminded the working group that the aviation industry manages to provide clear safety instructions in a visual manner, and convinced the working group that respective efforts should be made for the safe use of medicines by those who are illiterate/poorly literate or are non-native speakers of the local language. Also, it was considered that pictures may be remembered more easily.

The working group reached agreement that tailoring communication for patients and their carers requires:

- careful planning of communication in order to study patient populations as audiences, initiate early dialogue with patient and healthcare professional organizations for joint development of communication interventions, and perform user testing of communication materials;
- appropriate participation models for cooperation between regulators, patients and healthcare professionals for communication planning and outreach models for the implementation of risk minimization measures;
- additional communication tools supporting healthcare professionals in their communication with patients and carers;
- measuring communication effectiveness in order to optimize patient-tailored communication;
- development of communication interventions in parallel with engaging in transparency and education.

With regard to transparency, it was considered that transparency of rationales of regulatory decisions helps in gaining understanding and trust from healthcare professionals in risk minimization measures, a prerequisite for their successful implementation in healthcare and incorporation in the healthcare professionals' communication with the patient. Education of the general public, on the other hand, prepares the ground for being receptive for communication, should one become a patient or carer. Therefore the working group came to the view that education should be provided to all age groups, and to children and teenagers in schools in particular.

An example of tools to support healthcare professionals in their communication with patients and carers would be a set of information sheets designed for the various patient subpopulations. Important interaction between patients and their healthcare professionals could also be supported from the side of the patients and carers through providing them with materials allowing them to prepare their questions. For example, the three most important questions could then be submitted to the healthcare professional for preparing answers relevant to the individual case in advance.

4.2 Patient-Tailoring: Challenges

In relation to tailoring communication for patients and their carers, the working group identified the need for continuing in-depth discussion of a number of questions, including how to best approach patients and their carers in an Internet-based communication environment; how to make use of the social media; and which tools to effectively apply for supporting healthcare professionals such as physicians, nurses and pharmacists in their one-to-one communication with patients and carers. The need for guidelines was expressed.

Also, resource constraints remain an issue, and the need for training healthcare professionals as well as those working in national pharmacovigilance centres in communication with patients and carers was stressed. The idea of specially trained pharmacovigilance counsellors working in healthcare facilities emerged during the discussion.

5. Recommendations to the WHO from the Annual 2010 and 2011 Meetings

Based on the feedback from the working groups, the plenary made the following recommendations to the WHO.

At the annual meeting in 2010:

- Social marketing of pharmacovigilance should be geared towards behavioural changes that will promote the safe use of medicines and reporting of adverse reactions, and target not only healthcare professionals but also the general public.
- Social marketing should be done via various means, such as the media and other public initiatives.
- The impact of any social marketing efforts should be measured by analysing prescription data, media coverage and other data indicating behavioural changes before and after the intervention;[23]

At the annual meeting in 2011:

- Education related to medicines safety should start at an early age, e.g. in schools.
- Relevant information should be provided to the public by means of audio and/or visual tools such as radio programmes and short films.

- There needs to be face-to-face communication between healthcare professionals and patients on medicines safety.
- Information sheets, pictograms and various visual tools that target different subpopulations of the public should be developed; and such materials should be adjusted to country, culture, lifestyle, accessibility to media and specific patient characteristics.[24]

6. Next Steps

In light of these recommendations, it seems appropriate for the authors to propose next steps towards investigating and piloting the application of the social marketing approach and methods for patient-tailored communication to pharmacovigilance.

The WHO Programme for International Drug Monitoring could schedule a follow-up working group at the next annual meeting, where an outline of a health campaign on a pharmacovigilance topic applying social marketing and patient-tailored communication could be developed for piloting in a volunteering country. The pilot could be conducted on a small scale, for example in a hospital. How to best obtain input from communication, education and social science experts and how to involve stakeholders in the development of such pilots would be crucial to investigate.

However it should not be forgotten that a number of successful initiatives are already happening, as the working group discussions revealed. For example, in Kenya, informative short films are shown to patients in hospital waiting rooms; in Togo, a radio- and TV-based education programme for pharmacovigilance received funding recently; in Nigeria, the telephone number of the national pharmacovigilance centre has recently been included systematically in all package leaflets; in Brazil, telephone hotlines maintained by marketing authorization holders get audited by the authorities; and in Croatia, a journalist works within the national pharmacovigilance centre and successfully responds to media enquires with an understanding of the enquiring journalists' information needs.[25] The sharing of these initiatives during the working group discussions proved fruitful; the colleagues from Mauritius now intend to include contact details for adverse reaction reporting in the methadone communication materials, and the upcoming switch of emergency contraception to availability without prescription in Croatia is likely to profit from increased planning in cooperation with all concerned stakeholders. It is hoped that all these initiatives will continue to be successful and grow further in the future. In the meantime, it would be worthwhile to support WHO in their initiatives, arranging for sharing the valuable experiences gained so far through publications and at the next annual meetings of the WHO programme. This should encourage others and build up an evidence base for guidance, in particular on critical success factors and lessons learnt for communication interventions in general.

7. Conclusions

Over the last decade, the annual meetings of representatives of national centres participating in the WHO Programme for International Drug Monitoring have increasingly discussed how to improve communication between national pharmacovigilance centres, patients, healthcare professionals, policy makers and the general public with the aim of promoting the safe use of medicines. At the most recent meetings, the focus was on methods, namely the social marketing and patient-tailored approaches, and practical recommendations have been made to the WHO to take this further. Additionally, the authors propose that small-scale projects at national pharmacovigilance centres could investigate and pilot new approaches. There will be challenges in applying new communication methods to pharmacovigilance for supporting safe medicines behaviours in patients and healthcare professionals, but it is hoped that it will give the pharmacovigilance community new tools to achieve their goal to minimize risks with medicines and improve patient safety.

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