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RESEARCH ARTICLE

A Centralized Automated System of Monitoring Adverse Events of Medications- "Medreminder"

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Abstract

Research Objective

To develop and test the methodology of the centralized automated system of monitoring adverse events of medications in the Republic of Kazakhstan.

Research Tasks

- The analysis of the existing practice of monitoring adverse events of medication in the Republic of Kazakhstan, the identification of problems and the directions to improve the situation.
- Testing the models of an automated system collecting information about adverse events of medications and the evaluation of effectiveness of the developed system collecting information about adverse events of medications, identifying patients/consumers' roles of Kazakhstan medical products in the system of pharmacovigilance.

Keywords: *pharmacovigilance, monitoring the safety of medications, patients, consumers, monitoring adverse events, "yellow card", consumer reporting.*

Introduction

The primary method in the work of almost all departments monitoring the safety of medicines in all countries is the method of spontaneous messages, where appropriate regulatory measures can be taken based on the analysis. The importance of information from patients is underestimated. The World Health Organization (WHO) and the European commission acknowledge the role of consumers in the spontaneous messages. [1].

Consumers, patients and their organizations are becoming increasingly involved in pharmacovigilance, especially when it comes to the transmission of information about risks. [2,3]. Since 2012, the WHO has periodically been publishing recommendations to create a system of "consumer reporting", some countries use the term "patient messages" but "consumer messages" is a broader term. Currently, in an increasing number of countries, for example Australia, Canada, India, the Netherlands, Sweden, the UK and the USA, patients/consumers are becoming increasingly involved in pharmacovigilance, especially when it comes to the transmission of information about over-the-counter (OTC) medical products. In three studies [4, 6] the situation was assessed when the patients reported by using questionnaires, interviews or phone calls to the national regulatory authorities in different countries.

The global trend of health development is closely linked with the development of IT. There is an active process of introduction of new information and communication technologies, which allow simplifying the interpretation between a doctor and a patient significantly. The smart medicine evolution is becoming the main trend of the industry development. Presently, health authorities in 44 countries emphasize the importance of spontaneous messages on adverse reaction to

some medicines and the need for more accessible reporting system [7]. According to the new European legislation (Directive 2010/84 EC), the member states have to create for their patients a reporting system of adverse reactions to medicines. Therefore, the application of "e-health" might be a convenient method for closer cooperation among a patient, a doctor and the authority of pharmacovigilance [8]. The modern level of state of the society and the economy is characterized by the dynamic development and introduction of new information technologies in all spheres of activities.

Informatization as a process of introducing new information technologies, means of collection, transmission, storage and processing the information is a necessary prerequisite and one of the main directions of the state program called "digital Kazakhstan" [9]. In accordance with tha approved Decree of the President of the State health development program of the Republic of Kazakhstan "Densaulyk" for 2016- 2019, informatization of the health care industry will be developing. This confirms the relevance of IT introduction in healthcare industry in general and, in particular, in pharmacovigilance, where active application of IT will enable to organize the data and provide an opportunity for deeper analysis of the frequency of adverse reactions occurrence as well as gender, age and other characteristics in a given time period. The formation of a single information space and the provision of competent authorities with reliable and timely information require a transition to a new level of organization of work in this direction. Despite the existence of legislative acts in the pharmacovigilance field in Kazakhstan, there is a number of problems such as low detection, registration and information transmission about the adverse events.

Since 2013, the centre of pharmacovigilance and monitoring the adverse events of medications, which is a structural subdivision of «National Centre for Expertise of medicines, medical devices and medical equipment», has received 110077 card messages about the side effects of medicines. More detailed information by years is shown in Table 1. According to National Centre for Expertise of medicines, medical devices and medical equipment the following numbers of occurrence of adverse events were revealed during the reporting period 2013-2017: 2013 -1784, 2014-1669, 2015-1916, 2016-2675, 2017-3033.

Table 1: Comparative analysis of retail sales RX/OTC medications to incoming data about adverse events of the medicines [10]

	2013	2014	2015	2016	2017
The audit of retail sales of medical products in Kazahstan.	541 418 902	541 418 902	541 418 902	541 418 902	541 418 902
The number of received card-messages about the side effects of medicines	1784	1669	1916	2675	3033

One of the reasons of low activity of collecting information about adverse events is the lack of an integrated information system for all participants of the monitoring adverse events, as well.

In Kazakhstan, despite a notable progress in the health sphere such as modern IT implementation, the establishment of a number of portals, the improvement of computer equipment provision, some developed and implemented web-applications focused on single issues of funding and management of the healthcare system. It is necessary to structure the existing portals and sites. The aim of the study is to increase the detectability of information about adverse events by involving all the participants of the pharmaceutical market: healthcare specialists, pharmacists and patients.

The analysis of the current situation in healthcare indicates the need to improve the system of collecting data to detect adverse events of medications in pharmacovigilance system and it also shows the lack integrated information system for all the participants of the monitoring [11]. Given the above written, the optimal solution for collecting data from patients is to develop a mobile application.

One of the functions of the application is to inform a doctor about patient's health condition after taking the medicines. Another function is to remind patients to take medicines. "Med Reminder" application was

installed by those patients who were involved in the research. The market of mobile operational systems, which are more frequently used in Kazakhstan, was carefully researched to choose the platform of programming language.

The Android operational system takes 74, 37% of the market share, iOS- 22, 73% and others- 2, 9% [12]. So, the mobile application "Med Reminder" was developed for those mobile devices with Android and iOS operational systems. The web-portal "MedReminder.kz" functioned as an informative portal, where any participant of the research might acquaint with basic information about pharmacovigilance system, its aims and objectives.

Results

The Evaluation of the Effectiveness of the Monitoring System in the Performance of Active Pharmacovigilance in the Republic of Kazakhstan

There has been a survey of doctors and patients done between 2017 and 2018 to study the awareness of the safety of medications and pharmacovigilance, where 75 doctors took part in the research.
The respondents of the doctors were divided into two groups:

- The first group of 35 doctors who used the mobile application
- The second control group of 40 doctors who didn't use the mobile app.

For those doctors who used the application and the web-portal, the questionnaire was presented twice: before they started using the app and a month later. All the patients and doctors were informed about pharmacovigilance by using the app. For those who didn't use the application, the survey was presented in a printed form once only. Both groups of the respondents didn't have any time limits to fill in the form. There was created a 10-question survey for doctors who allowed evaluating basic knowledge on key issues in the operation of the pharmacovigilance system the doctors were surveyed in hospitals and clinics.

Among the respondents, there were 44 women (65%) and 31 men (41%) aged from 35 to 66 (on average aged 49, 5±18, 4), Table 2. An electronic database was created to process the survey results, where all the information from the questionnaires was introduced. The analysis of the survey results was performed using methods of descriptive statistics and applying the software package Microsoft Excel 2010, including Likert scale [13], using Google forms of the file hosting Google Disk. The results are introduced as mean values and standard deviations (μ±σ), absolute values and the percentage values. More details can be found in Table 3.

Table 2: The categorization of the respondents among the doctors by gender and age

Age	Group using the app, n=35				Control group, n=40				Total number of participants, n=75			
	female	male	total	%	female	male	total	%	female	male	total	%
30-40	3	2	5	14	2	2	4	10	5	4	9	12
41-50	10	7	17	48	12	9	21	52	22	16	38	50
51-60	8	5	13	38	9	6	15	38	17	11	28	38
Total	21	14	35	100	23	17	40	100	44	31	75	100

Table 3: The results of survey of the doctors

Вопрос		Before using the mobile app			After using the mobile app			Control group		
1. Reporting about adverse events is a part of the duties of medical worker	**Score**	**n=35**	**%**	**points**	**n=35**	**%**	**points**	**n=40**	**%**	**points**
Completely agree	5				20	57	285			
Agree	4	30	86	344	17	43	172	37	92	368
Difficult to answer	3	5	14	42				3	8	24
Disagree	2									
Completely disagree	1									
Total score				386			457			392

Вопрос		Before using the mobile app			After using the mobile app			Control group		
2. Do you think that consumers have to participate independently in reporting about adverse events of medications?	**Score**	**n=35**	**%**	**Points**	**n=35**	**%**	**Points**	**n=40**	**%**	**Points**
Completely agree	5				16	46	230			
Agree	4	29	83	332	19	54	216	35	87	348
Difficult to answer	3	6	7	21				5	13	39
Disagree	2									
Completely disagree	1									
Total score				353			446			387
3. Reporting about adverse events is important to show to patients that their problems are taken seriously.	**Score**	**n=35**	**%**	**Points**	**n=35**	**%**	**Points**	**n=40**	**%**	**Points**
Completely agree	5				16	46	230			
Agree	4	27	77	308	19	54	216	32	80	320
Difficult to answer	3	8	23	69				8	20	60
Disagree	2									
Completely disagree	1									
Total score				377			446			380
4. Is it necessary to warn patients about possible adverse events when a doctor prescribes medication?	**Score**	**n=35**	**%**	**Points**	**n=35**	**%**	**Points**	**n=40**	**%**	**Points**
Completely agree	5	31	88	440	31	88	440	36	90	450
Disagree	4	4	12	48	4	12	48	4	10	40
Difficult to answer	3									
Disagree	2									
Completely disagree	1									
Total score				488			488			490
5. Do you consider the information about pharmacovigilance important?	**Score**	**n=35**	**%**	**Points**	**n=35**	**%**	**Points**	**n=40**	**%**	**Points**
Completely agree	5				17	49	245			
Agree	4	29	83	332	15	43	172	38	95	380
Difficult to answer	3	6	17	51	3	8	24	2	5	15
Disagree	2									
Completelty disagree	1									
Total score				383			441			395
6. Is it necessary to receive information about pharmacovigilance in the form of conference meetings, seminars or the visits of medical representatives?	**Score**	**n=35**	**%**	**Points**	**n=35**	**%**	**Points**	**n=40**	**%**	**Points**
Completely agree	5				12	34	170			
Agree	4	33	94	376	21	60	240	38	95	380
Difficult to answer	3	2	8	24	2	6	18	2	5	15
Disagree	2									
Completely disagree	1									
Total score				400			428			395

Questions			Control group
	Before using the mobile application	After using the mobile application and web-portal	

Questions	Before using the mobile application	After using the mobile application and web-portal	Control group
7. Which of the following definitions in your opinion fully characterizes the meaning of pharmacovigilance of medical products?			
The monitoring, analysis and evaluation system about the safety of registered medicines (the right answer)	3/8%	35/100%	2/5%
The system of monitoring patients, who take registered medications	17/49%		17/42%
The system which defines the effectiveness of registered medicines	15/43%		21/53%
Interpretation: In general, doctors are ill-informed about the pharmacovigilance system. The awareness has improved after using the application and portal.			
8. Which of the following definitions in your opinion fully characterizes the meaning of an adverse event?			
An organism reaction related to taking medicines and assuming at least the existence of a possible correlation with the use of the alleged medicines (the right answer)	18/51%	35/100%	21/53%
Any effect of the medicines, emerging while taking them in igher doses and due to the physic-chemical properties of the active substances	17/49%		19/47%
Interpretation: In general, doctors are ill-informed about the pharmacovigilance system. The awareness has improved after using the application and portal.			
9. Which of the following organizations in your opinion is responsible for monitoring the safety of medications?			
Control Committee of medical and pharmaceutical actions Health Ministry of the Repulic of Kazakhstan.	17/49%		21/53%
«National Centre for Expertise of medicines, medical devices and medical equipment » (the right answer)	15/43%	35/100%	17/42%
МЗ РК	3/8%		2/5%
Interpretation: In general, doctors are ill-informed about the pharmacovigilance system. The awareness has improved after using the application and portal.			
10. Who in your opinion has to report about the adverse events of medications?			
A doctor	17/49%		19/47%
A nurse			
A pharmacist			
A pharmaceutical company	18/51%		21/53%
All the above (the right answer)		35/100%	
11. Have you ever faced with the information about adverse events of medications received from your patients?			
Yes	35/100%	35/100%	35/100%
No			
Interpretation: All groups of respondents say they have had such an experience			
12. Point out the problems you faced with while reporting			
Not enough information for a message	2/6%		4/10%
The reporting form is complicated to fill in	7/20%	8/23%	10/25%
I do not know how and where to report	2/6%		2/5%
I am afraid of legal responsibility for reporting about adverse events	7/20%		8/20%
No motivation to report	7/20%	11/31%	6/15%
Others	10/28%	16/46%	10/25%
Interpretation: In general, doctors are ill-informed about the pharmacovigilance system. The awareness has improved after using the application and portal.			

The Interpretation of the Research Results

The analysis of the responses of the researched groups before and after using the application demonstrates an increase in the level of in formativeness of doctors about the pharmacovigilance system and the need to train the workers of healthcare system. During the research, the doctors were interviewed to identify the advantages and disadvantages of the mobile application.

It was noted that regular reporting from patients informed promptly about the course of the disease and allowed to make corrections immediately upon identification adverse events. In general, wariness in relation to the timely identification of adverse events increased during treatment, especially while outpatient treatment. That is due to the fact that while the deferred examination and monitoring a patient forgets or does not attach the importance to episodes of poor health.

The Results of the Survey of Patients

The study of in formativeness on the safety issues of medications and pharmacovigilance was done with the patients, as well. 142 patients from medical organizations in Almaty took part in the research, which was done between 2017 and 2018.

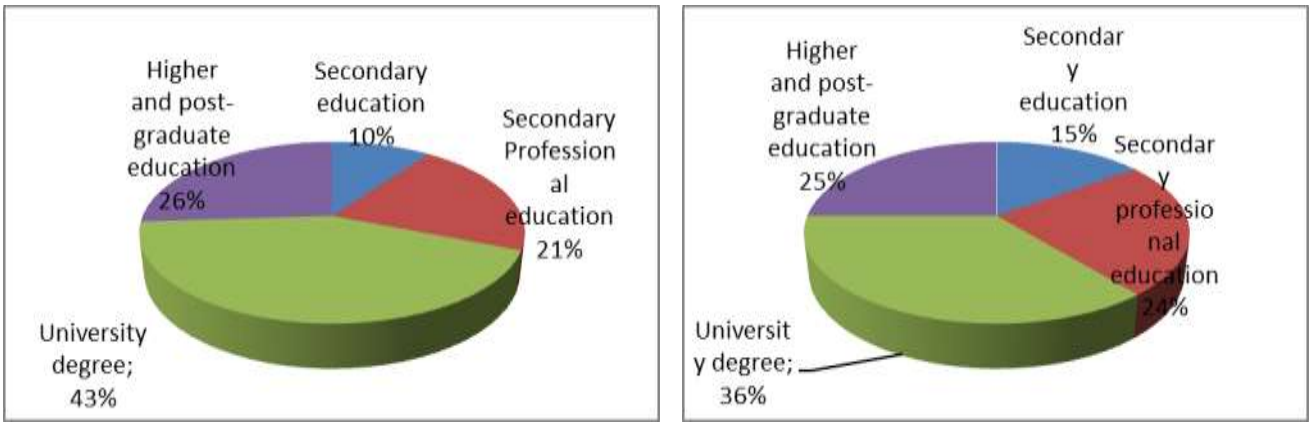
The research was done by questioning two groups of patients:

- The first group of 67 patients who were using the mobile application;
- The second group of 75 patients who were not using the mobile application

The patients were characterized by gender, age and the level of education; more details can be found in Table 4, pictorial 1.

Table 4: The categorization of the patients by gender and age

Age	Group using the application, n=67				Control group, n=75				Total number of participants, n=142			
	female	male	total	%	female	male	total	%	female	male	total	%
21-30	2	4	6	9	4	3	7	9	6	7	13	9
31-40	13	17	30	45	20	16	36	48	33	33	66	47
41-50	10	8	18	27	11	10	21	28	21	18	39	27
51-55	7	6	13	19	6	5	11	15	13	11	24	17
Total	32	35	67	100	41	34	75	100	73	69	142	100



The level of education of the test group, n=67 **The level of education of the control group, n=75**

Pictorial 1: The level of education of the patients

The analysis of the respondents' answers to the question "Do you always read the instruction for medical use of products before you have taken them?" showed that the opinions of both control group and research group before using the mobile application were quite comparable with a greater percentage response in both groups was "Sometimes", with 41% and 37% respectively.

Having used the application, the percentage of the answer "Always" reached 48% in the research group. The respondents' answers to the question "Do you follow prescriptions from a doctor on how long to take the medicines?" also revealed that the opinions of both control group and research group before using the mobile application was within an average of 30%.

Having used the application, the percentage of the definitely positive answer "Yes" rose up to 52% in the research group. The respondents' answers to the question "Do you follow the prescriptions from a doctor on when to take the medicines: before or after meals?" showed that the percentage of the answers in control group and research group before using the mobile application was "Not always", with 41% and 37% respectively. ; "It depends"- 34% and 33%. Having used the application, the percentage of the definitely positive answer "Yes" increased to 43% in the research group. The analysis of answers to the question "Do you ever forget to take medicines at the appropriate time?" indicated the dynamics in the direction of an increase from 28% to 46%.

The analysis of the respondents' answers to the question "Have you ever faced with any adverse events of medicines?" showed that the number of positive answers went up from 22% to 31%. The question "Who do you think have to report about side effects of medicines?" provides evidence for the lack of patients' awareness on the problem of pharmacotherapy safety, which also rose after having used the mobile application. The answers to the question "Do you think that patients have to take part in the reporting about side effects of medicines?" demonstrated high interest in both of the groups and ranged from 44% to 53%.

The analysis of the respondents' answers to the question "Which means of communication do you prefer to report about adverse events of medicines?" revealed that most of the patients from both of the groups prefer using the mobile phone. It showed that 36%- in the control group, while in the research group 57 % (before using the application) and 66 % (after using the application.

The Interpretation of the Study Results

In general, the results of the survey demonstrate the lack of patients' awareness and a high level of interest in safety issues of pharmacotherapy. After the survey and using both, the mobile application and the web portal, the situation has generally improved. The mobile application has had a good effect upon commitment to treatment from patients.

For example, the answer "Yes" to the question "Do you always follow doctors' prescriptions on how long to take medicines?" after using the mobile application increased to 52%. Another example is that the answer "Yes" to the question "Do you always follow doctors' prescriptions on when to take medicines (before or after meals)?" showed a higher percentage after using the application in the research group and rose up to 43%. All the above indicates that the app "Med Reminder" is found to be a good platform for doctor-patient-communication.

The Results of the Survey of the Patients to Identify the Commitment of the Treatment

The selection criteria of the patients was a verified diagnosis, the availability of all laboratory and instrumental results, receiving medical therapy at least a month before the study and informed consent for the study.

The research included the observation of two groups of patients:

- The first group of 25 patients who were using the mobile application.
- The second control group of 20 patients who were not using the application.

The patients are categorized by gender and age, which is shown in Table 5.

Table 5: The categorization of the patients by gender and age

Age	Group using the application, n=25				Control group, n=20				Total number of participants, n=45			
	female	male	total	%	female	male	total	%	female	male	total	%
21-30	0	1	1	4	0	0	0	0	0	1	1	2
31-40	6	2	8	32	5	3	8	40	11	5	18	40
41-50	5	3	8	32	4	2	6	30	9	5	12	27
51-55	5	3	8	32	4	2	6	30	9	5	14	31
Total	16	9	25	100	13	7	20	100	29	16	45	100

All patients were specially surveyed and questioned; moreover, careful consideration was given to all the data from clinical-laboratory and instrumental research. During the survey, the following data, not related to the disease, was collected: gender, age, marital status, residence, education, occupation and experience in long-term use of medicines in case of chronic diseases in anamnesis. Every participant of the research was assigned to have a unique two-digit number, which matched the patient's serial number in the centre.

All the patients included in the research were registered in the research centre; the registered data included a serial number of a patient, the date of inclusion in the study and other information. Both, the patients of the research group and the doctors installed the mobile app. They were also regularly informed about the aims of the research, the opportunities of using the app and pharmacovigilance service in Kazakhstan.

Both groups of patients filled in the questionnaire during the appointments, including Morisky-Green test [14]. Morisky-Green scale of compliance is a clinical and psychological testing methodology, which is traditionally used for a preliminary assessment of compliance and screening identification of the patients who are not compliant enough in routine medical practice. It includes 4 questions:

- Have you ever forgotten to take your medication? ("Yes"- 0 points, "No"- 1 point)
- Are you sometimes careless about the time when to take medicines? ("Yes"- 0 points, "No"- 1 point)
- Do you miss taking medicines if you are feeling well? ("Yes"- 0 points, "No"- 1 point)
- If you are feeling unwell or worse after you have taken medicines, do you miss the following medication? ("Yes"- 0 points, "No"- 1 point)

The mobile application "Med Reminder", which was installed by the first research group, reminded patients when to take their medications prescribed by a doctor.

A testee reported about his health and reaction to the medication every day with a help of the reminder app. That report went to the email of electronic portal and then in its turn was sent to the doctor. The observation period lasted for 3 months; according to the research protocol, every testee had to visit the doctor at least 3 times during the observation:

- The first visit was considered to be medical examination, familiarization with the research program, the signing of the informed consent and the consent for personal data processing.
- The next visit was supposed to be 10-14 days later, where the patient's condition was assessed by the doctor then, if necessary, the correction of treatment and, finally, questioning the testee according to Morisky-Green test.

The information about patient's condition, which was received by a doctor, was represented in a patient's record book. In the analysis of clinical and anamnestic data, the following characteristics were taken into account: the duration of medication intake, the number of tablets taking a day and the relation to meals. During the research, the doctors were interviewed to identify the advantages and disadvantages of the mobile application and to resolve technical failures, as well.

The Interpretation of the Study Results

The low compliance was defined as the answer "Yes" to 1 or more questions, whereas, the high compliance was defined as the answer "No" to every question. Compliant patients were considered to be those who got 4 points. Those who got 2 points and less were considered to be incompliant. The patients who got 3 points were not considered to be compliant enough and were allocated to a group at risk of incompliance development. The compliance of the patient to the treatment was determined as the degree of compliance to medical recommendations to change the lifestyle, regular visits to a doctor and taking prescribed medications, Table 6.

Table 6: The results of testing patients according to Morisky-Green method

Research group, n -25				Control group, n -20			
1st visit	2nd visit	3rd visit	p	1st visit	2nd visit	3rd visit	p
1,8+0,9	2,5+0,1	3,9+0,2	<0,05	1,9+0,8	2,0+0,3	2,9+0,2	<0,05

It was noted that on the background of the treatment there was a significant increase in compliance in both of the groups. However, in the research group there was a more dramatic change in the answers.

Conclusion

The analysis of the current situation in healthcare system in the Republic of Kazakhstan points out the need for improvements to the information collection system, the detection of adverse events of medications in pharmacovigilance system and the need to form the integrated informational system for all the participants of the monitoring of advert events.

The received data testifies to insufficient level of doctors' awareness on the problem of pharmacotherapy safety and the reporting system about adverse reactions to medicines. The low level of registering data about detected adverse reactions is connected with the lack of information about them, the lack of time and in certain cases with the fear of administrative measures. The comparative study of two groups of doctors and two groups of patients shows that using the system not only allows to inform them, but to increase the involvement of both, doctors and patients, in pharmacovigilance system. In general, the received data testifies to insufficient level of doctors' awareness on the problem of pharmacotherapy safety and the need of educational events among doctors and patients on pharmacovigilance issues. It is also assessed that there was a contribution of the mobile application in the formation of compliance to treatment from patients.

The analysis of the results and doctors' interviews showed that during the study, patients who used the application became more careful about following the regime for medications intakes, doctor's prescriptions and sending information about health, which allows making such a conclusion about formation of compliance to treatment and an increase in patients' responsibility. In general, using the mobile application involves both, doctors and patients, as active participants in pharmacovigilance system.

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