



APEAS Study: Patient Safety in Primary Care in the Spanish Healthcare System



GOBIERNO
DE ESPAÑA

MINISTERIO
DE SANIDAD
Y POLÍTICA SOCIAL

Patient Safety Strategy of the Spanish National Health System

Plan de Calidad
para el Sistema Nacional
de Salud



APEAS Study

Cross-sectional observational study

Objectives:

- Estimate the prevalence of AEs in PC
- Analyse the factors contributing to the emergence of AEs
- Identify the barriers for patient safety among PC professionals



Sample:

- Convenience sample
- 16 Health Regions: 48 Primary care centres
- 452 Professionals: 251 GPs, 49 paediatricians, 152 nurses
- 96.047 patient visits

Inclusion criteria:

- PC centres were selected through regional experts
- Healthcare teams: at least 3 GPs, 1 paediatrician, 1 nurse



Methodology

- Period studied:
 - Two weeks in June 2.007
- Subjects:
 - All patients seen, for any reason, by the PC teams in the healthcare centres selected.
- Result variables:
 - Patient safety incidents (near misses and AEs) and preventable AEs.
- Determinations:
 - Frequency of AEs
 - Proportion of preventable AEs.

Case definition

- **Patient safety incident:**

An event or circumstance which could have resulted, or did result, in unnecessary harm to a patient.

- **Near miss:** an incident that did not cause harm
- **Adverse event (AE):** an incident which has resulted in harm to a patient and is identified during patient visit

- **Preventable adverse event:**

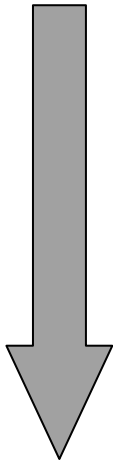
An AE which the professional regards to be avoidable in the particular set of circumstances



Relationship with Medical Attention

Harm or complication assessed by the PC professional as ≥ 2 on a 1 to 6 scale:

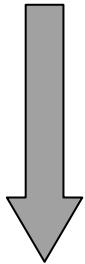
1. No evidence of relationship with attention.
2. Minimal probability.
3. Minor probability.
4. Moderate probability.
5. High probability.
6. Total evidence.



Preventable adverse event

Harm or complication assessed by the PC professional as ≥ 4 on a 1 to 6 scale:

1. No evidence of preventability
2. Minimal probability.
3. Minor probability.
4. **Moderate probability.**
5. **High probability.**
6. **Total evidence of preventability**



Severity

Severe AE:

Causes death, permanent or long term harm or requires surgery

Moderate AE:

Causes hospital stay of at least 1 day (degree 2)
Requires emergency or specialist visit (degree 1)

Minor AE:

Harm or complication with none of the former consequences

Tools

Restablecer formulario Imprimir formulario

ENEAS II
Atención Primaria

Cuestionario de notificación de Incidentes y EA

Datos del centro
Tipo de centro
 Urbano Rural

Datos del paciente:
Caso:
Edad:

Señale el efecto que se produjo en el paciente:

Relacionados con un procedimiento

Hemorragia o hematoma relacionadas con intervención quirúrgica o procedimiento
 Quemadura (relacionada con sondaje)
 Trastorno circulatorio (férula muy ajustada)
 Ausencia de suturas
 Abscesos
 Infección timpánica

Relacionados con infección nosocomial

Infección de herida quirúrgica y/o traumática
 Infección asociada a sondaje
 Infección asociada a dispositivo
 Infección oportunista por tratamiento inmunosupresor
 Infección de úlcera por presión
 Neumonía por aspiración

Relacionados con los cuidados

Lesión por presión
 Quemaduras, erosiones y contusiones (incluyendo laceraciones consecuentes)
 Lesión de cólico por inyectables
 Otras consecuencias de la inmovilización prolongada

Relacionados con la medicación

Náuseas, vómitos o diarrea secundarios a medicación
 Hipotensión por fármacos
 Prurito, rash o lesiones dérmicas reactivas a fármacos o apósitos
 Cefaleas por fármacos
 Alteraciones neurológicas por fármacos
 Neutropenia
 Hemorragia digestiva alta (relacionada con la medicación)
 IAM, AVC, TEP, TVP
 Hemorragia por anticoagulación
 Desequilibrio de electrolitos
 Alteración del ritmo cardíaco o actividad eléctrica por fármacos
 Agravamiento de la función renal
 Insuficiencia cardíaca y shock
 Dolor por ausencia de medicación

Otros

Evolución más tórpida de enfermedad de base
 Otro EA:
 Ningún efecto

¿Qué es lo que se podría haber hecho para resolver este problema?

APEAS

Estudio sobre la seguridad de los pacientes en atención primaria de salud

ESTUDIO ENEAS II



Para descargar el programa Apeas v1.0 por favor pulse [aquí](#)

Materiales de apoyo del estudio :

1. [Formulario](#)
2. [Manual](#)
3. Presentaciones:
 1. [Seguridad del paciente](#)
 2. [Estudio de Efectos Adversos ligados a la Atención Primaria](#)
 3. [Casos prácticos](#)
 4. [Ejemplos](#)
- 4.- A su juicio, ¿hay alguna evidencia de que el EA se podría haber evitado?
- 5.- Valore en una escala de 6 puntos la evidencia de posibilidad de prevención:
 - 1 Ausencia de evidencia de posibilidad de prevención
 - 2 Mínima posibilidad de prevención
 - 3 Ligera posibilidad de prevención
 - 4 Moderada posibilidad de prevención
 - 5 Elevada posibilidad de prevención
 - 6 Total evidencia de posibilidad de prevención

IDENTIFICACION DE EFECTOS ADVERSOS EN ATENCIÓN PRIMARIA

CENTRO DE SALUD

Sistema de Información para la Vigilancia y Control de Efectos Adversos



APEAS

Entrar

Salir

APEAS Versión 1.0 - Mayo 2007



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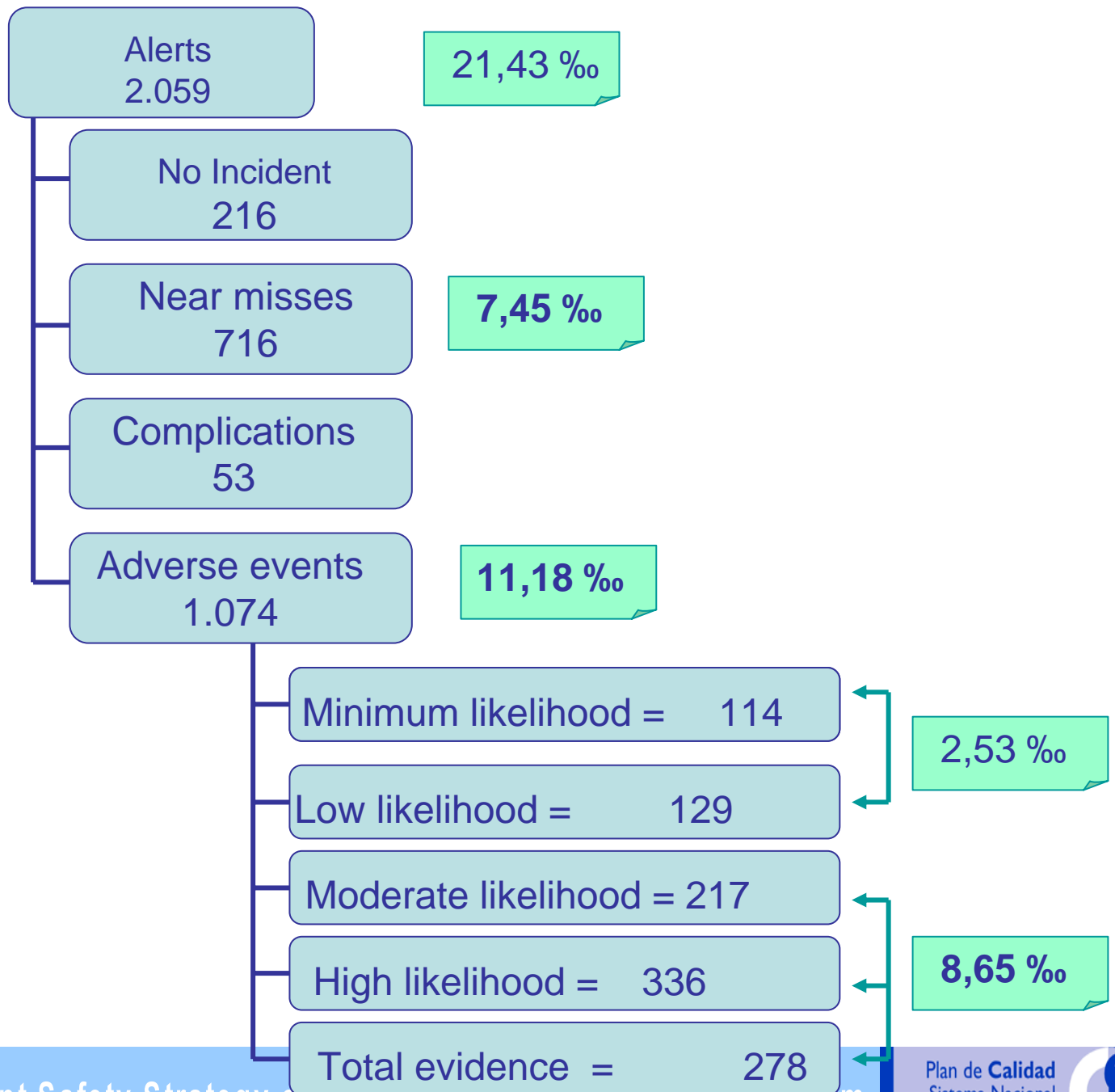
Patient Safety Strategy

salud

Results: denominator

Professional	Number of professionals	Number of visits
GP	251	61.049
Nurse	152	25.436
Paediatrician	49	9.563
Total	452	96.047

96.047 visits



Prevalence per professional level

Professional	Patients with AE	Visits	Prevalence ‰	CI 95‰
GP	632	61.049	10,35	9,55 - 11,16
Nurse	293	25.436	11,52	10,21 - 12,83
Paediatrician	46	9.563	4,81	3,42 – 6,20
Total	971	96.047	10,11	9,48 - 10,74



Types of AEs

	n	%
Connected with medication	530	47,8%
Worse evolution of original disease	221	19,9%
Associated with procedures	118	10,6%
Healthcare-associated infections	93	8,4%
Others	74	6,7%
Care-related	72	6,5%
Total	1.108	

Types of AE per professional level

Type of AE	GP	Nurse	Paediatrician
Connected with medication	395 57,3%	109 29,8%	26 49,1%
Worse evolution of original disease	161 23,4%	43 11,7%	17 32,1%
Associated with procedures	44 6,4%	73 19,9%	1 1,9%
Healthcare-associated infections	37 5,3%	31 8,5%	26 11,3%
Others	35 5,1%	57 15,6%	1 1,9%
Care-related	17 2,5%	53 14,5%	2 3,8%
Total	689	366	53



Causal factors

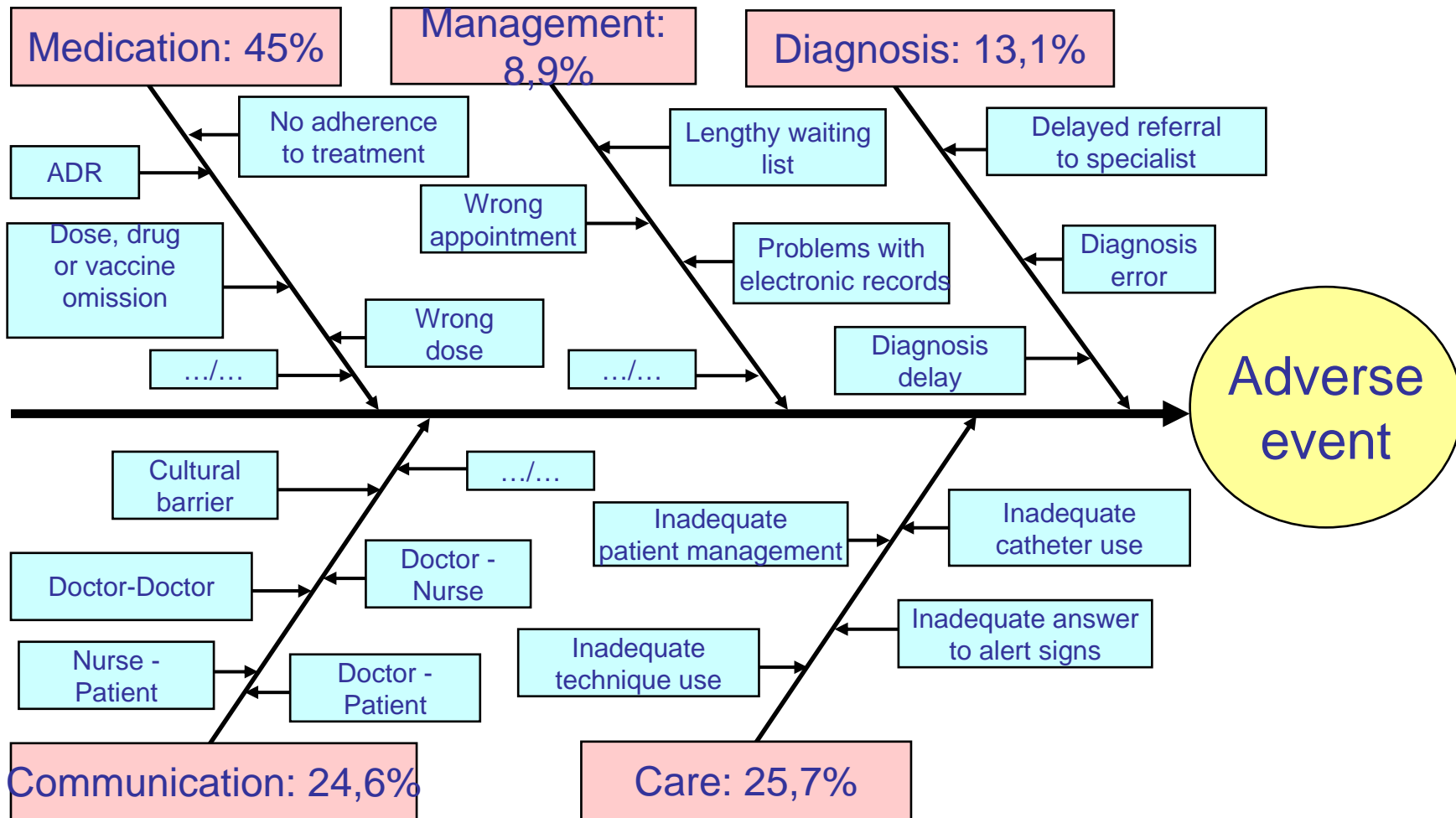
Causal factors of AE	GP	Nurse	Paediatrician
Connected with medication	406 58,90%	103 28,10%	25 47,20%
Associated with communication	179 26,00%	80 21,90%	14 26,40%
Care-related	102 14,80%	175 47,80%	8 15,10%
Associated with the diagnosis	100 14,50%	34 9,30%	11 20,80%
Other causes	71 10,30%	77 21,00%	11 20,80%
Associated with management	66 9,60%	31 8,50%	2 3,80%
Total	671 97,4%	357 97,5%	52 98,1%

Care-related AEs

Type of AEs	n	%
Care-related	72	6,5%
Pressure ulcers	38	3,4%
Burns, grazes, falls and bruises (including the resultant fractures)	18	1,6%
Other consequences from a lengthy immobilization	10	0,9%
Phlebitis	6	0,5%



Causal factors



Medication-related causes

	n	%
Connected with medication	534	48,20%
ADR	288	26,0%
Wrong dose	58	5,2%
No adherence to treatment	53	4,8%
Dose, drug or vaccine omission	52	4,7%
Wrong drug	43	3,9%
Drug interaction	39	3,5%
Wrong frequency of administration	30	2,7%
Wrong treatment length	30	2,7%
Inadequate monitoring	21	1,9%
Wrong patient	14	1,3%
Preparation or handling error	11	1,0%

* There can be more than one related factor

Care-related causes

	n	%
Care-related	285	25,70 %
Inadequate patient management	136	13,7%
Inadequate technique use	103	10,4%
Inadequate answer to alert signs	89	8,9%
Inadequate catheter use	6	0,6%

* There can be more than one related factor



Communication-related causes

	n	%
Associated with communication	273	24,60%
Doctor-patient communication	166	15,0%
Nurse-patient communication	54	4,9%
Doctor-doctor communication	40	3,6%
Other communication factors	34	3,1%
Cultural barrier	25	2,3%
Language barrier	18	1,6%
Doctor-nurse communication	9	0,8%

* There can be more than one related factor



Diagnosis-related causes

	n	%
Other causes	159	14,40 %
Diagnosis delay	83	7,5%
Diagnosis error	47	4,0%
Delayed referral to specialist	34	3,0%



Management and organization-related causes

	n	%
Management and organization related	99	8,90%
Lengthy waiting list	59	5,3%
Wrong appointment	24	2,2%
Problems with electronic records	12	1,1%
Health information mistake	6	0,5%
Patient identification mistake	3	0,3%



AE original healthcare context

Type of AE	PC centre	Specialized care	Pharmacy	Total
Associated with procedures	63 54,3%	53 45,7%	0	116 10,7%
Healthcare associated infections	58 63,0%	34 37,0%	0	92 8,5%
Care- related	51 72,9%	19 27,1%	0	70 6,4%
Connected with medication	441 85,0%	74 14,2%	4 0,8%	519 47,7%
Other	187 64,3%	103 34,7%	3 1,0%	291 26,7%
Total	800 73,5%	281 25,8%	7 0,7%	1.088

*There are 20 cases with no information of origen.

AE severity

Type of AE	Minor	Moderate	Severe	Total
Connected with medication	341 64,3%	159 30,0%	30 5,7%	530 47,8%
Worse evolution of original disease	107 48,4%	100 45,2%	14 6,3%	221 20,0%
Associated with procedures	61 57,1%	46 39,0%	11 9,3%	118 10,6%
Healthcare-associated infections	34 36,6%	50 53,8%	9 9,7%	93 8,4%
Others	39 52,7%	30 40,5%	5 6,8%	74 6,7%
Care-related	24 33,3%	36 50,0%	12 16,7%	72 6,5%
Total	606 54,7%	421 38,0%	81 7,3%	1.108

Impact of AE

Care received as a result of AE	EA	%
No effect on healthcare received	262	23,6 %
Higher observation and monitorization in PC	367	33,1 %
Additional tests (radiography, analysis,..) in PC	83	7,5 %
Additional treatment or surgery (antibiotics, minor surgery...) in PC	190	17,1 %
New visit or referral to Specialized care or Emergency care	276	24,9 %
Hospitalization: life support care	64	5,8 %

Preventability

Type of AE	n	Preventability	Preventability Moderate+Severe
Connected with medication	530	59,1%	66,1%
Worse evolution of original disease	221	82,8%	82,5%
Associated with procedures	118	79,7%	80,7%
Healthcare-associated infections	93	79,6%	83,1%
Others	74	83,8%	88,6%
Care-related	72	72,2%	77,1%
Total	1.108	70,2%	76,1%

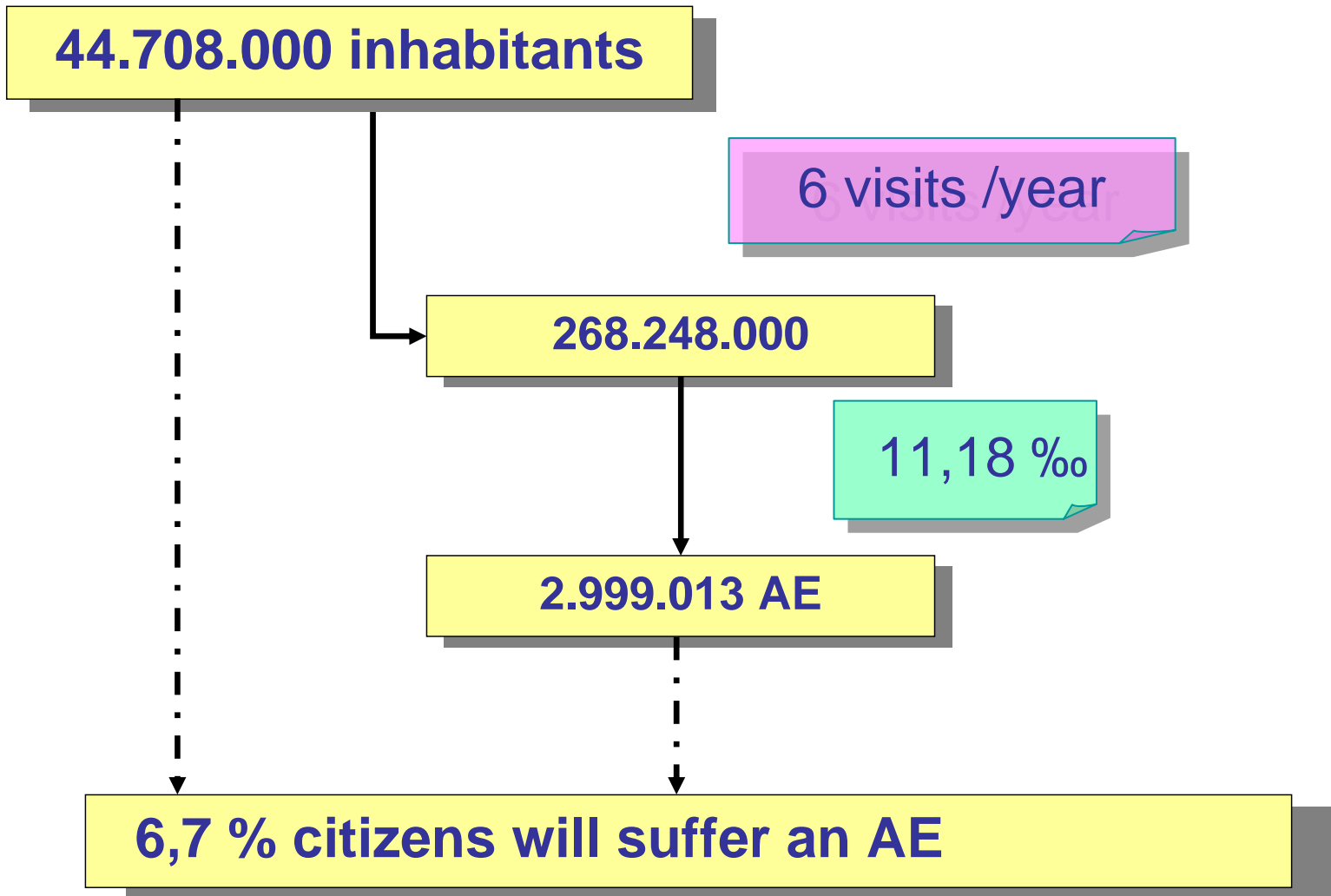


Preventability

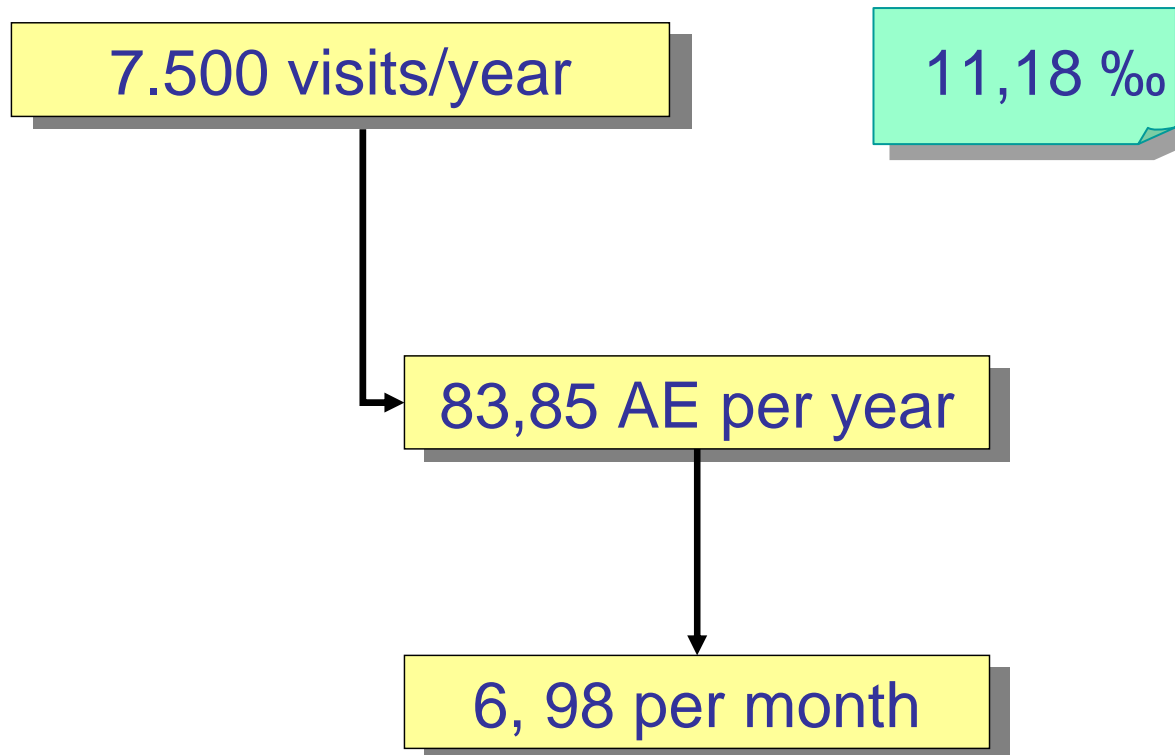
Type of AE	GP	Nurse	Paediatrician	Total
Associated with procedures	75,0	82,2	100,0	79,7
Healthcare associated infection	74,3	82,5	100,0	79,6
Care-related	70,6	73,6	50,0	72,2
Connected with medication	58,0	64,2	53,8	59,1
Worse evolution of original disease	81,4	86,0	88,2	82,8
Other	83,8	87,1	66,7	83,8
Total	67,1	76,5	67,9	70,2
p	<0,001	0,007	0,234	<0,001



Impact on population



Impact on professionals



Conclusions and lessons learned

- ✓ Primary healthcare is safe: low occurrence rate and low severity of AE
- ✓ Multicausality: factors associated with medication use, communication, management and patient care
- ✓ Most frequent AE: connected with medication, worse evolution of original disease, associated with procedures, care-related and healthcare infections
- ✓ One quarter of AEs required no additional care, one quarter required referral to specialist services and the other half was directly resolved at the PC level.



Conclusions and lessons learned

- ✓ Prevention of avoidable AEs in PC must be prioritized
- ✓ AE prevention strategies in PC are effective: high number of patient visits and high preventability
- ✓ Multicausality demands a multifaceted and a systemic approach to effectively improve Patient Safety
- ✓ APEAS represents a diagnosis of the situation in the Spanish healthcare system and opens up a line of research and initiatives development



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Castro N, Cayuela I, Chico J, Ciria C, Clavería AM, Cloquell B, Cobano C, Cobo R, Codina A, Conde MCP, Conesa P, Corrales D, Cruz A, Cuerno Y, Cumbreiras MA, Curto C, Cutillas A, de Benito H, de Benito V, de Casas X, de Felipe M, de la Cal A, de la Figuera E, De la Puebla P, de Miguel A, de Scal I, del Campo A, del Castillo M, del Dedo P, Delgado M, Díaz J, Díaz JA, Diego L, Dierssen T, Diez MA, Diez MJ, Donoso R, Duran C, Echarri MJ, Eguiluz M, Esain MJ, Escobar C, Escobar M, Esparza R, Espel C, Esquisábel R, Esteban O, Farrés X, Feijoo C, Fernández Buergo A, Fernández Calderón E, Fernández Castro M, Fernández Cuadrillero C, Fernández de la Mota E, Fernández Hernandez JA, Fernandez Hernández MJ, Fernández Julia, Fernández Lago MR, Fernández Martín J, Fernández Pérez MA, Fernández Pro V, Fernández Taní MJ, Fernández Valverde A, Fernando J, Ferrer AC, Ferrer FJ, Filloy E, Flores A, Fraile M, Gaisan C, Galindo J, Gallardo D, Gallego P, Gallés M, Galván A, García Aparicio JM, García 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Herrero ML, Herrero T, Hornilla G, Huertas JA, Ibarrondo I, Imbernón C, Iragui I, Irazabal L, Iruyoyen V, Iruzubieta MI, Jaraba M, Jiménez E, Jiménez L, Jiménez MC, Jordan J, Jover S, Juárez F, Jurado M, Lacaba V, Laguillón Y, Lahoz MJ, Laviada B, Leal M, Ledesma A, León MC, Lezaun MD, Limón R, Liñero A, Lizarraga C, Lizcano G, Llàrenda Y, Lliver E, López JL, López MJ, Lorenzo MJ, Loscos J, Lostal I, Lozano C, Lozano Quijada C, Luaces A, Maestro N, Magaña JE, Manrique MV, Mantecon JF, Marcé E, Marcos MP, Marín J, Marín MD, Martín C, Martín F, Martín J, Martín MA, Martín MC, Martín MT, Martínez Bretones R, Martínez Ceballos A, Martínez de Zuñiga A, Martínez Lao MT, Martínez Larios A, Martínez Martínez LM, Martínez Milián JA, Martínez Ochoa E, Martínez Pascual I, Martínez Porcel AJ, Martínez Saenz MJ, Martínez Villalba MJ, Mas JV, Massó P, Mateos C, Mateos M, Matilla C, Mayoral J, Medel E, Medrano R, Meléndez J, Mena P, Méndez M, Mendia JL, Mendiguren MA, Meneu R, Merino S, Milán F, Millan ML, Millaruelo JM, Mingo M, Minogorance L, Mintegui I, Miralles JJ, Moleiro A, Montalvo N, Morales MJ, Moreno P, Moreno RM, Moreno V, Moris J, Munárriz MP, Muñoz JC, Muñoz R, Muñoz S, Murcia JL, Murillo C, Muro E, Najjar M, Navarro S, Nieto A, Ocete I, Ocio C, Olias E, Oliver R, Olivera R, Oliveros P, Ordoño J, Orive JM, Ortega P, Ortuño P, Osés F, Palacio F, Pardo A, Pardo B, Pardo C, Pardo I, Paredes J, Pascual T, Peinado A, Peña JA, Peralta F, Pereda L, Pérez Díaz T, Pérez F, Pérez Gimenez A, Pérez Hernández AI, Pérez Martínez JS, Pérez Navarro A, Pérez Nicolás A, Pérez Rodríguez A, Pérez Sánchez S, Pérez Vázquez A, Pérez Villarroya JC, Pérez-Crespo C, Pericas P, Pertusa S, Plaza A, Polo MA, Postigo C, Praena M, Priede MI, Puente M, Puertas J, Quesada E, Quintero LM, Rabell MV, Ramos A, Ramos E, Raquejo C, Reig E, Reimúndez JA, Requena J, Requena M, Reus L, Rey M, Ricarte F, Ricci MA, Rivero C, Roca E, Rodríguez Fabre MJ, Rodríguez L, Rodríguez Pulido I, Rodríguez Samaniego LC, Rodríguez Semper V, Rodríguez Virginia, Roldan J, Romeo J, Romero S, Royo C, Rubal T, Rubio C, Ruiz E, Ruiz E, Ruiz J, Ruiz JL, Ruiz L, Ruiz-Zorrilla I, Saiz A, Sáiz N, Salas F, Salcedo JA, Salinas MT, San Nicolás EM, Sánchez Benitez MA, Sánchez de las Matas MJ, Sánchez Librán MA, Sánchez López MI, Sánchez Marqués V, Sánchez Martín A, Sánchez Ortiz FJ, Sánchez Villar R, Sandoval MC, Santamaría E, Santamaría P, Santoro E, Santos J, Santos JC, Sanz P, Sanz R, Sanz X, Sebastián R, Sellers E, Serna MJ, Serradell M, Sirvent MC, Sobrino T, Sola AB, Suárez M, Sukia G, Tafalla M, Tapia A, Tejera E, Tobías E, Toribio C, Torralba L, Torres V, Tosao A, Toscano B, Trabada E, Tremps R, Triana L, Trinidad R, Trullas G, Turienzo N, Unceta L, Valbuena S, Valdeperez J, Valverde S, Vaquero E, Vara LA, Varela JC, Varela JC, Vargas ME, Vargas R, Vázquez F, Vázquez P, Vecín JC, Velasco C, Velasco MT, Vercher E, Verde F, Verdes-Montenegro JC, Verdú I, Villalba C, Villanueva JM, Villanueva R, Vinyoles E, Vitaller C, Vitaller M, Yetano JM.