

Drug Safety

Adverse Drug Reactions in Children – International Surveillance and Evaluation (ADVISE)

A Multicentre Cohort Study

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Supplemental Digital Content

This Supplemental Digital Content contains the figures and tables referred to in the full version of this article, which can be found at <http://adisonline.com/drugsafety>

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Figure S1: ADVISE flowchart

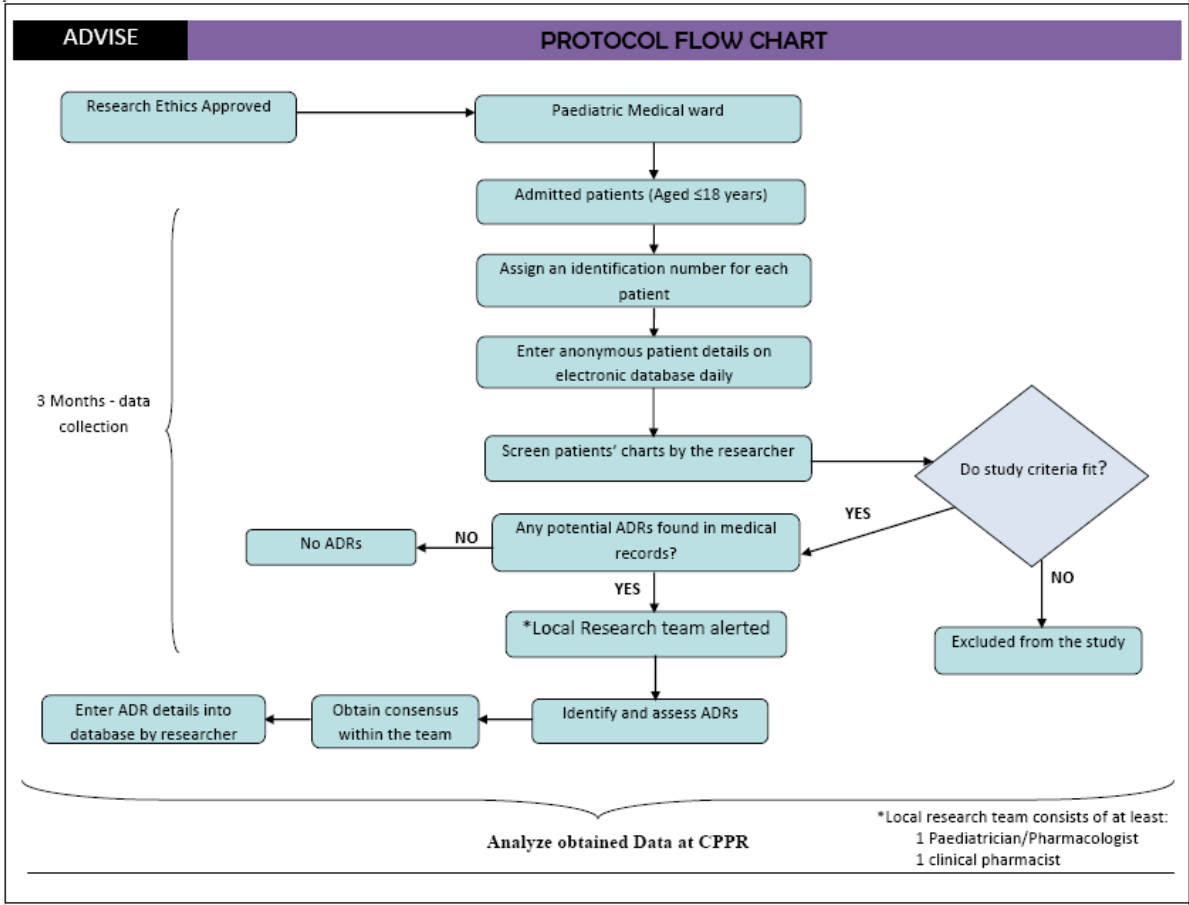


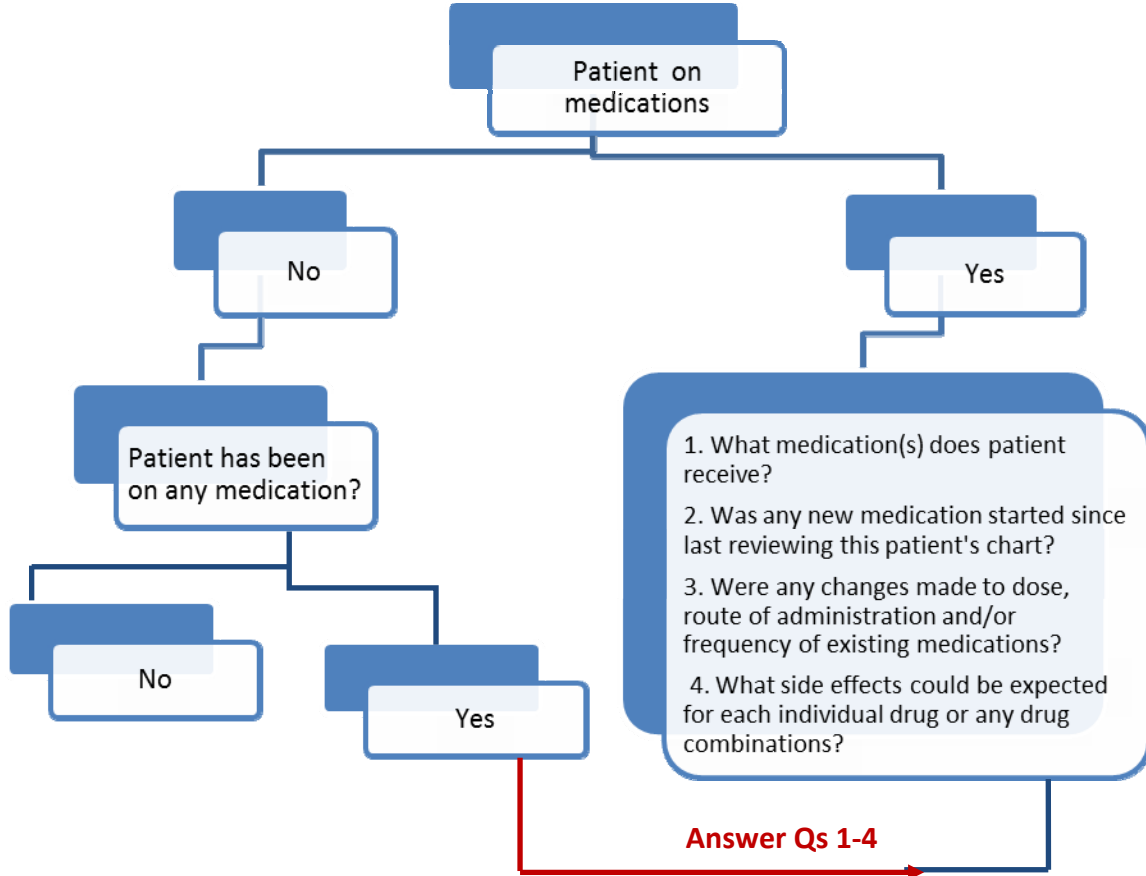
Figure S2: Check list for reviewing patient records

ADVISE

SIMPLE GUIDANCE FOR REVIEWING PATIENT RECORDS

Screen Patient record considering the following to identify any potential ADRs:

1. Medication



2. Clinical condition

- Body Temperature } any sudden changes or changes over time?
 - Blood pressure }
 - Bowel movement (did pt develop diarrhoea or constipation?)

- Are these conditions either wanted or unwanted? (e.g., lowering body temperature or blood pressure)
 - Can these conditions be seen as related to patient diagnosis and/or medical interventions?

If no, this should be considered as related to the medication and causal relationship should be further investigated

3. Laboratory Data

- Normal?
- Abnormal?
- Any significant changes since the last measurement?

- What are the abnormal results?
- Can the abnormalities be explained by patient diagnosis and/or medical intervention?
- If no, assess the potential impact of the medication.

- What is the suspected drug causing these abnormalities.
- e.g. high blood glucose level, electrolytes level disturbance ..etc.

4. Physician Notes

- Any notes indicating and/or pointing towards an ADR?
- Any explanations given why changes were made in drug regimen?

- What are the further recommendation given in case an ADR was recognized?

5. Nurse Notes

- Any symptoms mentioned which can not be explained by patient's clinical condition? e.g. thrush, exanthema, fall, loss of consciousness, changes in behaviour.

- If any indicators are found further review the chart to verify the causality of the event.

- Consult literature sources (e.g. National Formulary, SPCs, Drugdex, etc.) to identify whether the event was previously reported in relation to this drug.
- What evidence is available?

*****If Consensus is reached within the local research team, continue to ADRs assessment.*****

Table SI: Most frequent main diagnose recorded for children and number of patients with ADRs in study cohort and in country cohort

Diagnosis	ICD-10 code	Total no. of patients n (%)	Number of diagnosis (No. of patients with ADR)					Total no. of patients with ADRs (%)
			Australia	Germany	UK	HK	Malaysia	
Diseases of the respiratory system	J00-J99	424 (33.2)	45 (3)	89 (7)	83 (30)	23 (4)	184 (27)	71 (33.6)
Certain infectious and parasitic diseases	A00-B99	148 (11.6)	11 (0)	85 (1)	29 (4)	4 (0)	19 (4)	9 (4.3)
Diseases of the nervous system	G00-G99	95 (7.4)	6 (0)	27 (2)	19 (9)	8 (1)	35 (14)	26 (12.3)
Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified	R00-R99	93 (7.3)	9 (0)	20 (0)	28 (8)	20 (0)	16 (3)	11 (5.2)
Diseases of the genitourinary system	N00-N99	80 (6.3)	14 (2)	24 (3)	14 (5)	17 (2)	11 (0)	12 (5.7)
Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism	D50-D89	43 (3.4)	5 (1)	6 (3)	23 (14)	5 (2)	4 (1)	21 (10)
Certain conditions originating in the perinatal period	P00-P96	35 (2.7)	3 (0)	2 (0)	16 (7)	9 (1)	5 (1)	9 (4.3)
Congenital malformations, deformations and chromosomal abnormalities	Q00-Q99	25 (2)	6 (1)	4 (2)	12 (2)	2 (0)	1 (0)	5 (2.4)
Injury, poisoning and certain other consequences of external causes	S00-T98	74 (5.8)	2 (0)	40 (2)	20 (5)	12 (0)	-	7 (3.3)
Other diseases	-	261 (20.4)	45 (4)	79 (7)	69 (22)	43 (2)	61 (5)	40 (19)
Total	-	1278 (100)	146 (11)	376 (27)	313 (106)	143 (12)	300 (55)	211 (100)