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HISTORY ARTICLE

Institutional Pharmacovigilance Center at *Hospital General de México Dr. Eduardo Liceaga*

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The *Hospital General de México Dr. Eduardo Liceaga* (HGM) was 101 years old when, in February 2006, on the instructions of Dr. Francisco Higuera Ramírez, director of our hospital, Dr. Octavio Amancio Chassín was asked to create the Institutional Pharmacovigilance Center, as an institutional need, to obtain the hospital certification granted by the General Health Council, which at that time, it was an essential requirement to guarantee patient safety and provide quality care and thus, belong to the National Program for the Certification of Health Establishments.

To establish the Institutional Pharmacovigilance Center, a series of strategies were programmed, supported by the Official Mexican Standard NOM-220-SSA1-2002, Installation and Operation of Pharmacovigilance[1], published on November 15, 2004, which established the mandatory guidelines in Mexico for the detection, registration, evaluation and prevention of adverse reactions to drugs and vaccines, guaranteeing the safety and efficacy of drugs and vaccines and the Guide for the installation and operation of an Uppsala Monitoring Pharmacovigilance Center[2].

The Institutional Pharmacovigilance Center was established in unit 204, special studies, and according to the guidelines for the facility, it was incorporated into the QFB. Silvia Naranjo Rosales and, later, in August 2006, nurse Petra Ortega Cedillo. At present, the center is located in the clinical pharmacology service, unit 405 E.

The second strategy consisted of establishing an interaction with the National Center for Pharmacovigilance, which at that time was directed by Q. Carmen Becerril Martínez, who served as executive director of pharmacopoeia and pharmacovigilance. From the first contact, Q. Becerril supported the formation of the Institutional Pharmacovigilance Center at the HGM, mainly in the strategy of training health professionals.

The next activity consisted of developing the data collection format to be able to obtain information on adverse drug reactions (ADRs) produced in patients and implementing the tactics to be followed for the identification of ADRs in the different services and units. With the support of NOM 220, the fundamental information to obtain quality notification was established: patient data, suspected adverse reaction, medication, concomitant pharmacotherapy, and medical history (SSA-03-021. Report of possible ADRs).

To identify ADRs in the hospitalization area, it was determined that it was necessary to personally visit the different services or units of our hospital, asking the doctor or nurse responsible about the presence of ADRs in patients, identified during the visit and maintain a permanent telephone line, where the health personnel would report the suspicion of ADRs and immediately the center staff would go to collect the information corresponding.

With the support of the National Pharmacovigilance Center, through Q. Carmen Becerril and her work team: LFs. Yenny Medecigo Hernández, Karla Félix, Mireya Salinas, and the collaboration of the QFB. Juana Leticia Rodríguez and Betancour, Dr. Miguel Gómez, and

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Dr. César Misael Gómez Altamirano, training courses were given (one every 6 months) aimed at doctors and nurses of the HGM. The first was held from 17 to 19 May 2006, with the attendance of 80 health professionals, the second from 15 to 17 November 2006 with 60 participants, and the third in May 2007 with 83 attendees. Subsequently, at least one refresher course was incorporated for undergraduate interns, medical specialist residents, nurses, patients, and patients' relatives. The training courses are theoretical and practical, where clinical cases of patients with ADRs are presented, and the suitability or not of reporting ADRs and their relevance to patient safety are discussed. The importance of obtaining all the information from the antimicrobial resistance (AMR) notification is highlighted, especially about the medicine (generic name, distinctive name, producing laboratory, batch number, expiry date, and reason for prescription).

Always with the objective of sensitizing health personnel to inform about the presence of adverse reactions to drugs, contrast media, biotechnology, and vaccines and to generate the culture of reporting adverse reactions to drugs in health professionals and emphasizing that it is the doctor and nurse of the Institutional Center of the HGM who will collect information from patients who present adverse reactions to drugs to prepare the corresponding notification.

It should be noted that on May 24, 2006, 5 days after the end of the course, the Institutional Pharmacovigilance Center received the first notification of a therapeutic inefficacy of calcium gluconate lactate, 500 mg tablets, in a 36-year-old patient, post-operative: total thyroidectomy, parathyroidectomy, and radical neck dissection for papillary thyroid cancer, which required calcium replacement to prevent hypocalcemia. The second notification was made on 25 May 2006, when the 35-year-old patient developed a generalized rash following intravenous administration of trimethoprim sulfamethoxazole.

From the first notification in May 2006 to December 2025, the Institutional Pharmacovigilance Center has maintained the notification of adverse reactions to drugs, contrast media, biotechnological, and vaccines to the National Pharmacovigilance Center (CNF); so far, a total of 4,700 spontaneous reports or adverse events have been reported and, adding the number of adverse reactions presented by patients, some with two or more symptoms or syndromes, a total of 10,096 adverse reactions are obtained (Table 1). The notification of AMRs was maintained even in the H1N1 (2009) and COVID-19 (2020-2022) flu pandemics, with all the difficulties involved in the sanitary measures that were implemented for each of the services and units of the HGM. In the years in which fewer notifications are observed, it is due to the decrease in health professionals who left the Institutional Center due to retirement, in 2013, the retirement of the QFB. Silvia Naranjo, and in 2017, the nurse Ortega Cedillo. Fortunately, in that period, the MC. Maritza Martínez Venegas was incorporated into the pharmacovigilance activities; in 2018, the nurse Mireya Velázquez Zarco; in 2023, the nurses Ma. Guadalupe Cruz Aguilar and Verónica González Chávez and QFI. Massiel M. Marquez Pulido; and in 2024, the LF. Yazmin N Neri Sánchez and the nurse Ernestina Martínez Mendoza.

Table 1. Number of notifications and adverse reactions sent to the National Pharmacovigilance Center by the Institutional Pharmacovigilance Center of the *Hospital General de México Dr. Eduardo Liceaga*

Year	No. patients	No. adverse reactions
May 24-December 31, 2006	151	307
January-December 2007	366	845
January-December 2008	207	342
January-December 2009	163	298
January-December 2010	338	643
January-December 2011	313	672
January-December 2012	230	495
January-December 2013	180	362
January-December 2014	214	463
January-December 2015	254	552
January-December 2016	288	673
January-December 2017	171	378
January-December 2018	257	467
January-December 2019	258	525
January-December 2020	178	406
January-December 2021	100	208
January-December 2022	134	363
January-December 2023	203	519
January-December 2024	321	716
January-December 2025	374	862
Total notifications	4,700	10,096

Table 2. Group of drugs responsible for adverse reactions reported by the Institutional Pharmacovigilance Center of the *Hospital General de México Dr. Eduardo Liceaga*

Group	Patients		Adverse reactions	
	No.	%	No.	%
Antineoplastics	1,331	28.3	3,813	37.8
Antimicrobials	988	21.0	1878	18.6
Algology	487	10.4	948	9.4
Contrast media	568	12.1	936	9.3
Ophthalmology	319	6.8	649	6.4
Gastroenterology	189	4.0	378	3.7
Cardiology	113	2.4	225	2.2
Endocrinology	119	2.5	218	2.2
Nervous system	89	1.9	146	1.4
Anesthesiology	78	1.7	133	1.3
Urology	73	1.6	118	1.2
Hematology	53	1.1	108	1.1
Vaccinations	36	0.8	101	1.0
Allergology	58	1.2	71	0.7
Corticosteroids	35	0.7	68	0.7
Psychiatry	41	0.9	65	0.6
Nutrition	20	0.4	49	0.5
Pneumology	22	0.5	43	0.4
Obstetrics-gynecology	19	0.4	43	0.4
Rheumatology	19	0.4	41	0.4
Electrolytes	20	0.4	26	0.3
Dermatology	3	0.1	9	0.1
Immunosuppressants	5	0.1	8	0.1
Others	15	0.3	22	0.2
Total	4,700	100.0	10,096	100.0

Table 2 shows the groups of drugs that cause the highest number of adverse reactions; first, antineoplastic drugs, with 1,331 (28.3%) of patients and 3,813 (37.8%) of adverse reactions; Within this group, we find drugs such as paclitaxel (5.7%), 5-fluorouracil (5.6%), cisplatin (2.4%), etoposide (2.1%), oxaliplatin (1.6%), carboplatin (1.6%), doxorubicin (1.0%), L asparaginase (0.7%), ifosfamide (0.9%), and methotrexate (0.9%). In the second place, antimicrobials with 988 (21.0%) of notifications and 1,878 (18.6%) of ADRs, where the following are identified: ciprofloxacin (4.5%), ceftriaxone (4.1%), vancomycin (2.3%), clindamycin (1.2%), and metronidazole (1.1%). Contrast media presented 568 (12.1%) spontaneous reports and 936 (9.3%) adverse reactions, with iopromide (4.3%), iopamidol (2.9%), and iobitridol (2.1%) being the most frequent cases and in the fourth place, the analgesic group with 487 (10.4%) of patients and 948 (9.4%) of notifications, where tramadol (1.6%), lysine clonixinate (1.4%), and paracetamol (1.1%) stand out from this group (Table 3).

Table 3. Drugs with the highest number of adverse reactions and notifications reported to the National Pharmacovigilance Center

Generic name	Patients		Adverse reactions	
	No.	%	No.	%
Paclitaxel	269	5.7	883	8.7
5 fluorouracil	265	5.6	755	7.5
Sodium fluorescein	311	6.6	620	6.1
Ciprofloxacin	212	4.5	458	4.5
Ceftriaxone	191	4.1	363	3.6
Iopromide	204	4.3	329	3.3
Cisplatin	114	2.4	303	3.0
Etoposide	98	2.1	239	2.4
Oxaliplatin	74	1.6	215	2.1
Iopamidol	134	2.9	209	2.1
Carboplatin	76	1.6	207	2.1
Vancomycin	108	2.3	189	1.9
Tramadol	76	1.6	171	1.7
Iobitridol	98	2.1	162	1.6
Doxorubicin	47	1.0	134	1.3
L-Asparaginase	35	0.7	121	1.2
Rituximab	39	0.8	121	1.2
Ifosfamide	43	0.9	108	1.1
Sildenafil	66	1.4	107	1.1
Clindamycin	56	1.2	105	1.0
Lysine clonixinate	68	1.4	105	1.0
Clobenzorex	57	1.2	105	1.0
Methotrexate	40	0.9	102	1.0
Metronidazole	50	1.1	99	1.0
Paracetamol	54	1.1	89	0.9
Others	1,915	40.7	3,797	37.6
Total	4,700	100.0	10,096	100.0

It should be noted that sodium fluorescein, a diagnostic medium used for retinal fluorangiography, occupies the third position among the drugs with 311 (6.6%) reports and 619 (6.1%) of ADRs. In addition, table 3 identifies two drugs that presented adverse events during bioequivalence studies in the clinical pharmacology service: sildenafil with 1.4% and clobenzorex with 1.2% of notifications.

On the other hand, the hospital's Institutional Pharmacovigilance Center participated as a pilot center for the implementation of the 2010 notification system for the capture of adverse reaction notifications implemented by the National Pharmacovigilance Center, which allowed all the notification information to be entered: report data, the patient, the suspected ADR, suspicious drug, concomitant medications, medical history, and assessment

of ADRs (causality, severity, severity of symptoms, quality of information and frequency of adverse reactions) and their subsequent referral to the CNF. The 2010 reporting system generated a database that made it possible to analyze the adverse reactions that occurred in the Institutional Center.

Since January 2020, the Institutional Pharmacovigilance Center of the HGM has been integrated into the Vigiflow Monitoring system of the Uppsala Center through the National Pharmacovigilance Center, where the notification is entered directly into the database, after the evaluation of the suspected adverse reaction and the subsequent review of the CNF. The Vigiflow system uses the MedDRA medical dictionary to code adverse reactions and thus harmonize information internationally. At present, 1310 adverse reactions have entered the Vigiflow system from January 2020 to December 2025. All of them meet the quality standards required for submission to the Uppsala Monitoring Center.

20 years after the formation of the Institutional Pharmacovigilance Center, it has established itself as a center that promotes the detection, identification, quantification, evaluation, and prevention of possible risks derived from the use of drugs, contrast media, biotechnology, and vaccines administered to patients; in addition, to establish the probable causal relationship between the drugs and the adverse reaction. The Institutional Center has regularly and permanently established itself as a unit that notifies the National Pharmacovigilance Center in a timely manner, through the Vigiflow system of the Uppsala Monitoring Center, always maintaining the quality standards of notifications of ADRs.

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Conflicts of interest

The author declares no conflicts of interest.

Ethical considerations

Protection of human subjects and animals. The author declares that the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation and with the World Medical Association and the Declaration of Helsinki. The procedures were authorized by the Institutional Ethics Committee.

Confidentiality, informed consent, and ethical approval. This study does not involve personal patient data, medical records, or biological samples and does not require ethical approval. SAGER guidelines do not apply.

Declaration on the use of artificial intelligence. The author declares that no generative artificial intelligence was used in the writing or creation of the content of this manuscript.

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