

API Documentation

Project Name: Learn From Patient
Safety Events (LFPSE)

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V0.2	03/10/2018	David Taylor	Added information about security and environments
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V1.1	06/11/2018	David Taylor	Added Private Beta compliance checklist
V1.2	13/03/2019	Ryland Karlovich	Added example resources in Section 8
V1.3	26/06/2020	Ryland Karlovich	Minor updates to account for further taxonomy releases
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V1.5	29/06/2021	Alykhan Esmail	Update DPSIMS/PSIMS references to LFPSE
V1.6	06/08/2021	Ryland Karlovich	Add LFPSE launch date
V1.7	01/02/2022	Mandy Williams	Add LFPSE integration compliance assessment and UAT and production URLs
V1.8	14/06/2022	Alykhan Esmail	Update information and screenshots for new developer portal – Remove hyperlinks from API URLs in section 6.

1. Introduction

The LFPSE (Learn From Patient Safety Events) project offers an opportunity to use modern technology to improve the health service for patients and carers, healthcare staff, NHS organisations and decision-makers, so that time and energy can be invested in the right things: **working to reduce harm**.

The LFPSE project is currently in the Beta phase, where the objective is to build a working version of the service based on the prototypes developed in Alpha.

The LFPSE (Learn From Patient Safety Events) solution contains two RESTful APIs that will be used by systems looking to integrate with LFPSE; the Adverse Event API and the Taxonomy API. Sections 2 and 3 of this document outline the purpose of each of these APIs, and provide supporting information for developers looking to integrate with LFPSE. Section 4 of the document provides a brief overview of the FHIR (Fast Healthcare Interoperability Resources) standard, and how it has been utilised by LFPSE. Section 5 gives an overview of the Azure API Developer Portal, which is used for requesting access to the APIs, viewing technical documentation, testing the APIs, and reporting issues. The environment details for UAT, Private Beta and Public Beta can be found in section 6. The Private Beta and Public Beta integration compliance assessment is documented in section 7, and finally, example FHIR resources are provided in section 8.

2. Adverse Event API

2.1. Overview

As per the HL7 FHIR specification, an Adverse Event is defined as an “actual or potential/avoided event causing unintended physical injury resulting from or contributed to by medical care, a research study or other healthcare setting factors that requires additional monitoring, treatment, or hospitalisation, or that results in death”.

The Adverse Event API surfaces create, read and update operations for Adverse Events. When an Adverse Event is recorded in a local risk management system, it can be sent to LFPSE automatically by sending a POST request to the Adverse Event API. For detailed documentation of the available API operations, refer to the Azure API Developer Portal (more information in section 5).

When an Adverse Event is created through the API, it is assigned a unique ID and version number. The response will contain the entire Adverse Event resource with these additional properties (see example below). Integrating systems may choose to store the ID internally so that they can perform read and update operations on this Adverse Event in the future.

```
<AdverseEvent xmlns="http://hl7.org/fhir">
  <id value="6dc50e70-9f25-49fe-9216-99ec8d2ccf55" />
  <meta>
    <versionId value="1.0.0" />
    <lastUpdated value="2018-10-03T11:58:40.961+00:00" />
  </meta>
  <!--Rest of Adverse Event data-->
</AdverseEvent>
```

2.2. Interoperability

The Adverse Event API conforms to the HL7 FHIR standard. For more information about FHIR, refer to section 4 of this document and the online documentation available at <https://www.hl7.org/fhir>.

All Adverse Events sent to the API will be validated against the LFPSE profile (available through the Taxonomy API) before being saved. The profile, along with the various extension definitions, value sets and code systems, will provide all of the information required to build a valid Adverse Event. See Section 8 for annotated examples of a selection of resources.

All Adverse Events submitted to the API must contain a Meta element with a reference to the LFPSE profile that should be used for validation. **For example:**

```
<AdverseEvent xmlns="http://hl7.org/fhir">
  <meta>
    <profile value="https://psims-uat.azure-
      api.net/taxonomy/fhir/StructureDefinition/patient-safety-adverse-
      event-5" />
  </meta>
  <!--Rest of Adverse Event data-->
</AdverseEvent>
```

2.3. Security

All requests sent to the Adverse Event API require a subscription key in the HTTP headers for authentication purposes. If a valid subscription key is not provided, a 401 unauthorised error is returned. For more information about requesting access to the API and generating subscription keys, refer to section 5 of this document.

Access to the Read and Update operations is protected, in that an organisation can only read or update Adverse Events that they created.

3. Taxonomy API

3.1. Overview

The Taxonomy API surfaces read operations for resources that describe the Adverse Event data required by LFPSE. This includes information about all data fields that can be captured, which fields are required, and what lists should be used for coded values. For detailed documentation of the API operations, refer to the Azure Developer Portal (more information in section 5).

3.2. Interoperability

The Taxonomy API conforms to the HL7 FHIR standard. For more information about FHIR, refer to section 4 of this document and the online documentation available at <https://www.hl7.org/fhir>.

The Taxonomy API is responsible for providing all of the FHIR conformance and terminology resources for LFPSE (Structure Definitions, Value Sets and Code Systems). These resources will help clients build an understanding of how to build a valid Adverse Event resource for the Adverse Event API.

3.3. Security

All requests sent to the Taxonomy API require a subscription key in the HTTP headers for authentication purposes. If a valid subscription key is not provided, a 401 unauthorised error is returned. For more information about requesting access to the API and generating subscription keys, refer to section 5 of this document.

Access to the Create and Update operations is restricted, meaning that only NHSI administrators can create or update Taxonomy resources.

4. HL7 FHIR

4.1. Overview

FHIR (Fast Healthcare Interoperability Resources) is a growing international standards framework created by HL7. FHIR is designed to be fast and easy to implement, interoperable out-of-the-box, with a strong foundation in open web standards. To find out more about FHIR, refer to the official documentation:

<https://www.hl7.org/fhir/index.html>

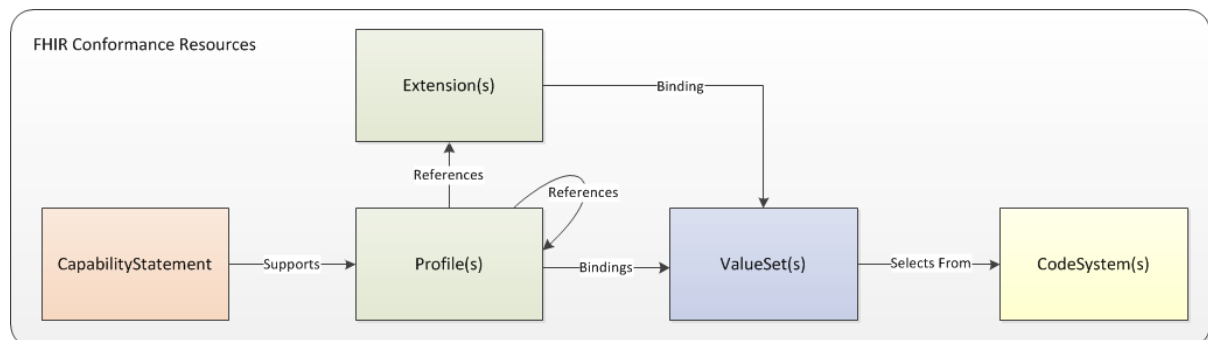
LFPSE utilises the FHIR standard in order to maximise interoperability with other systems in healthcare. Patient safety incidents, outcomes, risks and near misses are mapped to the FHIR Adverse Event resource (<https://www.hl7.org/fhir/adverseevent.html>). The Adverse Event API exposes operations for creating, reading and updating Adverse Event resources. The Taxonomy API exposes a number of FHIR conformance and terminology resources, which collectively specify LFPSE requirements about the data to be captured.

The remainder of this section outlines how the FHIR conformance resources are linked together, and how clients can build an understanding of the required request body structure for the Adverse Event API.

4.2. Conformance Resources

This section describes the purpose of the various FHIR conformance resources used by LFPSE. Examples for each of these resource types are provided in Section 8.

The diagram below illustrates the relationships between each type of resource:



4.2.1. Capability Statements

A capability statement documents the capabilities of a FHIR server. It will specify information about the REST operations available on the server, including the type of resources that it handles and which profiles are supported.

For example, the capability statement for the Adverse Event API will specify that it is possible to perform a number of operations on Adverse Event resources, where the resources must conform to the LFPSE profile.

For more information about capability statements, refer to the FHIR documentation: <https://www.hl7.org/fhir/capabilitystatement.html>

4.2.2. Profiles

The base FHIR specification creates a common foundation on which various different solutions are implemented. In order to document the specific requirements for a given system, a profile is created which specifies:

- Rules about which resource elements are used or not used
- What elements may be included that aren't part of the base resource (extensions)
- Rules about which terminologies are used for particular elements

For example, the LFPSE Adverse Event profile will specify that an Adverse Event may include a Never Event type (an extension), and values for this field must come from a specific Value Set.

For more information about profiles, refer to the FHIR documentation: <https://www.hl7.org/fhir/profiling.html>

4.2.3. Extensions

Extensions in FHIR allow you to create additional elements that do not exist in the base resource definition. A profile specifies which extensions are used by a system for a specific resource. If an extension relates to a terminology, it will usually specify a Value Set to use.

For more information about extensions, refer to the FHIR documentation: <https://www.hl7.org/fhir/extensibility.html>

4.2.4. Value Sets

Value Sets select a set of codes from one or more code systems to specify which codes can be used in a particular context.

For more information about Value Sets, refer to the FHIR documentation:

<https://www.hl7.org/fhir/terminologies.html>

4.2.5. Code Systems

A Code System is a master catalogue of a particular set of codes and their meanings.

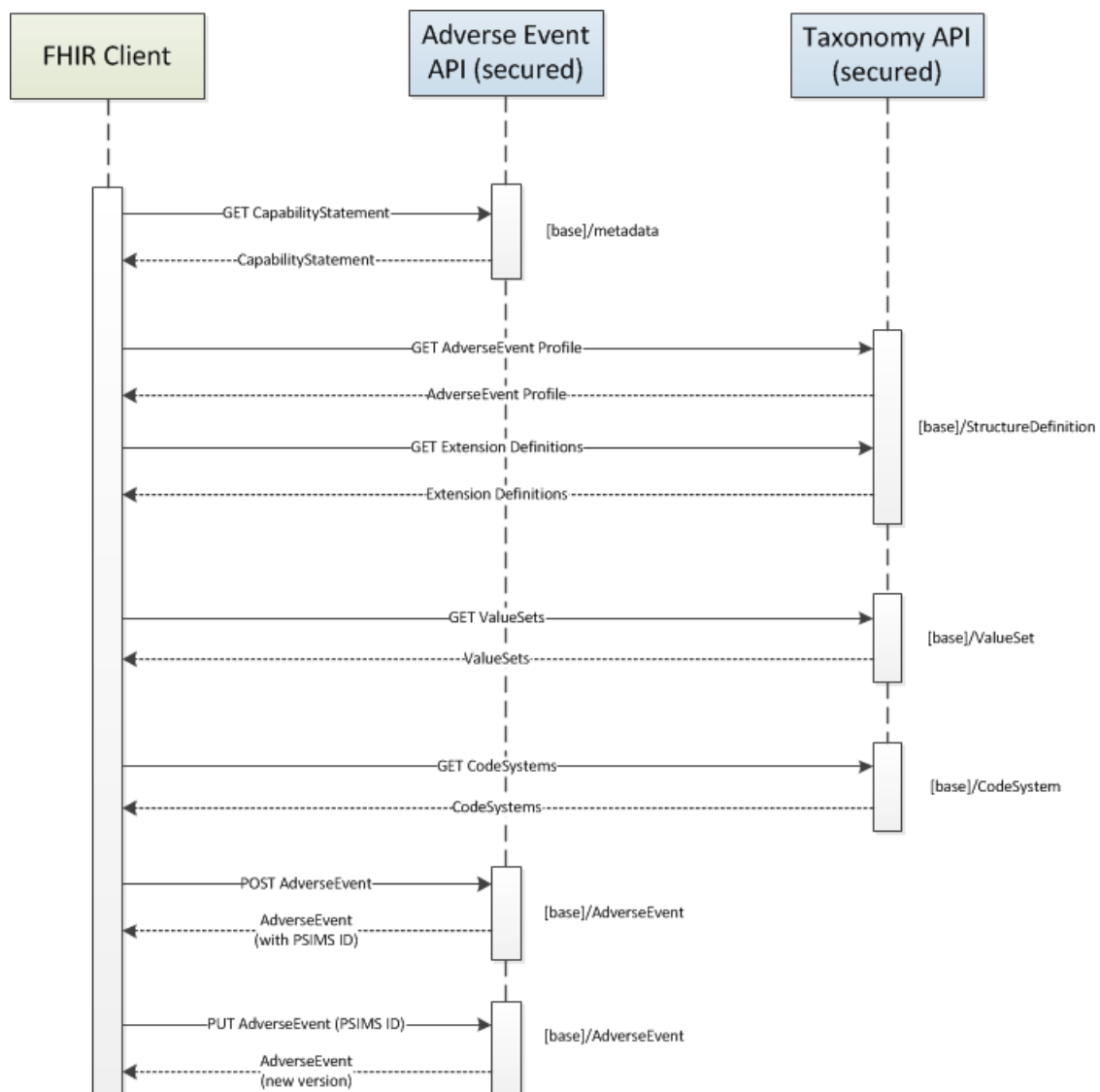
For more information about Code Systems, refer to the FHIR documentation:

<https://www.hl7.org/fhir/terminologies.html>

4.3. Sequence Diagram

The diagram below illustrates the order in which requests must be made in order to build a full picture of the LFPSE FHIR conformance resources. A client must be able to access all of the conformance resources in order to build a compliant Adverse Event resource.

When an Adverse Event is created, the response body will contain the unique LFPSE ID for this Event. The ID can subsequently be used with a PUT request to submit an updated version of the Adverse Event to LFPSE.



5. Azure Developer Portal

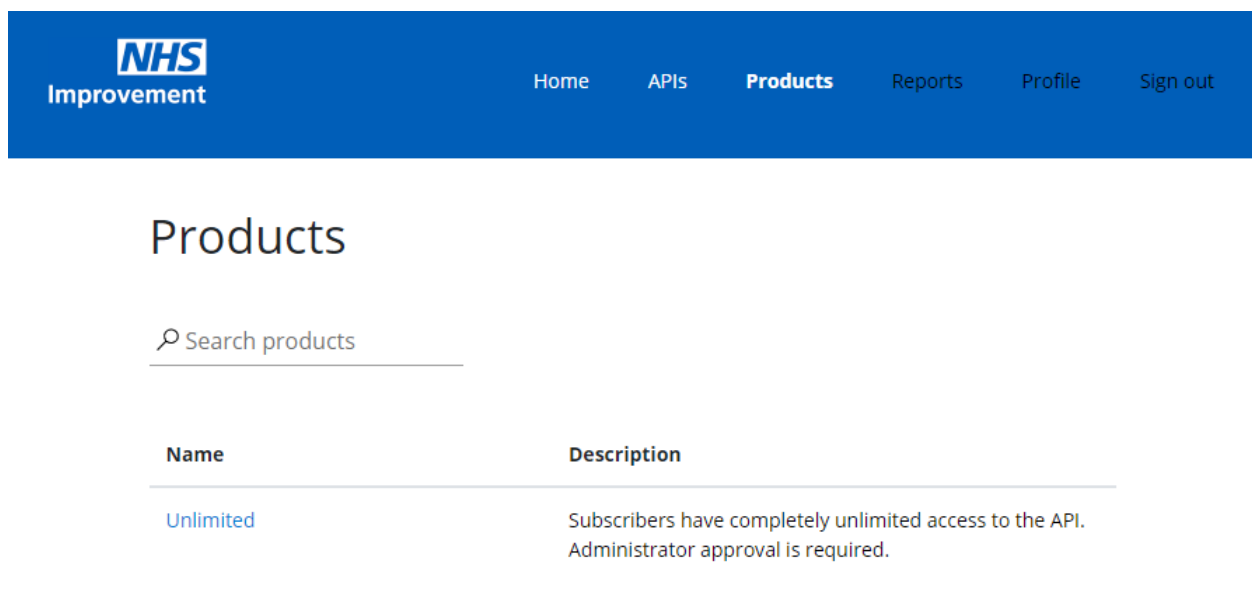
Azure API Management is being used as a gateway for the LFPSE APIs. API Management offers a self-service developer portal that gives access to an auto-generated API catalogue, documentation and code samples. Developers can also manage access keys and test using the APIs through the portal.

5.1. Requesting Access

In order to gain access to the Developer Portal, go to the relevant URL (see section 6 of this document) and register for a new account. Note that a new account should be created for each organisation integrating with LFPSE, the email address used for sign up should be the one you would like to be associated with the API keys.

After registering, you will receive an activation link via email that you must click before proceeding.

After activating your account, log in to the developer portal and go to the '**Products**' page via the menu link:

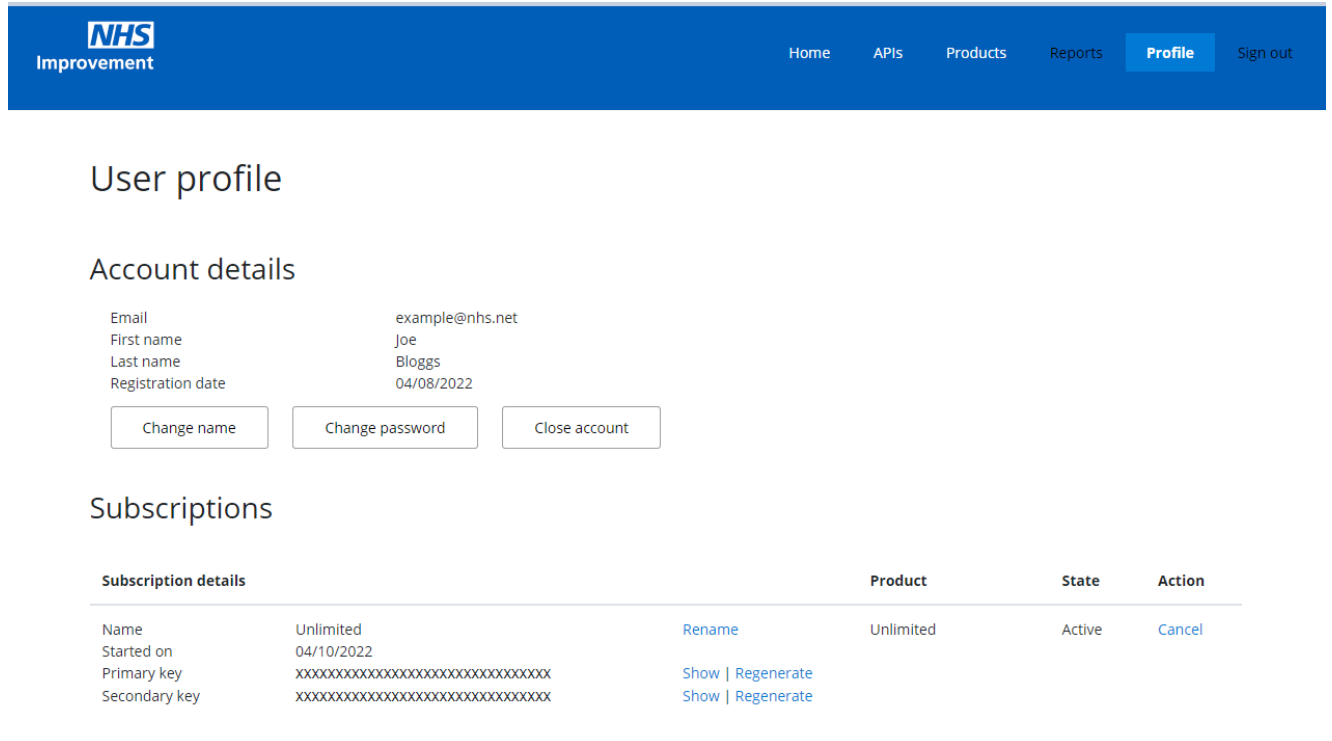


Name	Description
Unlimited	Subscribers have completely unlimited access to the API. Administrator approval is required.

Select '**Unlimited**', Enter a useful name you would like to give the subscription for reference, then click '**Subscribe**' in order to request access. An administrator is required to approve your request before you can access the APIs. You will receive an email notification after your request has been reviewed.

5.2. Subscription Keys

After your subscription has been approved, you can retrieve your subscription keys by logging in to the developer portal, and clicking on **'Profile'** in the top menu.



The screenshot shows the 'User profile' page in the NHS Improvement developer portal. The top navigation bar includes 'Home', 'APIs', 'Products', 'Reports', 'Profile' (highlighted), and 'Sign out'. The 'Account details' section displays the following information:

Email	example@nhs.net
First name	Joe
Last name	Bloggs
Registration date	04/08/2022

Below the account details are three buttons: 'Change name', 'Change password', and 'Close account'.

The 'Subscriptions' section contains a table with the following data:

Subscription details	Product	State	Action
Name	Unlimited	Active	Cancel
Started on	04/10/2022		Rename
Primary key	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx		Show Regenerate
Secondary key	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx		Show Regenerate

On this page you can view or regenerate your subscription keys. In order to use a subscription key with an API request, set the HTTP header **'Ocp-Apim-Subscription-Key'** to contain either your primary or secondary key.

5.3. Testing APIs

When logged in to the Developer portal, API documentation can be accessed through the **'APIs'** link in the top menu. After selecting an API, a list of the available operations is visible on the left:

Taxonomy API

Search operations

API definition [Changelog](#)

FHIR ASP.NET Core Web API

Group by tag

POST Create a FHIR resource

GET Get metadata about the ...

POST Read a FHIR resource wi...

GET **Read a FHIR resource ...**

GET Read a FHIR resource wi...

PUT Update an existing FHIR ...

POST Updates an array of valu...

Read a FHIR resource with a specified ID

Read a FHIR resource with a specified ID

Request

GET `https://psims-uat.azure-api.net/taxonomy/fhir/{type}/{id}[?_format]`

Request parameters

Name	In	Required	Type	Description
type	template	true	string	The type of FHIR resource to read
id	template	true	string	The unique ID of the resource
_format	query	false	string	The desired response format

Response: 200 OK
Returns the FHIR resource

Response: 404 Not Found
If the FHIR resource was not found

[Try it](#)

From here, you can select an operation and find details about the required request parameters, headers and body. The documentation also describes the possible responses, including what the body will contain for different HTTP response codes.

It is also possible to click the 'Try it' button to test the API without writing any code.

5.4. Reporting Issues

If you identify any issues during testing, they can be reported by sending an email to england.patientsafetyhelpdesk@nhs.net.

In order to support with the investigations, please include details of the request parameters, headers and body if possible.

6. Environment Details

The table below gives details of the different API environments. In order to request access to the APIs, go to the relevant developer portal URL and follow the steps provided in section 5.1 of this document.

Please note that the Private Beta and Public Beta environments will be using the same underlying infrastructure, meaning that users created during Private Beta can continue to use the Public Beta APIs with the same subscription key. Any Adverse Events submitted during Private Beta will also be retained in the system.

Developer Portal (For subscription key)

Environment	URL
UAT (Developer only)	https://psims-uat.developer.azure-api.net/signup
Production (Provider only)	https://psims-prd.developer.azure-api.net/signup

API base URL

Environment	Base URL
UAT	https://psims-api-net-uat.azurefd.net
Production	https://developer.learn-from-patient-safety-events.nhs.uk

URL for all FHIR resources (For POST request body)

Environment	URL
UAT	https://psims-uat.azure-api.net
Production	https://beta-data.patientsafety.nhs.uk

Endpoints

Title	Endpoints	Method
Create a FHIR resource	<API base URL>/adverse-event/fhir/AdverseEvent	POST
Update an existing FHIR resource	<API base URL>/adverse-event/fhir/AdverseEvent/{id}	PUT
Read a FHIR resource with a specified ID	<API base URL>/adverse-event/fhir/AdverseEvent/{id}	GET

7. LFPSE integration compliance assessment

Vendors or developers of bespoke LRMS must demonstrate full compatibility and compliance with Adverse Event API and Taxonomy API through NHS I Public Beta assessment. The LFPSE service team together with the vendor/developer will test LRMS compliance against LFPSE APIs principles. The LFPSE integration compliance assessment for LRMS comprises of three stages:

Stage 1 - LRMS self-assessment: vendor/developer will access LFPSE UAT environment to perform tests and self-assessments on digital capabilities 1 – 12, collating required evidence as per specified in the Assessment Table;

Stage 2 - LFPSE service team evaluation of LRMS self-assessment evidence: after successfully completing Stage 1, LRMS vendor/developer will submit evidence to service team and request Stage 2 to start. The service team will verify the provided evidence against Assessment Table and will issue the outcome which could include recommendations and the digital capabilities they would like to explore in Stage 3;

Stage 3 - LRMS and LFPSE service team workshop assessment: after the service team issues Stage 2 compliance, the vendor/developer is required to run a demo of its products and demonstrate to the service team how well the LRMS delivers the digital capabilities 1 – 12 as per specified in the Assessment Table. The service team will provide within 10 working days a report to vendor/developer with the outcome and recommendations.

The assessments use a traffic light system which determines if the vendor/developer has provided the required evidence, as follows: **Fully compliant**, **Partial compliant**, **Compliance Fail**.

Please note: software is considered fully compliant once it can deliver sustainable interoperability, i.e. updates to questions, lists, descriptions and help texts are automatically reflected on all client versions, so that changes to national minimum datasets are automatically realised on entry forms.

The assessment table below presents all digital capabilities to be weighed for LFPSE compliance:

ID	Digital Capability	Evidence	Comments	Assessment outcome
1	Ability to consume LFPSE Taxonomy from LFPSE API	Test scenarios events submitted		
2	Ability to consume LFPSE Taxonomy from LFPSE API Taxonomy form LFPSE API (e.g. different versions – V5 & V6)	Screen shots before and after and test scenarios events submitted in different versions	Update one version and then replace for another one	
3	Ability to present to local users all LFPSE questions, respective lists and descriptions	Screen shots	Please check the taxonomy labels and guidance text file	
4	Ability to automate submission of single and multiple (batch) events via LFPSE API	Test scenarios events successfully submitted	Must be able to automate real-time submissions	
5	Ability to automate update of previous events	Successfully update few testing incidents after uploading test data		
6	Easy to present users upload history to local users	Screen shots		
7	Ability to present error and warning messages to local users	Screen shots	Please check the validation guide	
8	Easy to manage local LFPSE API security keys	Demonstrate how key rotation are managed; Screen shots		
9	Easy to diagnose and report APIs issues to users and back to NHS England and NHS Improvement	Test with API down; screen shots		
10	Local feature to prevent submission of duplicate events	Test sending test data twice; screen shots	When incidents are submitted, unique event ids are returned via the API. Event ids should be stored locally to flag that an instance of the event already exists in LFPSE. A record should only be resubmitted when updated	

11	Easy searching of events: successfully submitted, with error messages, with warning messages, not submitted	Screen shots	This is to enable local action on returned messages	
12	Display successful events submitted by date of submission, date of event, degree of physical and psychological harm as a minimum	Screen shots	This is to enable local reconciliation of records between LRMS and LFPSE	

8. Example FHIR Resources

To assist with development activities, we have provided annotated examples of FHIR resources that are applicable to the LFPSE APIs. These are indicative of the way FHIR resources are structured, but for active development it is necessary for developers to request the current resources from the Taxonomy API.

8.1. Profile

As discussed in Section 4 the LFPSE APIs are based around the FHIR Adverse Event. LFPSE has a bespoke Adverse Event profile which extends the HL7 Adverse Event. The resource, as released at version 4 of the Taxonomy releases, appears below. Note that the “snapshot” element has been removed for brevity; the “differential” provides all necessary information to understand how this profile differs from the standard version published by HL7. The submissions that are made to the LFPSE APIs are validated against this profile but are structured differently. See Section 8.5 for an example Adverse Event submission which conforms to this profile.

```
<?xml version="1.0" encoding="UTF-8"?>
<StructureDefinition xmlns="http://hl7.org/fhir">
  <id value="patient-safety-adverse-event-4" />
  <url value="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/patient-safety-adverse-event-4" />
  <version value="4.0.0" />
  <name value="PatientSafetyAdverseEvent" />
  <title value="Patient Safety Event Profile for Adverse Event" />
  <status value="draft" />
  <experimental value="false" />
  <description value="A profile for patient safety events used by the NHS Improvement Patient Safety Incident Management System" />
  <fhirVersion value="3.0.1" />
```

ID (appended with version), URL to this profile (environment specific) and name

```

<kind value="resource" />
<abstract value="false" />
<type value="AdverseEvent" />
<baseDefinition value="http://hl7.org/fhir/StructureDefinition/AdverseEvent" />
<derivation value="constraint" />
<differential>
  <element id="AdverseEvent">
    <path value="AdverseEvent" />
    <definition value="Actual or potential/avoided event causing unintended physical injury resulting from or contributed to by medical care, a research study or other healthcare setting factors that requires additional monitoring, treatment, or hospitalization, or that results in death." />
  </element>
  <element id="AdverseEvent.extension">
    <path value="AdverseEvent.extension" />
    <slicing>
      <discriminator>
        <type value="value" />
        <path value="url" />
      </discriminator>
      <ordered value="false" />
      <rules value="closed" />
    </slicing>
  </element>
  <element id="AdverseEvent.extension:AdverseEventEstimatedDate">
    <path value="AdverseEvent.extension" />
    <sliceName value="AdverseEventEstimatedDate" />
    <min value="1" />
    <max value="1" />
    <type>
      <code value="Extension" />
      <profile value="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-event-estimated-date-4" />
    </type>
  </element>
  <element id="AdverseEvent.extension:AdverseEventProblem">
    <path value="AdverseEvent.extension" />
    <sliceName value="AdverseEventProblem" />
    <min value="0" />
    <max value="1" />
    <type>
      <code value="Extension" />
      <profile value="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-event-problem-4" />
    </type>
  </element>
  <element id="AdverseEvent.extension:AdverseEventAgent">
    <path value="AdverseEvent.extension" />
    <sliceName value="AdverseEventAgent" />
    <min value="0" />
    <max value="1" />
    <type>
      <code value="Extension" />
      <profile value="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-event-agent-4" />
    </type>
  </element>
  <element id="AdverseEvent.extension:AdverseEventOutcome">
    <path value="AdverseEvent.extension" />
    <sliceName value="AdverseEventOutcome" />
    <min value="0" />
    <max value="1" />
    <type>
      <code value="Extension" />
      <profile value="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-event-outcome-4" />
    </type>
  </element>
  <element id="AdverseEvent.extension:AdverseEventInitialEventAssessment">
    <path value="AdverseEvent.extension" />
    <sliceName value="AdverseEventInitialEventAssessment" />
  </element>

```

The base HL7 profile that this profile extends

Differential is where anything that differs from the base profile is documented

Reference to an extension which is allowed on a submission. The min value of 1 indicates this extension is mandatory

```

    <min value="0" />
    <max value="1" />
    <type>
      <code value="Extension" />
      <profile value="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-event-
initial-event-assessment-4" />
    </type>
  </element>
  <element id="AdverseEvent.extension:AdverseEventProcess">
    <path value="AdverseEvent.extension" />
    <sliceName value="AdverseEventProcess" />
    <min value="0" />
    <max value="1" />
    <type>
      <code value="Extension" />
      <profile value="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-event-
process-4" />
    </type>
  </element>
  <element id="AdverseEvent.extension:AdverseEventRiskDetails">
    <path value="AdverseEvent.extension" />
    <sliceName value="AdverseEventRiskDetails" />
    <min value="0" />
    <max value="1" />
    <type>
      <code value="Extension" />
      <profile value="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-event-
risk-details-4" />
    </type>
  </element>
  <element id="AdverseEvent.extension:AdverseEventWentWell">
    <path value="AdverseEvent.extension" />
    <sliceName value="AdverseEventWentWell" />
    <min value="0" />
    <max value="1" />
    <type>
      <code value="Extension" />
      <profile value="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-event-
went-well-4" />
    </type>
  </element>
  <element id="AdverseEvent.extension:DetectionFactors">
    <path value="AdverseEvent.extension" />
    <sliceName value="DetectionFactors" />
    <min value="0" />
    <max value="1" />
    <type>
      <code value="Extension" />
      <profile value="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/detection-
factors-4" />
    </type>
  </element>
  <element id="AdverseEvent.extension:AdverseEventClassification">
    <path value="AdverseEvent.extension" />
    <sliceName value="AdverseEventClassification" />
    <min value="0" />
    <max value="1" />
    <type>
      <code value="Extension" />
      <profile value="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-event-
classification-4" />
    </type>
  </element>
  <element id="AdverseEvent.extension:AdverseEventReferenceMetadata">
    <path value="AdverseEvent.extension" />
    <sliceName value="AdverseEventReferenceMetadata" />
    <min value="0" />
    <max value="1" />
    <type>
      <code value="Extension" />

```

```

    <profile value="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-event-
reference-metadata-4" />
  </type>
</element>
<element id="AdverseEvent.extension:AdverseEventSafetyChallenges">
  <path value="AdverseEvent.extension" />
  <sliceName value="AdverseEventSafetyChallenges" />
  <min value="0" />
  <max value="1" />
  <type>
    <code value="Extension" />
    <profile value="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-event-
safety-challenges-4" />
  </type>
</element>
<element id="AdverseEvent.type">
  <path value="AdverseEvent.type" />
  <min value="1" />
  <max value="1" />
  <binding>
    <strength value="required" />
    <valueSetReference>
      <reference value="https://psims-uat.azure-api.net/taxonomy/fhir/ValueSet/event-type-4" />
    </valueSetReference>
  </binding>
</element>
<element id="AdverseEvent.subject">
  <path value="AdverseEvent.subject" />
  <min value="0" />
  <type>
    <code value="Reference" />
    <targetProfile value="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-
event-patient-4" />
    <aggregation value="contained" />
  </type>
</element>
<element id="AdverseEvent.location">
  <path value="AdverseEvent.location" />
  <min value="1" />
  <type>
    <code value="Reference" />
    <targetProfile value="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-
event-location-4" />
    <aggregation value="contained" />
  </type>
</element>
<element id="AdverseEvent.recorder">
  <path value="AdverseEvent.recorder" />
  <min value="0" />
  <type>
    <code value="Reference" />
    <targetProfile value="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-
event-practitioner-4" />
    <aggregation value="contained" />
  </type>
</element>
<element id="AdverseEvent.suspectEntity.instance">
  <path value="AdverseEvent.suspectEntity.instance" />
  <min value="0" />
  <type>
    <code value="Reference" />
    <targetProfile value="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-
event-medication-4" />
    <aggregation value="contained" />
  </type>
  <type>
    <code value="Reference" />
    <targetProfile value="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-
event-device-4" />
    <aggregation value="contained" />
  </type>

```

Modification to the default type element to make it mandatory and bind it to a bespoke value set

Modification to the default subject element to make it accept a bespoke profile (similar modifications below for location, recorder etc.)

```

    </type>
  </element>
</differential>
</StructureDefinition>

```

8.2. Extension

Extensions have the same structure as profiles but do not extend an existing HL7 resource.

```

<?xml version="1.0" encoding="UTF-8"?>
<StructureDefinition xmlns="http://hl7.org/fhir" > Versioned extension id, environment-specific URL and name

```

```

  <id value="adverse-event-device-details-4" />
  <url value="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-event-device-
  details-4" />
  <version value="4.0.0" />
  <name value="AdverseEventDeviceDetails" />

```

```

  <status value="draft" />
  <date value="2020-06-08" />
  <publisher value="NHS Improvement" />
  <description value="Further details about a device which is related to an adverse event" />
  <fhirVersion value="3.0.1" />
  <mapping>
    <identity value="rim" />
    <uri value="http://hl7.org/v3" />
    <name value="RIM Mapping" />
  </mapping>
  <kind value="complex-type" />
  <abstract value="false" />
  <contextType value="resource" />
  <context value="Device" />
  <type value="Extension" />
  <baseDefinition value="http://hl7.org/fhir/StructureDefinition/Extension" />
  <derivation value="constraint" />
  <differential>
    <element id="Extension">
      <path value="Extension" />
      <short value="Further details about a device which is related to an adverse event" />
      <definition value="Further details about a device which is related to an adverse event" />
      <max value="1" />
    </element>

```

Definition of a data property, which consists of four elements (box continues)

```

    <element id="Extension.extension:DeviceType">
      <path value="Extension.extension" />
      <sliceName value="DeviceType" />
      <short value="The type of medical device that was involved in an incident" />
      <definition value="The type of medical device that was involved in an incident" />

```

Cardinality indicating this element is not mandatory on this extension and can be provided as many as 100 times

```

      <min value="0" />
      <max value="100" />
      <type>
        <code value="Extension" />
      </type>
    </element>

```

```

    <element id="Extension.extension:DeviceType.extension">
      <path value="Extension.extension.extension" />
      <max value="0" />
    </element>

```

```

    <element id="Extension.extension:DeviceType.url">
      <path value="Extension.extension.url" />
      <type>
        <code value="uri" />
      </type>
      <fixedUri value="DeviceType" />
    </element>

```

The data type accepted for this element – in this case a code lookup

```

    <element id="Extension.extension:DeviceType.valueCode">
      <path value="Extension.extension.valueCode" />

```

```

<type>
  <code value="code" />
</type>
<binding>
  <strength value="required" />
  <description value="The type of medical device that was involved in an incident" />
  <valueSetReference>
    <reference value="https://psims-uat.azure-api.net/taxonomy/fhir/ValueSet/device-type-4" />
  </valueSetReference>
</binding>
</element>
<element id="Extension.extension:DeviceTypeOther">
  <path value="Extension.extension" />
  <sliceName value="DeviceTypeOther" />
  <short value="Other device type" />
  <definition value="Other device type" />
  <min value="0" />
  <max value="1" />
  <type>
    <code value="Extension" />
  </type>
</element>
<element id="Extension.extension:DeviceTypeOther.extension">
  <path value="Extension.extension.extension" />
  <max value="0" />
</element>
<element id="Extension.extension:DeviceTypeOther.url">
  <path value="Extension.extension.url" />
  <type>
    <code value="uri" />
  </type>
  <fixedUri value="DeviceTypeOther" />
</element>
<element id="Extension.extension:DeviceTypeOther.valueString">
  <path value="Extension.extension.valueString" />
  <type>
    <code value="string" />
  </type>
</element>
<element id="Extension.url">
  <path value="Extension.url" />
  <fixedUri value="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-event-device-details-4" />
</element>
</differential>
</StructureDefinition>

```

Specification of which value set contains the accepted code values

8.3. Value Set

Value sets provide the link between code choices in a code system and the data elements of an extension or profile. In LFPSE value sets and their corresponding code systems are always consistently named to match.

```

<?xml version="1.0" encoding="UTF-8"?>
<ValueSet xmlns="http://hl7.org/fhir" >
  <id value="level-of-psychological-harm-4" />
  <url value="https://psims-uat.azure-api.net/taxonomy/fhir/ValueSet/level-of-psychological-harm-4" />
  <version value="4.0.0" />
  <name value="Level of Psychological Harm" />
  <status value="draft" />
  <contact>
    <telecom>
      <system value="email" />
    </telecom>
  </contact>
</ValueSet>

```

Versioned value set id, environment-specific URL and name

```

    </telecom>
  </contact>
  <description value="Level of Psychological Harm" />
  <compose>
    <include>
      <system value="https://psims-uat.azure-api.net/taxonomy/fhir/CodeSystem/level-of-psychological-harm-4" />
    </include>
  </compose>
</ValueSet>

```

The linked code system from which the value set draws its code options

8.4. Code System

Code systems contain the code/display pairs that are bound to a value set and a given data element. When making a submission the code – rather than display – value should be provided.

```

<?xml version="1.0" encoding="UTF-8"?>
<CodeSystem xmlns="http://hl7.org/fhir">
  <id value="level-of-psychological-harm-4" />
  <url value="https://psims-uat.azure-api.net/taxonomy/fhir/CodeSystem/level-of-psychological-harm-4" />
  <version value="4.0.0" />
  <name value="Level of Psychological Harm" />
  <status value="draft" />
  <contact>
    <telecom>
      <system value="email" />
    </telecom>
  </contact>
  <description value="Level of Psychological Harm" />
  <caseSensitive value="true" />
  <valueSet value="https://psims-uat.azure-api.net/taxonomy/fhir/ValueSet/level-of-psychological-harm-4" />
  <compositional value="false" />
  <versionNeeded value="true" />
  <content value="complete" />
  <count value="4" />
  <concept>
    <code value="4" />
    <display value="No psychological harm" />
  </concept>
  <concept>
    <code value="3" />
    <display value="Low psychological harm" />
  </concept>
  <concept>
    <code value="2" />
    <display value="Moderate psychological harm" />
  </concept>
  <concept>
    <code value="1" />
    <display value="Severe psychological harm" />
  </concept>
</CodeSystem>

```

Versioned code system id, environment-specific URL and name

The associated value set

A code and display pair that is valid for elements using this code system. The display value is the one to be visually presented whereas the code value should be the submitted response

8.5. Adverse Event

The example below is a valid adverse event submission that conforms with the PSIMS taxonomy (see the profile in Section 8.1). It targets the root profile and includes elements which are defined by that profile, its sub-profiles, extensions, and individual code system / value set elements.

<AdverseEvent xmlns="http://hl7.org/fhir"> **The submission targets an accepted PSIMS FHIR profile**

```
<meta>
  <profile value="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/patient-safety-
adverse-event-4" />
</meta>
```

```
<contained>
  <Location> The id for each contained resource must match the one given on its element
    <id value="location1" /> (see bottom of event)
    <extension url="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/location-
```

```
details-4">
  <extension url="LocationKnown">
    <valueCode value="y" />
  </extension>
  <extension url="Organisation">
    <valueCode value="RVV" />
  </extension>
  <extension url="LocationWithinService">
    <valueCode value="1" />
  </extension>
  <extension url="ServiceArea">
    <valueCode value="5" />
  </extension>
  <extension url="ResponsibleSpecialty">
    <valueCode value="86" />
  </extension>
</contained>
```

A contained resource (sub-profile), in this case a Patient, which must conform to the bespoke Profile profile referenced by the parent Adverse Event profile. This patient includes a single extension with six data elements.

```
<contained>
  <Patient>
    <id value="patient1" />
    <extension url="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/patient-
information-4">
      <extension url="AgeYears">
        <valueCode value="8" />
      </extension>
      <extension url="Gender">
        <valueCode value="2" />
      </extension>
      <extension url="StrengthOfAssociation">
        <valueCode value="4" />
      </extension>
      <extension url="PhysicalHarm">
        <valueCode value="1" />
      </extension>
      <extension url="ClinicalOutcome">
        <valueString value="test" />
      </extension>
      <extension url="PatientSequence">
        <valueInteger value="1" />
      </extension>
    </extension>
  </Patient>
</contained>
```

```
<contained>
  <Practitioner>
    <id value="practitioner1" />
    <extension url="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/practitioner-
details-4">
      <extension url="ReporterType">
        <valueCode value="3" />
      </extension>
      <extension url="ReporterOrganisation">
        <valueCode value="RVV" />
      </extension>
    </extension>
  </Practitioner>
</contained>
```

An extension within the root adverse event

```
<extension url="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-event-
estimated-date-4">
  <extension url="IncidentOccurredToday">
    <valueCode value="y" />
  </extension>
  <extension url="TodaysDate">
    <valueDate value="2020-06-26" />
  </extension>
  <extension url="EstimatedTime">
    <valueCode value="4" />
  </extension>
</extension>
<extension url="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-event-agent-
4">
  <extension url="InvolvedAgents">
    <valueCode value="9" />
  </extension>
```



```

    </extension>
    <extension url="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-event-
classification-4">
      <extension url="LevelOfConcern">
        <valueCode value="3" />
      </extension>
    </extension>
    <extension url="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-event-safety-
challenges-4">
      <extension url="SafetyChallenges">
        <valueCode value="3" />
      </extension>
    </extension>
    <extension url="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-event-
problem-4">
      <extension url="ITSystemsInvolvementFactors">
        <valueCode value="1" />
      </extension>
    </extension>
    <extension url="https://psims-uat.azure-api.net/taxonomy/fhir/StructureDefinition/adverse-event-
reference-metadata-4">
      <extension url=" DataSharingOptOut ">
        <valueBoolean value="false" />
      </extension>
    </extension>
    <category value="AE" />
    <type>
      <coding>
        <code value="1" />
      </coding>
    </type>
    <subject>
      <reference value="#patient1" />
    </subject>
    <date value="2020-06-26" />
    <location>
      <reference value="#location1" />
    </location>
    <recorder>
      <reference value="#practitioner1" />
    </recorder>
    <description value="Test description" />
  </AdverseEvent>

```

Each extension must be defined to target a specific PSIMS extension definition

Supplying a response to a code data type

A data element belonging to the extension, which accepts a boolean type

Category should always be "AE"

The type code must be chosen from the values in the bound code system as specified by the profile

The id for a reference instance must match the one given in the contained resource

A default element from the HL7 base Adverse Event definition