API Validation Guide

Project Name: Learn From Patient Safety Events (LFPSE)

Date: 06/08/2021

Contents

1. Document Controls

1.1. Document Owner

The following personnel have provided input into this document.

Name	Role/Title	E-mail
Ryland Karlovich	Developer	ryland.karlovich@informed.com

1.2. Prepared By

The following personnel have provided input into this document.

Name	Role/Title	E-mail
Lauren Workman	Developer/Tester	lauren.workman@informed.com

1.3. Reviewers

Name	Role /Title	E-mail	Action	Date

1.4. Approvals

Name	Role/Title	E-mail

1.5. Version History

Version No.	Date	Revised by	Amended Section & Description of Change
V0.1	24/06/2020	Lauren Workman	Initial version of document
V0.2	26/06/2020	Ryland Karlovich	Minor revisions
V0.3	30/06/2020	Ryland Karlovich	Update to rule VR23
V0.4	29/06/2021	Alykhan Esmail	Added VR25/26, Update DPSIMS/PSIMS references to LFPSE
V0.5	06/08/2021	Ryland Karlovich	Updates to rules including new VR27-31

2. Purpose and Scope

This guide describes the validation rules relating to the LFPSE project, specifically around submitting an Adverse Event via the Adverse Event API.

3. Overview

3.1. Introduction

This document covers several types of validation rules, which have been split into three sections.

- Bespoke business validation rules which have been implemented based on the dependencies between responses and extensions that cannot be captured by the FHIR resource validation.
- FHIR validation responses which may be returned from the API when native FHIR validation checks the submission body against the LFPSE FHIR profiles defined for an adverse event.
- Invalid operations and similar responses which are external to validation of the submission, including responses pertaining to permissions, personal information and any other responses that do not fit into the two categories above.

When referring to errors and warnings throughout this document, in the case of an “error” the Adverse Event submission will be rejected with a message explaining the reason, whereas a “warning” will display a detailed message alerting of potential problems in the data however the submission will still be accepted and an id and reference number will be returned in the response. If a submission encounters several warnings they will all be displayed together and none will affect the submission of the Adverse Event.

4. Bespoke business validation rules

4.1. Overview

Bespoke business validation rules validate important dependencies between properties, for example Physical and Psychological harm levels, as well as specific date ranges.

The response codes returned by the triggering of business validation rules are as follows:

- 422 – A validation error was encountered, submission rejected
- 200 – AdverseEvent has been updated
- 201 – AdverseEvent has been created

For all rules in this section both POST and PUT AdverseEvent are applicable requests, with the exception of VR1 where the PUT AdverseEvent is the only applicable request.

4.2. Responses

Note that column “Vs” refers to applicable Taxonomy versions for the rule.

Id	Description	Triggering criteria	Outcome	Vs	Example message
VR 1	Submission data unchanged on re-submit	An existing record was updated but the data in the update has no changes from the existing version.	Submission rejected	All	“Submission data unchanged compared to previous version, update has not been processed.”
VR 2	Event date invalid	The event date is either in the future or is not in a valid format, or is too far in the past (prior to 1 January 1948). Accepted formats are YYYY-MM-DD and YYYY-MM.	Submission rejected	All	"AdverseEvent.Date cannot be in the future" / "AdverseEvent.Date cannot b e prior to 1 January 1948"
VR 3	No agent details are defined for an incident	An "Incident" type submission lacks an answer to the "InvolvedAgents" property (what things were involved in what went wrong) on the "adverse-event-agent" extension, or it lacks the extension	Submission rejected	All	"The extension 'adverse-event-agent' is required for Incident submissions" / "A value for 'InvolvedAgents' on extension 'adverse-event-agent' is required for Incident submissions"

		altogether.			
VR 4	Device missing	The "AgentsInvolved" property indicates a device was involved in the event but the Device resource was not provided (v4, v5) or the "adverse-event-problem-devices" extension was not provided (v5).	Submission accepted with descriptive warning	All	"AgentsInvolved indicates a Device was involved in this submission but no device details were found"
VR 5	Medication missing	The "AgentsInvolved" property indicates a medication was involved in the event but the Medication resource was not provided (v4) or the "adverse-event-problem-medication" extension was not provided (v5).	Submission accepted with descriptive warning	All	"AgentsInvolved indicates a Medication was involved in this submission but no medication details were found"
VR 6	Risk details missing	A "Risk" type submission does not include the "adverse-event-risk-details" extension.	Submission rejected	All	"Risk submission does not include any risk details as expected in extension 'adverse-event-risk-details'"
VR 7	Unexpected risk details provided	An "Incident" or "Outcome" type incident includes the "adverse-event-risk-details" extension, which is not applicable to these event types.	Submission accepted with descriptive warning	All	"Submission includes extension 'adverse-event-risk-details' which is not expected for Incident or Outcome events"
VR 9	People Actions missing	The "AgentsInvolved" property indicates people actions was involved in the event but the "PeopleActionFactors" property was not provided on the "adverse-event-problem" extension (v4) or the "adverse-event-problem-people" extension was not provided (v5).	Submission accepted with descriptive warning	All	"AgentsInvolved indicates people's actions were involved in this submission but no people action details were found"
VR 10	Furniture and Fittings missing	The "AgentsInvolved" property indicates furniture and fittings were involved in the event but the "FurnitureFittingsInvolvementFactors" property was not provided on the "adverse-event-problem" extension.	Submission accepted with descriptive warning	4	"AgentsInvolved indicates a furniture or fitting was involved in this submission but no furniture or fitting details were found"
VR 11	Built Environment missing	The "AgentsInvolved" property indicates the built environment was involved in the event but the "BuiltEnvironmentInvolveme	Submission accepted with descriptive	4	"AgentsInvolved indicates a built environment was involved in this submission but no built environment details were found"

		ntFactors" property was not provided on the "adverse-event-problem" extension.	warning		
VR 12	Blood and Blood Products missing	The "AgentsInvolved" property indicates blood and blood products were involved in the event but the "BloodProductsInvolvement Factors" property was not provided on the "adverse-event-problem" extension.	Submission accepted with descriptive warning	4	"AgentsInvolved indicates a b lood or blood product was inv olved in this submission but n o blood or blood product deta ils were found"
VR 13	Tissue and Organs missing	The "AgentsInvolved" property indicates tissue and organs were involved in the event but the "TissueOrgansInvolvementF actors" property was not provided on the "adverse-event-problem" extension (v4) or the "adverse-event-problem-tissues-organs" extension was not provided (v5).	Submission accepted with descriptive warning	All	"AgentsInvolved indicates tis sue or organs were involved i n this submission but no tissu e or organ details were found "
VR 14	IT Systems missing	The "AgentsInvolved" property indicates IT systems were involved in the event but the "ITSystemsInvolvementFact ors" property was not provided on the "adverse-event-problem" extension (v4) or the "adverse-event-problem-it-systems" extension was not provided (v5).	Submission accepted with descriptive warning	All	"AgentsInvolved indicates IT systems were involved in this submission but no IT system s details were found"
VR 15	Psychological harm when Physical is not fatal	For "Incident" type submissions, if physical harm is not fatal then psychological harm is mandatory	Submission rejected	All	"A value for 'PsychologicalHa rm' is required for Incident su bmissions"
VR 16	Mandatory incident questions	Mandatory incident questions that are not down a "branch" to be checked and a warning raised if any are not provided.	Submission accepted with descriptive warning	All	"LocationKnown was not incl uded in the submission"
VR 17	Mandatory outcome questions	Mandatory outcome questions that are not down a "branch" to be checked and a warning raised if any are not provided	Submission accepted with descriptive warning	All	"PatientAge was not included in the submission"
VR 18	Mandatory risk	Mandatory risk questions that are not down a "branch"	Submission accepted	All	"IncidentOccurredToday is n ot included in the submission

	questions	to be checked and a warning raised if any are not provided	with descriptive warning		"
VR 19	Mandatory good care questions	Mandatory good care questions that are not down a "branch" to be checked and a warning raised if any are not provided	Submission accepted with descriptive warning	All	
VR 20	Organisation, Reporting Organisation, Date	A warning will be raised if these particularly important properties are not provided, but submission will still be accepted because genuine cases of these being unknown exist.	Submission accepted with descriptive warning	All	"AdverseEvent.Date is not in cluded in the submission"/ "Organisation is not included in the submission" / "ReporterOrganisation is not i ncluded in the submission"
VR 21	Description missing	For "Incident", "Outcome" and "Good care" types, the description is mandatory.	Submission rejected	All	"The adverse event descripti on is required for this type of submission."
VR 22	Description length	The description should be a minimum of 5 characters.	Submission accepted with descriptive warning	All	"AdverseEvent.Description is less than 5 characters."
VR 23	Mis-classified incident	If the question CL024 (PatientSafetyIncidentHasO ccurred) is answered "Yes" and the submission type is "Outcome", warn that the event should be resubmitted as an "Incident" type.	Submission accepted with descriptive warning	All	"Submission may be misclas sified as an Outcome."
VR 24	Physical harm missing	For "Incident" types, the Physical Harm level is mandatory	Submission rejected	All	"A value for 'PhysicalHarm' is required for Incident submis sions"
VR 25	No patient incident	For "Incident" types with no patient involved, it is mandatory to include an answer to RiskImminent on the adverse-event-risk-details extension.	Submission rejected	All	“A value for 'RiskImminent' on extension 'adverse-event-risk-details' is required for Incident submissions where no patient was involved”
VR 26	Blood missing	The "AgentsInvolved" property indicates blood was involved in the event but the "adverse-event-problem-blood" extension was not provided.	Submission accepted with descriptive warning	5	“AgentsInvolved indicates a blood problem was involved in this submission but no blood problem details were found”
VR 27	Blood Products missing	The "AgentsInvolved" property indicates blood products were involved in the event but the "adverse-event-problem-blood-	Submission accepted with descriptive	5	"AgentsInvolved indicates a blood product problem was involved in this submission but no blood product problem details were found"

		products" extension was not provided.	warning		
VR 28	Buildings and Infrastructure missing	The "AgentsInvolved" property indicates buildings and infrastructure were involved in the event but the "adverse-event-problem-buildings-infrastructure" extension was not provided.	Submission accepted with descriptive warning	5	"AgentsInvolved indicates a buildings or infrastructure problem was involved in this submission but no buildings or infrastructure problem details were found"
VR 29	Estates Services missing	The "AgentsInvolved" property indicates estates services were involved in the event but the "adverse-event-problem-estates-services" extension was not provided.	Submission accepted with descriptive warning	5	"AgentsInvolved indicates an estates services problem was involved in this submission but no estates services problem details were found"
VR 30	Age Validation	For Incidents and Outcomes that include patients, each patient is checked and a warning raised if no precise age is given: AgeAtTimeOfIncident (v4), AgeAtTimeOfIncidentDays (v5)	Submission accepted with descriptive warning	All	"AgeAtTimeOfIncidentDays was not included in the submission"
VR 31	Patient Sequencing	When multiple patients are involved, each patient's PatientSequence must be a unique integer	Submission rejected	All	“Patient sequence must contain unique integers and be greater than 0, error when validating”

5. FHIR Validation

5.1. Overview

FHIR validation involves validation of the Adverse Event request body against the FHIR profiles defined in LFPSE, including the cardinality (minimum and maximum) of each extension. This is native validation from FHIR, which checks that the submission conforms to the data model specified in the LFPSE FHIR resources. There are many different permutations of FHIR validation triggering an error so the below list is not exhaustive.

5.2. Responses

Description	Triggering criteria	Applicable requests	Response code	Example message
Incorrect profile type	This message indicates that the profile specified in the meta.profile of the request body did not match an accepted LFPSE profile.	POST AdverseEvent PUT AdverseEvent	422	"FhirOperationException: Request does not target a recognised FHIR profile"
Validation against the LFPSE profile	This is an example of the request body failing FHIR validation against the LFPSE profile. There are many possible variants of validation failure messages depending on which constraint was violated.	POST AdverseEvent PUT AdverseEvent	422	"Instance count for 'Extension.extension:ResponsibleSpecialty' is 0, which is not within the specified cardinality of 1..1"
Invalid structure	This is an example message that indicates the request body was structurally invalid (JSON or XML).	POST AdverseEvent PUT AdverseEvent	400	"FhirOperationException: Cannot parse json: Error reading JObject from JsonReader. Current JsonReader item is not an object: String. Path '', line 2, position 16."
Event date invalid	The event date is not in a valid format. Accepted formats are YYYY-MM-DD and YYYY-MM.	POST AdverseEvent PUT AdverseEvent	400	"AdverseEvent.Date is not in a valid format"

6. Invalid Operations and Miscellaneous

6.1. Overview

The below table describes invalid operations that may not pertain directly to the data being submitted, including responses where a resource cannot be found or the requester does not have permission or authorisation. The miscellaneous responses include responses where personal information has been detected in an otherwise valid adverse event.

6.2. Responses

Description	Triggering criteria	Applicable requests	Response Code	Example message
Cannot access/find resource	This message indicates that a resource with the provided id does not exist, or the user is not authorized to access it	PUT AdverseEvent GET AdverseEvent	404	“NotFoundException: Exception of type 'NHSI.Fhir.Infrastructure.Exceptions.NotFoundException' was thrown.”
Unauthorised operation	This is a response given when an endpoint is accessed which is only intended to be used by LFPSE internal applications.	PUT AdverseEvent POST AdverseEvent GET AdverseEvent	404	"UnauthorizedAccessException: Attempted to perform an unauthorized operation."
Unauthorised request	This is a response given when the request is not allowed to reach the API because the user making the request does not have valid/current access to the LFPSE subscription.	PUT AdverseEvent POST AdverseEvent GET AdverseEvent	401	"Access denied due to invalid subscription key. Make sure to provide a valid key for an active subscription."
Personal information in submission	This message indicates that personal information may have been present in the submission. The submission is still accepted and the response includes details of the locations (start and end characters, property) where the suspect personal information was identified.	POST AdverseEvent PUT AdverseEvent	200 201	"Suspected personal information was detected in the textual content of the submission"

7. Example response bodies

7.1. Adverse Event response body (201)

The below example represents a successful response from the creation of an AdverseEvent, where no Personal Information was detected. It is a copy of the data sent by the user, and includes modifications made by the API in saving the data – specifically the inclusion of the id and the generation of the reference number extension. Note: version number will be automatically incremented on PUT (update).


```
{
    "resourceType": "AdverseEvent",
    "id": "6afea822-e87c-4e8d-a308-ac803a4c2e0c",
    "meta": {
        "versionId": "1.0.0",
        "lastUpdated": "2020-06-26T18:39:54.62+01:00",
        "profile": [
            "https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/patient-safety-adverse-event-4"
        ]
    },
    "contained": [
        {
            "resourceType": "Location",
            "id": "location1",
            "extension": [
                {
                    "url": "https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/location-details-4",
                    "extension": [
                        {
                            "url": "LocationKnown",
                            "valueCode": "y"
                        },
                        {
                            "url": "Organisation",
                            "valueCode": "RVV"
                        },
                        {
                            "url": "LocationWithinService",
                            "valueCode": "1"
                        },
                        {
                            "url": "ServiceArea",
                            "valueCode": "5"
                        },
                        {
                            "url": "ResponsibleSpecialty",
                            "valueCode": "86"
                        }
                    ]
                }
            ]
        },
        {
            "resourceType": "Patient",
            "id": "patient1",
            "extension": [
                {
                    "url": "https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/patient-information-4",
                    "extension": [
                        {
                            "url": "AgeYears",
                            "valueCode": "8"
                        },
                        {
                            "url": "Gender",
                            "valueCode": "2"
                        },
                        {
                            "url": "StrengthOfAssociation",
                            "valueCode": "4"
                        },
                        {
                            "url": "PhysicalHarm",
                            "valueCode": "1"
                        },
                        {
                            "url": "ClinicalOutcome",
                            "valueString": "test"
                        },
```

```
                        {
                            "url": "PatientSequence",
                            "valueInteger": 1
                        }
                    ]
                }
            ]
        },
        {
            "resourceType": "Practitioner",
            "id": "practitioner1",
            "extension": [
                {
                    "url": "https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/practitioner-
details-4",
                    "extension": [
                        {
                            "url": "ReporterType",
                            "valueCode": "3"
                        },
                        {
                            "url": "ReporterOrganisation",
                            "valueCode": "RVV"
                        }
                    ]
                }
            ]
        }
    ],
    "extension": [
        {
            "url": "https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-event-
estimated-date-4",
            "extension": [
                {
                    "url": "IncidentOccurredToday",
                    "valueCode": "y"
                },
                {
                    "url": "TodaysDate",
                    "valueDate": "2020-06-26"
                },
                {
                    "url": "EstimatedTime",
                    "valueCode": "4"
                }
            ]
        },
        {
            "url": "https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-event-agent-
4",
            "extension": [
                {
                    "url": "InvolvedAgents",
                    "valueCode": "9"
                }
            ]
        },
        {
            "url": "https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-event-
classification-4",
            "extension": [
                {
                    "url": "LevelOfConcern",
                    "valueCode": "3"
                }
            ]
        },
        {
            "url": "https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-event-safety-
challenges-4",
            "extension": [
                {
                    "url": "SafetyChallenges",
                    "valueCode": "3"
                }
            ]
        },
        {
            "url": "https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-event-
problem-4",
            "extension": [
                {
                    "url": "ITSystemsInvolvementFactors",
                    "valueCode": "1"
                }
            ]
        },
```

```
        {
            "url": "https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-event-
reference-metadata-4",
            "extension": [
                {
                    "url": "ReferenceNumber",
                    "valueString": "146924634"
                },
                {
                    "url": "FromOnlineForms",
                    "valueBoolean": false
                },
                {
                    "url": "IsAnonymous",
                    "valueBoolean": false
                },
                {
                    "url": "DataSharingOptOut",
                    "valueBoolean": false
                }

            ]
        }
    ],
    "category": "AE",
    "type": {
        "coding": [
            {
                "code": "1"
            }
        ]
    },
    "subject": {
        "reference": "#patient1"
    },
    "date": "2020-06-26",
    "location": {
        "reference": "#location1"
    },
    "recorder": {
        "reference": "#practitioner1"
    },
    "description": "Test description"
}
```


7.2. Warning response body (200/201)

The response body below is generated when an Adverse Event submission includes a warning, but is still created/ updated. In this case the warning is with regards to VR 16, where the LocationKnown is a mandatory question for an Incident but the extension was not included within the submission.


```
{
    "resourceType": "OperationOutcome",
    "issue": [
        {
            "severity": "warning",
            "code": "incomplete",
            "details": {
                "text": "LocationKnown was not included in the submission"
            },
            "location": [
                "location-details.LocationKnown"
            ]
        }
    ]
}
```

7.3. Error response body (422)

The response body below is an operation outcome that includes “diagnostics” indicating the exact reason for the submission rejection. In this case it is VR3.

```
{
    "resourceType": "OperationOutcome",
    "issue": [
        {
            "severity": "error",
            "code": "invalid",
            "diagnostics": "FhirOperationException: A value for 'InvolvedAgents' on
              extension 'adverse-event-agent' is required for Incident submissions"
        }
    ]
}
```

7.4. Unauthorised response body (401)

The response body below is a generic type generated when a request is not allowed to reach the API, usually due to invalid authorisation (e.g. subscription key). This is not a FHIR response, because the API never received the request.

```
{
"statusCode": 401,
"message": "Access denied due to invalid subscription key. Make sure to provide a
valid key for an active subscription."
}
```

7.5. Not found response body (404)

The response body below is a generic type generated when a resource cannot be found.

```
<OperationOutcome xmlns="http://hl7.org/fhir">
    <issue>
        <severity value="error" />
        <code value="invalid" />
        <diagnostics value="NotFoundException: Exception of type 'NHSI.Fhir.Infrast
ructure.Exceptions.NotFoundException' was thrown." />
    </issue>
</OperationOutcome>
```

7.6. Personal information detected response body

The example below represents an OperationOutcome in which personal information was detected in a submission. Note the issue contains a list of items (only one item in this example), each of which represents the location in which suspected PI was identified (diagnostics is the range of characters that raised the warning, location is the physical position within the AdverseEvent). Note that the event is still successfully created in this case, and the reference number and id are returned in the response.


```
{
    "resourceType": "OperationOutcome",
    "id": "f011edf8-a832-41e1-aa7e-a9ff983bd2db",
    "text": {
        "status": "generated",
        "div": "<div xmlns=\"http://www.w3.org/1999/xhtml\">\n <p>Suspected
personal information was detected in the textual content of the submission.</p>\n
</div>"
    },
    "extension": [
        {
            "url": "https://psims-uat.azure-
api.net/taxonomy/fhir/StructureDefinition/adverse-event-reference-metadata-4",
            "extension": [
                {
                    "url": "ReferenceNumber",
                    "valueString": "146924517"
                }
            ]
        }
    ],
    "issue": [
        {
            "severity": "warning",
            "code": "informational",
            "details": {
                "text": "Suspected personal information was detected in the textual
content of the submission"
            },
            "diagnostics": "0,12",
            "location": [
                "description"
            ]
        }
    ]
}
```