

## Medication Safety in donor-sponsored public health programmes

C.P.E. van Bommel<sup>1</sup>, BSc; A.R.G. van Slobbe<sup>2\*</sup>, PharmD; dr. A.K. Mantel<sup>1</sup>

1: Pharmacoepidemiology and Clinical Pharmacology, Department of Pharmaceutical Sciences, University Utrecht; Managing Director of WHO Collaborating Centre for Pharmaceutical Policy and Regulation, Utrecht

2: Global Initiative on Medication Safety (GIMS) Foundation

Further correspondence should be directed to \*.

---

**Medication safety has been a major topic among pharmacists and other healthcare professionals throughout the world, both pharmaceutical care (PC) as pharmacovigilance (PV). While PV consists of passive retrospective analysis, PC is considered to be an active engagement at the dispensing level including checks on interactions, contra-indications, allergies and improving patients' adherence. However, not much is known about the quality of medication safety at the level of the individual patient in the developing world. The aim was to find out about the current efforts to improve medication safety in donor-sponsored public health programmes (PHPs). The research was an initiative of the Global Initiative on Medication Safety (GIMS) Foundation. This is an organisation which emphasises the importance of minimizing health risks originated by the global use of medication, with a focus on the developing world.**

**To collect the data required on this matter, some of the biggest organizations involved in the financing and distribution of medication through public health programs were studied. The websites of the organizations were studied along with direct contact through e-mailing, telephone calls and meetups.**

**The main organisations who responded or were of the biggest interest were the WHO, The Global Fund, Médecins sans Frontières, SIAPS programme and Healthy Entrepreneurs. The WHO has issued more focus on PV and the importance of medication safety and follows up with funding. The Global Fund funds many PHPs, but since changing the funding system it is unclear how involved they are in medication safety. MSF and SIAPS have developed tools to improve PV, while MSF is also focusing on PC through its field workers. Healthy Entrepreneurs works in a different way by using a socially commercial way of operating with a focus on access to medicines, but less on medication safety.**

**Our findings seem to show that although PV has received proper attention, individual medication safety in the form of PC, also in donor-sponsored programs, is still in its infancy, underreported or completely absent.**

---

### Introduction

Through the years there has been much attention for medication safety on a global scale. Medication safety is however a wide term and includes several factors. One of them is PC, the term used for pharmacists acting as a health care provider who can actively participate in illness prevention and health promotion [1]. The pharmacist does this on a patient level by checking dosages, contra-indications, allergies, interactions, improve adherence and inform the patient to

ensure a safe and effective treatment. Another factor of medication safety, consists of PV which is defined by the WHO as “the science and activities related to the detection, assessment, understanding and prevention of adverse drug effects or any other possible drug-related problems” [2]. However, the definition of the WHO also includes the detection and collection of medication errors, lack of efficacy and counterfeit or substandard medicines. Therefore, a shift to a more

broadened view has been noticed in recent years, stressing the importance of PV [3, 4].

In 2006, the WHO published a report to stress the importance of PV in PHPs in order to improve medication safety in developing countries. In this report it was claimed that “the idea that PV is a luxury, affordable only in the developed world, should be replaced by the realization that a reliable system of PV is essential for the rational, safe and cost-effective use of medicines in all countries and consequently for public health, and should produce clear advantages in relation to cost” [5]. PV became of apparent importance due to the improved access to medicines which put many more individuals consequently at risk of treatment-related adverse effects. Therefore, The Global Fund (GF) introduced PV as a requirement in the proposals for the 10<sup>th</sup> round of grant applications back in 2010. GF is one of the main parties responsible for providing medication in developing countries on a widespread level [3]. However, since 2011 GF has changed its ways of funding and now uses a network of country coordinating mechanisms (CCMs) to distribute grants [6]. It is unclear what effect this change of funding has had on the medication safety agenda.

The focus on the importance of medication safety and thus PV, has led to many countries starting up national PV systems between 2000 and 2010. However, there is a clear lack of resources and staff to support these [7]. Recently the PV agenda in these countries has become very much donor-driven, with most efforts going into setting up PV programs for medicines used in PHPs, such as malaria and HIV [7]. The need for adequate medication safety activities is growing as non-communicable diseases (diabetes, cardiovascular disease) are becoming more prevalent in developing countries. Therefore, the main point in this project was to find out what the current situation is of efforts to improve medication safety in donor-sponsored PHPs, ten years after the WHO emphasized its importance?

## Method

This project was initiated by the Global Initiative on Medication Safety (GIMS) Foundation in conjunction with the University of Utrecht. The GIMS Foundation’s main objective is to minimize health risks originated by the global use of medication. The writer is a student who is at the end of his Master’s degree in Pharmacy at the University of Utrecht.

To collect the data required for this project, some of the biggest organizations involved in the financing and distribution of medication through PHPs were studied. To achieve this the websites of the organizations were studied along with any files detailing their incorporation of medication safety. Direct contact was initiated by e-mailing, followed up by calling through telephone in case of a lack of response. The collected information was discussed and analysed and in some cases summarized in short abstracts. These proved to be the basis of this article.

## Results

Table 1 summarises the findings of the different organisations studied for this project. Detailed information is found further up this section.

### World Health Organization (WHO)

The WHO plays a big part in supporting developing countries to improve their healthcare. Their main aim is to direct international health within the United Nations community. Next to providing financial aid, the WHO sets up policies, norms, standards and guidelines, such as how to start and maintain functional national PV centres, but also how to perform PV for medicines against malaria, HIV/AIDS and tuberculosis [8,9]. They keep a watchful eye over developments in medication safety throughout the world and publish scientific articles to keep the scientific world aware and updated [3,5,7]. The WHO also has close bonds with the Global Fund and these two parties collaborate on many fronts.

Organisation	Response?	Policy on PV	Actions towards PV	Actions towards PC
<b>WHO: several departments</b>	No or not helpful	Yes	<ul style="list-style-type: none"> <li>• Setting up guidelines, standards, etc.</li> <li>• Drug Monitoring Programme</li> <li>• Financing</li> </ul>	Unclear
<b>The Global Fund</b>	Yes, not helpful	Unclear	<ul style="list-style-type: none"> <li>• Financing</li> </ul>	Unclear
<b>MSF</b>	Yes	Yes	<ul style="list-style-type: none"> <li>• Field work</li> <li>• Electronic tools</li> <li>• Training</li> </ul>	<ul style="list-style-type: none"> <li>• MSF Clinical guidelines</li> <li>• Training</li> </ul>
<b>SIAPS</b>	Yes	Yes	<ul style="list-style-type: none"> <li>• Electronic tools</li> <li>• Financing</li> </ul>	Unclear
<b>HE</b>	Yes	No	-	<ul style="list-style-type: none"> <li>• Awareness through applications on tablets</li> </ul>
<b>ISMP</b>	No	Unclear	Unclear	Unclear
<b>AMREF Flying Doctors</b>	No	Unclear	Unclear	Unclear
<b>Aidspan, GF Watchdog</b>	No	Unclear	Unclear	Unclear
<b>Cordaid</b>	No	Unclear	Unclear	Unclear
<b>Bill and Melinda Gates Foundation</b>	No	Unclear	Unclear	Unclear

Table 1: Overview of results of the studied organisations.

One of the WHO biggest accomplishments on medication safety is the creation of the WHO Programme for International Drug Monitoring. This programme was set up after the thalidomide tragedy and saw the appointment of the Uppsala Monitoring Centre in Sweden as WHO Collaborating Centre for Drug Monitoring to internationally collect individual case safety reports in their database 'VigiBase™'. This database comprises of over 10 million entries, which allow the detection of potential medicinal safety hazards. [10]

On a more local level, the WHO has created a WHO Collaborating Centre for Advocacy and Training in PV at the University of Ghana. This institution is focused on training healthcare

professionals and supporting national PV centres as well as performing research in PV like cohort event monitoring of specific medicines [11]. The centre has been involved in the introduction of several modules of MedSpina, a longitudinal safety data management system, into the clinical field of Ghana. It consists of software for a healthcare situation which supports patient data records and prescribing software [12, 13]. The intention was to improve the PC by adding health technology. However, it is not known what effect this software has had in practice.

## [The Global Fund to Fight AIDS, Tuberculosis and Malaria \(GFATM\)](#)

GFATM raises and invests resources to support programs run by local experts in countries and communities most in need. Its existence started through some of the Millennium Development Goals set by the United Nations at a G8 summit in 2000. As its name indicates, GFATM focuses on the three major diseases and invests the money of the largest developed nations to improve the healthcare in developing countries [14]. Through process-indicators they monitor and evaluate their funded projects in order to reach pre-set goals [15].

Although it is described that The Global Fund has made PV a requirement since the Round 10 proposals, not much is known about how individual medication safety is put into practice. It is to be expected that due to the local nature of the proposals much variation will exist in the execution of medication safety by healthcare professionals.

## [Médecins sans frontières \(MSF\)](#)

Through the help of M. Serrano, section pharmacist at MSF Holland, we received information on the MSF activities and way of working. MSF works principally to assist populations caught up in humanitarian crises where there is a high level of medical need. MSF Holland (Artsen zonder Grenzen) is present in about 23 countries. In 2015, it spent 34 million euros of which roughly 50% was spent on pharmaceuticals. MSF is frequently perceived as an organization fully committed to emergencies, but the organization has very long standing interventions as well. Non-communicable diseases have received increased focus in recent years, like hypertension and diabetes. MSF aims to provide these treatments integrated in their programs as well. The pharmacists in MSF do various kinds of jobs, some of these comprise of approving manufacturer or supplier couples for the procurement lists; investigating markets, prices, prescription protocols, together with

other healthcare professionals and there are periods where they do field work as well. [16]

As for medication safety during general practice, when patients are treated their data is collected in patient files to keep track of the clinical history, medical and pharmaceutical information. MSF provides standard therapeutic protocols to prescribers which take patient's age and weight into account and are adjusted, where appropriate to national protocols. The most general is called "MSF clinical guidelines", which is published once a year. Contra-indications and interactions are further explained in disease specific training. For instance, doctors attending training to work on anti-tuberculous centers re-learn that rifampicin interacts with about everything. Known allergies are investigated during the clinical history, however it is often impossible to retrieve such data in the contexts where MSF works. Additionally, MSF provides field teams with updated versions of the 'British National Formulary'. MSF also owns a formulary, a rationalized and restrictive assortment list of products, which is updated once a year with new available products and special considerations. However, MSF does not have a standard ICT system for prescribing and dispensing, as most locations rely on paper based systems to date. [16]

## [Systems for Improved Access to Pharmaceuticals and Services \(SIAPS\) Program](#)

Management sciences for health (MSH) started the Strengthening Pharmaceutical Systems (SPS) Program which over time evolved into the SIAPS Program. Nowadays this program is funded by USAID and has many influential partners, such as Harvard University and the University of Washington. The SIAPS approach to pharmaceutical systems strengthening has been implemented in over 50 countries since the program began in 2011. [17]

The program enhances countries' capacity to procure and distribute high-quality medicines

and health technologies, but also works with local partners to develop strong systems for health financing, human resources, governance, information, service delivery, and PV [18]. By promoting local ownership of wide-ranging initiatives, stronger, more sustainable health systems overall are fostered. As part of this, they have developed several electronic tools, such as an electronic dispensing tool (EDT) and a web-based application for PV data capturing (PViMS). Other applications consist of disease-specific software (e-TB manager, QuanTB) or for quantification and distribution purposes (Quantimed, RxSolution) [19]. RxSolution is a tool on which a small facility or hospital could function in order to manage patient information, appointments, prescribing, ordering and dispensing. New modules could be added to support prescribing decisions.

SIAPS focuses on improving pharmaceutical systems, mostly through sponsors who determine the needs of the systems to be implemented. Therefore, they don't have a generic approach to work on individual medication safety. They are however actively working on setting up PV systems in countries and developing a PV automated information system (PAIS) to be used in PV centres to manage the data entries [17].

### Healthy Entrepreneurs (HE)

HE is a small business set up by two Dutch businessmen who apply a financially sustainable micro-franchise formula to a network of local entrepreneurs. Their aim is to reach and provide basic care to people in remote villages whom are isolated from standard care and are often not included in major vertical medication programmes. HE works with micro entrepreneurs who offer essential health products, like painkillers, contraceptives, sanitary pads, antibiotics, soap, vitamins and health information. They have set up an education application on tablets to raise awareness people about topics such as sexual and reproductive health, nutrition and hygiene. Some of the medication

requires a prescription, through use of the tablet information is supplied about correct dosing. HE is focused on logistics and therefore does not provide information about medication safety. The entrepreneurs are not pharmacists, although HE has national pharmacists employed in the areas where they are active. [20]

### Discussion

The WHO is heavily active in the area of PV through their International Drug Monitoring Programme. Health care professionals get trained to help improve PV reporting. Yet it is not known if the WHO directly acts on medication errors through training pharmacists to perform proper PC. Analysing PV data is one step to improve medication safety through rational use of medicine and setting up standards and policies. The other is to improve the practice, although this might be harder to measure through indicators. Efforts have been made to include health technology to this cause, such as MedSpina and the electronic tools of the SIAPS programme.

Funded vertical medication programs by the WHO or The Global Fund focus on one disease and therefore only provide medication safety for the respective medicines. Next to this, it is not clear if pharmacists (or other medical professionals) perform PC as in checking dosages, interactions, contra-indications, allergies, conform to prescribing guidelines and more activities. The focus in most PHPs still seems to be focused on logistics, to reach the patients in order to be able to treat them. Another option is that there could be a severe underreporting of PC efforts in developing countries in scientific literature. Just like PV at first, PC might be seen as a luxury, affordable only in the developed world. However, proper PC by pharmacists fuelled by knowledge and tools might save more lives than one could imagine.

Despite being started up in many countries by medical professionals, national PV centres currently lack the resources and staff to

function normally. The efforts that are put in setting up PV programs in PHPs could be integrated into national PV centres to support the development of PV and eventually individual medication safety in the long run. A shift of efforts towards national or regional PV centres is of great importance to cover these issues in the near future.

Another point is the use of electronic prescribing tools and other supporting software for healthcare purposes. The SIAPS programme is one program that has started developing and spreading electronic tools to aid local healthcare. Many of these tools are focused on the distribution, logistics and patient management, while one performs basic pharmaceutical care (e-TB manager). PViMS is a tool which they created to collect PV data. Another company consisting of staff of the WHO Collaborating Centre in Ghana created an electronic pharmaceutical system called MedSpina. Software like MedSpina is exciting because it consists of several functions combined into one system, such as patient records, logistics, management and prescribing tools. Health technology is a helpful tool in improving medication safety through advancements, like addition of decision-supporting prescribing software.

Most organizations seem hesitant in releasing any information about medication safety not described on the websites. Nor do they respond to e-mails when asked about the topic. Therefore, it has proven to be somewhat of a struggle, in the given time frame, for an outsider to perform a proper analysis of the current situation of medication safety in donor-sponsored PHPs. There is not much scientific literature available on the topic of practical medication safety in developing countries. Most hits concern PV and not the level of PC.

Much of the medical slang surrounding medication safety has been standardized by the WHO. However, in the (scientific) field there seems to be a lot of confusion [21]. For instance, PV is a much wider meaning than

many people in the field seem to realise. It comprises of all the issues drug-related, which like put forward in the introduction includes medication error, lack of efficacy and substandard or fake medicines. Another example is medication safety, which is often directly linked to PV. However, medication safety comprises not only of detection and reporting of many different drug-related problems. Medication safety also consists of the direct consequences of a medication error to the individual patient and is therefore tied to the practical work of pharmacists: PC. Perhaps this confusion in medical slang is one of the reasons why not much is reported about the level of PC in developing countries or the funding or training concerning this matter.

## Conclusion

Although medication safety in developing countries has received much attention from funding organisations in recent years, the efforts seem to have mainly gone to introducing PV in the form of PV centres and integrating PV into PHPs. Individual medication safety in the form of PC, also in donor-sponsored programs, is still in its infancy, underreported or completely absent. This surely imposes a (serious) health risk.

## Acknowledgements

Special thanks to M. Serrano, A. Kwiecien, I. Padri, M. Neve and many others for the correspondence. Your information added extra value to this project. Thanks for the employees of GF and WHO who responded as best they could. Many thanks to A.R.G. van Slobbe and A.K. Mantel in supervising this project.

## References

- [1] World Health Organisation. The Role of the Pharmacist: Quality Pharmaceutical Services – Benefits for Governments and the Public. Geneva: WHO, 1994: p. 7.  
<http://apps.who.int/medicinedocs/en/d/Jh2995e/2.2.html>
- [2] Report of the Thirty-first Annual Meeting of Representatives of National Pharmacovigilance Centres participating in the WHO Programme for International Drug Monitoring, 20–23 October 2008. WHO Pharmaceuticals Newsletter. 2008;4.
- [3] Olsson S, Pal S, Dodoo A. Pharmacovigilance in resource-limited countries. *Expert Rev Clin Pharmacol*. 2015; 8(4): 449-600.
- [4] World Health Organisation. WHO Pharmacovigilance indicators: A practical manual for the assessment of pharmacovigilance systems. Geneva: WHO, 2015: p. 1-3.
- [5] World Health Organisation. The safety of medicines in public health programmes: pharmacovigilance, an essential tool. Geneva: WHO, 2006: p. 21-24.
- [6] The Global Fund. Country Coordinating Mechanism. <http://www.theglobalfund.org/en/ccm/>. Consulted on: 5-7-2016.
- [7] Pal S, Dodoo A, Mantel A, Olsson S. The World Medicines Situation 2011: Pharmacovigilance and safety of medicines. 3<sup>rd</sup> ed. Geneva: WHO, 2011: p. 6.
- [8] World Health Organisation. Reporting and learning systems for medication errors: the role of pharmacovigilance centres. Geneva: WHO, 2014: p. 9.
- [9] World Health Organisation. A Practical Handbook on the Pharmacovigilance of Antimalarial medicines. Geneva: WHO, 2007: p. 10.
- [10] Pal S, Duncombe C, Falzon D, Olsson S. WHO Strategy for Collecting Safety Data in Public Health Programmes: Complementing Spontaneous Reporting Systems. *Drug Saf*. 2013; 36: 75-81.
- [11] WHO Collaborating Centre for Advocacy and training in Pharmacovigilance. About us. <http://www.who-pvafrica.org/index.php/home/about-us>. Consulted on: 7-7-2016.
- [12] WHO Collaborating Centre for Advocacy and training in Pharmacovigilance. MedSpina. <http://www.who-pvafrica.org/index.php/med-spina>. Consulted on: 7-7-2016.
- [13] Ghana News Agency. Ghana adopts electronic health records for patients. <http://www.ghananewsagency.org/health/ghana-adopts-electronic-health-records-for-patients-70537>. Consulted on: 7-7-2016.
- [14] The Global Fund. History of The Global Fund. <http://www.theglobalfund.org/en/history/>. Consulted on: 5-7-2016.
- [15] Aidspan, Independent observer of The Global Fund. A Beginner's Guide to The Global Fund. 3<sup>rd</sup> ed. Nairobi: 2013: p.28-35.
- [16] Médecins sans Frontières. MSF Activities. <http://www.msf.org/en/msf-activities>. Consulted on: 5-7-2016.
- [17] Systems for Improved Access Pharmaceuticals and Services (SIAPS). Annual Report: Program Year 4. Arlington, VA: Management Sciences for Health, 2015.
- [18] Strengthening Pharmaceutical Systems (SPS). Supporting Pharmacovigilance in Developing Countries: The Systems Perspective. Arlington, VA: Management Sciences for Health, 2009.
- [19] Systems for Improved Access Pharmaceuticals and Services (SIAPS). Tools and Guidance. <http://siapsprogram.org/tools-and-guidance/>. Consulted on 5-7-2016.
- [20] Healthy Entrepreneurs. Our Way of Working. <http://www.healthyentrepreneurs.nl/our-way-of-working/>. Consulted on 5-7-2016.

[21] World Health Organisation. Reporting and learning systems for medication errors: the role of pharmacovigilance centres. Geneva: WHO, 2014: p. 21.