

CONTENT REVIEW SUMMARY: ADVERSE REACTION RISK(FHIR/OPENEHR) (REVISION: 13) (SUMMARY VIEW OF 19 REVIEWS)

ADVERSE REACTION RISK(FHIR/OPENEHR)

HEADER

Archetype ID	openEHR-EHR-EVALUATION.adverse_reaction_fhir.v1	<p><i>Ines Vaz (03-Nov-2014)</i> Ok</p> <p><i>Luis Marco Ruiz (04-Nov-2014)</i> Please reconsider the appropriateness the name of the FHIR standard in the id. This is already stated in the concept name.</p>
Concept name	Adverse Reaction Risk(FHIR/openEHR)	<p><i>Fatima Almeida (22-Oct-2014)</i> Adverse Reaction Risk (FHIR/openEHR) [blank space is missing]</p> <p><i>Lin Zhang (30-Oct-2014)</i> As described its use, the meaning of this concept includes not only Adverse Reaction Risk, but also Adverse Reaction per se, so the concept name seems incomplete.</p> <p><i>Ines Vaz (03-Nov-2014)</i> Ok</p> <p><i>Richard Townley-O'Neill (05-Nov-2014)</i> Why not Allergen or Allergy/Intolerance ?</p>
Keywords	reaction, allergy, allergic, adverse, event, effect, sensitivity, intolerance, hypersensitivity, side effect, toxicity, interaction, drug, food, medication, agent, substance, immune, non-immune, chemical	<p><i>Koray Atalag (29-Oct-2014)</i> anaphylaxis?</p> <p><i>Lin Zhang (30-Oct-2014)</i> skin test? allergen?</p> <p><i>Ines Vaz (03-Nov-2014)</i> Ok</p>
Purpose	<p>To record a clinical assessment of a propensity, or potential risk to an individual, of an adverse reaction upon future exposure to the specified substance, or class of substance.</p> <p>Where a propensity is identified, to record information or evidence about a reaction event that is characterised by any harmful or undesirable, physiological response that is unique to the individual, and triggered by exposure of an individual to the identified substance or class of substance.</p>	<p><i>Ines Vaz (03-Nov-2014)</i> Ok</p>
Use	<p>Use to provide a single place within the health record to document a range of clinical statements about adverse reactions, including:</p> <ul style="list-style-type: none"> - record a clinical assessment of the individual's propensity to a potential future reaction upon re-exposure; and - record cumulative information about the reaction to each exposure, including 'no reaction' if appropriate. <p>Use to record information about the positive presence of the risk of an adverse reaction:</p> <ul style="list-style-type: none"> - to support direct clinical care of an individual; - as part of a managed adverse reaction or allergy/intolerance list; - to support exchange of information about the propensity and events related to adverse reactions; - to inform adverse reaction reporting; and - to assist computerised knowledge-based activities such as clinical decision support and alerts. <p>Use to record information about adverse reactions to a broad range of substances, including: biological & blood products; incipients and excipients in medicinal preparations; metal salts; and organic chemical compounds.</p> <p>Adverse reactions may be:</p> <ul style="list-style-type: none"> - an immune mediated reaction - Types I-VI (including allergic reactions and hypersensitivities); or - a non-immune mediated reaction - including pseudo-allergic reactions, side effects, intolerances, drug toxicities (eg to Gentamicin), drug-drug interactions, food-drug interactions, and drug-disease interactions. <p>In clinical practice distinguishing between immune-mediated and non-immune mediated reactions is difficult and often not practical. Identification of the type of reaction is not a proxy for seriousness or risk of harm to the patient, which is better expressed by the manifestation in clinical practice.</p> <p>The risk of an adverse reaction event or manifestation should not be recorded without identifying a proposed causative substance or class of substance. If there is uncertainty that a specific substance is the cause, this uncertainty can be recorded using the 'Status' data element. If there are multiple possible substances that may have caused a reaction/manifestation, each substance should be recorded using a separate instance of this adverse reaction archetype/FHIR resource with the 'Status' set to an initial state of 'Unconfirmed' so that adverse reaction checking can be supported in clinical systems. If a substance, agent or class is later proven not to be the cause for a given reaction then the 'Status' can be modified to 'Refuted'.</p> <p>This archetype/FHIR resource has been designed to allow recording of information about a specific substance (amoxycillin, oysters, or bee sting venom) or, alternatively, a class of substance (eg Penicillins)). If a class of substance is recorded then identification of the exact substance can be recorded on a per exposure basis.</p> <p>The scope of this archetype/FHIR resource has deliberately focused on identifying a pragmatic data set that are used in most clinical systems or will be suitable for most common clinical scenarios, however it permits extension of the model when additional detail is</p>	<p><i>Fatima Almeida (22-Oct-2014)</i> "Adverse reactions may be: ... drug-drug interactions, food-drug interactions, and drug-disease interactions." It is true that these are adverse reactions but does it make sense to include these in here? Assuming that these risks are already described in literature, this is not really an "individual risk" and is not just related to the exposure to a single substance (or group of substances). When it is known that this is the cause of the reaction, I think that it would be more logical to record these separately, in some archetype that would just</p>

required, for example 'Reaction details', 'Exposure details', and 'Reporting details' slots. Examples of clinical situations where the extension may be required include: a detailed allergist/immunologist assessment, for reporting to regulatory bodies or use in a clinical trial.

The act of recording any adverse reaction in a health record involves the clinical assessment that a potential hazard exists for an individual if they are exposed to the same substance/agent/class in the future – that is, a relative contraindication - and the default 'Criticality' value should be set to 'Low risk'. If a clinician considers that it is not safe for the individual to be deliberately re-exposed to the substance/agent again, for example, following a manifestation of a life-threatening anaphylaxis, then the 'Criticality' data element should be amended to 'High risk'.

A formal Adverse Event Report to regulatory bodies is a document that will contain a broad range of information in addition to the specific details about the adverse reaction. The report could utilise parts of this Risk of adverse reaction archetype/FHIR resource plus include additional data as required per jurisdiction.

An adverse reaction or allergy/intolerance list is a record of all identified propensities for an adverse reaction for the individual upon future exposure to the substance or class, plus provides potential access to the evidence provided by details about each reaction event, such as manifestation.

Valuable first-level information that could be presented to the clinician when they need to assess propensity for future reactions are:

- statements about previous clinical manifestations following exposure;
- source of the information/reporter; and
- the 'Criticality' flag.

Second-level information can be drawn from each exposure event and links to additional detailed information such as history, examination and diagnoses stored elsewhere in the record, if it is available.

openEHR only: Links to other parts of the health record where further details may be located, such as consultation notes, is allowed by the openEHR reference model, but not modelled explicitly in this archetype.

record this type of occurrences, somewhat related to "failures of clinical process"/ medication errors (in case there is any medication involved). If included here, at least these should be clearly identified and not just classified as "non-immune mediated".

Lin Zhang (30-Oct-2014)

How to use it within a context where reporting of adverse reactions need to be de-identified according to local patient safety requirements so that privacies of related persons can be protected and reporting of adverse reactions can be promoted within the context of "friendly" patient safety culture?

Ines Vaz (03-Nov-2014)

Ok

Vebjoern Arntzen (04-Nov-2014)

".. 'no reaction' if appropriate", this should only be used when a substance or class of substance has been registered previously.

Stephen Chu (05-Nov-2014)

If this archetype is constrained for record adverse reaction risk assessment, there should be mention that recording of information about the allergy or intolerance is to be handled by a separate archetype, e.g. problem/diagnosis. The inclusion of "allergy", "intolerance", "sensitivity", "hypersensitivity" under "keywords" easily gives the impression that this archetype is intended/may be used for capturing information about these conditions

References

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Ines Vaz (03-Nov-2014)

Ok

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Thien FC. Drug hypersensitivity. Med J Aust. 2006 Sep 18;185(6):333-8. Review. PubMed PMID: 16999678.

- Uppsala Monitoring Centre (WHO): <http://www.who-umc.org/>






- European Medicines Agency: <http://www.ema.europa.eu/ema/>








- DIRECTIVE 2010/84/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, of 15 December 2010, amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use: http://ec.europa.eu/health/files/eudralex/vol-1/dir_2010_84/dir_2010_84_en.pdf







DATA

Substance T Text Mandatory (1..1)	<p>Identification of a substance, or a class of substances, that is considered to be responsible for the adverse reaction.</p> <p>Comment: The Substance field allows for the use of a either specific substance (for example 'Amoxycillin') or a group or class of substances (for example 'Penicillins'). Duplication in the 'Substance' and 'Specific substance' fields is acceptable if clinically appropriate. It is strongly recommended that both 'Substance' and 'Specific substance' be coded with a terminology capable of triggering decision support, where possible. For example: including but not limited to RxNorm, Snomed CT, DM+D, NDFRT, ICD-9, IDC-10, UNI, ATC and CPT. Plain text should be used only if there is no appropriate terminology available.</p> <p>source: openEHR,FHIR,DAM</p>		<p><i>Koray Atalag (29-Oct-2014):</i> SNOMED in capital letters Is ICD, CPT relevant? Maybe add AMT, NZULM</p> <p><i>Lin Zhang (30-Oct-2014):</i> In the clinical content of Archetype Adverse Reaction Risk (FHIR/openEHR), there are some example terminologies that could be used to encode a Substance or a Specific substance. Among them, ICD9, ICD10 and CPT might be not suitable for identification of a substance, or a specific substance, or a class of substances, although these terminologies are all more or less related to the above substance concepts. Their primary purposes/scopes focus on diseases or medical services rather than the substance concepts. Maybe ICD9, IDC10 and CPT should be removed from the list of example terminologies for identification of a substance the above substance concepts. Possible Typo 1: IDC10 --> ICD10 ? Possible Typo 2: UNI --> UNII ?</p> <p><i>Ines Vaz (03-Nov-2014):</i> Ok</p>
Status T Coded Text Optional (0..1)	<p>Assertion about the propensity, or potential risk, of a reaction to the identified 'Substance'.</p> <p>Comment: Decision support would typically raise alerts for 'Unconfirmed', 'Confirmed', and 'Resolved' and ignore a 'Refuted' reaction. In particular, 'Refuted' may be useful for reconciliation of the adverse reaction list. Some implementations may choose to make this field mandatory.</p> <p>source: FHIR,DAM</p>	<ul style="list-style-type: none"> Unconfirmed [A low level of certainty about the propensity for a reaction to the identified 'Substance'.] Confirmed [A high level of certainty about the propensity for a reaction to the identified 'Substance', which may include clinical evidence by testing or re-challenge.] Resolved [A previously known reaction to the identified 'Substance' has been clinically reassessed by testing and/or re-challenge and considered no longer to be an active risk.] Refuted [A propensity for a reaction to the identified 'Substance' has been reassessed by testing and/or re-challenge, and has been disproved with a high level of clinical certainty.] <p>Possible reasons why null:</p> <ul style="list-style-type: none"> unknown 	<p><i>Sam Heard (23-Oct-2014):</i> I think the refuted and resolved break a rule of negativity in the information. I have never seen this sort of information in a problem list and I think it is difficult as it is not possible to import into systems safely if they do not check this field. I would suggest that we have an exclusion statement about adverse reactions, remembering that in openEHR we can look back at the history. It is possible to record no reaction to a specific substance that might mean you lower the status to unconfirmed - but resolved and refuted I think are dangerous. FHIR may want this but if so we should transform on arrival.</p> <p><i>Koray Atalag (29-Oct-2014):</i> I'm not comfortable with refuted & resolved as they are. I think the primary idea is to report a particular hazard is no longer present yet these are two distinct reasons. Suggest pre-coordinating: * not present - resolved * not present - refuted can use a more appropriate term for "not present" but the idea is to make explicit semantically the potential hazard is not in place.</p> <p><i>Ian McNicoll (30-Oct-2014):</i> We may need to better document safe use of the 'negated' values (see Sam's comments), particularly 'refuted' which I would probably not allow in my system other than as a flag on a logically deleted record. There will be other approaches.</p> <p><i>Lin Zhang (30-Oct-2014):</i> Pending?</p> <p><i>Rong Chen (31-Oct-2014):</i> Very useful attribute.</p> <p><i>Andrew Yap (23-Nov-2014):</i> I think the description is confusing. In its current form I think it is describing the "criticality" field. Perhaps it's an 'assertion about the certainty of a reaction to a particular substance.'</p>
Criticality	<p>Estimate of the potential clinical harm, or</p>	<ul style="list-style-type: none"> Low risk [The potential clinical 	<p><i>Sam Heard (23-Oct-2014):</i> Not sure that we should use the word risk</p>




<p>T Coded Text Optional (0..1)</p>	<p>seriousness, of the reaction to the identified 'Substance'. Comment: The default Criticality value for any propensity to an adverse reaction should be 'Low risk', indicating at the very least a relative contraindication to deliberate or voluntary exposure to the identified 'Substance'. 'High risk' is flagged if the clinician has identified a propensity for a more serious or potentially life-threatening reaction, such as anaphylaxis, and implies an absolute contraindication to deliberate or voluntary exposure to the substance. source: DAM, openEHR</p>	<p>impact of a future reaction is estimated as low risk. Future exposure to the identified 'Substance' is considered a relative contraindication.]</p> <ul style="list-style-type: none"> • High risk [The potential clinical impact of a future reaction is estimated as high risk. Future exposure to the identified 'Substance' may be considered an absolute contraindication.] 	<p>and criticality together with risk. Does this mean a low risk of a critical state? This is a signal to future prescribers and I think it needs to be more explicit. This may already be in some specifications and so stay - but I think the advice should be absolute or relative contraindication. Why obfuscate?</p> <p><i>Koray Atalag (29-Oct-2014):</i> Very subjective but potentially useful for decision support and is supported by many existing implementations. Most probably there will be different levels but it all boils down to whether to put a red flashing flag or not on the screen so probably mapping to low/high risk would be feasible. Putting moderate for example would make things very difficult.</p> <p><i>Lin Zhang (30-Oct-2014):</i> We might need more levels rather than two.</p> <p><i>Rong Chen (31-Oct-2014):</i> This is very helpful from decision support perspective.</p> <p><i>Stephen Chu (05-Nov-2014):</i> "Criticality" is not a concept for qualifying the risk. It is a concept for asserting the potential for or actuality of critical system organ damage or life threatening damages. As such, the valueset of "low risk" and "high risk" is inappropriate. The valid values should be: high low unknown unable to determine The unknown and unable to determine values are important and should be included</p>
<p>Special Question</p>	<p>While renaming this data element from 'Seriousness' to 'Criticality' has probably clarified the intent to a significant degree, criticality is still a rather obscure word outside of the world of health informatics. We are trying to provide an indication of future risk on exposure here. Would renaming to 'Risk' be clearer to non-informaticians, and require an associated update to the description along the lines of: "Potential for harm or seriousness of a future reaction to the identified 'Substance'".</p>		<p><i>Anoop Shah (22-Oct-2014)</i> Maybe rename it to 'Potential for harm' so that it is absolutely clear?</p> <p><i>Sam Heard (23-Oct-2014)</i> What is serious? Is it the patient or the clinician who estimates this. The clinician will have some idea of likelihood and clinical seriousness, but a patient may never want to have the substance again under any circumstances. Should we separate this to therapeutic precautions? It may be radical but you can see the problem here as we try and capture more data that was traditionally static and got lost.</p> <p><i>Koray Atalag (29-Oct-2014)</i> Risk level?</p> <p><i>Ian McNicoll (30-Oct-2014)</i> I do like the suggestion of changing the name to "Potential for Harm"</p> <p><i>Vebjoern Arntzen (04-Nov-2014)</i> 'Criticality' works fine, the norwegian word equivalent to criticality (kritikalitet or kritisk) is commonly used also for non-informatics. 'Risk' could be misinterpreted as a risk for being exposed to the agent/substance</p> <p><i>Steve Bentley (04-Nov-2014)</i> As previous review I am not convinced that this would be used in a repeatable manor. Whether it is an absolute contraindication depends upon the clinical situation. Both the seriousness of the illness being treated and the clinical setting of the patient. Risk is more descriptive than criticality.</p> <p><i>Stephen Chu (05-Nov-2014)</i> The proposed description for criticality is inappropriate. Criticality is an indication of the potential for or actuality of critical system organ damage or life threatening consequence. Suggest change the description to above in improve clarity</p> <p><i>Andrew Yap (23-Nov-2014)</i> I agree - criticality is too obscure.</p> <p><i>Micaela Thierley (22-Dec-2014)</i> Risk is more intuitive for me as a clinician. At the same time it may lead to some confusion between this risk and the archetype openEHR-EHR-EVALUATION.risk.v1 Because of this I vote to keep "criticality" as long as we have "risk" in the coded text.</p>
<p>Reaction type T Coded Text Optional (0..1)</p>	<p>Identification of the underlying physiological mechanism for the adverse reaction. Comment: Immune-mediated responses have been traditionally regarded as an indicator for escalation of significant future risk. Contemporary knowledge suggests that some reactions previously thought to be immune and non-immune and still carry life threatening</p>	<ul style="list-style-type: none"> • Immune mediated [Immune mediated reaction, including allergic reactions and hypersensitivities.] • Non-immune mediated [A non-immune mediated reaction, which can include pseudo-allergic reactions, side effects, intolerances, drug toxicities (for 	<p><i>Fatima Almeida (22-Oct-2014):</i> "...drug-drug interactions, food-drug interactions, and drug-disease interactions." As explained before I don't think these should be included here. If these are already described in literature this is not really an "individual" risk of the patient, and in some cases it might be closer to failure in clinical practice. If included here, at least these should be clearly identified and not just classified as "non-immune mediated".</p> <p><i>Sam Heard (23-Oct-2014):</i> This has been shown to be difficult to assess.</p> <p><i>Koray Atalag (29-Oct-2014):</i></p>

	<p>risk. It is acknowledged that many clinicians may not be in a position to distinguish the mechanism of a particular reaction. This data element is included nevertheless because many legacy systems have captured this attribute. Immunological testing may provide supporting evidence for the basis and causative substance, but no tests are 100% sensitive or specific for a sensitivity.</p> <p>source: FHIR,DAM</p>	<p>example, to Gentamicin), drug-drug interactions, food-drug interactions, and drug-disease interactions.]</p> <p>Possible reasons why null:</p> <ul style="list-style-type: none"> unknown 	<p>I'd suggest expanding non-immune mediated items as many existing systems will have enumerations like "food intolerance", "drug reaction" etc. So to be inclusive and allow for easy mappings maybe pre-coordinate (e.g. non-immune mediated: food intolerance) and also include "non-immune mediated: other" to capture all others.</p> <p><i>Vebjoern Arntzen (04-Nov-2014):</i> Is there something wrong in the sentence: "Contemporary knowledge suggests that some reactions previously thought to be immune and non-immune and still carry life threatening risk.", maybe an "and" too much? If not, I don't understand. A non-immune mediated rreaction caused by a Drug-drug interaction, is meant to record a reaction in a specific individual, not a general contra-indication due to known interaction between drugs? E.g drug A gives an adverse reaction in combination with drug B for Mr X, while it's OK for anyone else?</p> <p><i>Stephen Chu (05-Nov-2014):</i> Suggest add other null values: for example - undetermined (which is distinctly different from unknown)</p>
<p>Substance category  Coded Text Optional (0..1)</p>	<p>Category of the identified 'Substance'. Comment: This data element has been included because it is currently being captured in some clinical systems. This data can be derived from the Substance where coding systems are used, and is effectively redundant in that situation.</p>	<ul style="list-style-type: none"> Food [Any substance consumed to provide nutritional support for the body.] Medication [Any substance administered to achieve a physiological effect.] Environment [Any substance encountered in the environment.] 	<p><i>Sam Heard (23-Oct-2014):</i> Is Venom worth putting in here?</p> <p><i>Koray Atalag (29-Oct-2014):</i> Can it be internal?, e.g. rupture of a cyst/abscess releasing high doses of a substance/agent?</p> <p><i>Ines Vaz (03-Nov-2014):</i> Ok</p> <p><i>Vebjoern Arntzen (04-Nov-2014):</i> Is sunscreen or makeup "Environment"? Jewellery?</p> <p><i>Silje Ljosland Bakke (04-Dec-2014):</i> Should reactions to blood products be part of this archetype? If so, Blood products should be an option.</p>
<p>Date of last reaction  Date/Time Optional (0..1)</p>	<p>Represents the date and/or time of the last known occurrence of a reaction event. Comment: This date may be replicated by one of the Onset of Reaction dates. Where a textual representation of the date of last occurrence is required e.g 'In Childhood, '10 years ago' the Comment element should be used.</p> <p>source: IMH</p>		<p><i>Ines Vaz (03-Nov-2014):</i> Ok</p>
<p>Comment  Text Optional (0..1)</p>	<p>Additional narrative about the propensity for the adverse reaction, not captured in other fields. Comment: For example: including reason for flagging a 'Criticality' of 'High risk'; and instructions related to future exposure or administration of the Substance, such as administration within an Intensive Care Unit or under corticosteroid cover.</p> <p>source: openEHR</p>		<p><i>Ines Vaz (03-Nov-2014):</i> Ok</p>
<p>Reaction event  Cluster Optional, repeating (0..*) Cardinality: Mandatory, repeating, unordered (1..*)</p>	<p>Details about each adverse reaction event linked to exposure to the identified 'Substance'. source: openEHR,FHIR,DAM</p>		<p><i>Steve Bentley (04-Nov-2014):</i> I am not sure what the optionality/cardinality means here.</p>
<p>Specific substance  Text Optional (0..1)</p>	<p>Identification of the specific substance considered to be responsible for the adverse reaction event. Comment: For example: 'Amoxycillin'. Duplication of the value recorded in the 'Substance' and 'Specific substance' fields is acceptable if clinically appropriate. It is strongly recommended that 'Specific substance' be coded with a terminology capable of triggering</p>		<p><i>Lin Zhang (30-Oct-2014):</i> In the clinical content of Archetype Adverse Reaction Risk (FHIR/openEHR), there are some example terminologies that could be used to encode a Substance or a Specific substance. Among them, ICD9, ICD10 and CPT might be not suitable for identification of a substance, or a specific substance, or a class of substances, although these terminologies are all more or less related to the above substance concepts. Their primary purposes/scopes focus on diseases or medical services rather than the substance concepts. Maybe ICD9, IDC10 and CPT should be removed from the list of example terminologies for identification of a</p>

	<p>decision support, where possible. For example: including but not limited to RxNorm, Snomed CT, DM+D, NDFRT, ICD-9, IDC-10, UNI, ATC and CPT. Plain text should be used only if there is no appropriate terminology available.</p> <p>source: FHIR, openEHR, DAM</p>		<p>substance the above substance concepts.</p> <p>Possible Typo 1: IDC10 --> ICD10 ? Possible Typo 2: UNI --> UNII ?</p> <p><i>Ines Vaz (03-Nov-2014):</i> Ok</p> <p><i>Richard Townley-O'Neill (05-Nov-2014):</i> If this is a record of an event, this substance may be less specific than the one in the evaluation of allergy/intolerance. This could be 'Thai food' while the allergen is 'sesame oil'.</p>
<p>Certainty</p> <p> Coded Text Optional (0..1)</p>	<p>Statement about the degree of clinical certainty that the identified 'Specific substance' was the cause of the 'Manifestation' in this reaction event.</p> <p>source: FHIR</p>	<ul style="list-style-type: none"> • Unlikely [There is a low level of clinical certainty that the reaction was caused by the identified 'Specific substance'.] • Likely [There is a high level of clinical certainty that the reaction was caused by the identified 'Specific substance'.] • Confirmed [There is a very high level of clinical certainty that the reaction was due to the identified 'Substance', which may include clinical evidence by testing or re-challenge.] <p>Possible reasons why null:</p> <ul style="list-style-type: none"> • unknown 	<p><i>Richard Townley-O'Neill (05-Nov-2014):</i> This suggests recording by reaction symptoms with a list of substances that are candidates for the cause.</p> <p><i>Andrew Yap (23-Nov-2014):</i> Isn't this the same as the status field? The status field has more specific options which are less subjective.</p>
<p>Reaction description</p> <p> Text Optional (0..1)</p>	<p>Narrative description about the adverse reaction as a whole, including details of the manifestation if required.</p> <p>source: FHIR, openEHR</p>		<p><i>Ines Vaz (03-Nov-2014):</i> Ok</p>
<p>Onset of the reaction</p> <p> Date/Time Optional (0..1)</p>	<p>Record of the date and/or time of the onset of the reaction.</p> <p>source: openEHR, FHIR, DAM</p>		<p><i>Ines Vaz (03-Nov-2014):</i> Ok</p>
<p>Duration of reaction</p> <p> Duration Optional (0..1)</p>	<p>The total amount of time that the manifestation of the adverse reaction persisted.</p> <p>source: openEHR</p>		<p><i>Ines Vaz (03-Nov-2014):</i> Ok</p>
<p>Severity of reaction</p> <p> Coded Text Optional (0..1)</p>	<p>Clinical assessment of the severity of the reaction event as a whole, potentially considering multiple different manifestations.</p> <p>Comment: It is acknowledged that this assessment is very subjective. There may be some specific practice domains where objective scales have been applied. Objective scales can be included in this model using the 'Reaction details' Cluster in openEHR or extensions in FHIR.</p> <p>source: DAM</p>	<ul style="list-style-type: none"> • Mild [Causes mild physiological effects.] • Moderate [Causes moderate physiological effects.] • Severe [Causes severe physiological effects.] 	<p><i>Ines Vaz (03-Nov-2014):</i> Very subjective, consider revision. The term 'severe' is used to describe the intensity (severity) of a specific event (as in mild, moderate or severe), and not to describe the physiological effects. The event itself may be of relatively minor medical significance (such as severe headache).</p> <p><i>Stephen Chu (05-Nov-2014):</i> It is unclear why there is a need to include an element for overall severity while there is an indication for "criticality" Severity as an attribute is more useful as a qualifier at signs and symptoms level</p>
<p>Reaction details</p> <p> ASLOT (Cluster) Optional, repeating (0..*)</p>	<p>Additional details about the adverse reaction, including anatomical location and Common Toxicity Criteria, can be provided by inclusion of specific archetypes in this SLOT.</p> <p>Comment: For example, photos captured using the Multimedia CLUSTER archetype. [Note: FHIR - These would be extensions as specified in a profile.]</p> <p>source: FHIR, openEHR</p>	<p>Include: openEHR-EHR-CLUSTER.anatomical_location.v1 and specialisations Or openEHR-EHR-CLUSTER.multimedia.v1</p>	<p><i>Stephen Chu (05-Nov-2014):</i> Does this cluster exclude the recording of coded/codeable entries of individual reaction signs and symptoms? If they are excluded, where are the signs and symptoms recorded?</p>
<p>Initial exposure</p> <p> Date/Time Optional (0..1)</p>	<p>Record of the date and/or time of the first exposure to the Substance for this Reaction Event.</p> <p>Comment: Exposure can</p>		<p><i>Ines Vaz (03-Nov-2014):</i> Ok</p>

	be more complicated by more than one exposure events leading to a reaction. Further details about the nature of the exposure can be provided by use of additional archetypes in the 'Exposure details' SLOT or as text in the 'Exposure description'. source: FHIR, openEHR, DAM		
Duration of exposure  Duration Optional (0..1)	The total amount of time the individual was exposed to the identified 'Specific substance'. source: openEHR		<i>Ines Vaz (03-Nov-2014):</i> Ok
Route of exposure  Text Optional (0..1)	Identification of the route by which the subject was exposed to the identified 'Specific substance'. Comment: Coding of the Route of Exposure with a terminology should be used wherever possible. source: FHIR, DAM		<i>Ines Vaz (03-Nov-2014):</i> Ok
Exposure description  Text Optional (0..1)	Narrative description about exposure to the identified 'Specific substance'. source: openEHR		<i>Ines Vaz (03-Nov-2014):</i> Ok
Exposure details  SLOT (Cluster) Optional, repeating (0..*)	Additional details about exposure to the 'Specific substance', especially in situations where there may have been multiple or cumulative exposures can be provided by inclusion of specific archetypes in this SLOT. Comment: [Note: FHIR - These would be extensions as specified in a profile.]	Include: openEHR-EHR-CLUSTER.citation.v1 and specialisations Or openEHR-EHR-CLUSTER.amount.v1	<i>Ines Vaz (03-Nov-2014):</i> Ok
Clinical management description  Text Optional (0..1)	Narrative description about the clinical management provided. source: openEHR		<i>Ines Vaz (03-Nov-2014):</i> Ok
Reaction comment  Text Optional (0..1)	Additional narrative about the adverse reaction event not captured in other fields. source: openEHR		<i>Ines Vaz (03-Nov-2014):</i> Ok

PROTOCOL

Reporting details  Cluster Optional (0..1) Cardinality: Mandatory, repeating, unordered (1..*)	Additional structured details required for reporting to regulatory bodies can be provided by inclusion of specific archetypes in this SLOT.		<i>Silje Ljosland Bakke (04-Dec-2014):</i> As this entire cluster pertains to a specific reaction event, should it perhaps be moved into the Reaction event cluster in DATA?
Subject  URI Mandatory (1..1)	The patient who has the allergy or intolerance. Comment: openEHR: implicit in the reference model ENTRY/subject. source: FHIR		<i>Richard Townley-O'Neill (05-Nov-2014):</i> This is in the openEHR reference model. Why repeat it here?
Recorder  URI Optional (0..1)	Indicates who has responsibility for the record. Comment: openEHR: implicit in the reference model ENTRY/provider. source: FHIR		<i>Richard Townley-O'Neill (05-Nov-2014):</i> What is this role: author, creator, reporter, responsible supervisor, undefined? 'Responsible for the record' could even be the custodian.

OVERALL COMMENTS

Completeness and/or any missing elements	<p><i>Anoop Shah (22-Oct-2014)</i> This seems to me to include all the important elements.</p> <p><i>Sam Heard (23-Oct-2014)</i> I think there are a lot of 'soft' data options which are related to traditional paper records and not focussed on eHealth. I would favour removing some of these and using the comment fields unless these are processable.</p> <p><i>Koray Atalag (29-Oct-2014)</i> How to report absolute exclusion of an</p>
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	<p>adverse reaction risk due to a substance?</p> <p><i>Richard Townley-O'Neill (05-Nov-2014)</i> Provide some guidance on what to do when the symptoms are clear but the agent is unknown. Maybe suggest the use of Problem/Diagnosis.</p>
General design issues of this archetype	<p><i>Anoop Shah (22-Oct-2014)</i> The design is sensible, and allows differing levels of detail depending on what information is available.</p> <p><i>Sam Heard (23-Oct-2014)</i> I think retaining the event data is important and should be copied with the rest - otherwise it will get lost.</p> <p><i>Ian McNicoll (30-Oct-2014)</i> I do agree with the views from Sam Heard and Steve Bentley among others that some of the elements are somewhat 'soft' and potentially unreliable in terms of computability but right or wrong they remain established in clinical thinking / recording and it is difficult to exclude them at present.</p> <p><i>Luis Marco Ruiz (04-Nov-2014)</i> A more scalable designs could be to mode Reaction Event as a separate archetype and leave this archetype with an slot pointing to it.</p> <p><i>Richard Townley-O'Neill (05-Nov-2014)</i> ONE The purpose statement and design lead me to summarise the primary purpose as: Record information of the form * substance - is safe; and * substance - is dangerous with the other information supporting that core information. That seems like a list of allergens, not a list of allergies/intolerances and not a list of adverse reaction risks. TWO 1/ As I see it an allergy/intolerance is a condition, and is naturally a type of Problem/Diagnosis where the cause is sensitivity to exposure to a substance. 2/ I do not see why reports of adverse reaction events are included in an evaluation. They should be observations. 3/ So this archetype is a blend of things that should be separate. 2/ It should have a data element about the typical symptoms. THREE The agent involved in allergy/intolerance may be 1 substance, a combination of substances, one of several known substances, or some unknown selection from a set of substances. All of these options should be recordable. To record an evaluation of the agent behind a patient's adverse reactions one needs to be able to record combinations (agent is the combination of AAA together with BBB) as well as alternatives due to ignorance (agent may be AAA or may be BBB). If two different agents cause the same adverse reactions that could be recorded by two instances of the archetype, or by enriching the archetype to allow 'symptom caused by agent A and caused by agent B'</p>
Overall comments	<p><i>Koray Atalag (29-Oct-2014)</i> Very difficult concept...Thinking about Grahame's recent example about the diversity of several systems on capturing adverse reactions (e.g. coding of severity SNOMED has 6 levels, this one 2 levels others probably have 3 or 4 etc.) there is obviously a big problem. The truth is there is hardly ever deep enough discussion during medical school on these topics and I guess every physician pretty much rediscovers some of these facts by own experience and synthesis as a result of practice. It becomes implicit knowledge. Luckily physicians can deal with ambiguity much better than our health information systems (plus human beings are so robust they can survive in modern health systems!). 80/20 rule of FHIR sounds like a good idea but what if most are doing the wrong thing and then I think one has the responsibility to correct things so I think this review is an opportunity.</p> <p><i>Lin Zhang (30-Oct-2014)</i> Good.</p> <p><i>Ines Vaz (03-Nov-2014)</i> I still have some doubts about this Archetype, namely according to the relevance of (not) including in this archetype the concept of drug ineffectiveness. I've made a comment on the concept of "severity", and I consider that it should be revised.</p> <p><i>Vebjoern Arntzen (04-Nov-2014)</i> Only minor adjustments of language, to clarify. See my comments. Else: Good job!</p> <p><i>Steve Bentley (04-Nov-2014)</i> The change of some attributes from mandatory to optional make this acceptable</p> <p><i>Silje Ljosland Bakke (04-Dec-2014)</i> Major revision because of my suggestion to move the reporting details cluster.</p>

Overall recommendation	<p><i>Fatima Almeida (22-Oct-2014)</i> Minor Revision</p> <p><i>Anoop Shah (22-Oct-2014)</i> Accept</p> <p><i>Sam Heard (23-Oct-2014)</i> Minor Revision</p> <p><i>Koray Atalag (29-Oct-2014)</i> Minor Revision</p> <p><i>Ian McNicoll (30-Oct-2014)</i> Accept</p> <p><i>Lin Zhang (30-Oct-2014)</i> Accept</p> <p><i>Rong Chen (31-Oct-2014)</i> Accept</p> <p><i>Howard Edidin (01-Nov-2014)</i> Accept</p> <p><i>Konstantinos Kalliamvakos (02-Nov-2014)</i> Accept</p> <p><i>Ines Vaz (03-Nov-2014)</i> Minor Revision</p> <p><i>Vebjoern Arntzen (04-Nov-2014)</i> Minor Revision</p> <p><i>Steve Bentley (04-Nov-2014)</i> Accept</p> <p><i>Luis Marco Ruiz (04-Nov-2014)</i> Minor Revision</p> <p><i>Stephen Chu (05-Nov-2014)</i> Major Revision</p> <p><i>Richard Townley-O'Neill (05-Nov-2014)</i> Reject</p> <p><i>Andrew Yap (23-Nov-2014)</i> Minor Revision</p> <p><i>Silje Ljosland Bakke (04-Dec-2014)</i> Major Revision</p> <p><i>Micaela Thierley (22-Dec-2014)</i> Accept</p> <p><i>Einar Fosse (08-Jan-2015)</i> Abstain</p>
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