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Preventable Adverse Drug Reaction in pharmacovigilance database

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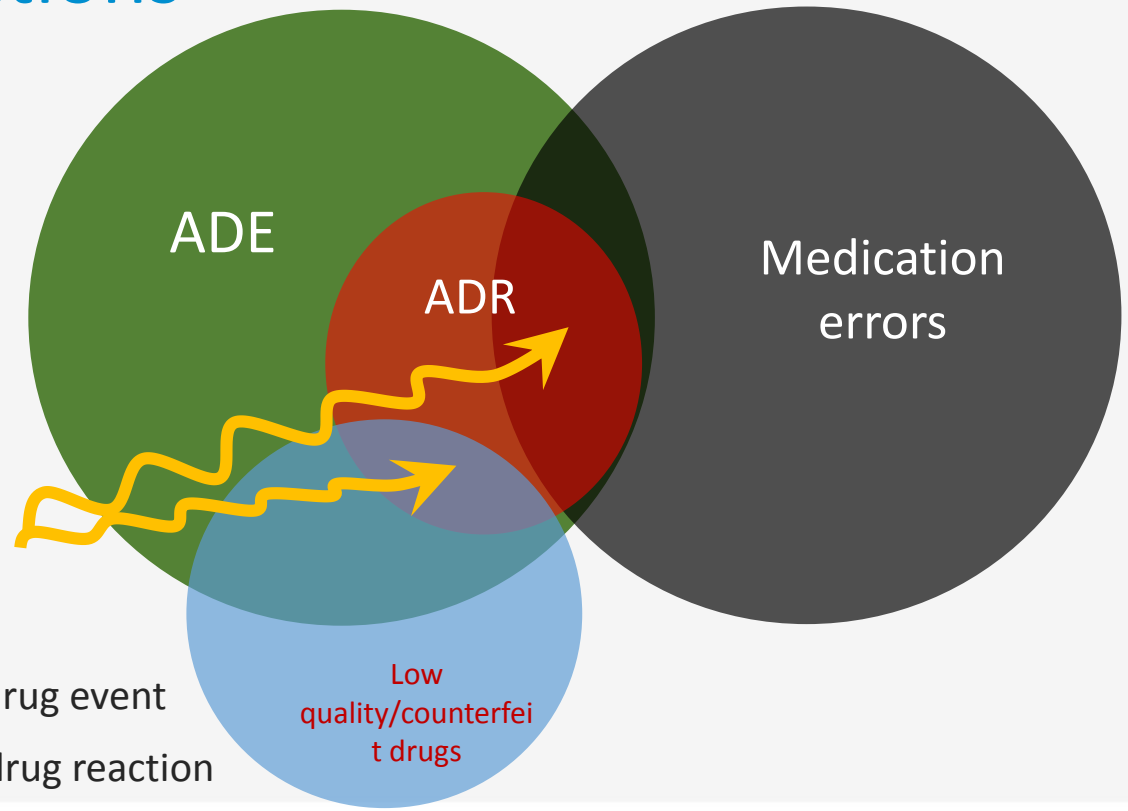
Introductions



Preventable ADR

- ADE: Adverse drug event
- ADR: Adverse drug reaction

Until 2017: 66000 reports in the database

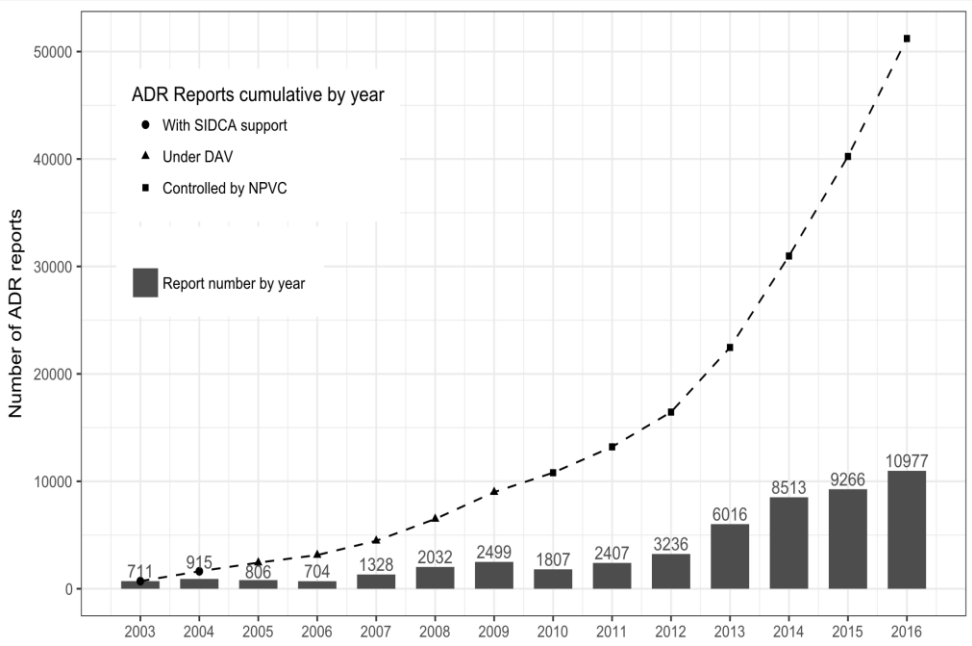


Fig. 4 Number of ADR reports in Vietnamese database. *SIDCA* Swedish International Development Cooperation Agency, *DAV* Drug Administration of Vietnam, *NPVC* National Pharmacovigilance center, *ADR* Adverse Drug Reaction

Nguyen KD et al. Drug Saf. 2018 Feb;41(2):151-159

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Methods

Spontaneous ADR reports: 1546

↓

Causal relationship:
3203 drug-event pairs/1508 report
“certain”,”probably”,”possibly”

↓

Preventable/Partly preventable
ADR: 132

Causality assessment:
WHO criteria, routine process in NPVC

Preventability assessment:
French method:
Imbs (1998), Olivier (2005) [1]

Preventability accessment form

Annexe 4 - Fiche d'évaluation de l'évitabilité de EIM Code: VNM.....

Effet indésirable :

Effet indésirable connu*? → Non : **score inévaluable**

↓ Oui

Erreur dans le circuit du médicament pouvant expliquer directement l'effet indésirable ?
(cocher 1 ou plusieurs items) → Oui: **effet évitable**

□ fabrication □ dispensation □ prescription
□ administration □ transcription □ auto – prescription d'un médicament listé
□ problème d'observance

↓ Non

Recommandations[a] accessibles à la date de la dernière prescription ou de la dernière prise ?
(De .....) → Non : **score non applicable**

↓ Oui

LE MEDICAMENT	Score	Nom du médicament			
A – Respect de recommandations du médicament[a] (choisir a, b ou c)					
a – Recommandation(s) respectée(s) ; ou : l'absence de prise de précaution n'a joué aucun rôle dans ce cas	+3				
b – Item inévaluable	0				
c – Négligence de(s) recommandation(s) par le prescripteur ou le patient	-5				
LE MALADE					
B – Autre(s) facteur(s) de risque identifié(s) chez ce malade (remplir a, b, c ou d)					
a – Présent(s), facile(s) à détecter (maladies concomitantes ou effets indésirables, association à d'autres médicaments à risque)	-3				
b – Présent(s), difficile(s) à détecter (maladies concomitantes ou effets indésirables, association à d'autres médicaments à risque)	-1				
c – Absent(s)	+2				
d – Item inévaluable	0				
C – Adaptation de la prescription aux conditions de vie et à l'environnement du patient (choisir a, b ou c)					

Level	Preventability	Score
1	Preventable	-13 to -8 or ME
2	Partly preventable	-7 to -3
3	Not assessable	-2 to +2
4	Not preventable	+3 to +8

1. Therapie. 2005 Jan-Feb;60(1):39-45

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Results

Patient characteristic and the most common pADR (n=132)

	N (%)
Patient information	
Female (n, %)	65 (49.2)
Age (years)	42.3 ± 21.3
Weight (kg)	50.5 ± 15.5
Health care staff's occupation	
Pharmacists	71 (53.8)
Doctors	25 (18.9)
Others (Nurses. midwives…)	30 (22.7)

Most common pADR	N (%)
Pruritus	34 (25.8)
Rash erythematous	33 (25.0)
Anaphylactic reaction/shock	24 (18.2)
Rash	15 (11.4)
Oedema eyelid	11 (8.3)
Application site reaction	10 (7.6)
Urticaria	10 (7.6)
Fatigue	8 (6.1)

- Pharmacist played important role
- Type B ADR are common

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Results

Most common drugs/drug groups related to the pADR (n=132)

ATC code	Drug groups	N(%)
J01D	Other betalactams (*)	101 (76.5)
J01M	flouroquinolons	73 (55.3)
J01C	penicilines	22 (16.7)
M01A	NSAIDs	16 (12.1)
J01X	Other antibiotics (**)	10 (7.6)
N02B	Antipyretics and analgesocs (***)	9 (6.8)
J04A	Antituberculosis agents	6 (4.5)

(*) cephalosporins, monobactams và carbapenems

(**) glycopeptids, polymyxins, imidazols and others

(***) acid salycilic and derivatives, pyrazolons, anilids and others

Most common causal drugs	N (%)
Cefotaxim	7 (5.3)
Ciprofloxacin	6 (4.5)
Diclofenac	6 (4.5)
Paracetamol	(4.5)
Moxifloxacin	6 (4.5)
Amoxicilin/sulbactam	5 (3.8)
Ceftazidim	5 (3.8)
Cefoperazon	4 (3.0)

Antimicrobial agents and NSAIDs

Results

Severity of the pADR (N=132)

Level	Severity	N (%)
1	Mild	21 (15.9)
2	Moderate	19 (14.4)
3	Severe	62 (47.0)
4	Life threatening	6 (4.5)
5	Fatal	1 (0.8)
-	Others (*)	23 (17.4)

(**) Lack of information for CTCAE grading scale

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Results

Suspect reason for pADR (N=132)

Drug use process	Reason for error	N (%)	Involved person
Dispensing	Self medication	11 (8.3)	Patients, Pharmacists
Prescribing	Allergic history/cross allergic	33 (25.5)	Doctors
	Irrational indications	73 (55.3)	
	Inappropriate dose	5 (3.8)	
Preparation	Injection dilution errors	3 (2.3)	Nurses
Administration	Inappropriated route	4 (2.3)	Nurses
	Infusion rate error	2 (1.5)	
	Wrong drug	1 (0.8)	

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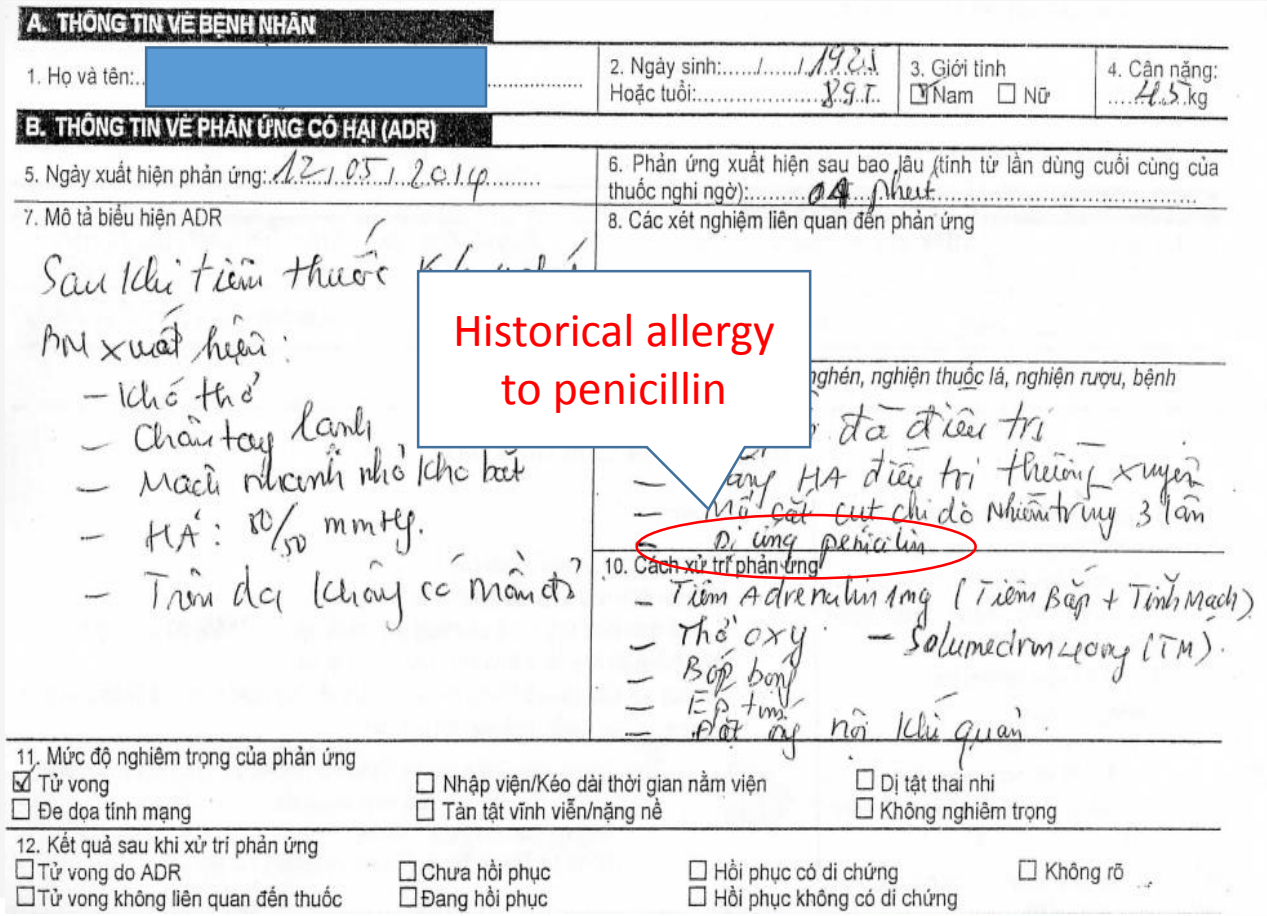
Results

Case:

- Patient aged 89, surgery prophylaxis by UNASYN (ampiciline + sulbactam) 1.5g
- Anaphylactic shock after 4 min: dyspnea; 80/50 mmHg, tachycardia, cold extremities.
- Patient died even after being treated according to the standard anaphylaxis shock guideline.
- Penicillin allergic history



A. THÔNG TIN VỀ BỆNH NHÂN

1. Họ và tên: [redacted]
2. Ngày sinh: 1921 Hoặc tuổi: 89 T.
3. Giới tính ☒ Nam ☐ Nữ
4. Cân nặng: 45 kg

B. THÔNG TIN VỀ PHẢN ỨNG CÓ HẠI (ADR)

5. Ngày xuất hiện phản ứng: 12/05/2014
6. Phản ứng xuất hiện sau bao lâu (tính từ lần dùng cuối cùng của thuốc nghi ngờ): 04 phút
7. Mô tả biểu hiện ADR

Sau khi tiêm thuốc
BN xuất hiện:
- khó thở
- chân tay lạnh
- mạch nhanh nhỏ khó bắt
- HA: 80/50 mmHg.
- Tím da không có mầu đỏ

8. Các xét nghiệm liên quan đến phản ứng

Historical allergy to penicillin

nghén, nghiện thuốc lá, nghiện rượu, bệnh
đã điều trị
- ... HA điều trị thường xuyên
- Mổ cắt cụt chi do Nhiễm trùng 3 lần
- Dị ứng penicilin

10. Cách xử trí phản ứng
- Tiêm Adrenalin 1mg (Tiêm Bắp + Tĩnh Mạch)
- Thở oxy - Solumedrol 40mg (TM).
- Bóp bóng
- Ép tim
- Đặt ống nội khí quản

11. Mức độ nghiêm trọng của phản ứng
☒ Tử vong ☐ Nhập viện/Kéo dài thời gian nằm viện ☐ Dị tật thai nhi
☐ Đe dọa tính mạng ☐ Tàn tật vĩnh viễn/nặng nề ☐ Không nghiêm trọng

12. Kết quả sau khi xử trí phản ứng
☐ Tử vong do ADR ☐ Chưa hồi phục ☐ Hồi phục có di chứng ☐ Không rõ
☐ Tử vong không liên quan đến thuốc ☐ Đang hồi phục ☐ Hồi phục không có di chứng

Conclusion

- Determining the preventability (or ME) is possible from spontaneous ADR reports.
- The pADR reflect drug use behavious: cutaneous reactions were common, related to antibiotics/NSAIDs (most common used drug).
- Common reasons to define preventability: self medication, used historical allergic drug, irrational indication and dose, wrong dilution, wrong route, wrong infusion rate, wrong drug.

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THANK YOU!!

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