

GIMS Model

for the screening and rating of Medication Safety in a country

version 1.0, September 2016

This GIMS Model version 1.0 is the result of a MSc. Thesis Research Project for GIMS foundation in collaboration with Utrecht University.



Research student:
A.P. (Aradhana) Kohli, BPharm, MSc-student Pharmacy, Utrecht University, The Netherlands
For correspondence:
A.R.G (Richard) van Slobbe, PharmD, Chairman GIMS foundation, arg@gims-foundation for correspondence, www.gims-foundation.org
Referee:
Dr. A.K. (Aukje) Mantel-Teeuwisse, Division Pharmacoepidemiology & Clinical Pharmacology at Utrecht University

Content

1. Content summary	3
2. The GIMS model for the screening and rating of Medication Safety in a country.....	3
2.1. Introduction.....	3
2.2. Development of the GIMS model.....	4
2.3. Explanation of the GIMS model.....	4
2.4. Suggestions for practical use of the GIMS model	6
2.5. Abbreviations	7
3. The GIMS model	8
4. Bibliography.....	26
5. Attachments	27
5.1. Attachment GIMS model: additional information critical dynamics.....	27
5.2. Attachment: Ideal situation regarding Medication Safety in a country	36

1. Content summary

Nowadays Medication Safety is still an issue. The World Health Organization estimates that more than half of all medication is inappropriately prescribed, dispensed or sold. Also, half of all patients fails to take them correctly.¹ Medication errors occur and pharmacovigilance is introduced to reduce these error rates. The Global Initiative for Medication Safety (GIMS) is a pharmacovigilance (PV) organization and drafted its own definition for Medication Safety (MS): 'Minimize health risks originated by the global use of medicines'. GIMS aims at creating awareness, insights and responsibility in the whole of the medical chain. In order to achieve this and get insight in the actual situation regarding MS in a country, GIMS foundation created the GIMS model. The first goal of the GIMS model is facilitating countries to identify the situation of the stakeholders regarding MS in their country. The second goal is identifying strengths and weaknesses and with that good practices and room for improvements. This is a first version of the model. It need to be tested in different countries to establish whether the model is of real practice in the international setting. This model can be used, after adaptations if necessary, to finally create an end report with improvements and a total overview of the situation of MS in a country.

2. The GIMS model for the screening and rating of Medication Safety in a country

2.1. Introduction

Medication is used on a global level. However, there has always been a safety aspect when using medication. For example, the World Health Organization estimates that more than half of all medication is inappropriately prescribed, dispensed or sold. Furthermore, half of all patients fails to take them correctly.¹ Also medication errors are still the leading cause of harm to patients in hospitals. Every five doses given to patient in typical US hospitals, one medication error occurs.² Also medication incidents are the second highest reported type of incident in Australian hospitals with error rates of 18%. United Kingdom and the United States have similar figures.² Pharmacovigilance is introduced to reduce these error rates.³ Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine related problem.⁴ The aim of pharmacovigilance is to optimize safe use of medicines and should be patient-focused, because patients are the ones who experience harm associated with using medication. Patients have more knowledge about the nature, personal significance and consequences of ADRs than the reports of healthcare professionals. Also patients give more detailed information about the quality of life including effect on everyday tasks and psychological effects.⁵

GIMS is a pharmacovigilance (PV) organization and drafted its own definition for Medication Safety (MS): 'Minimize health risks originated by the global use of medicine'. To minimize these health risks, GIMS aims at creating awareness, insights and responsibility in the whole of the medical chain. This also includes industry, healthcare governance and patients worldwide. Academic research into the theme helps in creating insights and data. In order to get better insight in the actual situation in a country, for all the stakeholders, a structured scientific analysis is needed, which is the main purpose of the model. This is a first version of an innovative comprehensive qualitative model (international applicable) concerning the actual status, and improvement possibilities, on the theme of Medication Safety in a country. This is the first model ever created which gives an overview about the actual status of Medication Safety in a country. Till now, not much information was available about this innovative concept. To establish whether this model is of real practice value in the international setting it needs to be tested in different countries. It is likely that national adaptations are needed to increase fitness for use in the different countries. Hopefully, by applying the model on different countries by collaborating with international academia, more information can be provided about the international applicability in the future.

Goals of the GIMS model:

- 1) Facilitate countries to identify the situation of the stakeholders regarding Medication Safety in their country.
- 2) Identify strengths and weaknesses and with that good practices and room for improvements regarding Medication Safety in a country.

The model has no absolute value and should be adapted to local situations. It is mainly an innovative concept to achieve a comprehensive overall assessment regarding Medication Safety in a country on a scientific level. Furthermore, this model has been produced in the Netherlands. There is a possibility of incorporation of West-European influences in the model. Before applying the model on your country, please look at the questions and adapt them if necessary based on the cultural views in your country.

2.2. Development of the GIMS model

To create the GIMS model, the visual representation of groups of all actors and factors concerning Medication Safety in a country, created by the GIMS foundation, is used as base for the model (see Figure 1).

Literature has been gathered, mostly of the WHO, in order to gain more knowledge about MS and the different stakeholders influencing it. By reading the literature an ideal situation for all stakeholders regarding MS in a country is designed, see attachment 2. This situation is created as a tool to create the critical dynamics. The ideal situation of the alpha actors is made with the knowledge, attitude and tools (KAT) model. The KAT model is derived from the 'knowledge, attitudes and practices (KAP) model'⁴ to make it fitting for the GIMS model.⁶ This model provides information of a situations reality and in this case the reality of the situation of the stakeholders. Also it shows the level of knowledge, attitude and tools of the stakeholders at that moment. And it identifies what is known and done about Medication Safety related subjects by the stakeholders.

The KAT model provides access about quantitative and qualitative information. However, the KAT model only records opinions and what is based on statements by other people. So the KAT model can reveal what is said, but there can be a considerable gap by what is said and what is done.⁶

The other ideal situations for stakeholders are made by reading (scientific) literature. If more information was needed, search continued on the websites of stakeholders. Some points in the ideal situation are self-devised after discussing with stakeholders and professors and added to the model. They have no confirmation of scientific literature.

Critical dynamics were formulated for each stakeholder, by using the ideal situation as starting point. The critical dynamic evaluates the situation regarding MS in the country of that certain question. The critical dynamics are self-devised and the Likert scale rating is added. It is a scale where respondents can express their strength of agreement with each of the statements; in this case the critical dynamics. Each critical dynamic can be rated on a 4 point Likert scale. If 1 is rated, the critical dynamic is not at all present or an issue in your country. If 4 is rated, it is very much present or an important issue in your country. Also a place to put remarks and sources is added to the model.

When the first draft of the model was completed, a panel of different stakeholders with a broad view on MS gave their feedback about the quality of the model. Based on their feedback, the critical dynamics are adapted.

Finally, the Netherlands will be the first country on which the model will be applied, in order to determine further the quality and usability of the model. This model will also be tested on other countries, to determine if adaptations are necessary.

2.3. Explanation of the GIMS model

Actors and factors

The main structure of the GIMS model is constructed of actors and factors.

An actor is an entity which can have influence on a situation. Examples are a company, an organization or an individual. A factor is a circumstance which has influence, but is of course not a true entity with corresponding possibilities of making choices. Examples are culture, religion and politics.

The stakeholders (actors and factors) are sorted by reading several literature with connections to MS and PV. They are sorted in the GIMS model on the amount of direct influence on the patients and consumers regarding MS (see Figure 1). They are called Alpha, Beta and Gamma actors and Delta factors. Alpha actors have the most direct influence on patients and consumers regarding MS, therefore they are the nearest to patients and consumers in the model.



Figure 1: GIMS actors and factors concerning Medication Safety in a country⁷

Alpha actors: patient and consumer, health care practitioner (doctor, pharmacist, nurse), hospital and retail.

Beta actors: professional organization of health care practitioners, national health care institute (like NICE for the UK), health care software provider, pharmaceutical retail formula, pharmaceutical wholesaler, pharmacovigilance organization.

Gamma actors: national medicines regulatory body, national inspectorate, ministry of health, academia, patient & consumer organization, pharmaceutical industry, insurance body and/or company, international bodies like WHO, EMA, EFPIA, PGEU, Cochrane.

Delta factors: national medicines and healthcare legislation, technology, culture, religion, economics, politics, stability and prosperity of a society and media.

Critical dynamics

Secondly, for each alpha, beta, gamma actor and delta factor questions are made to evaluate the situation regarding Medication Safety in the country. These questions are called critical dynamics. The critical dynamic evaluates the situation regarding MS in the country of that certain question. If all critical dynamics are answered and results appear, a total overview of the situation of Medication Safety in the evaluated country can be made.

If more information is needed about the critical dynamics, there will be referred to the source added to the critical dynamic. Also additional information to most of the critical dynamics is added to attachment.

<i>Alpha</i>	<i>Actor</i>	<i>Critical dynamic – Status</i>	<i>Rating</i>	<i>Remark</i>
55	Pharmacist	A5: Do pharmacists closely collaborate with doctors and nurses in the medication system?	0 0 0 0	Remarks: Pharmacists of different specializations are asked about their opinion. Based on their opinions the critical dynamic is rated. Source(s):
58	Pharmacist	A7: Is professional cooperation with doctors welcomed?	0 0 0 0	Remarks: Source(s): Koninklijke Nederlandse Maatschappij ter bevordering van de Pharmacie. Handvest van de apotheker. 14 mei 2013.

Figure 2: Example of a source and remark of the alpha actor Pharmacist in the Netherlands.

Remarks

Furthermore, remarks and sources can be added. A source always needs to be added to the answer of the critical dynamic, even if opinions are asked. Also a free remark can be made if you consider it as necessary. An example is shown in Figure 2.

Rating of the model

For the rating a Likert scale will be used.⁴ It is a scale where respondents can express their strength of agreement with each of the statements; in this case the critical dynamics. Each critical dynamic can be rated on a 4 point Likert scale.

If 1 is rated, the critical dynamic is not at all present or an issue in your country.

If 2 is rated, the critical dynamic is slightly present or an issue in your country.

If 3 is rated, the critical dynamic is present and an issue in your country.

If 4 is rated, it is very much present or an important issue in your country.

2.4. Suggestions for practical use of the GIMS model

1. Determine if the GIMS model is appropriate to apply on your country. If not, make adaptations if you consider it if necessary.
2. Each stakeholder and each critical dynamic is supported by a source. The source can be found in the bibliography.
3. It would be recommended to let someone with a broad view on Medication Safety fill in the model. This can be a PhD or master student, a professor or a governmental body. This person is the only one deciding the rating of each critical dynamic based on his/her scientific assessment.
4. Each critical dynamic must be answered. The one filling in the model decides the Likert scale rating in the most scientific way possible.
 - Firstly, read the additional information about the critical dynamic, before answering the question.
 - Scientific literature must be searched to find the answer of the critical dynamic. PubMed and Scopus are examples of databases for finding scientific literature;
 - If scientific literature can't be found, information has to be searched on the websites of stakeholders and governmental websites;
 - Finally opinions of stakeholders can be asked if information still hasn't been found. Also, to ensure the accuracy of the answers, opinions of stakeholders can always be asked and added to the model.
 - If opinions are needed of stakeholders, they will not rate the critical dynamic based on their opinions. Opinions of the stakeholders will be gathered and only the one authorized to fill in the model will rate the critical dynamic.
 - Each critical dynamic must be supported with a source. If opinions are asked, it must be notified in the 'Remarks'. Also the names of the stakeholders must be added under 'Sources'.
 - Other remarks, which are an addition to the rating, can always be added to the model.
 - If a critical dynamic can't be rated, because the question doesn't apply on you country, please write 'does not apply' under 'Remarks'.
5. When all critical dynamics are answered by the person filling in the model, the model can be discussed with a panel of different stakeholders of the evaluated country. The answers will be discussed with the panel and adaptations can be made. Every panel member has to be able to give their opinion. If you don't consider discussing the results with a panel as necessary, please explain the opinion in the model.
6. Finally, the results of the model will be evaluated by the 'bar char method' to get a good overview of which critical dynamics need to be improved. Every critical dynamic with a Likert rating of and above 3 has less focus. Every critical dynamic with a Likert rating of or under 2 is an improvement opportunity.

7. It is preferred to develop an end report with recommendations of improvements based on the results of the GIMS model. This report can be shared with the national regulatory body and/or the government.

2.5. Abbreviations

MS - Medication Safety: Minimize health risks originated by the global use of medicine.⁷

PV - Pharmacovigilance: The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine related problem.⁴

ADR – Adverse Drug Reactions

EAC – East African Community

EMA – European Medicines Agency

FDA – United States Food and Drug Administration

FIP – International Pharmaceutical Federation

HC – Healthcare

HCP – Healthcare practitioners

IT – Information Technology

KAT – Knowledge, Attitude, Tools

OTC – Over-the-counter

WAPS – World Alliance of Patient Safety

WHO – World Health Organization

3. The GIMS model

			Not at all-Very much				
			1	2	3	4	
Alpha	Actor	Critical dynamic – Status	Rating				Remark
1	Patient and consumer ^{8,9}	Is safe medication usage considered as a relevant theme by patients and consumers? ¹⁰	0	0	0	0	Remarks: Source(s):
2		Do patients understand all information communicated by HCPs? ^{9,11}	0	0	0	0	Remarks: Source(s):
		Rate the following aspects on the positive influence on safe medication usage by patient and consumer: ¹²					
3		- Culture	0	0	0	0	Remarks: Source(s):
4		- Religion	0	0	0	0	Remarks: Source(s):
5		- (Social) media	0	0	0	0	Remarks: Source(s):
6		- Family and friends	0	0	0	0	Remarks: Source(s):
7		To what extent do families use a fixed family doctor? ¹⁰	0	0	0	0	Remarks: Source(s):
8		Do patients and consumers trust HCPs in guidance in their medication therapy? ^{9,12}	0	0	0	0	Remarks: Source(s):
9		Do patients and consumers accept an active role of pharmacists in the medication therapy? ^{9,12}	0	0	0	0	Remarks: Source(s):
10		Do patients contact HCPs if they experience allergies, side-effects and/or interactions? ¹²	0	0	0	0	Remarks: Source(s):
11		How health literate are patients and consumers on average? ⁹	0	0	0	0	Remarks: Source(s):
12	To what extent are patients willing to obtain information of patient and consumer organizations? ¹⁰	0	0	0	0	Remarks: Source(s):	
13	Doctor ^{8,9}	K1: To what extent are medical students trained in MS and PV? ^{2,8,9}	0	0	0	0	Remarks: Source(s):
14		K2: To what extent are medical students educated in reducing ADEs and ADRs? ⁹	0	0	0	0	Remarks: Source(s):

15	K3: To what extent do medical students learn to prevent prescribing medication errors? ²	0	0	0	0	Remarks: Source(s):
16	K4: To what extent do medical students learn how to communicate with family and patients about medication therapy? ⁹	0	0	0	0	Remarks: Source(s):
17	K5: Do doctors feel educated enough to guide patients with their medication therapy? ¹⁰	0	0	0	0	Remarks: Source(s):
18	K6: What is the average actual knowledge of doctors about MS and PV? ¹⁰	0	0	0	0	Remarks: Source(s):
19	A1: To what extent are MS and PV considered to be a relevant theme within the medical world? ¹⁰	0	0	0	0	Remarks: Source(s):
20	A2: To what extent do doctors feel their responsibility in MS and PV? ¹⁰	0	0	0	0	Remarks: Source(s):
21	A3: Are doctors participating in PV programs? ⁹	0	0	0	0	Remarks: Source(s):
22	A4: How well does the doctor collaborate with pharmacist and nurse in the medication system? ²	0	0	0	0	Remarks: Source(s):
23	- Do they feel involved?	0	0	0	0	Remarks: Source(s):
24	A5: How welcomed is the professional cooperation with pharmacists by the doctor? ¹⁰	0	0	0	0	Remarks: Source(s):
25	A6: To what extent accept doctors pharmacists as co-manager in medication therapy? ⁹	0	0	0	0	Remarks: Source(s):
26	A7: How welcomed is the professional collaboration with the nurse? ⁹	0	0	0	0	Remarks: Source(s):
27	A8: To what extent are doctors stimulating health literacy among patients and society? ⁹	0	0	0	0	Remarks: Source(s):
28	A9: Are doctors legally liable for (the quality) of their prescriptions? ¹⁰	0	0	0	0	Remarks: Source(s):
29	A10: To what extent do doctors explain the medication therapy to the patient? ⁹	0	0	0	0	Remarks: Source(s):
30	T1: Are medical and pharmaceutical patient records stored on a local level? ^{2, 8}	0			0	Remarks: Source(s):
31	T2: Are patient records stored on a national level? ^{2, 8}	0			0	Remarks:

						Source(s):	
32		- In primary care?	0	0	Remarks: Source(s):		
33		- In secondary care?	0	0	Remarks: Source(s):		
34		T3: Is there an electronic storage system to store patient records? ^{2, 8}	0	0	Remarks: Source(s):		
		T4: Does the (electronic) storage system contain: ^{2, 8}					
35		- A relevant patient medication history?	0	0	0	0	Remarks: Source(s):
36		- Dosage, allergies, interactions, contra-indications, side-effects, co-morbidities?	0	0	0	0	Remarks: Source(s):
37		T5: To what extent are doctors notified if other HCPs make changes in the patient medication history? ¹⁰	0	0	0	0	Remarks: Source(s):
		T6: Are formularies available: ¹⁰					
38		- In primary care?	0	0	Remarks: Source(s):		
39		- In secondary care?	0	0	Remarks: Source(s):		
40		- Is there an electronic tool for formularies?	0	0	Remarks: Source(s):		
41		Is there an electronic tool to report ADRs? ⁹	0	0	0	0	Remarks: Source(s):
42		T7: Is there an electronic tool for prescribing? ²	0	0	Remarks: Source(s):		
43		- Are prescribing errors notified by pharmacist and fed back to the doctor?	0	0	0	0	Remarks: Source(s):
44		- The indication of prescribing?	0	0	0	0	Remarks: Source(s):
45		- Are interactions and side-effects mentioned?	0	0	0	0	Remarks: Source(s):
46	Pharmacist ^{8, 9}	K1: To what extent are pharmacy students trained in MS and PV? ^{8, 9}	0	0	0	0	Remarks: Source(s):
47		K2: To what extent are pharmacy students educated in reducing ADRs and ADEs? ²	0	0	0	0	Remarks:

				Source(s):
48		K3: To what extent are pharmacy students educated in communicating with family and patients? ⁹	0 0 0 0	Remarks: Source(s):
49		K4: To what extent do pharmacists feel educated to treat and guide patients with their medication therapy? ¹⁰	0 0 0 0	Remarks: Source(s):
50		K5: What is the average actual knowledge of pharmacists in the workfield about MS and PV? ¹⁰	0 0 0 0	Remarks: Source(s):
51		A1: To what extent are MS and PV considered to be a relevant theme within the pharmaceutical field? ¹⁰	0 0 0 0	Remarks: Source(s):
52		A2: To what extent do pharmacists feel that MS and PV are one of their main responsibilities? ²	0 0 0 0	Remarks: Source(s):
53		A3: Do pharmacists position themselves as experts on MS and PV towards society? ²	0 0 0 0	Remarks: Source(s):
54		A4: Do pharmacists stimulate health literacy among patients and society? ²	0 0 0 0	Remarks: Source(s):
55		A5: Do pharmacists closely collaborate with doctors and nurses in the medication system? ²	0 0 0 0	Remarks: Source(s):
56		- Do pharmacists feel closely involved? ²	0 0 0 0	Remarks: Source(s):
57		A6: Do pharmacists provide sufficient guidelines for nurses to distribute and administrate medication, especially high-alert medication? ²	0 0 0 0	Remarks: Source(s):
58		A7: Is professional cooperation with doctors welcomed? ²	0 0 0 0	Remarks: Source(s):
59		A8: Is professional cooperation with nurses welcomed? ²	0 0 0 0	Remarks: Source(s):
60		A9: Are pharmacists legally liable for (the quality of) their dispensed prescriptions with regards to MS? ²	0 0 0 0	Remarks: Source(s):
61		A10: To what extent do pharmacists explain the medication therapy to the patient? ⁹	0 0 0 0	Remarks: Source(s):
62		T1: Are patient records stored on a local level? ^{2,8}	0 0	Remarks: Source(s):
		T2: Are patient records stored on a national level? ^{2,8}		
63		- In primary care?	0 0	Remarks:

					Source(s):		
64		- In secondary care?	0	0	Remarks: Source(s):		
65		T3: Is there an electronic storage system to store pharmaceutical patient records? ^{2, 8}	0	0	Remarks: Source(s):		
		T4: Does the electronic tool, that store patient records, contain: ^{2, 8}					
66		- A relevant patient medication history?	0	0	Remarks: Source(s):		
67		- Dosage, allergies, interactions, contra-indications, side-effects and co-morbidities?	0	0	Remarks: Source(s):		
68		T5: Is it used on a national level? ^{2, 8}	0	0	0	0	Remarks: Source(s):
69		T6: Are pharmacists able to see changes (by HCPs) in patient medication history when necessary? ^{2, 8}	0	0	0	0	Remarks: Source(s):
70		T7: Are pharmacists co-responsible for the maintainace of formularia? ¹⁰	0	0	0	0	Remarks: Source(s):
71		T8: Are pharmacists responsible for the compliance of formularia by HCPs? ¹⁰	0		0		Remarks: Source(s):
72		T9: Is there an electronic tool to report ADRs en ADEs? ²	0	0	0	0	Remarks: Source(s):
73		T10: Is there an electronic tool for dispensing? ²	0		0		Remarks: Source(s):
74		- How good is the quality of the electronic tool?	0	0	0	0	Remarks: Source(s):
75		- Is a barcode system used?	0	0	0	0	Remarks: Source(s):
76		- Are interactions and side-effects mentioned?	0	0	0	0	Remarks: Source(s):
77	Nurse ^{8, 9}	K1: To what extent are nursing students trained in the risks of medication? ⁹	0	0	0	0	Remarks: Source(s):
78		K2: To what extent are nursing students educated in distributing and administrating medication? ⁹	0	0	0	0	Remarks: Source(s):
79		K3: To what extent are nursing students educated in communicating with family and patients about medication? ^{9, 9, 9}	0	0	0	0	Remarks: Source(s):

80		K4: How knowledgeable are nurses in guiding patients in their medication therapy? ⁹	0	0	0	0	Remarks: Source(s):
81		- How knowledgeable do they feel? ⁹	0	0	0	0	Remarks: Source(s):
82		A1: To what extent are MS and PV considered to be a relevant theme in the nursing world? ¹⁰	0	0	0	0	Remarks: Source(s):
83		A2: To what extent do nurses collaborate with doctors and pharmacists in the medication system? ²	0	0	0	0	Remarks: Source(s):
84		- Do nurses feel closely involved? ²	0	0	0	0	Remarks: Source(s):
85		A3: When in doubt, do nurses pro-actively obtain information from doctors and pharmacists about the medication treatment of the patient? ²	0	0	0	0	Remarks: Source(s):
86		A4: To what extent do nurses stimulate a safety culture among nurses? ²	0	0	0	0	Remarks: Source(s):
87		A5: Do nurses stimulate health literacy among patients and society? ⁹	0	0	0	0	Remarks: Source(s):
88		T1: Is there a distribution and administration tool for nurses? ²	0			0	Remarks: Source(s):
89		- Is the tool electronic? ²	0			0	Remarks: Source(s):
		T2: Does the (electronic) tool contain:					Remarks: Source(s):
90		- Relevant information of the patient (allergies, interactions, co-morbidities)? ²	0			0	Remarks: Source(s):
91		- Which medication need to be administrated at moment of administration? ²	0			0	Remarks: Source(s):
92		- Way of administration? ²	0			0	Remarks: Source(s):
93	Hospital-board ⁹	K1: Are the board members of a hospital educated about the relevance of MS and PV? ⁹	0	0	0	0	Remarks: Source(s):
94		A1: Do board members of hospitals understand the relevance of MS and PV? ¹⁰	0	0	0	0	Remarks:

				Source(s):
95		A2: Do board members of hospitals understand their responsibility of improving MS and PV? ¹⁰	0 0 0 0	Remarks: Source(s):
96		A3: Do hospitals have policies and guidelines on covering medication risks? ¹⁰	0 0 0 0	Remarks: Source(s):
		A4: Do they collaborate with: ¹⁰		
97		- HCP organizations?	0 0 0 0	Remarks: Source(s):
98		- Patient and Consumer organizations?	0 0 0 0	Remarks: Source(s):
99		- HCPs in primary care?	0 0 0 0	Remarks: Source(s):
100		T1: Do board members have tools to gain insight in the amount of medication errors occurring in the hospital? ¹⁰	0 0 0 0	Remarks: Source(s):
101	Retailer⁸	K1: Are retailers trained in (selling) OTC medication? ⁸	0 0 0 0	Remarks: Source(s):
102		K2: Do retailers feel knowledgeable enough to sell OTC medication? ⁸	0 0 0 0	Remarks: Source(s):
103		K3: Are retailers aware of the risks of OTC medication? ⁸	0 0 0 0	Remarks: Source(s):
104		K4: Are retailers educated in communicating with consumers about OTC medication? ⁸	0 0 0 0	Remarks: Source(s):
105		A1: Are MS and PV considered to be a relevant theme among retailers? ¹⁰	0 0 0 0	Remarks: Source(s):
106		T1: Is a tool available to find information about OTC medication? ⁸	0 0	Remarks: Source(s):
107		- Is this an electronic system? ⁸	0 0	Remarks: Source(s):

<i>Beta</i>	<i>Actor</i>	<i>Critical dynamic – Status</i>	Not at all-Very much				<i>Rating</i>	<i>Remark</i>
			1	2	3	4		
1	Healthcare practitioner organizations ^{8,9}	Does an organization of medical professionals exist? ¹⁰	0			0		Remarks: Source(s):
2		K1: Are MS and PV considered as relevant themes? ¹⁰	0	0	0	0		Remarks: Source(s):
3		A1: Are MS and PV one of its focus points? ⁸	0	0	0	0		Remarks: Source(s):
		A2: Does it collaborate with: ⁸						
4		- Organization of pharmaceutical professionals?	0	0	0	0		Remarks: Source(s):
5		- Patient and Consumer organizations?	0	0	0	0		Remarks: Source(s):
6		- Government?	0	0	0	0		Remarks: Source(s):
7		- Insurance companies?	0	0	0	0		Remarks: Source(s):
8		T1: Does it develop and guide doctors in their qualities and professional knowledge in systems and structures concerning MS and PV? ⁸	0	0	0	0		Remarks: Source(s):
9		T2: Do they develop best practices in MS and PV? ⁸	0	0	0	0		Remarks: Source(s):
10		T3: Do they provide guidance and guidelines about MS and PV? ⁸	0	0	0	0		Remarks: Source(s):
11		Does an organization of pharmaceutical professionals exist? ¹⁰	0			0		Remarks: Source(s):
12		K1: Are MS and PV considered as relevant themes? ¹⁰	0	0	0	0		Remarks: Source(s):
13		A1: Are MS and PV one of its focus points? ⁸	0	0	0	0		Remarks:

				Source(s):
		A2: Does it collaborate with: ⁸		
14		- Organizations of medical professionals?	0 0 0 0	Remarks: Source(s):
15		- Patient and Consumer organizations?	0 0 0 0	Remarks: Source(s):
16		- Government?	0 0 0 0	Remarks: Source(s):
17		- Insurance companies?	0 0 0 0	Remarks: Source(s):
18		T1: Does it develop and guide pharmacists in their qualities and professional knowledge in systems and structures in MS and PV? ⁸	0 0 0 0	Remarks: Source(s):
19		T2: Does it develop best practices in MS and PV? ⁸	0 0 0 0	Remarks: Source(s):
20		T3: Does it provide guidance and guidelines about MS and PV? ⁸	0 0 0 0	Remarks: Source(s):
21	National healthcare institute ⁸	Does a national healthcare institute exist? ¹⁰	0 0	Remarks: Source(s):
22		Does it provide scientific guidance about MS and PV to HCPs and HCP organizations? ¹⁰	0 0 0 0	Remarks: Source(s):
23	Pharmaceutical wholesale ^{8,9}	Are they battling against counterfeit and substandard products? ⁸	0 0 0 0	Remarks: Source(s):
24		Is the total wholesale market just existing of a few entities? ⁸	0 0 0 0	Remarks: Source(s):
25		Is Good Distribution Practice the standard? ⁸	0 0 0 0	Remarks: Source(s):
26	Pharmacovigilance organization ⁹	Does a national pharmacovigilance organization exist? ¹⁰	0 0	Remarks: Source(s):
27		Does it stimulate reporting ADRs and ADEs by HCPs and patients? ⁹	0 0 0 0	Remarks: Source(s):

28		Does it have the capacity, knowledge and tools to examine ADRs and ADEs? ⁹	0	0	0	0	Remarks: Source(s):
29		Is there an storage tool for ADRs and ADEs? ⁹	0	0	0	0	Remarks: Source(s):
30		○ Is it used on national level?	0	0	0	0	Remarks: Source(s):
31		○ Does it have the capacity to store ADRs and ADEs?	0	0	0	0	Remarks: Source(s):
32		○ Are employees knowledgeable enough to store and evaluate ADRs and ADEs?	0	0	0	0	Remarks: Source(s):
33		○ Is it an electronic tool?	0	0	0	0	Remarks: Source(s):
34		○ Is the tool adequate enough to achieve a good overview of the situation of PV in a country?	0	0	0	0	Remarks: Source(s):
35		Does it have the authority to take further steps in the evaluation of ADRs and ADEs? ⁹	0	0	0	0	Remarks: Source(s):
36		Does it provide guidelines on PV? ⁹	0	0	0	0	Remarks: Source(s):
37		Does it share information and communicate safe medication usage to HCPs and patient? ⁹	0	0	0	0	Remarks: Source(s):
38		Is there an open culture in reporting ADRs? ⁹	0	0	0	0	Remarks: Source(s):
39		Does it promote a safety culture among patients and consumers? ⁹	0	0	0	0	Remarks: Source(s):
		Does it collaborate with: ⁹					
40		○ Patient and Consumer organizations?	0	0	0	0	Remarks: Source(s):
41		○ HCP organizations?	0	0	0	0	Remarks: Source(s):
42		○ International pharmacovigilance centres (Uppsala Monitoring Centre)?	0	0	0	0	Remarks: Source(s):
43		○ World Health Organization?	0	0	0	0	Remarks: Source(s):

44	Healthcare software provider ^{2, 8, 9}	Does it provide the required software and systems to maintain optimal MS in close collaboration with HCPs? ^{2, 9}	0	0	0	0	Remarks: Source(s):
45		○ Does it contain dosage, allergies, interactions, contra-indications, side-effects, co-morbidities? ¹⁰	0	0	0	0	Remarks: Source(s):
46		Does it cooperate with HCPs? ^{2, 8, 9}	0	0	0	0	Remarks: Source(s):
47	Pharmaceutical retail formula ⁸	Do pharmaceutical retail formulas exist? ¹⁰	0			0	Remarks: Source(s):
48		Do they position pharmacists as experts in MS and PV towards society? ¹⁰	0	0	0	0	Remarks: Source(s):
49		Do they provide information and knowledge about MS to retailers and pharmacists? ⁸	0	0	0	0	Remarks: Source(s):
50		Do they provide guidelines about MS for retailers and pharmacists according to the formula? ¹⁰	0	0	0	0	Remarks: Source(s):
51		Do they promote a safety culture among patients and consumers? ⁸	0	0	0	0	Remarks: Source(s):

			Not at all-Very much				
			1	2	3	4	
Gamma	Actor	Critical dynamic – Status	Rating				Remark
1	National medicines regulatory board⁹	Does a national medicines regulatory board exist? ¹⁰	0			0	Remarks: Source(s):
2		How valuable is the authority of the national regulatory body in the country? ¹³	0	0	0	0	Remarks: Source(s):
3		Does it have the capacity to fulfill their tasks? ¹⁴	0	0	0	0	Remarks: Source(s):
4		Is it independent? ¹³	0	0	0	0	Remarks: Source(s):
5		Is it responsible for the market authorization of all medication in the country? ¹³	0	0	0	0	Remarks: Source(s):
6		Is it responsible for the risk assessment of medication? ¹³	0	0	0	0	Remarks: Source(s):
		Does it have an international collaboration with: ¹³					
7		○ EMA and/or FDA?	0	0	0	0	Remarks: Source(s):
8		○ Other national medicines regulatory bodies?	0	0	0	0	Remarks: Source(s):
9	National inspectorate⁸	Does a national inspectorate concerning medical and pharmaceutical items exist? ¹⁰	0			0	Remarks: Source(s):
10		Are MS and PV considered as relevant themes? ¹⁰	0	0	0	0	Remarks: Source(s):
11		Does it inspect quality and safety of medication according to national legislation? ⁸	0	0	0	0	Remarks: Source(s):
12		Does it inspect if (the working methods of) HCPs are qualified enough according to national legislation? ⁸	0	0	0	0	Remarks: Source(s):
13		Does it have the right and authority to intervene? ¹⁰	0	0	0	0	Remarks: Source(s):
14		Does it have the sources and tools to take appropriate action according to national legislation? ⁸	0	0	0	0	Remarks: Source(s):
15		Is it sufficiently independent to act? ¹⁵	0	0	0	0	Remarks: Source(s):

16	Ministry of Health⁸	Are MS and PV considered as relevant themes? ¹⁰	0	0	0	0	Remarks: Source(s):
17		To what extent does it support stakeholders to invest in MS and PV? ⁸	0	0	0	0	Remarks: Source(s):
18		Does it develop legislation about the role of HCPs in authorizing medication? ⁸	0	0	0	0	Remarks: Source(s):
19		Does it have a license register system in which all licenses are stored of all HCPs of the country? ¹⁰	0	0	0	0	Remarks: Source(s):
20		To what extent does it stimulate research and education on academia about MS and PV? ¹⁰	0	0	0	0	Remarks: Source(s):
		Does it productively collaborate with:					
21		○ All other stakeholders? Rate and write the stakeholders down at 'Remarks'. ⁸	0	0	0	0	Remarks: Source(s):
22		○ International organizations? For example the WHO, FIP, EMA and European Union. ¹⁰ (Rate and write the organizations down at 'Remarks')	0	0	0	0	Remarks: Source(s):
23	National laboratory⁹	Does a national laboratory exist where product research is done about safety and quality of medication? ¹⁰	0	0	0	0	Remarks: Source(s):
24		Is it NOT necessary to approve the quality before (batch) release of medication? ⁹	0			0	Remarks: Source(s):
25		Are laboratory workers knowledgeable enough to perform their tasks? ⁹	0	0	0	0	Remarks: Source(s):
26		Does it have the capacity, knowledge and tools to perform their tasks? ⁹	0	0	0	0	Remarks: Source(s):
27		Is it non corrupt? ¹⁰	0	0	0	0	Remarks: Source(s):
28	Academia⁹	Do academia consider MS and PV as relevant themes? ¹⁰	0	0	0	0	Remarks: Source(s):
29		Are subjects about MS and PV implemented in the curricula of healthcare students? ^{2,9}	0	0	0	0	Remarks: Source(s):
30		Do academia stimulate education on MS and PV? ^{2,9}	0	0	0	0	Remarks: Source(s):
31		Do academia stimulate research on MS and PV? ⁹	0	0	0	0	Remarks:

				Source(s):
		Do they collaborate with: ⁹		
32		○ Government?	0 0 0 0	Remarks: Source(s):
33		○ HCP organizations?	0 0 0 0	Remarks: Source(s):
34		○ Student associations?	0 0 0 0	Remarks: Source(s):
35	Patient and Consumer organization⁹	Do Patient and Consumer organizations exist in your country? ¹⁰	0 0	Remarks: Source(s):
36		Do they consider MS and PV as relevant themes? ^{8,9}	0 0 0 0	Remarks: Source(s):
37		Do they inform patients about medication risks? ⁹	0 0 0 0	Remarks: Source(s):
		Do they collaborate with: ⁹		
38		○ HCP organizations?	0 0 0 0	Remarks: Source(s):
39		○ Government?	0 0 0 0	Remarks: Source(s):
40	Pharmaceutical industry^{8,9}	Are MS and PV a point of interest? ⁹	0 0 0 0	Remarks: Source(s):
41		Do they understand their responsibilities in MS and PV? ^{8,12}	0 0 0 0	Remarks: Source(s):
42		Do they feel shared responsibilities in safe medication usage? ⁸	0 0 0 0	Remarks: Source(s):
43		Do they battle counterfeit medication, substandard products and corruption? ⁸	0 0 0 0	Remarks: Source(s):
44		Is there NO direct influence by the pharmaceutical industry on HCPs on commercial level? ⁹	0 0 0 0	Remarks: Source(s):
45		Do they collaborate with other stakeholders concerning MS and PV? ⁹ Rate and write the stakeholders down at 'Remarks'.	0 0 0 0	Remarks: Source(s):

46	Healthcare insurance company/ public health insurance ⁸	Do they consider MS and PV as relevant themes to discuss? ¹⁰	0	0	0	0	Remarks: Source(s):
47		To what extent are they active in improving MS and PV? ⁸	0	0	0	0	Remarks: Source(s):
48		Do they feel shared responsibilities in safe medication usage? ⁸	0	0	0	0	Remarks: Source(s):
49		Do they collaborate with HCP organizations? ¹⁰	0	0	0	0	Remarks: Source(s):
	International bodies ^{8,9}						
50	WHO ¹⁶	Is it NOT necessary for a country to be supported by the WHO in the legislation and policy making about MS and PV? ⁸	0	0	0	0	Remarks: Source(s):
51		Does it cooperate with national pharmacovigilance centers to research ADRs and ADEs? ⁹	0			0	Remarks: Source(s):
52	The World Alliance for Patient Safety ¹⁷	Is it NOT necessary for a country to be supported by the WAPS? ¹⁷	0	0	0	0	Remarks: Source(s):
53		Does the country use the patient safety education and trainings provided by the WAPS? ¹⁷	0			0	Remarks: Source(s):
54	International Society of Pharmacovigilance ¹⁸	How many active members does it have in your country? ¹⁸	0	0	0	0	Remarks: Source(s):
55		Does it stimulate research about PV in your country? ¹⁸	0	0	0	0	Remarks: Source(s):
56		Does it stimulate awareness about PV among HCPs, patients and consumers? ¹⁸	0	0	0	0	Remarks: Source(s):
57		Does it improve best practices considering MS and PV? ¹⁸	0	0	0	0	Remarks: Source(s):
	Supranational entities, for example;						
58	European Union (European	Are MS and PV considered as relevant themes? ¹⁰	0	0	0	0	Remarks: Source(s):

59	council) ¹⁹	To what extent do they support the stakeholders in your country to invest in MS and PV? ¹⁹	0	0	0	0	Remarks: Source(s):
60		Do they develop legislation about MS and PV? ¹⁹	0	0	0	0	Remarks: Source(s):
61		○ Are GMP and GDP incorporated in the legislation? ¹⁰	0	0	0	0	Remarks: Source(s):
62		Is there collaboration with international organizations like the WHO, FIP and EMA? ¹⁹	0	0	0	0	Remarks: Source(s):
63	East African Community ²⁰	Is it NOT necessary for a country to be supported by the EAC in the legislation and policy making about MS and PV? ²⁰	0	0	0	0	Remarks: Source(s):
64		Does it provide policies to the country about MS and PV? ²⁰	0	0	0	0	Remarks: Source(s):
65		Does it help to improves best practices considering MS and PV in your country? ²⁰	0	0	0	0	Remarks: Source(s):

			Not at all-Very much				Rating	Remark
			1	2	3	4		
Delta	Factor	Critical dynamic – Status						
	National medicines and healthcare legislation⁸	Rate to what extent the following is included in national medicines and healthcare legislation: ^{8, 21}						
1		○ Distinction between OTC medication and medication on prescription.	0	0	0	0		Remarks: Source(s):
2		○ The responsibilities of HCPs to ensure MS and PV.	0	0	0	0		Remarks: Source(s):
3		○ Wholesale import and export of medicines.	0	0	0	0		Remarks: Source(s):
4		○ Market access of medication.	0	0	0	0		Remarks: Source(s):
5		○ Ones authorized to prescribe medication.	0	0	0	0		Remarks: Source(s):
6		○ Ones authorized to distribute medication.	0	0	0	0		Remarks: Source(s):
7		○ MS and PV.	0	0	0	0		Remarks: Source(s):
8	Technology^{2, 8, 9}	Do software tools for HCPs reach the required standards to execute MS and PV according to legislation, guidelines or policies? ²	0	0	0	0		Remarks: Source(s):
9	Religion¹⁰	How often do patients refuse intake of prescribed medication because of their religion? ¹⁰	0	0	0	0		Remarks: Source(s):
10		○ Do HCPs explain to these patients the disadvantages of refusing intake of medication?	0	0	0	0		Remarks: Source(s):
11	Culture²²	Do alternative medicines play an important role? ²²	0	0	0	0		Remarks: Source(s):
12		Is the use of alternative medication monitored? ²²	0	0	0	0		Remarks: Source(s):
13		Are HCPs knowledgeable enough to guide patients in the use of alternative medicines? ²²	0	0	0	0		Remarks: Source(s):
14		How critical is society about use of medication? ¹⁰	0	0	0	0		Remarks: Source(s):

15	Economics⁸	Are there financial ties between HCPs? ⁸	0	0	0	0	Remarks: Source(s):
16		○ Prescription bonuses for doctors?	0	0	0	0	Remarks: Source(s):
17		○ Other economic motives for HCPs?	0	0	0	0	Remarks: Source(s):
18		Is innovation stimulated, even if the margins are low or high? ⁸	0	0	0	0	Remarks: Source(s):
19	Politics⁸	Is the government aware of the risks of medication? ⁸	0	0	0	0	Remarks: Source(s):
20		Does the government recognize MS and PV as relevant topics to invest in and make policies? ⁸	0	0	0	0	Remarks: Source(s):
21	Stability and prosperity of a society⁸	Is your country a Low, Middle or High Income Country? ¹⁰ (rating 1 is Low, rating 5 is High)	0	0	0	0	Remarks: Source(s):
22	Media⁸	Does a restrictive legislation on advertising medication to the common public exist in your country? ⁸	0	0	0	0	Remarks: Source(s):
23		○ About OTC medication?	0	0	0	0	Remarks: Source(s):
24		○ About medication on prescription?	0	0	0	0	Remarks: Source(s):

4. Bibliography

1. Shutterstock. Poor prescription practices across Africa are putting patients at risk. 29/09,2016; Available at: <http://theconversation.com/poor-prescription-practices-across-africa-are-putting-patients-at-risk-64250>. Accessed 09/08, 2016.
2. Mansur JM. Medication Safety Systems and the Important Role of Pharmacists. *Drugs Aging* 2016 Mar;33(3):213-221.
3. Lapkin S, Levett-Jones T, Gilligan C. Using the Theory of Planned Behaviour to examine health professional students' behavioural intentions in relation to medication safety and collaborative practice. *Nurse Educ Today* 2015 Aug;35(8):935-940.
4. World Health Organization. Looking at the pharmacovigilance: ensuring the safe use of medicines. 2004.
5. Harmark L, Raine J, Leufkens H, Edwards IR, Moretti U, Sarinic VM, et al. Patient-Reported Safety Information: A Renaissance of Pharmacovigilance? *Drug Saf* 2016 Oct;39(10):883-890.
6. Médecins du Monde. The KAP Survey Model (Knowledge, Attitudes, and Practices). 2011; Available at: <https://www.spring-nutrition.org/publications/tool-summaries/kap-survey-model-knowledge-attitudes-and-practices>. Accessed 07/03, 2016.
7. GIMS Foundation. GIMS gets the picture. 2016; Available at: www.gims-foundation.org. Accessed 08/19, 2016.
8. World Health Organization. Public-private roles in the pharmaceutical sector: Implications for equitable access and rational drug use. 1997.
9. World Health Organization. Reporting and learning systems for medication errors: the role of pharmacovigilance centers. 2014.
10. AUTHORS: Aradhana Kohli and Richard van Slobbe.
11. World Health Organization. Patient Safety. 2013.
12. World Health Organization. Patient Safety Curriculum Guide. 2011.
13. World Health Organization. Assessing national medicines regulatory systems. 2016; Available at: http://www.who.int/medicines/areas/quality_safety/regulation_legislation/assessment/en/. Accessed 08/29, 2016.
14. World Health Organization. National drug regulatory systems. 1999.
15. Inspectie voor de Gezondheidszorg. Inspectie voor de gezondheidszorg. 2016; Available at: <http://www.igz.nl>. Accessed 08/27, 2016.
16. World Health Organization. World Health Organization. 2016; Available at: <http://www.who.int/en/>. Accessed 08/27, 2016.
17. World Health Alliance for Patient Safety. Patient Safety. 2016; Available at: <http://www.who.int/patientsafety/worldalliance/en/>. Accessed 08/29, 2016.
18. International Society of Pharmacovigilance. Pharmacovigilance. 2016; Available at: <http://isoponline.org/>. Accessed 08/29, 2016.
19. European Commission. Patient Safety. 2016; Available at: http://ec.europa.eu/health/patient_safety/policy/index_en.htm. Accessed 08/29, 2016.
20. East African Community. Health. 2016; Available at: <http://www.eac.int/sectors/health>. Accessed 08/29, 2016.
21. World Health Organization. Chapter 6 Pharmaceutical regulations and legislation. 2012.
22. Alhomoud F, Dhillon S, Aslanpour Z, Smith F. South Asian and Middle Eastern patients' perspectives on medicine-related problems in the United Kingdom. *Int J Clin Pharm* 2015 Aug;37(4):607-615.

5. Attachments

5.1. Attachment GIMS model: additional information critical dynamics

ALPHA ACTORS	
Actor	Additional information
1	Relevant theme: Patients and consumers are aware of the importance of safe medication usage.
2	Understand explanation of HCPs about the medication therapy, including indication, basic work mechanism of prescribed medication, risks and usage.
3-6	Patients and consumers often have strong connections with culture, religion, (social) media and/or family and friends. This can influence the medication therapy, which can have influence on the medication safety.
7	A fixed family doctor is able to follow the medication therapy of the whole family for a long term period. This can result in better guidance in the medication therapy of all family members, which can result in improvement of safe medication usage of the patients.
8	Medication therapy: is a service or group of services that optimize therapeutic outcomes for individual patients. Medication therapy management services include medication therapy reviews, pharmacotherapy consults, anticoagulation management, immunizations, health and wellness programs and many other clinical services. Pharmacists provide medication therapy management to help patients get the best benefits from their medications by actively managing drug therapy and by identifying, preventing and resolving medication-related problems.
9	See Alpha actor 8
10	-
11	Health literate: is the ability to obtain, read, understand and use healthcare information to make appropriate health decisions and follow instructions for treatment.
12	-
13	Are MS and PV part of their curriculum?
14	Are recognizing and evaluating ADRs and ADEs part of their curriculum?
15	Is preventing prescribing medication errors part of their curriculum? Do they learn to apply theoretical information?
16	Is education in communicating with family and friend about medication therapy part of their curriculum?
17	-
18	What is the amount of knowledge they are able to apply in the workfield? Do doctors follow retrainings to gain knowledge about MS and PV?
19	Relevant theme: are aware and actively obtain and share information about MS and PV.
20	-
21	PV programs: set up by pharmacovigilance centers to improve PV on a local and national level.
22	Medication system: prescribing, dispensing, distributing and administrating.
23	-
24	Is it desirable that pharmacist and doctor collaborate? Are both parties willing to collaborate with each other?
25	-
26	Is it desirable that nurse and doctor collaborate? Are both parties willing to collaborate with each other?

27	See Alpha actor 11.
28	Is the doctor financially and lawfully liable for the quality of prescriptions? This can also be noted in the national legislations or guidelines provided by stakeholders.
29	-
30	Local level: local doctors.
31	-
32	-
33	-
34	-
35	All medication stored what is necessary for further or new medication therapy. This can include high risk medication, medication which is used for a long period of time and medication which showed interactions, allergies or contra-indications.
36	-
37	-
38	-
39	-
40	-
41	-
42	-
43	-
44	-
45	-
46	Are MS and PV part of their curriculum?
47	Is recognizing and evaluating ADRs and ADEs part of their curriculum?
48	-
49	See Alpha actor 8.
50	What is the amount of knowledge they are able to apply in the workfield? Do pharmacists follow retrainings to gain knowledge about MS and PV?
51	See Alpha actor 19.
52	Do they feel responsible in their role as pharmacist and main responsibility in medication therapy?
53	In communication with HCPs, patients and consumers, government and other bodies.
54	See Alpha actor 11.
55	See Alpha actor 22.
56	-
57	High-alert medication: https://www.ismp.org/tools/highalertmedications.pdf .
58	Is it desirable that doctor and pharmacist collaborate? Are both parties willing to collaborate with each other?
59	Is it desirable that nurse and pharmacist collaborate? Are both parties willing to collaborate with each other?

60	Is the doctor financially and lawfully liable for the quality of the dispensed prescriptions? This can also be noted in the national legislations or guidelines provided by stakeholders.
61	-
62	Local level: public pharmacies. Public hospital pharmacies.
63	-
64	-
65	-
66	All medication stored what is necessary for further or new medication therapy. This can include high risk medication, medication which is used for a long period of time and medication which showed interactions, allergies or contra-indications.
67	-
68	-
69	-
70	-
71	-
72	-
73	-
74	-
75	-
76	-
77	Is risks of medication part of their curriculum?
78	Is education about distributing and administrating medication part of their curriculum?
79	Is education about communicating with family and patients about medication therapy part of their curriculum?
80	Is education in guiding patients in medication therapy part or their curriculum?
81	-
82	See Alpha actor 19.
83	See Alpha actor 22.
84	-
85	-
86	Safety culture: Do nurses stimulate each other in providing safe medication therapy?
87	See Alpha actor 11.
88	-
89	-
90	-
91	-
92	-

93	Being educated about MS and PV before or at the beginning of their term as a board member.
94	See Alpha actor 19.
95	-
96	-
97	-
98	-
99	-
100	-
101	Schooling in (selling) OTC medication before starting their work as a retailer.
102	-
103	-
104	Schooling in communication with consumers about OTC medication before starting their work as a retailer.
105	See Alpha actor 19.
106	-
107	-

BETA ACTORS	
Actor	Additional information
1	-
2	Relevant theme: Is aware and actively obtain and share information about MS and PV.
3	Topics regarding MS and PV high on the agenda.
4	-
5	-
6	-
7	-
8-9	Provide information and trainings.
10	-
11	-
12	See Beta actor 2.
13	See Beta actor 3.
14	-
15	-
16	-

17	-
18-19	See Beta actor 8-9.
20	-
21	-
22	Scientific guidance: give advice to HCPs based on scientific research. Guidelines can also be provided.
23	-
24	-
25	-
26	-
27	-
28	Capacity and knowledge: Educated and trained employees in MS and PV. Enough finances to invest in tools to evaluate and research ADRs and ADEs.
29	-
30	-
31	-
32	-
33	-
34	Is the tool relevant to use? Is the tool capable of analyzing pharmacovigilance data of the country and make an overview of all ADRs and ADEs? Finally, if an overview is made, is it possible to give advice about the situation of MS and PV in the country?
35	Produce a conclusive medication safety report for the country with the information of ADRs and ADEs. This report can eventually be used by national regulatory bodies and the government.
36	-
37	-
38	Reporting ADRs and ADEs is stimulated by all stakeholders.
39	Safety culture: creating awareness among patients about safe medication usage.
40	-
41	-
42	-
43	-
44	Required software according to for example professional standards or national legislation.
45	-
46	-
47	-
48	Every pharmacy has an owner (mostly a pharmacist). But he/she can be part of a retail formula. A retail formula is a business with a shared vision; in this case pharmacies with a shared vision on medication therapy. This also includes MS and PV and pharmacists have the responsibility to express themselves to this shared vision.

49	-
50	-
51	See Beta actor 39.

GAMMA ACTORS	
Actor	Additional information
1	-
2	Authority: Is the board knowledgeable, adequate and independent to act regarding the quality standards according to guidelines or national legislation? And capable to execute their duties?
3	Educated and trained employees in MS and PV. Enough money to invest in tools.
4	No governmental or other stakeholders influences
5	This also considers having the authority to withdraw permits for all medication.
6	Registration of drugs based on quality, safety and efficacy, with cost and appropriateness to the local or national health system.
7	-
8	-
9	-
10	Relevant theme: Are aware and actively obtain and share information about MS and PV.
11	-
12	-
13	-
14	-
15	See Gamma actor 4
16	See Gamma actor 10.
17	-
18	-
19	License system: All officially recognized healthcare workers are stored in a database. Also clarifies responsibilities of HCPs.
20	-
21	-
22	-
23	<p>In some countries quality of medication before distribution can't be guaranteed, because of corruption or other reasons. The goal of a national laboratory is to get safe batches on the market. It is a laboratory where all batches are verified on quality standards.</p> <p>In some countries a national laboratory is not necessary, because the quality of batches is verified in a different way (for example a certificate of approval of the batch quality from a renowned institute).</p> <p>If a national laboratory is not necessary, please write down at 'Remarks': 'does not apply' with explanation.</p>

24	Does the quality of medication need to be checked before it is distributed to patients and consumers?
25	-
26	-
27	-
28	See Gamma actor 10.
29	-
30	-
31	-
32	-
33	-
34	-
35	-
36	See Gamma actor 10.
37	-
38	-
39	-
40	Are aware and actively obtain and share information about MS and PV.
41	Main responsible for providing medication according to GMP, provides guidelines about safe usage of their medication and post market surveillance
42	Together with other stakeholders (especially HCPs).
43	-
44	-
45	-
46	See Gamma actor 10.
47	-
48	See Gamma actor 42.
49	-
50	-
51	-
52	-
53	-
54	-
55	-
56	-
57	-
58	-

59	-
60	-
61	-
62	-
63	-
64	-
65	-

DELTA FACTORS	
Actor	Explanation
1	-
2	Responsibilities in medication therapy.
3	-
4	-
5	-
6	-
7	-
8	According to the national legislation and policies about MS and PV.
9	An example is not using medication by day during Ramadan, or not accepting blood transfusion.
10	-
11	In some countries alternative medicines have a big influence on the medication therapy. Not only do patients and consumers follow the prescription by the doctor, but sometimes they also take alternative medicines for the same indication.
12	Stored in the medical patient records?
13	-
14	In some countries medication use is more accepted compared to other countries. As result more medication can be administered to or used by patients and consumers. If the medication usage rate is high, more medication errors can occur.
15	-
16	-
17	-
18	Some countries can have a large amount of pharmacies. Because of the large competition, the margins can be structurally low for pharmacies in primary and secondary care. As result, pharmacies don't have the finances to invest in innovation to meet the professional standards.
19	Are aware and actively obtain and share information about MS and PV.
20	-
21	Economic status can determine capacity to invest in MS and PV. Because of finances, a Low Income Country has more often issues improving MS and PV, than a

	High Income Country.
22	Economic status can determine capacity to invest in MS and PV. Because of finances, a Low Income Country has more often issues improving MS and PV, than a High Income Country.
23	-
24	-

5.2. Attachment: Ideal situation regarding Medication Safety in a country

This document presents the ideal situation regarding Medication Safety in a country.

The ideal situation is used to create the critical dynamics in the GIMS model.¹

For the Alfa actors the Knowledge, Attitude and Tools (KAT) model is used.²

ALPHA ACTORS

Patient and consumer^{3,4}

- Understands relevance of safe medication usage.⁵
- Understands risks and benefits if they use medication in another way than HCP proposes.⁶
- Examples of influence in medication usage:⁶
 - Culture
 - Religion
 - (Social) media
 - Family and friends
- Understands all information communicated by HCPs.^{4,7}
- Trusts HCPs in good guidance in their medication usage.^{4,6}
- Cooperates with Patient and Consumer organizations and patient initiatives.^{4,7}
- Feels well guided if they buy OTC medication of a retailer.⁵
- When a patient experiences interactions, allergies or side effects of medication, he will discuss them with HCPs.⁶
- Is health literate.⁴

Doctor^{3,4}

Knowledge:

- Education
 - About MS and pharmacovigilance (PV) and knows how to apply it in the work field.^{3,4,8}
 - Education about medication risks and the reasons why certain processes have been put in place to mitigate these risks.⁸
 - Prescribing medication (to reduce prescribing error rates).⁸
 - Communication with patients and families.⁴

Attitude:

- Understands the relevance of MS and PV.⁵
- Interprofessional collaboration (especially doctor to nurse and doctor to pharmacist)
 - Doctor, pharmacist and nurse closely involved in the medication system. The medication system includes prescribing, dispensing and administration.⁸
- Stimulates health literacy.⁴

- Active participation in PV programs.⁴
- Co-manager in the medication therapy.⁵
- Accepts pharmacist as co-manager in the medication therapy.⁵

Tools:

- Doctor is knowledgeable enough to store and evaluate ADRs en ADEs.^{5,8}
- An IT system in which patients and doctors can work:^{3,8}
 - Use on national level.
 - Use for secondary and primary care.
 - Contains patient medication history.
 - Total medication history of medication received from public and hospital pharmacies. It also contains other OTC and alternative medication.
 - All medication from birth to mortality.
 - Checks on dosage, interactions, contra-indications and allergies.
 - Doctors and pharmacists are notified if changes are made in the patient medication history.
 - Patient co-morbidity history.
 - Not documented on paper, but stored in an electronic database.
- An electronic tool for formularies.
- An electronic tool to report ADRs.
- An electronic tool for prescribing.⁸
 - Pharmacist is immediately notified if a doctor prescribes medication.
 - Interactions and side-effects must be mentioned by the tool.
- An electronic tool for pro-active searches.⁵

Pharmacist^{3,4}

Knowledge:

- Education
 - About MS and PV.^{3,4,8}
 - Education about medication risks and the reasons why certain processes have been put in place to mitigate these risks.⁸
 - Education about GDP, GMP and product quality.
 - Communication with patients and families.⁴
- Able to identify patients who actually suffer from adverse drug events (or other drug-related problems), those exposed to potential drug-related problems, and patients who may benefit from interventions aiming to maximize drug benefit, decrease drug risk, and increase cost effectiveness of the medication treatment.⁸
- Stimulates health literacy.⁴

Attitude:

- Understands the relevance of MS and PV.⁵
- Must feel main responsible about MS and PV.⁵

- Positions himself as expert on MS and PV towards society and other HCPs.
- Responsible for developing a safety culture.⁸
 - Encourages reporting errors.
 - Spreads information about MS.
 - Stimulates health literacy among population.
- Co-manager in the medication therapy.⁸
- Stimulates and participates in interprofessional collaboration.
 - Pharmacist, doctor and nurse are closely involved in the medication system.⁸
 - Provides sufficient guidelines for nurse for administration and distribution of medication, especially high-alert medication.⁸
- Responsible for safe disposal of returned medicines.⁵

Tools:

- An IT system in which patients and doctors can work:^{3,5,8}
 - Use on national level
 - Use for secondary and primary care
 - Contains patient medication history
 - Total medication history of medication received from public and hospital pharmacies. It also contains other OTC and alternative medication.
 - All medication from birth to mortality.
 - Checks on dosage, interactions, contra-indications and allergies.
 - Doctor and pharmacists are notified if changes are made in the patient medication history.
 - Patient co-morbidity history.
 - Not documented on paper, but stored in an electronic databases (IT).
 - Capacity to store information.
- An electronic tool for formularies
- An electronic tool for dispensing
 - Pharmacist is immediately notified if a doctor prescribes medication.
- Electronic tool for pro-active searches.⁵

Nurse^{3,4}

Knowledge:

- Education⁴
 - Risks of medication (usage).
 - Distribution and administration of medication.
 - Communication with patients and families.

Attitude:

- Understands the relevance of MS and PV.⁵
- Stimulates and participates in interprofessional collaboration.
 - Nurse, doctor and pharmacist are closely involved in the medication system.⁸
 - Nurse has an active role in obtaining information of doctor and pharmacist to ensure if the right medication is administered to the patient.⁵
- Stimulates a safety culture among nurses.⁸
- Stimulates health literacy.⁴
- Is knowledgeable enough to administrate medication.^{4,8}

Tools:

- Distribution and administration tool.⁸
 - Relevant information of the patient is added.
 - Which medication needs to be administered to the patient at time of administration.
 - Way of administration.

Hospitalboard⁴

Knowledge:

- Education
 - About the relevance of MS and PV.⁴

Attitude:

- Board members of hospital understand the relevance and their responsibility of improving MS and PV.⁵
- MS and PV are a points of interest.⁵
 - Hospitals have policies and guidelines on covering risks in MS.
 - Collaboration with HCP organizations and Patient and Consumer organizations.
 - Collaboration with HCPs in primary care.

Tools:

- A tool which gives board members insight in the amount of medication errors occurring in the hospital.⁵

Retailer³

Knowledge

- Education about OTC medication.³
- Education in communication with consumers and families about medication.³

Attitude

- Understands the relevance of MS and PV.⁵
- Provides consumers the right information about medication and is able to answer questions.³
- Aware of the risks of OTC medication.³

Tools

- Electronic system with information about (OTC) medication.³

BETA ACTORS

Healthcare practitioner organizations^{3,4}

- Understand the relevance of MS and PV.⁵
- Draw attention to the subjects MS and PV.³
- Develop professional knowledge and qualities of HCPs in systems and structures in MS and PV and guides them.³
- Develop best practices in MS and PV.³
- Collaboration with:³
 - Patient and Consumer organizations.
 - Government.
 - Insurance companies.
- Provide guidance and guidelines about MS and PV.³

Pharmacovigilance organization⁴

- Has the capacity and knowledge to detect ADRs and ADEs.^{4,5}
- System is adequate enough to achieve a good overview of the situation regarding PV in a country.⁴
 - Used on national level.
 - Not documented on paper, but stored in an electronic database.
 - Has the capacity to store ADRs.
 - Employees are knowledgeable enough to store and evaluate ADRs.
 - Share information with HCPs and educate them.
 - Simulates HCPs and patients to report ADRs.
- Tools to examine medication errors.⁴
- Capacity to evaluate ADRs and take further steps.⁴
- Provides guidelines on PV.⁴
- Communicates safe medication usage to HCPs and patient.⁴
- Stimulates reporting errors by HCPs and patients.⁴
- Open culture in reporting medication errors.⁴

- Promotion of safety culture among patients and consumers.⁴
- Collaboration with:^{4,5}
 - HCP organizations.
 - Patient and Consumer organizations.
 - Market authorization entities (national medicines regulatory body).
- International collaboration with:^{4,5}
 - International pharmacovigilance centres (Uppsala Monitoring Centre).
 - WHO.

National healthcare institute³

- Gives scientific guidance about MS and PV to HCPs and HCP organizations.⁵

Health care software provider^{3,4,8}

- Provides the required software and systems to maintain MS in close collaboration with HCPs.^{4,8}
- Cooperation with HCPs.^{3,4,8}

Pharmaceutical retail formula³

- Positions the pharmacist as expert on the subjects PV and MS towards society.⁵
- Provides information and knowledge about MS to retailers and pharmacists. This needs to lead to the best possible medication treatment for the patient.³
- Provides guidelines about MS for retailers and pharmacists working for the formula⁵
- Promotes a medication safety culture among patients and consumers.³

Pharmaceutical wholesaler^{3,4}

- Does not trade in counterfeit and substandard products.³
- Works according to GDP.³

GAMMA ACTORS

National medicines regulatory body⁴

- Responsible for market authorization of all medication in a country. This also includes having the authority to withdraw permits of medication of pharmaceutical companies when necessary.⁹
- Responsible for the risk assessment of medication. The registration of drugs should be based on quality, safety and efficacy.⁹
- Has the knowledge and capacity to perform its tasks.¹⁰
- Has the co-responsibility to provide legislation about MS and PV.³
- Is non corrupt.⁵
- International collaboration with for example EMA and FDA.⁵

National inspectorate³

- Understands the relevance of MS and PV.⁵
- Inspects quality and safety of medication according to national legislation.³
- Has the right and authority to intervene and take appropriate action.⁵
- Has the tools and capacity to take appropriate action.³
- Inspects if HCPs and their work processes are qualified enough to take responsibility in MS and PV according to national legislation.³
- Is sufficiently independent to act.^{5,11}
- Is non corrupt.⁵

National laboratory⁴

- Ensures the quality and safety of medication.⁴
 - There is enough capacity to sustain the laboratories.
 - There is enough practical knowledge to perform their tasks.
 - Laboratory workers are knowledgeable enough to perform their tasks.
- Is non corrupt.⁵

Ministry of Health³

- Understands the relevance of MS and PV.⁵
- Supports stakeholders to invest in MS and PV.³
- Develops legislation which describes HCPs as the only ones authorized to provide medication therapy to patients.³
- Develops legislation about the role of HCPs in authorizing medication.³
- Stimulates research and education on academia about MS and PV.⁵
- Collaboration with all other stakeholders.³
- Collaboration with international organizations like.e.g. the WHO, FIP, EMA.⁵

Academia⁴

- Understand the relevance of MS and PV.⁵
- The systems and structures of MS and PV are implemented in curricula of healthcare students.^{4,8}
- Stimulate education about MS and PV.^{4,8}
- Stimulate research about MS and PV.⁴
- Collaboration with:^{4,5}
 - Government.
 - HCP organizations.
 - Student associations.

Patient & Consumer organization⁴

- Understands the relevance of MS and PV.^{3,4}
- Involves patients in medication safety initiatives by informing patients about MS and PV.⁴
- Collaboration with:⁴
 - HCP organizations.
 - Government.

Pharmaceutical industry^{3,4}

- MS and PV are a point of interest.⁴
- They have shared responsibilities in safe medication usage and understand their responsibilities.^{3,6}
- Battle counterfeit medication, substandard products and corruption.^{3,5}
- No influence on HCPs on prescribing and dispensing, only on a scientific level.³
- Have strong internal guidelines and act accordingly.⁴
- Collaboration with other stakeholders.⁴

Insurance body and/or company³

- Understands the relevance of MS and PV.⁵
- Acknowledges shared responsibilities in MS and PV.³
- Collaboration with HCP organizations.⁵

International bodies (entities)^{3,4}

- Understand the relevance of MS and PV.⁴

WHO¹²

- Advising role in legislation and policy making in a country. Cooperates with the government.³
- Cooperates with national pharmacovigilance centers to report ADRs.⁴
 - One of the main objectives is to facilitate the identification of rare incidents of medicine-related problems in clinical practice that were not identified during the pre-marketing development phase of a medicine.
- Provides management systems:¹³
 - Where all workers (including front-line staff, physicians and administrators) accept responsibility for the safety of themselves, their co-workers, patients and visitors.
 - That prioritize safety above financial and operational goals.
 - That encourage and reward the identification, communication, and resolution of safety issues.
 - That provide organizations to learn from accidents.
 - That provide appropriate resources, structure, and accountability to maintain effective safety systems.

The World Alliance for Patient Safety¹⁴

- Provides patient safety education and training.
- Collaboration with:
 - HCP organizations.
 - Government.

International society of pharmacovigilance¹⁵

- Provides training about PV.
- Stimulates research about PV.
- Improves best practices considering MS and PV.

Supra national entities, for example:

European Union (European council)¹⁶

- Supports stakeholders to invest in MS and PV.
- Develop legislation about MS and PV
 - Quality of medication.
 - GMP and GDP incorporated in legislation.
 - National use of medication.
- Collaboration with international organizations like the WHO, FIP and EMA.

East African Community¹⁷

- Understands relevance of MS and PV.
- Develops policies about MS and PV.
- Improves best practices considering MS and PV.
- Collaboration with international organizations like WHO, FIP and EMA.
- Collaboration with Ministries of Health of countries part of the East African Community.

DELTA FACTORS

National medicines and healthcare legislation³

- The national medicines and healthcare legislation should include:^{3,5,18}
 - Distinction between OTC medication and medication on prescription.
 - Responsibilities of HCPs in MS and PV.
 - Trade in medication.

- Market access of medication.
- Ones authorized to prescribe medication.
- Ones authorized to distribute medication.
- Implementation of WHO guidelines about MS and PV.

Technology^{3,4,8}

- Software tools and hardware conditions must reach the required standard to execute MS.⁸
- Use of technology in the healthcare system by HCPs in primary and secondary care.⁸
 - In prescribing, dispensing, distributing and administrating.
 - Medication history of patients.
 - Co-morbidity history of patients.
 - Formularies and background information of medication.

Culture¹⁹

- In some countries alternative medicines have a big influence on the medication therapy. Not only do they follow the prescription by the doctor, but sometimes they also take alternative medicines for the same indication. Society should be critical in the use of alternative medication and know the risks in using these medicines.^{5,19}
- The use of alternative medicines must be monitored. HCPs must be knowledgeable enough about alternative medication to guide patients in the use of these medicines.^{5,19}
- Society should know more about the risks of medication, to achieve a safe medication therapy. It should make society more critical about use of medication.^{5,19}
- Patients have a more close relationship and trust in family and friends than with HCPs. Family and friends can say or show patients motives to change the medication therapy recommended by HCPs. Family and (close) friends must have no negative influence in the medication usage of the patient.^{5,19}

Religion⁵

- In some cases patients reject medication because of their religion. Examples are not using medication by day during Ramadan, or not accepting blood transfusion. A HCP has the responsibility to clearly explain the patient the risks and benefits if he considers rejecting medication because of his religion.⁵

Economics³

- No financial ties between HCPs.^{3,5}
 - No prescription bonuses for doctors. Industry must have no influence.
 - No personal economic motives of HCPs concerning prescribing and dispensing.
- If the margins are low for pharmacies in primary and secondary care, less space is left to invest in innovation. Innovation must be stimulated, whether the margins are high or low.³

Politics³

- Is aware of the risks of medication.³
- Government recognizes MS and PV as relevant topics to invest in.³
- Makes policies about MS and PV.³

Stability and prosperity of a society³

- Society has enough money to invest in MS and PV.⁵

Media³

- Restrictive legislation for advertising medication.³

Abbreviations:

ADR – Adverse drug reactions

EMA – European Medicines Agency

FIP – International Pharmaceutical Federation

GDP – Good Distribution Practice

GMP – Good Manufacturing Practice

HCPs – Healthcare practitioners. This includes doctors, nurses and pharmacists.

IT – Information Technology

MS – Medication Safety

OTC – Over-the-counter

PV – Pharmacovigilance

WHO – World Health Organization

Bibliography

1. Document GIMS model
2. Spring Nutrition. The KAP Survey Model. <https://www.spring-nutrition.org/publications/tool-summaries/kap-survey-model-knowledge-attitudes-and-practices>. Updated: 2011. Accessed: 28-08-2016.
3. World Health Organization, Geneva(1997). Public-private roles in the pharmaceutical sector: Implications for equitable access and rational drug use (<http://apps.who.int/medicinedocs/pdf/whozip27e/whozip27e.pdf>). Accessed: 03-08-2016.
4. World Health Organization, France(2014). Reporting and learning systems for medication errors: the role of pharmacovigilance centers (http://apps.who.int/iris/bitstream/10665/137036/1/9789241507943_eng.pdf). Accessed: 13-07-2016.
5. Authors: Aradhana Kohli, BSc and Richard van Slobbe, MSc.
6. World Health Organization. Patient Safety Curriculum Guide(2011). (http://apps.who.int/iris/bitstream/10665/44641/1/9789241501958_eng.pdf). Accessed: 27-08-2016.
7. World Health Organization (2013). Patient Safety. (http://www.who.int/patientsafety/patients_for_patient/WHA2013_briefing-note.pdf). Accessed: 30-08-2016.
8. Mansur J. Medication Safety Systems and the Important Role of Pharmacists. Drugs Aging. 2016; 33:213–21.
9. World Health Organization. Assessing national medicines regulatory systems. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/assessment/en/. Updated: 2016. Accessed: 29-08-2016.
10. World Health Organization (1999). National drug regulatory legislation. http://www.who.int/medicines/technical_briefing/tbs/National_drug_regulatory_legislation_Annex8TRS885_en.pdf). Accessed: 29-08-2016
11. Inspectie voor de gezondheidszorg. <http://www.igz.nl/>. Updated: 2016. Accessed: 27-08-2016.
12. World Health Organization. <http://www.who.int/en/>. Updated: 2016. Accessed: 27-08-2016.
13. World Health Organization, Geneva (2004). Looking at the Pharmacovigilance: ensuring the safe use of medicines. (http://www.whqlibdoc.who.int/hq/2004/WHO_EDM_2004.8.pdf). Accessed: 29-08-2016.
14. World Health Organization. World Alliance for Patient Safety. <http://www.who.int/patientsafety/worldalliance/en/>. Updated: 2016. Accessed: 29-08-2016.
15. International Society of Pharmacovigilance. <http://isoponline.org/>. Updated: 2015. Accessed: 29-08-2016.
16. European Commission. Patient Safety. http://ec.europa.eu/health/patient_safety/policy/index_en.htm. Updated:2016. Accessed: 29-08-2016.
17. East African Community. Health. <http://www.eac.int/sectors/health>. Updated: 2016. Accessed: 29-08-2016.
18. World Health Organization(2012). Chapter 6 Pharmaceutical regulations and legislation. (<http://apps.who.int/medicinedocs/documents/s19583en/s19583en.pdf>). Accessed: 25-08-2016.
19. Alhomoud,F, Dhillon S, Aslanpour Z, Smith F. South Asian and Middle Eastern patients' perspectives on medicine-related problems in the United Kingdom. International Journal of Clinical Pharmacy. 2015;37: 607-15