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WEB- Recognising Adverse Drug Reactions

WP4 – Scientific Impact Evaluation

User Instruction Clinical Documentation tool

Article title: Development and validity testing of a Clinical Documentation-tool to assess Individual Case Safety Reports in an international setting

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Summary

It is important that Individual Case Safety Reports (ICSRs) have a certain level of clinical documentation in order to be useful in signal detection. For reports with a good clinical documentation grade, a proper causality assessment can be made. However, what do we mean by good clinical documentation and how can you measure it?

Until now, the quality of a ICSR has often been interpreted as a technical documentation grade, based on the completeness of the fields filled in the report form. However, the technical documentation grade does not always correspond with the documentation of clinical features that are relevant in the assessment of the report. Sometimes the technical documentation grade can be very good, while relevant clinical data is lacking, making it difficult to assess the report properly. On the other hand, with very little technical documentation, a report can be of excellent clinical quality when it contains all the relevant clinical information.

Currently there is no tool to measure the clinical documentation of a ICSR. As part of the WEB-RADR project[1] we have developed a tool which measures the completeness of clinical relevant data, resulting in a measure of the clinical documentation of a ICSR. This tool can be used next to a causality assessment method.

The following document will explain how the tool should be used, illustrated by practical examples. The first part of this document *'How to use the clinical quality tool'* will explain in-depth each domain included in the tool. The *'appendix'* contains a number of cases to describe how to apply the tool on real-life reports.

[1] The development of the Clinical Documentation tool was part of the WEB-RADR project (www.web-radr.eu) which is a public private partnership coordinated by the Medicines and Healthcare products Regulatory Agency. The WEB-RADR project has received support from the Innovative Medicine Initiative Joint Undertaking (www.imi.europa.eu) under Grant Agreement n° 115632, resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013) and EFPIA companies' in kind contribution.

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Background

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How to use the clinical quality tool

The clinical documentation tool contains four domains which are considered to be relevant in order to assess the clinical documentation of a report:

1. Adverse Drug Reaction
2. Chronology
3. Suspect drug
4. Patient characteristics

Each domain contains several items that may be important for the assessment of the clinical documentation of that particular report. These items will be explained below. ADRs can be very diverse, and the information that you need for a good clinical assessment varies depending on the ADR. We have therefore not created a static model, but a more flexible model which takes this diversity into account.

First, the assessor indicates which items are relevant for assessing the clinical documentation of the report. Then, the assessor indicates if this relevant information is present or not. During the development of the tool it was taken into account that assessors with different backgrounds might have different thoughts about what information is relevant. A few items are mandatory, these items are predetermined as relevant.

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For the assessment of the report it is important that you take into consideration all reported ADRs and suspected drugs and assess the report as a whole. The score given to each domain is the proportion of information present in relation to the information deemed relevant for assessing the report. When all the relevant information in a domain is present the maximum score is obtained. If relevant information is missing in the report, a lower score will be achieved. When none of the items included in a domain is considered to be relevant, this domain will not be included for calculation of the final clinical documentation score. The final score consists of the average of the domain scores of the domains deemed relevant for the assessment which will indicate the clinical documentation of the report.

To translate the score to a clinical documentation measure, the following cut offs are used:

- poor (≤45%)
- moderate (from 46 up till 74%)
- well (≥75%)

All domains and included items will now be explained, illustrated by examples.

1. Adverse drug reaction

The first domain is about information important to assess the clinical documentation of the reported adverse drug reaction (ADR). This domain aims to bring clarity to the adverse drug reaction: do you actually understand what reaction the patient experienced (items a, and b)? In addition, it also includes items which will strengthen the diagnosis of reported ADRs. For the strengthening of the diagnosis items *c, d* or *e* can be applicable.

Items included in this domain are:

a. Proper description of the ADR
b. Specification reaction 'localization' and 'characterization'
c. Treatment
d. Visual material (photos, videos)
e. Laboratory values, tests

The type of reporter is indirectly included in this domain. When for example, a Stevens-Johnson syndrome is reported by a dermatologist the diagnosis is clear. When this ADR is reported by a patient or pharmacist you may need extra information in order to strengthen the diagnosis.

a. Proper description of the ADR

For the *'proper description of the ADR'*, it is important to understand what reaction the patient experienced from the description of the ADR. This item is always relevant for the assessment of the clinical documentation. When only the *'organ system'* in which the ADR occurred is reported, for example *'eye disorder'*, than there is **no** proper description of the ADR. When a more specific reaction is reported, for example *'visual impairment'* you have more information of the ADR the patient experienced. In this case, you have a proper description of the ADR. You need, however, more information to specify the reaction, see *b. Specification reaction 'localization' and 'characterization'*. Some examples to illustrate this are given in Table 1.

Table 1. Examples of how to use the tool for the item Proper description of the ADR

1	Adverse drug reaction (ADR)	Relevant? 1=yes 0=no	Present? 1=yes 0=no	Explanation
a	Proper description of the ADR			
	Gastrointestinal discomfort	1	0	The kind of gastrointestinal discomfort is not clear
	Cardiac disorder	1	0	The kind of cardiac disorder is not clear
	Eye disorder	1	0	The kind of eye disorder is not clear
	Diarrhea, stomach pain, nausea	1	1	By this description you understand what reaction the patient experienced.
	Feeling unwell	1	1	By the description of the ADR you understand that the patient was feeling unwell. You want however more information about *why* he felt unwell. For this kind of information, see *b. Specification reaction 'localization' and 'characterization'.*
	Feeling unwell: headache, fever, cold chills, nausea	1	1	By this description you understand what reaction the patient experienced.

b. Specification reaction 'localization and 'characterization'

This item refers to specification of the reported ADR in terms of its localization and characterization. If *'hair loss'* is reported you may t want to have information on whether the hair loss is diffuse or localized. When a patient experiences *'taste alteration'* than you may want to know what kind of taste alteration, for example, does the patient experience a metallic taste or does everything taste salty? For some ADRs it is important to know the specific location of the reaction e.g. for a *'skin rash'* or *'pain'*. More examples are given in Table 2.

Table 2. Examples of how to use the tool for the item Specification reaction 'localization and 'characterization'

1	Adverse drug reaction (ADR)	Relevant? 1=yes 0=no	Present? 1=yes 0=no	Explanation
b	Other issues of importance concerning the ADR			
	Hair loss	1	0	Hair loss has various forms. You know nothing about this by only the description *hair loss.*
	Hair loss, bald spots and thinner hair	1	1	Proper description of the type of hair loss.
	Taste alteration	1	0	You might want to know what kind of taste alteration the patient experienced.
	Taste alteration, everything tastes sweet	1	1	Proper description of the kind of taste alteration.
	Feeling unwell	1	0	By the description of the ADR you understand that the patient was feeling unwell. You want however more information about *why* he felt unwell. This information in not present.
	Feeling unwell: headache, fever, cold chills, nausea	1	1	By this description you understand what reaction the patient experienced.

c. Treatment

For some ADRs it is necessary to have information about the treatment in order to confirm the diagnosis of the reported ADR. The type of reporter is important for this item. Example: a patient reports a *'depression'*. When the patient is treated with an antidepressant this will confirm that he/she is actually diagnosed with a depression. When no information about treatment is available it is unclear if the patient actually had a depression or if he/she was just feeling sad/down. When the reporter is a doctor you can assume that the *'depression'* has been properly diagnosed. Another example is when an *'allergy'* is reported. The treatment and effect of this treatment is important to understand what type of allergic reaction the patient underwent. Examples are also shown in Table 3.

Table 3. Examples of how to use the tool for the item Treatment

1	Adverse drug reaction (ADR)	Relevant? 1=yes 0=no	Present? 1=yes 0=no	Explanation
c	Treatment			
	Depression (patient report), no information about treatment	1	0	Information about the treatment is relevant in order to confirm the ADR. This information is not present.
	Depression (patient report), treated with antidepressant	1	1	Information about the treatment is relevant in order to confirm the ADR. This information is present.
	Depression (general practitioner report)	0		Because the depression is reported by a general practitioner, information about treatment is not necessary to confirm the diagnosis.
	Thrombocytopenia	0		Information about the treatment is not necessary to understand the ADR, however it can provide confirmation about the diagnosis. You might consider this item to be of relevance in order to provide clues about severity and/or etiology.
	Allergic reaction	1	0	In order to understand the allergic reaction information about treatment is relevant. This information is not reported.
	Allergic reaction treated with the antihistaminic drug clemastine and prednisolone	1	1	In order to understand the allergic reaction information about treatment is relevant. This information is reported.

d. Visual material (photo, video)

For some ADRs it is helpful to have visual material (photo, video) to support the reported ADR or diagnosis. For example, when it is unclear from the description of the ADR what kind of reaction the patient experienced. The type of reporter is important for this item. When a dermatologist reports a specific skin reaction you don't need a photo. When a pharmacist or patient reports a specific skin reaction you might want a photo to confirm the diagnosis.
It is important to keep in mind the other items included in the domain *ADR*. When, for example, the treatment of an ADR is specific so the diagnosis can be confirmed, you don't need visual material. Some examples are given in Table 4.

Table 4. Examples of how to use the tool for the item Visual material (photo, video)

1	Adverse drug reaction (ADR)	Relevant? 1=yes 0=no	Present? 1=yes 0=no	Explanation
d	Visual material (photo, video)			
	Psoriasis, treated with specific anti-psoriasis treatment	0		Because the reaction is treated with a specific treatment, visual material is not necessary to confirm the diagnosis.
	Skin rash (red spots, swollen, no itch), no treatment	1	1	Photo may be relevant in order to understand what kind of skin rash the patient experienced.
	Hair disorder, photo included on which you can see curly hair	1	1	A photo is relevant in order to get insight in the type of hair disorder, for example curly hair. This information is present.
	Cross-eyed looking. Photo included.	1	1	A photo is relevant in order to support the reaction the patient experienced. This information is present.
	Video included to illustrate strange behavior	1	1	A video is relevant in order to support the reaction the patient experienced. This information is present.
	Hypotension	0		For this ADR visual material is not relevant.
	Nausea	0		For this ADR visual material is not relevant.

e. Laboratory values and other diagnostic tests

For some ADRs it is helpful to have information about laboratory values to support the diagnosis of the reported ADR. The type of reporter is important for this item. When a specialist in internal medicine reports hepatitis, you do not necessarily need lab values. When a pharmacist or patient reports the same type of reaction, lab values can be used to confirm the diagnosis. Lab values may also give information about the seriousness of the ADR. Some examples are given in Table 5.

Table 5. Examples of how to use the tool for the item Lab values

1	Adverse drug reaction (ADR):	Relevant? 1=yes 0=no	Present? 1=yes 0=no	Explanation
d	Lab values, tests			
	Thrombocytopenia	1	0	Information about the degree of the thrombocytopenia is important to confirm the diagnosis if the reporter is not specialized in this field. It can also be used to assess the seriousness. This information is not present.
	Thrombocytopenia, lab values reported	1	1	Information about the degree of the thrombocytopenia is important confirm the diagnosis and to assess the seriousness. This information is present.
	Weight gain	1	0	Information about the amount of weight gain is relevant in order to understand the ADR. This information is not present.
	Weight gain: 24 kg in 2 months	1	1	Information about the amount of weight gain is relevant in order to understand the ADR. This information is present.
	Headache, feeling depressed	0		For these ADRs lab values or test results are not relevant.
	Abdominal pain and nausea	0		Lab values may be relevant for example to provide clues about etiology (liver function test). This however depends on the reported suspected drug and if you expect a certain etiology.

2. Chronology

This domain includes aspects related to the chronology:

a. Latency
b. Description of the course of the ADR
c. Action taken on drug
d. Outcome of the ADR

a. Latency

This item concerns the time of onset of the ADR and is always relevant.

b. Description of the course of the ADR

This item is only relevant when you expect a pattern in the course of the ADR. For example: *'nose bleeding'; does the patient experience this after each administration of the drug or spontaneously? Another* example is an ADR with a drug that is administrated only once a week or once a month. Some examples are given in Table 6.

Table 6. Examples of how to use the tool for the item Description of the course of the ADR

4	Chronology	Relevant? 1=yes 0=no	Present? 1=yes 0=no	Explanation
b	Description of the course of the ADR			
	Nose bleeding	1	0	Course of the ADR is relevant since it helps to understand how the reaction developed. You might want information about the frequency and duration of the nose bleeding. This information is not present.
	Nose bleeding 30 minutes after every intake of drug X. reaction lasts for about 20 minutes and then recovers	1	1	Course of the ADR is relevant since it helps to understand how the reaction developed. You might want information about the frequency and duration of the nose bleeding. This information is present.
	Drug X is administrated once per month. The patient experiences light headedness and blurred vision.	1	0	Course of the ADR is relevant since it helps to understand how the reaction developed. You might want information about if the patient experiences these reaction after each administration and duration.
	Skin rash 1 day after start of amoxicillin	0		Information about the course of the ADR is not relevant for this ADR.

c. Action taken on drug

This item is considered to be always relevant. There are a few exceptions:

- Single administration, for example vaccines
- When an ADR occurs after withdrawal of the drug

d. Outcome of the ADR

This item is considered to be always relevant. The only exception is for irreversible ADRs, for example ADRs that need surgery, and fractures.

3. Suspect drug

This domain includes aspects related to the suspected drug:

a. Brand name in case of drug substitution
b. Different forms or route of administration for suspected drug
c. Relationship with an ADR and dose of the drug
d. Batch number

a. Brand name in case of drug substitution

When it is reported that the ADR occurred after drug substitution the brand name is considered relevant.

b. Different forms or route of administration for suspected drug

When there are different forms or routes of administration of the drug you might expect different ADRs. For example, for an antibiotic applied on the skin you might not expect systemic reactions. For these cases, the item *'Different forms or route of administration for suspected drug'* is relevant.

c. Relationship with ADR and dose of the drug

When you expect that there is a dose-response relationship (e.g. Intoxication) or when it is reported that the ADRs occurred after dose adjustments this item is relevant.

d. Batch number

When it is reported that more ADRs are seen with a specific product, a batch number is considered relevant.

Examples of how to use the tool for items included in domain Suspect drug are shown in Table 7.

Table 7. Examples of how to use the tool for the items in domain Suspect drug

2	Suspect drug	Relevant? 1=yes 0=no	Present? 1=yes 0=no	Explanation
a	The ADR started after drug substitution of the drug simvastatin of brand A to brand B	1	0	Brand names are important in order to assess the report properly.
b	Burning eyes after use of fusidic acid eye drops.	1	1	Fusidic acid is available as eye drops, oral tablet and dermal cream. It is important to know which form was used.
c	Extrapyramidal symptoms in a child of 14 months after use of domperidone 20 mg.	1	1	Dose of the drug is important in order to assess possible intoxication.
d	A pharmacist reports that more injection site reactions are seen with the biosimilar 'infliximab'. Batch number: A1B2C3	1	1	Batch number is important in order to assess the report properly.

4. Patient characteristics

The last domain included in this tool is the *Patient*. For this domain we assess the clinical documentation of the patient-related information. Most items are related to confounding factors. Before assessing this domain it is important that you have a thought on possible risk factors for developing the reported ADR(s). Items included in this domain are:

a. Risk factors/medical history/comorbidity/indication
b. Concomitant medication
c. Age/gender/height/weight
d. Patient's life style or other risk factors

a. Risk factors/medical history/comorbidity/indication

Indicate if it is necessary to have information about risk factors for the ADR, medical history of the patients, comorbidities and indication in order to assess the clinical documentation. Some examples are given in Table 8.

Table 8. Examples of how to use the tool for the item Risk factors/medical history/comorbidity/indication

3	Patient	Relevant? 1=yes 0=no	Present? 1=yes 0=no	Explanation
a	Risk factors/medical history/comorbidity			
	Fracture 6 months after use of simvastatin. The patient is known with hypertension.	1	0	There are several risk factors for a fracture. Some risk factors are known but not all, e.g. osteoporosis. Therefore this information is not present.
	Aggravation of dyspnea 2 weeks after start of fluoxetine for depression.	1	0	Medical history is important. Information about the dyspnea is important. Is it aggravated due to use of fluoxetine or are there other factors? This information is not present.
	Eczema 2 weeks after use of an oral contraceptive. Patient is known with allergic rhinitis and allergy for apples.	1	1	Comorbidity is in this case important because this may be a confounding factor
	Skin rash 10 days after start of amoxicillin. The patient is not known with allergies. The patient never used antibiotics in the past.	1	1	Risk factors/medical history/comorbidity are relevant here. For example, about previous use of amoxicillin and skin rash. This information is present.
	Injection site reaction: painful, red, swollen	0		Risk factors/medical history/comorbidity are not relevant here.

b. Concomitant medication

This item is considered to be always relevant. The only exception is when a known drug-ADR association with a clear latency time is reported. For example an injection site reaction after vaccination.

c. Age/gender/height/weight

Indicate if it is necessary to have information about the patient's age, gender, length and weight (BMI) in order to assess the clinical quality. Some examples are given in Table 9.

Table 9. Examples of how to use the tool for the item Age/gender/height/weight

3	Patient	Relevant? 1=yes 0=no	Present? 1=yes 0=no	Explanation
c	Age/gender/length/weight			
	Anaphylaxis in a female, age unknown	0		For this ADR age and gender are not necessary in order to assess the report properly.
	Osteoporosis in a female, 87 years	1	1	For this ADR age and gender are important since these are also known risk factors. This information is present.
	Type 2 diabetes 2 months after start of drug X	1	0	Age, height and weight are important since they are known risk factors for Type 2 diabetes. This information is not present.

e. Patient's life style or other risk factors

Indicate if it is necessary to have information about the patient's life style or other risk in order to assess the clinical documentation. Think about sports, smoking, travel, diet. Some examples are given in Table 10.

Table 10. Examples of how to use the tool for the item Patient's life style or other risk factors

3	Patient	Relevant? 1=yes 0=no	Present? 1=yes 0=no	Explanation
d	Patient's life style or other risk factors			
	Deep venous thrombosis 7 months after start of drug X.	1	0	You want for example information about smoking, recent airplane flight. This information is not present.
	Lung cancer 4 years after start of drug X. Non-smoker, healthy 55-year old man. No family history of lung cancer.	1	1	For this ADR it is relevant to have information about the lifestyle of the patient. This information is present.
	Tendon rupture 2 days after start of levofloxacin. Patient is a 33-year old female. Rupture during exercise.	1	0	For this ADR it is important to have information about exercise. You don't know if this woman is used to do regular exercise. This information is not present.
	Hair loss	0		For this ADR, information about lifestyle or other risk factors is irrelevant.

Appendix: Examples of how to fill out the Clinical Documentation tool

Example A: Thrombocytopenia associated with aripiprazole

Description ADR:	thrombocytopenia
Start date:	not reported
Outcome ADR:	unknown
Treatment of ADR:	not reported
Did the patient ever use the suspect drug in the past?	no
If yes, did the patient experience similar ADRs?	
Possible other causes of ADR?	no
Seriousness?	non-serious
Suspected drug, dose:	aripiprazole 15mg
Start date:	not reported
Route of administration:	oral
Indication:	schizoaffective disorder
Adjustment of use after ADR?	not reported
Concomitant medication:	insulin aspart, lithium, metoprolol and metformin.
Patient's gender and age:	female, 69 years
Patient's weight and height:	not reported
Patient's medical history:	not reported
Reporter:	specialist doctor
Extra information:	not filled in

Calculation final score

1.	ADR	50%
2.	Chronology	0%
3.	Suspected drug	-
4.	Patient characteristics	100%

FINAL SCORE	**50%**	**Moderate**

1	ADVERSE DRUG REACTION (ADR)	Relevant? 1=yes 0=no	Present? 1=yes 0=no	Explanation
a	Proper description of the ADR	1	1	The ADR thrombocytopenia is clear.
b	Specification reaction 'localization' and 'characterization'	0		Specification reaction 'localization' and 'characterization' is not relevant in this case.
c	Treatment	0		Information is unnecessary since this ADR can be supported by lab values. Information about treatment adds nothing to support the ADR
d	Visual material (photo, video)	0	0	Information not relevant since this ADR cannot be visualized.
e	Lab values, test	1	0	The number of thrombocytes is relevant if support of the diagnosis is needed and to assess the severity of the ADR.

2	CHRONOLOGY	Relevant? 1=yes 0=no	Present? 1=yes 0=no	Explanation
a	Latency	1	0	Not reported
b	Description of the course of the ADR	0		Description of the course is not relevant for this ADR
c	Action taken on drug	1	0	Not reported
d	Outcome of the ADR	1	0	Not reported

3	SUSPECTED DRUG	1=yes 0=no	Present? 1=yes 0=no	Explanation
a	Brand name in case of drug substitution?	0		No drug substitution
b	Different forms or route of administration for suspected drug?	0		Not applicable
c	Relationship with ADR and dose of the drug?	0		No dose-relationship expected
d	Batch number of relevance?	0		Not applicable

4	PATIENT	Relevant? 1=yes 0=no	Present? 1=yes 0=no	Explanation
a	Risk factors/medical history/comorbidity	0		Information not relevant since there are no clear risk factors for this ADR.
b	Concomitant medication	1	1	Other drugs may have caused the reaction, this information is present.
c	Age/gender/length/weight	0		Information not relevant since there are no known risk factors.
d	Patient's lifestyle or other risk factors	0		Information not relevant since there are no clear risk factors for this ADR.

Example B: Headache associated with mirabegron

Description ADR:	headache
Start date:	22-12-2014
Outcome ADR:	recovered after 5 weeks
Treatment of ADR:	not reported
Did the patient ever use the suspect drug in the past?	no
If yes, did the patient experience similar ADRs?	
Possible other causes of ADR?	no
Seriousness?	non-serious
Suspected drug, dose:	mirabegron once daily 50 mg
Start date:	01-12-2014
Route of administration:	oral
Indication:	overactive bladder
Adjustment of use after ADR?	withdrawn
Concomitant medication:	no concomitant medication used
Patient's gender and age:	female, 69 years
Patient's weight and height:	not reported
Patient's medical history:	the patient has no diseases in the medical history that are still relevant.
Reporter:	specialist doctor
Extra information:	not filled in

Calculation final score

1.	ADR	100%
2.	Chronology	100%
3.	Suspected drug	-
4.	Patient characteristics	100%

FINAL SCORE	**100%**	**Well**

1	ADVERSE DRUG REACTION (ADR)	Relevant? 1=yes 0=no	Present? 1=yes 0=no	Explanation
a	Proper description of the ADR	1	1	The ADR headache is clear.
b	Specification reaction 'localization' and 'characterization'	0		Specification reaction 'localization' and 'characterization' is not relevant in this case.
c	Treatment	0		Information not relevant since it adds nothing to support the ADR.
d	Visual material (photo, video)	0		Information not relevant since it adds nothing to support the ADR.
e	Lab values, test	0		Information not relevant since it adds nothing to support the ADR.

2	CHRONOLOGY	Relevant? 1=yes 0=no	Present? 1=yes 0=no	Explanation
a	Latency	1	1	Reported
b	Description of the course of the ADR	1	0	Description of the course is relevant for this ADR: Continuously every day or intermittent?
c	Action taken on drug	1	1	Reported
d	Outcome of the ADR	1	1	Reported

3	SUSPECTED DRUG	1=yes 0=no	Present? 1=yes 0=no	Explanation
a	Brand name in case of drug substitution?	0		No drug substitution
b	Different forms or route of administration for suspected drug?	0		Not applicable
c	Relationship with ADR and dose of the drug?	0		No dose-relationship expected
d	Batch number of relevance?	0		Not applicable

4	PATIENT	Relevant? 1=yes 0=no	Present? 1=yes 0=no	Explanation
a	Risk factors/medical history/comorbidity	1	1	Information not relevant since there are no clear risk factors for this ADR.
b	Concomitant medication	1	1	Other drugs could have caused the reaction. This information is present.
c	Age/gender/length/weight	0		Information not relevant since there are no known risk factors.
d	Patient's lifestyle or other risk factors	0		Information not relevant since there are no clear risk factors or this ADR.

Example C: Lack of drug effect after substitution sumatriptan

Description ADR:	lack of drug effect following drug substitution of sumatriptan of the brand Mylan to sumatriptan of the brand Aurobinde
Start date:	not reported
Outcome ADR:	not recovered
Treatment of ADR:	not reported
Did the patient ever use the suspect drug in the past?	no
If yes, did the patient experience similar ADRs?	
Possible other causes of ADR?	no
Seriousness?	non-serious
Suspected drug, dose:	sumatriptan of the brand Aurobinde, not reported
Start date:	not reported
Route of administration:	oral
Indication:	migraine
Adjustment of use after ADR?	withdrawn
Concomitant medication:	not reported
Patient's gender and age:	female, 68 years
Patient's weight and height:	not reported
Patient's medical history:	the past drug therapy indicates that the patient had sumatriptan of the brand Mylan before without a similar reaction.
Reporter:	consumer
Extra information:	
• For patient reports:	
Who prescribed the drug?	general practitioner
Where did the patient got/buy the drug?	community pharmacy

Calculation final score

1.	ADR	50%
2.	Chronology	100%
3.	Suspected drug	-
4.	Patient characteristics	100%
	FINAL SCORE	**83%** **Well**

1	ADVERSE DRUG REACTION (ADR)	Relevant? 1=yes 0=no	Present? 1=yes 0=no	Explanation
a	Proper description of the ADR	1	1	ADR is clear because an indication is reported. If no indication is reported you might consider this item to be not present since you don't exactly know what reaction the patient experienced. This is especially the case when a drug is indicated for more than one disease.
b	Specification reaction 'localization' and 'characterization'	0		Information not relevant since it adds nothing to support the ADR
c	Treatment	0		Information not relevant since it adds nothing to support the ADR
d	Visual material (photo, video)	0		Information not relevant since it adds nothing to support the ADR
e	Lab values, tests	0		Information not relevant since it adds nothing to support the ADR

2	CHRONOLOGY	Relevant? 1=yes 0=no	Present? 1=yes 0=no	Explanation
a	Latency	1	0	Not reported
b	Description of the course of the ADR	1	0	It is relevant to know if the 'lack of drug effect' happened once or more often. This information is not present.
c	Action taken on drug	1	1	Reported
d	Outcome of the ADR	1	1	Reported

3	SUSPECTED DRUG	1=yes 0=no	Present? 1=yes 0=no	Explanation
a	Brand name in case of drug substitution?	1	1	Drug substitution. Brand names are reported.
b	Different forms or route of administration for suspected drug?	0		Not applicable
c	Relationship with ADR and dose of the drug?	0		No dose-relationship expected
d	Batch number of relevance?	0		Not applicable

4	PATIENT	Relevant? 1=yes 0=no	Present? 1=yes 0=no	Explanation
a	Risk factors/medical history/comorbidity	0		Information not relevant since there are no known risk factors for 'lack of drug effect after substitution'.
b	Concomitant medication	0		Information not relevant since there are no known risk factors for 'lack of drug effect after substitution'.
c	Age/gender/length/weight	0		Information not relevant since there are no known risk factors for 'lack of drug effect after substitution'.
d	Patient's lifestyle or other risk factors	0		Information not relevant since there are no known risk factors for 'lack of drug effect after substitution'.

Example D: Myocardial infarction associated with capecitabine

Description ADR:	myocardial infarction
Start date:	03-03-2015
Outcome ADR:	recovered
Treatment of ADR:	the patient was hospitalized for 6 days and was treated with a cardiac catheterization and unspecified cardiac medication.
Did the patient ever use the suspect drug in the past?	no
If yes, did the patient experience similar ADRs?	
Possible other causes of ADR?	no
Seriousness?	serious
Suspected drug, dose:	capecitabine tablets, 2 dd 2000 mg
Start date:	01-03-2015
Route of administration:	oral
Indication:	colon carcinoma
Adjustment of use after ADR?	withdrawn
Concomitant medication:	concomitant medications were salmeterol/fluticason and tiotropium bromide.
Patient's gender and age:	female, 68 years
Patient's weight and height:	weight 60 kg, height 171 cm
Patient's medical history:	the medical history and past drug therapy were not reported.
Reporter:	consumer
Extra information:	not filled in

Calculation final score

5.	ADR	100%
6.	Chronology	100%
7.	Suspected drug	-
8.	Patient characteristics	75%
	FINAL SCORE	**92%** **Well**

1	ADVERSE DRUG REACTION (ADR)	Relevant? 1=yes 0=no	Present? 1=yes 0=no	Explanation
a	Proper description of the ADR	1	1	The ADR myocardial infarction is clear.
b	Specification reaction 'localization' and 'characterization'	0		Specification reaction 'localization' and 'characterization' is not relevant in this case.
c	Treatment	1	1	Information about the treatment is relevant in order to support the reported ADR. This information is present.
d	Visual material (photo, video)	0		Information not relevant since it adds nothing to support the ADR.
e	Lab values, test	0		Information not relevant since it adds nothing to support the ADR.

2	CHRONOLOGY	Relevant? 1=yes 0=no	Present? 1=yes 0=no	Explanation
a	Latency	1	1	Reported
b	Description of the course of the ADR	0		Description of the course is not relevant for this ADR.
c	Action taken on drug	1	1	Reported
d	Outcome of the ADR	0		Not relevant since myocardial infarction is an irreversible ADR.

3	SUSPECTED DRUG	1=yes 0=no	Present? 1=yes 0=no	Explanation
a	Brand name in case of drug substitution?	0		No drug substitution
b	Different forms or route of administration for suspected drug?	0		Not applicable
c	Relationship with ADR and dose of the drug?	0		No dose-relationship expected
d	Batch number of relevance?	0		Not applicable

4	PATIENT	Relevant? 1=yes 0=no	Present? 1=yes 0=no	Explanation
a	Risk factors/medical history/comorbidity	1	1	Medical history is important information that is missing (e.g. cardiovascular disorders?), this information is lacking
b	Concomitant medication	1	1	Concomitant information is relevant, this information is present
c	Age/gender/length/weight	1	1	Gender, age, eight and height are important (to assess risk factors for myocardial infarction), this information is present.
d	Patient's lifestyle or other risk factors	1	0	Lifestyle is relevant to assess the risk factors for myocardial infarction (e.g. smoking), this information is lacking.

Example E: Fever associated with Infanrix Hexa®

Description ADR:	fever
Start date ADR:	28-03-2015
Outcome ADR:	recovered
Treatment of ADR:	paracetamol 120 mg
Did the patient ever use the suspect drug in the past?	no
If yes, did the patient experience similar ADRs?	
Possible other causes of ADR?	no
Seriousness?	non-serious
Suspected drug:	combined diphtheria-haemophilus-acellular pertussis-poliomyelitis-tetanus-hepatitisB vaccine (Infanrix hexa®; batch number ABCC00) and conjugated pneumococcal vaccine (Synflorix®; batch number ABB1234AA)
Start date:	28-03-2015
Dose, route of administration:	unknown, vaccination
Indication:	routine childhood vaccination
Adjustment of use after ADR?	not applicable
Concomitant medication:	not reported
Patient's gender and age:	female, 11 months
Patient's weight and height:	not reported
Patient's medical history:	not reported
Reporter:	community health service employee
Extra information:	not filled in

Calculation final score

1.	ADR	50%
2.	Chronology	67%
3.	Suspected drug	-
4.	Patient characteristics	-

FINAL SCORE **58%** **Moderate**

1	ADVERSE DRUG REACTION (ADR)	Relevant? 1=yes 0=no	Present? 1=yes 0=no	Explanation
a	Proper description of the ADR	1	1	The ADR fever is clear.
b	Specification reaction 'localization' and 'characterization'	0		Specification reaction 'localization' and 'characterization' is not relevant in this case.
c	Treatment	0		Information not relevant since it adds nothing to support the ADR.
d	Visual material (photo, video)	0		Information not relevant since it adds nothing to support the ADR.
e	Lab values, test	1	0	The height of the temperature was not reported and is important information in this report, this information is lacking.

2	CHRONOLOGY	Relevant? 1=yes 0=no	Present? 1=yes 0=no	Explanation
a	Latency	1	1	Reported
b	Description of the course of the ADR	0		Information is not relevant since the vaccine was only given once and fever has no specific time course.
c	Action taken on drug	1	0	Not relevant since it is a single administration.
d	Outcome of the ADR	1	1	Reported

3	SUSPECTED DRUG	1=yes 0=no	Present? 1=yes 0=no	Explanation
a	Brand name in case of drug substitution?	0		No drug substitution
b	Different forms or route of administration for suspected drug?	0		Not applicable
c	Relationship with ADR and dose of the drug?	0		No dose-relationship expected
d	Batch number of relevance?	0		Not applicable since it is not reported that these ADRs are seen more often with this vaccination.

4	PATIENT	Relevant? 1=yes 0=no	Present? 1=yes 0=no	Explanation
a	Risk factors/medical history/comorbidity	0		Information not relevant since there are no known risk factors.
b	Concomitant medication	0		Information not relevant since there are no known risk factors.
c	Age/gender/length/weight	0		Information not relevant since there are no known risk factors.
d	Patient's life style or other risk factors	0		Information not relevant since there are no known risk factors.