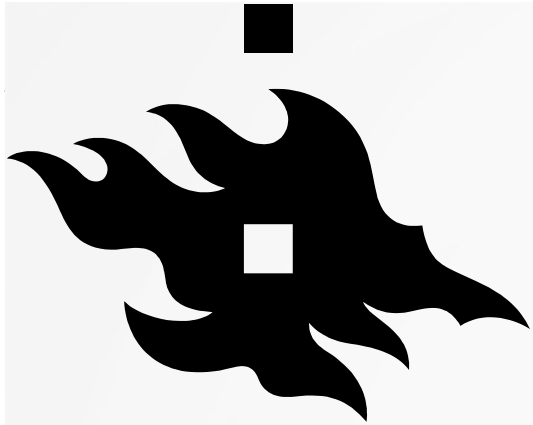


A photograph of a modern, brightly lit waiting area. The room features a grid of large windows that provide a view of the outdoors. Several people are seated in a row of chairs, facing away from the camera towards the windows. The chairs are in various colors, including red, grey, and dark blue. The ceiling is a white, perforated metal grid with recessed lighting fixtures. The overall atmosphere is clean, bright, and professional.

INVOLVE PATIENTS IN IMPROVING THEIR CARE!



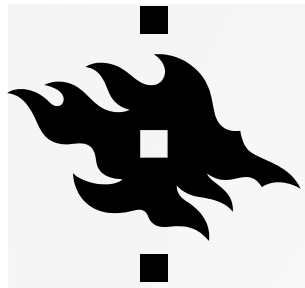
INVOLVE PATIENTS IN IMPROVING THEIR CARE!

PATIENT REPORTING IN PHARMACOVIGILANCE

Pedro Barroso Inácio, PhD

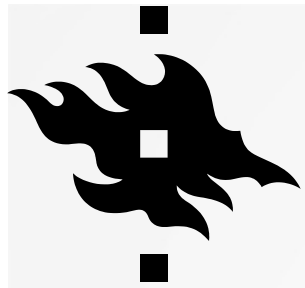
Clinical Pharmacy Group

Division of Pharmacology and Pharmacotherapy



CONFLICT OF INTEREST - DISCLOSURE

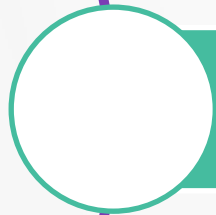
- Affiliated with Contract Research Organization PPD
- Views and information displayed are personal and do not hold PPD liable



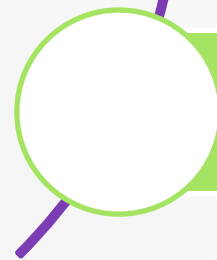
LEARNING QUESTIONS



Can patients identify adverse drug reactions?



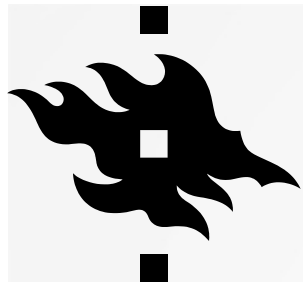
Can patients contribute with meaningful information to pharmacovigilance?



Are there barriers preventing patient from reporting?



60° 10 1.2 N, 24° 57 18 E



PHARMACOVIGILANCE: KEEPING THE PATIENT SAFE

Before

YellowCard It's easiest to report online at www.yellowcard.gov.uk MHRA

SUSPECTED ADVERSE DRUG REACTIONS

If you suspect an adverse reaction may be related to one or more drugs (or combination of drugs), please complete this YellowCard. One YellowCard should be used for each reaction. Do not be afraid of reporting adverse drug reactions. The more you report, the better we can protect patients.

PATIENT DETAILS Name (last, first, middle initials) Sex (M, F) Ethnicity Weight (kg) Age (years) Identification number (e.g. Your Practice or Hospital Ref)

SUSPECTED DRUGS (VACCINES) Drug/Vaccine (Brand Name) Batch Name Dose Date started Date stopped Periodicity

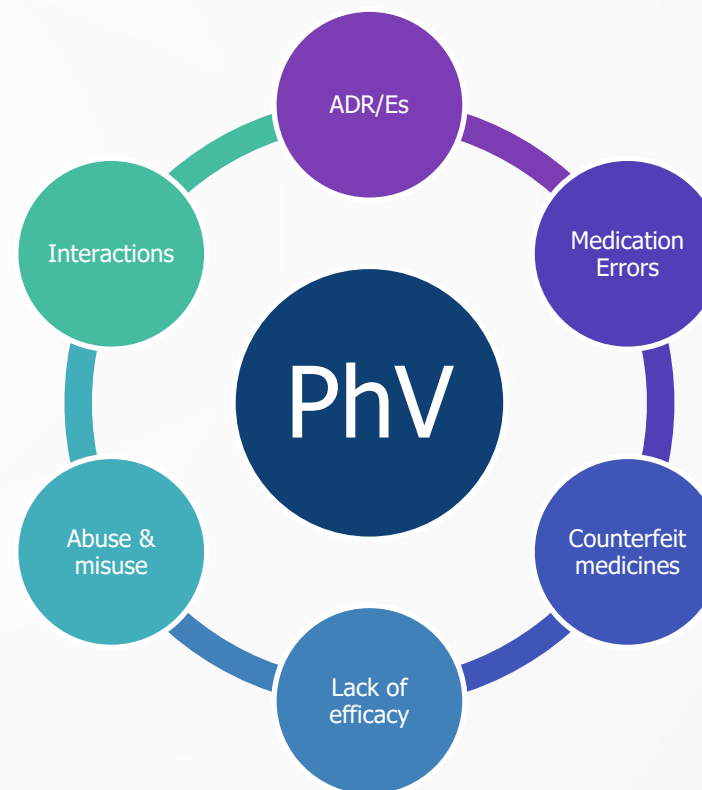
SUSPECTED REACTIONS(S) Please describe the reaction(s) and any treatment given. Outcome: Recovered, Resolving, Continuing, Other

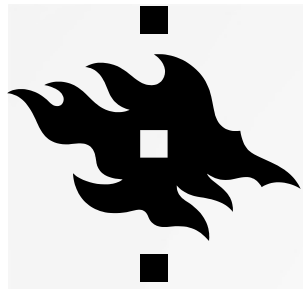
Date reaction started: Date reaction stopped: Do you consider the reaction to be serious? Yes/No If yes, please indicate why the reaction is considered to be serious (please tick all that apply): Fatal and/or life threatening, Hospitalized or prolonged hospitalization, Life threatening, Congenital abnormality, Medically significant, please give details.

Nowadays



Scope



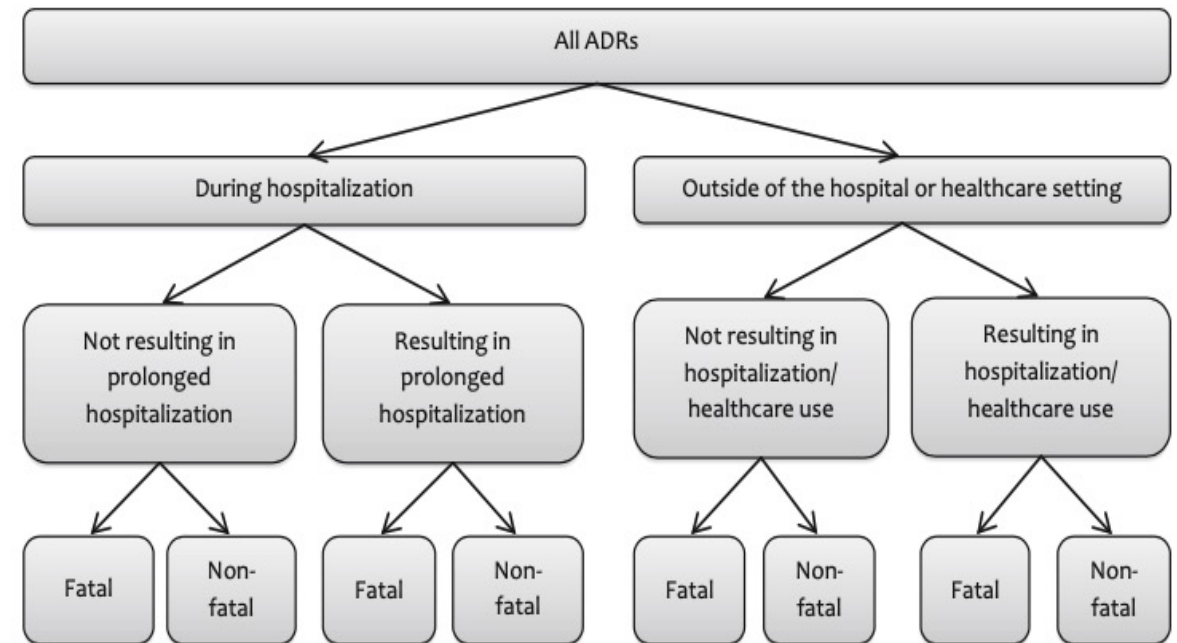


BURDEN OF ADRS

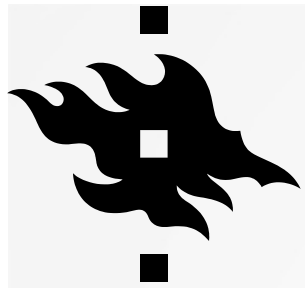
Cause of mortality & morbidity

In- & outpatient burden

Direct & indirect costs



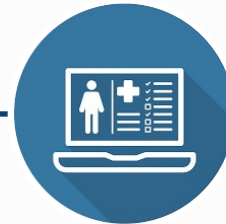
Bouvy et al. Drug Saf 2015



PHARMACOVIGILANCE: HOW DOES THE FUTURE LOOK LIKE?



Measurement of on - market performance



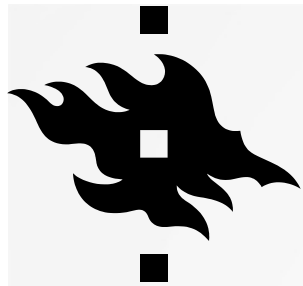
Smarter collection of ADRs



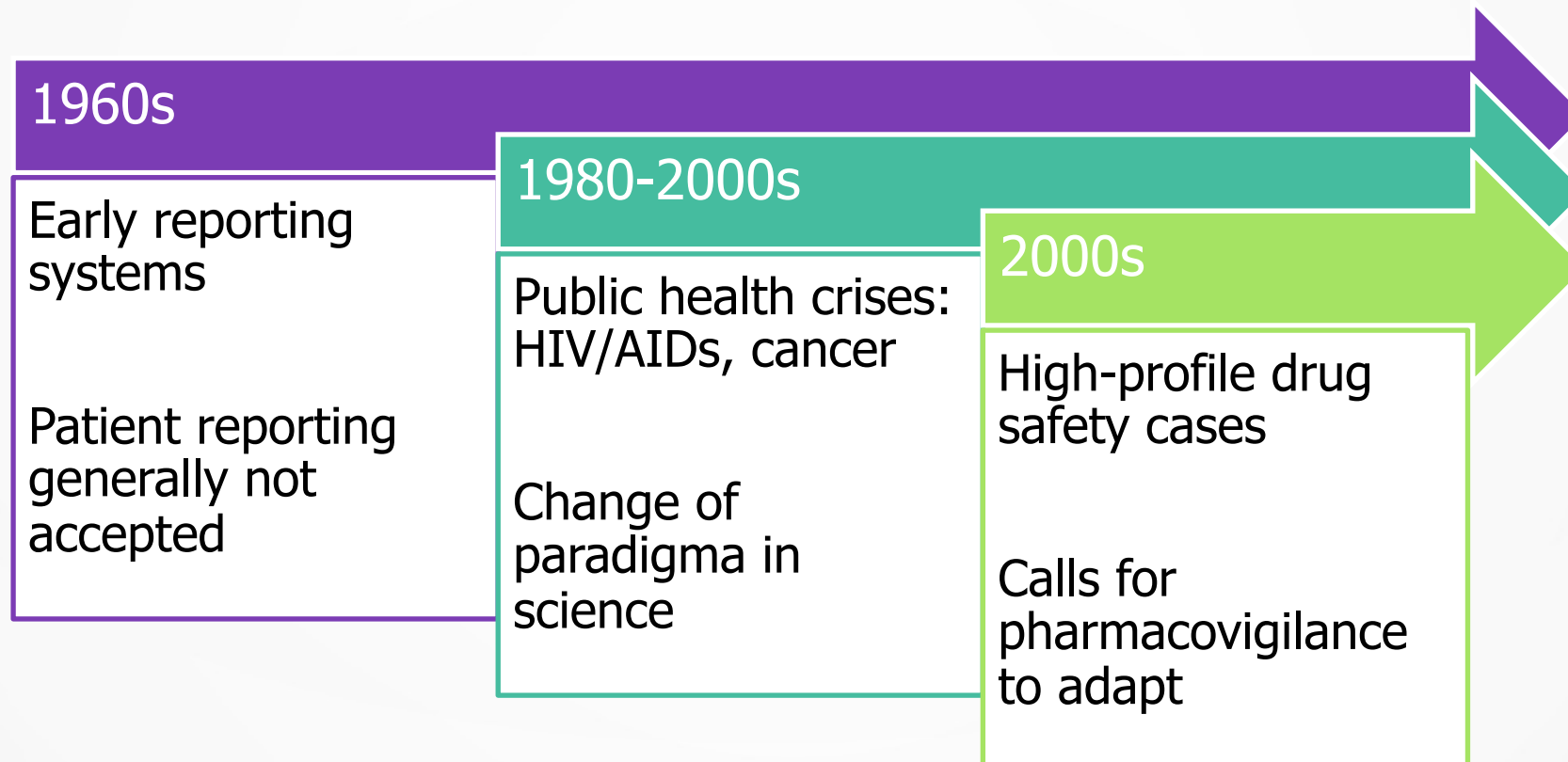
Improved engagement HCP-patients

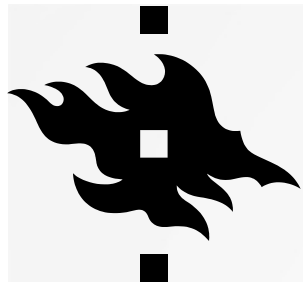


PATIENT REPORTING OF ADVERSE DRUG REACTIONS

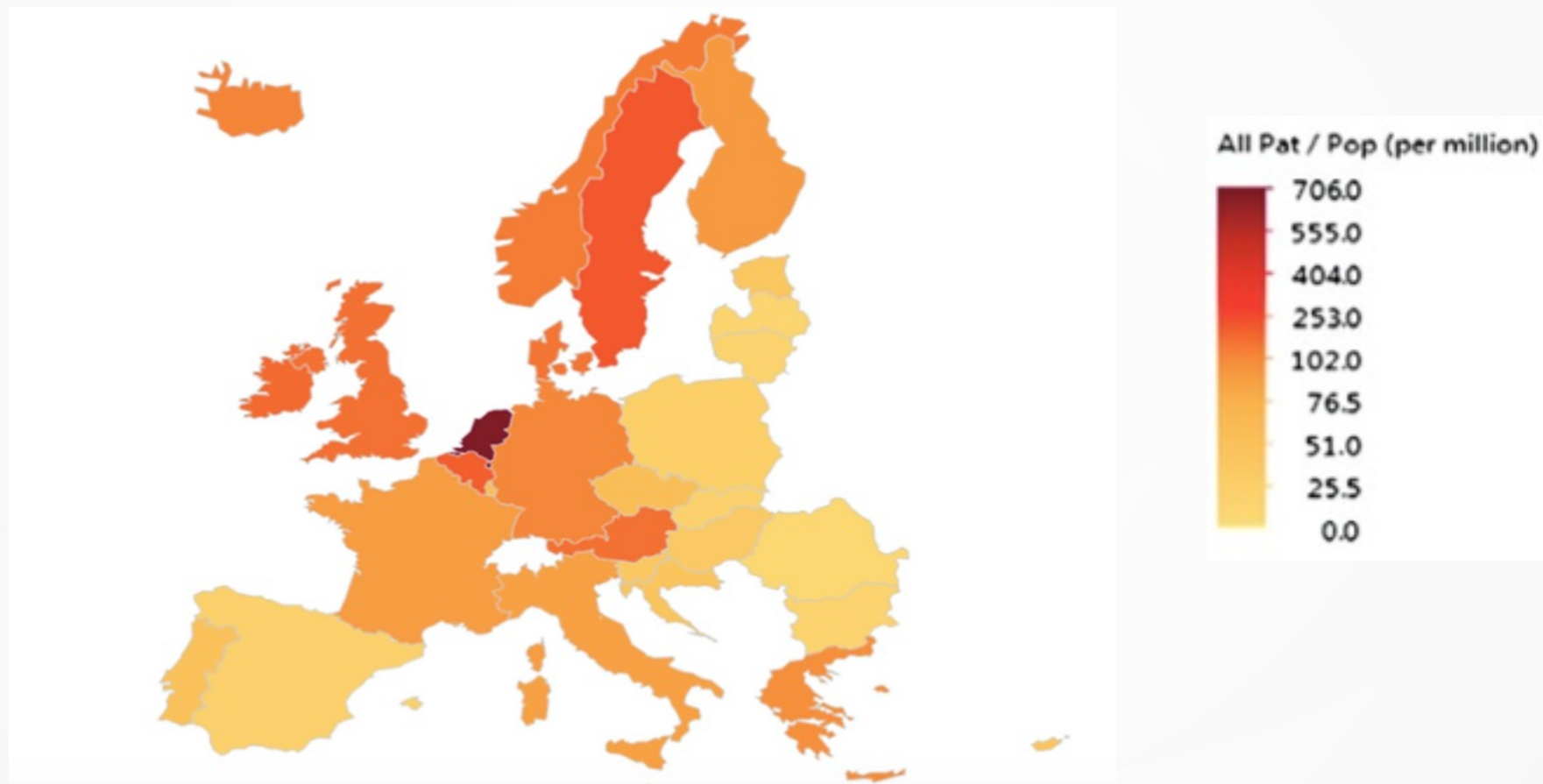


PATIENT REPORTING & INVOLVEMENT IN PHARMACOVIGILANCE: WHY?





PATIENTS REPORTING IN THE EUROPEAN UNION



Banovac et al., Drug Saf 2017



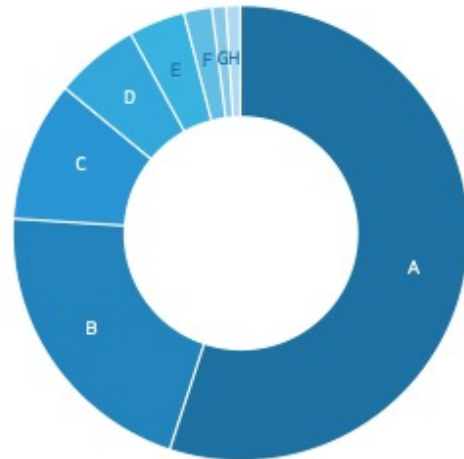
PATIENT REPORTING LEVELS DIFFER IN EUROPE



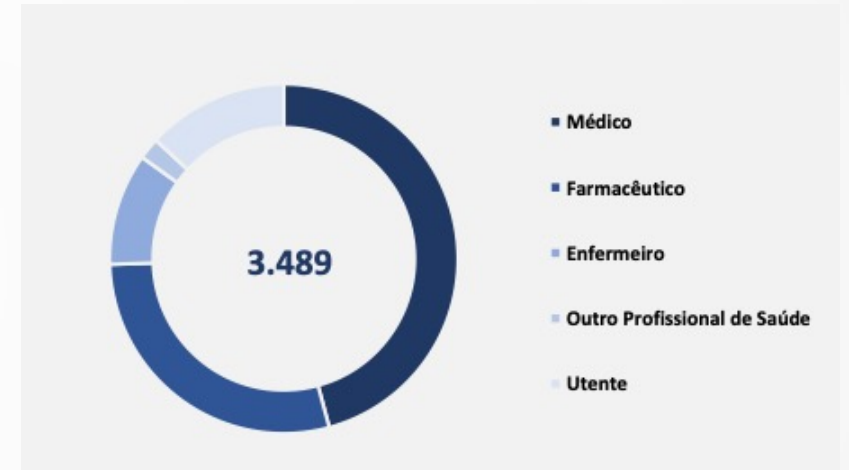
Reporters

Percentage of reports per group in 2017

A Patients	55%	E Nurses	4%
B Medical specialists	21%	F Public health specialists	2%
C Pharmacists	10%	G Other Healthcare professionals	1%
D General practitioners	6%	H Hospital pharmacists	1%



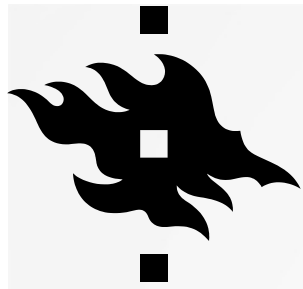
Lareb, Highlights 2017



Infarmed, Relatório Casuística 2018

Médico	1.598	46%
Farmacêutico	1.001	29%
Enfermeiro	362	10%
Outro Profissional de Saúde	70	2%
Utente	458	13%

MD
Pharmacist
Nurse
Other HCP
Patient



EXAMPLES OF PATIENT-REPORTED ADRS

**Levonorgestrel
intrauterine device –
Anxiety, panic attacks,
mood changes, sleep
disorders, and
restlessness**

**Hyperthyroidism
symptoms including
palpitations, fatigue, and
headache – thyroxine
(packaging change)**

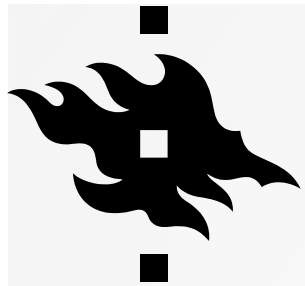


**High-dose vitamin
B6 products -
development of
neuropathy**

**Curling of hair in
female patients
taking alitretinoin**

**Gabapentin -
pathological
gambling**

Alting et al, Drug Saf Cas Rep 2018
Inacio et al, IJCP 2018
Hunsel et al, Exp Op Drug Saft 2018
Watson et al, Drug Saf 2018



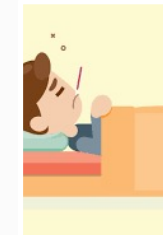
WHAT DO PATIENTS ADD TO PHARMACOVIGILANCE - SUMMARY OF EVIDENCE



Confirm or add new information



Report different ADRs



Impact of life

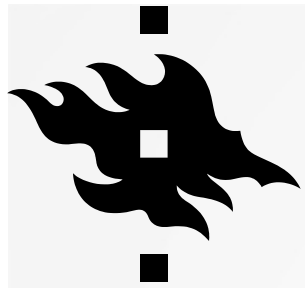


Complement information provided by HCP



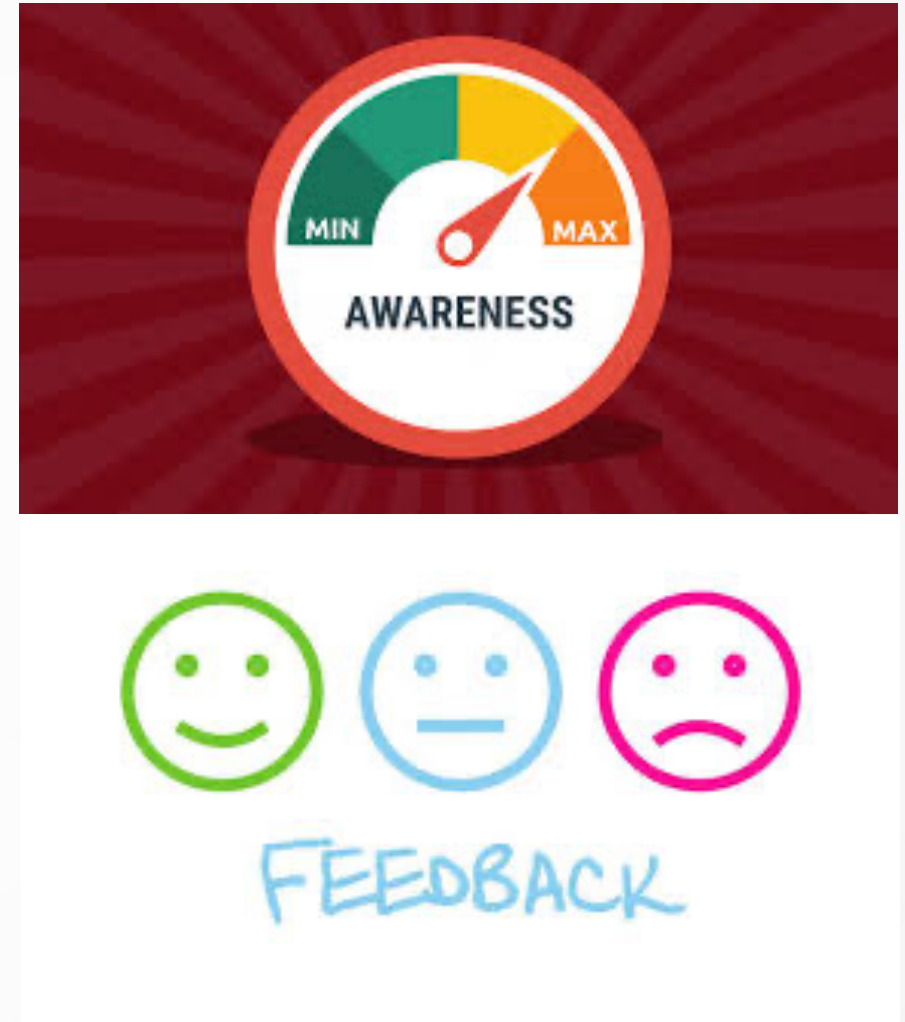
Subjective factors, more detail

Inacio et al., BJCP 2917



BARRIERS TO PATIENT REPORTING

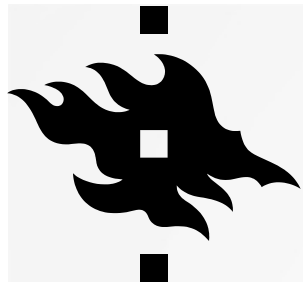
- Poor awareness
- Lack of feedback
- Responding to HCPs not reporting patients' ADRs





**HELSINGIN YLIOPISTO
HELSINGFORS UNIVERSITET
UNIVERSITY OF HELSINKI**

European Association of Hospital Pharmacists 25th Congress / Pedro Barroso Inácio



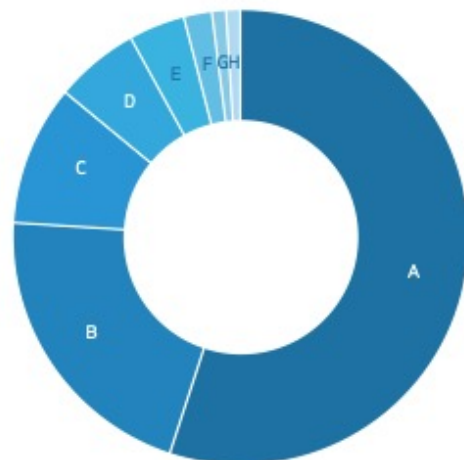
HOSPITAL PHARMACISTS' CONTRIBUTION



Reporters

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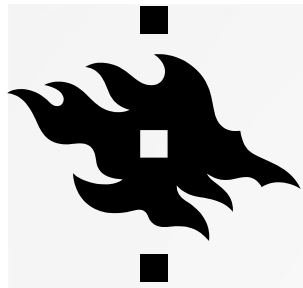
Lareb, Highlights
2017



Infarmed, Relatório
Casuística 2018

Farmacêutico

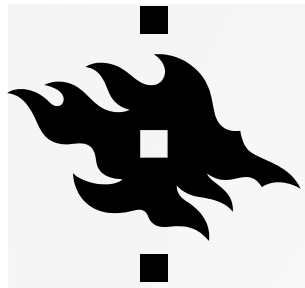
Comunitário	191	19%
Hospitalar	595	59%
Outro	26	3%
Não identificado	189	19%



PHARMACISTS' BARRIERS TO REPORTING

Possible Barrier	Agree (n = 368)	Identified as the Main Barrier (n = 102)	Significant Differences Between Nonreporters (NR) and Reporters (R) (Fisher's Exact Test)		
			NR	R	P value
I do not see many ADRs	194 (53%)	25 (25%)	–	–	–
I do not see many ADRs which meet the reporting criteria	133 (36%)	9 (9%)	43%	26%	<.0005
It is often too difficult to identify the causative drug	113 (31%)	13 (13%)	–	–	–
I am not sure which ones I am supposed to report	101 (27%)	10 (10%)	32%	21%	.012
I do not have the time	76 (21%)	19 (19%)	–	–	–
Nothing deters or prevents me from reporting	65 (18%)	2 (2%)	–	–	–
I'm not confident in identifying ADRs	55 (15%)	5 (5%)	20%	8%	.001
I just do not remember about the yellow card scheme	44 (12%)	5 (5%)	–	–	–
I assume the patient's GP will complete a yellow card instead	44 (12%)	1 (1%)	–	–	–
I would be worried I would have to complete "follow up" reports, which would generate a lot of work	41 (11%)	2 (2%)	–	–	–
I do not have access to the information I would need in order to report	29 (8%)	4 (4%)	–	–	–
It is too complicated to report	17 (5%)	–	–	–	–
I do not see ADR reporting as a priority	10 (3%)	–	–	–	–

Hughes et al,
Pharmacoepidemiol Drug
Saf. 2019



REACHING OUT TO PATIENTS

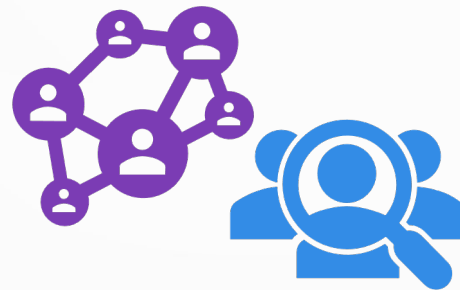
- **Mobile Apps**

- Reporting app can help in increasing reporting



- **Patient Organizations**

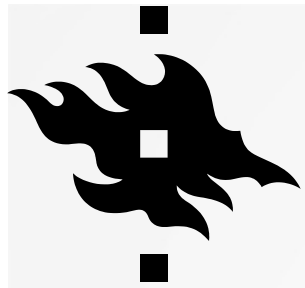
- Important source of creating links with patients



- **Cooperation with Pharmacovigilance Centres**

- Helps with missing information
- Several activities to increase reporting





CONCLUSIONS



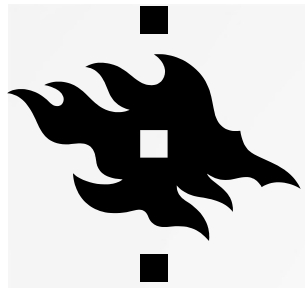
Patient reporting adds new, important information



Regulatory environment is changing – patients first



Patient-centeredness is going to increase



TAKE HOME MESSAGES

Pharmacovigilance's scope and methods have been changing

Patient reporting adds meaningful information on ADRs & impact in life

Pharmacists have a role to play in involving patients



**THANK YOU!
OBRIGADO!
KIITOS!**





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- pedro.inacio@helsinki.fi

