

Amplitude Functional Specification

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Version 2

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1. Introduction

Amplitude delivers a web-based PROMs (patient reported outcome measures) and clinical registry solution. There are a number of variants within the family:

- *pro-one*[™]
- *pro-enterprise*[™]
- *pro-registry*[™]

pro-one[™] – for **individual clinicians**, hosted on Amplitude cloud servers. *pro-one*[™] contains a series of pathways that enable clinicians to capture “entire-practice” patient metrics and outcomes. It can be linked with popular practice management systems, e.g. DGL, Bluespier, PPM, etc. Included in the suite of pathways that each clinician might use are the registry pathways that enable data to be upload directly to *pro-registry*[™] systems.

pro-enterprise[™] – for **hospitals, clinics** and large practices working in a shared environment. *pro-enterprise*[™] is hosted either on a secure N3 server or on an Amplitude cloud server. It is able to interface with the enterprise PAS or patient management system to enable automated synching of patient demographics and Worklists such as appointments, in-patient or theatre lists. *pro-enterprise*[™] contains the same “suite” of pathways as *pro-one*[™] and performs the identical function of automated upload of registry data items to *pro-registry*[™].

pro-registry[™] – for **groups of clinicians working together** nationally or globally on a specific set of data items specified by the registry steering committee. Hosted on Amplitude’s cloud servers, *pro-registry*[™] is accessed directly by users or can receive automated uploads from each of its sister products *pro-one*[™] and *pro-enterprise*[™]. In addition, Amplitude is able to accept “Bulk” upload of data into its registries from other systems where the format is compatible.

For *pro-one*[™] and *pro-enterprise*[™], pathways are configured by Amplitude to include the basic metrics needed to produce relevant and clinically validated outcomes. Pathways are site (anatomical) specific as well as diagnosis and procedure specific.

For *pro-registry*[™] customers, each registry formulates custom pathways to include the clinical metrics specific to their requirements. This system has the configurability to include or exclude the capture of specific outcome measures and/or patient data entry that can include patient experience questionnaires or patient history assessments. Data can be entered directly onto the live system or captured via paper forms and entered retrospectively by a data manager.

2. Solution Components

All solution components apply to all versions of Amplitude i.e. *pro-one*TM, *pro-registry*TM and *pro-enterprise*TM.

2.1 Patient Portal

The Patient Portal is the website to which patients are directed to complete scores and assessments. A patient will receive notification via email containing a web-link to their “open” questionnaire(s). The patient validates their identity by completing data relevant to a series of unique identifiers and then completes the PROMs form(s) that are indicated as due.

The patient portal can be configured to request consent from the patient where consent has not already been indicated on the system as having been given.

In the *pro registry*TM system, the consent information and declaration wording is set by the registry and not modifiable by the individual user.

Consents obtained are recorded (including date and time) in the Amplitude record audit trail. The actual wording of the message to which the patient consented is also recorded in the audit trail.

Once a patient has given consent, they cannot withdraw this via the patient portal. They would need to contact their consultant to request the withdrawal of consent.

The patient is expected to interact with the portal only a few times during the course of their treatment. The frequency will depend on which pathway the patient has been assigned.

Baseline Scores are completed either at home, prior to attending the clinic once their initial appointment is scheduled, or in clinic just before an initial appointment, usually via a tablet or kiosk.

Post Treatment Scores are generated at pre-defined intervals and the patient is emailed to remind/request them to complete the scores. The system provides each user with a report on their dashboard that shows what tasks are outstanding both for the clinician and their patients. This means that it is very simple for the clinician to remind the patients at follow up, or for the support staff to identify and chase up those patients who have omitted to complete their forms.

As the scores are completed they are plotted on a graph that gives the clinician a visual overview of how each patient is doing. The clinician can choose to share this graphic with the patient as an overview of how the patient has improved.

2.2 Clinical Portal

The Clinical Portal is the website which is used by the clinical personnel involved in the provision of patient services. This may include the surgeon, doctor, secretaries, nursing or other delegates.

The Clinical Portal is the main set of features that users of the system interact with. It includes features to conduct the following:

- Maintain basic patient demographics and details
- Maintain extended patient information
- View the patient record (document and interaction history)
- Review patient scorecards
- Add and remove patients to Worklists.
 - Worklists are user/system configurable lists of patients
 - They are a “convenience” feature to enable the clinician to see a shortlist of patients relevant to that day (outpatient clinic, inpatient list or Procedure list).
- Enter diagnosis and intended procedure details
- Complete other relevant data such as co-morbidities where the factors are likely to have a bearing on the (clinician) expected outcome of the procedure.
- Capture procedure details including any registry or enterprise mandated datasets.
- Enter a detailed OpNote which is procedure or pathway specific including any mandated datasets (e.g. registry data).

2.2.1 Clinical scores

On viewing the patient dashboard, a “Clinical scores” tile enables the clinician to access a summary of all completed scores. This breaks scores down into initial base-line scores, as well as 3, 6, 12 or 24 month scores which can be graphed for instant graphic of patient progress.

It is normal for all versions of Amplitude to have a set of scores linked to each pathway that go out at a set period, e.g. pre-treatment, 6 months, 1 year and 2 years. In *pro one*TM these baseline scores are generic to all pathways and serve to provide a baseline of performance of the population of clinicians at large from which to compare the individuals’ results. This enables each user to see only their specific results but provides them a bench mark of personal performance versus all *pro* users showing them the top and bottom 95th percentile.

In the case of registries, timescales for obtaining scores are defined by the Steering Group for each registry and then are set by Amplitude on their behalf, within the pathway/s, both in the registry system and *pro one*TM and *pro enterprise*TM systems where these pathways are available.

For registry pathways, benchmarks are available only to registry users and based only on users of the registry system – i.e. those who don’t contribute to the registry don’t benefit from it from this comparative data.

For *pro one*TM users, the comparative data is limited to *pro one*TM user comparatives.

Benchmarks are defined by the registries and set up by Amplitude accordingly. Amplitude will adjust these as and when asked to do so by the relevant Steering Groups.

2.2.2 Outstanding Forms/Tasks

On the User Dashboard a simple outstanding tasks tile highlights outstanding tasks. This simple report is visible on logging on to the opening dashboard and serves as a reminder to users, and their patients, of their outstanding tasks.

These are categorized and displayed separately. For the clinician their outstanding tasks are categorized according to the outstanding forms that still need completing. By opening of the specific category a list of patients enables simple link to the patients record in order to complete the outstanding task.

The patients with outstanding tasks are listed with a number against each patient to denote the number of outstanding tasks against that patient. Again a click on the patient hyperlinks into their specific home page pathway/record and enables an overview of the outstanding tasks, displayed in red on the patient dashboard

Completed and Future Scores

Completed and future outcomes scores are “Hidden” behind an Outcomes score heading that can be expanded with a simple click to demonstrate those scores that have been completed and are due in the future according to the pathway set up.

2.3 Admin Portal

The Admin Portal has two functions.

1. The **System Configuration** allows Amplitude customers/clients to configure personal settings or site specific ones in the case of Enterprise or Registry versions of Amplitude. It allows new users (including delegates) to be created and permissions added or removed. These functions are only available to authorized system users who are identified at the start of the project implementation and who may be appointed by the customer from time to time.

For registry customers, depending on how the registry steering committees wish to administer their registries, they have the ability to make all or some of the following system configuration changes:

- Authorise users
- Create security groups
- Create notifications
- Publish Help articles
- Views audit logs
- Run reports
- Create report templates
- Merge and delete patient records
- Delete a pathway
- Delete a document
- Delete a form or a task

Any setting changes made locally through the portal, by registry Super Users, only apply to that registry instance.

Pathway changes are managed by Amplitude, on behalf of the registries and these can be reflected in other environments.

It is the responsibility of the Consultant and/or registry Steering Committee to notify Amplitude who and when to deactivate in terms of any delegates who no longer require access to the system.

2. The **Clinical Content Builder** is used to create and manage the following:

- Questions and associated answers
- Forms (built from questions)
- Rules within forms which determine mandatory and optional questions and sections and govern the display and hiding of forms/sub-forms based on previous answers.
- Pathways which are composed of the relevant Forms/Assessments and the rules determining which assessments are due and when they appear on the patient timeline.

The Clinical Content Builder is not user-accessible and any preparation of forms and pathways is conducted by Amplitude Clinical in conjunction with the commissioning enterprise/Data Controller as part of the implementation roll-out.

3. Questions, Forms, Pathways

The Amplitude system provides the means to design various questionnaires. A questionnaire comprises a series of questions and answer options. Forms, Assessments, Questionnaires, Surveys and Scorecards are terms that are used interchangeably to refer to these questionnaires.

Amplitude maintains a library of questions (and the corresponding valid answers). When a Form is presented for completion on either the Patient Portal or the Clinical Portal – it is a copy of the template from the Forms Library that is being rendered in the browser for the user to complete.

Amplitude's Forms Engine reads the definitions which are created by our clinical content creators and presents the forms for users to complete. Forms are simply a way to present questions and store the answers.

3.1 Questions

The information provided here is for information only. Questions are not user-configurable but are built as part of system deployment following a design phase with the customer. In most cases Amplitude's standard Questions/Answers and Forms will, without modification, meet customer requirements.

Each question in Amplitude is defined in a Library of questions. When forms are being built – the questions are then picked from the library of pre-defined questions and answers.

The following are the presently supported question styles in Amplitude:

- Text – the user is invited to input some text into a box. This can be single line or multi-line.
- Multi-Select List – a list of options is presented in either buttons or as a drop-down list. The values can either be defined within the question or populated from a user defined personal (aka pre-defined) list. The items in the list can be sorted alphabetically or using an alternate key provided or by dragging the items into the desired sequence at the time of creating the list. (Within a multi-select group of answers stand-alone answers can be designated as such in order to prevent opposing answers to be selected simultaneously in the same set of answers)
- Single-Select List – same as previous but the user can only select a single item from the list.
- Date – the input required is a valid date (which can be defaulted to the current date)
- Time – the input required is a valid time (which can be defaulted to the current time)
- Date/Time – Input is a Date and Time (which can be defaulted to “now”).
- Month/Year – Input is just a Month/Year type (no specific date required)
- Numeric – a number value is required. Can have rules governing the min and max values as well as the decimal precision (or none).
- Drop-Down-List – this is like the previous List options but when a drop-down it will only occupy a small screen space and only a single value can be picked from the list.

- Slider – this is a form of numeric input where the value is input by moving a slider. The slider may be horizontal or vertical with minimum and maximum settings as well as default (initial) value option.
- Auto-Complete – this is a text input field but where the number of values is potentially large and the user refines the selection by typing the value they wish. The actual input is shown as a filtered list of matching options.
- A one unique question was developed for the validation of [EQ-5D][JT1][S2] – this is a specific tick box format compliant with the specification for such user input where it appears on an EQ-5D form.

The data capture of all PROMs within the system uses one or more of the above base types of data capture.

This list is extensive and continually being added to which means it is constantly changing.

In general, when questions are composed onto forms there is additional logic which may be specified. This includes whether a response is mandatory or not, and also whether, in the specific context, the question can have an alternative to list values (the “Other...” response). Where “Other...” is enabled, the user may then type the response into a text box provided which indicates that the response is not one of the default ones provided on the pre-configured answer list.

3.2 Forms

Forms are not user-configurable but are built as part of system deployment following a design phase with the customer. In most cases Amplitude’s standard Forms will, without modification, meet customer requirements.

Amplitude has a master list of Form Categories (such as Forms used to compute scorecards, Procedure forms or Diagnosis etc.).

- Each form can have an introductory page which describes its purpose or intent for the person completing it.
- Forms are composed of “pages” which group related sections. Sections are the principal hierarchy and grouping
- Questions can be marked as mandatory (response required). Where a question is mandatory the form cannot be saved without supplying a value
- Questions within a form can be marked as “conditional”. This means that whether the question is shown or not is dependent on the answer(s) to previous question(s).
- Where a form is defined as a scorecard the mapping between various responses and overall score are defined so that the relevant score can be computed and stored with the form when saved.
- Forms can be composed using sub-forms to arbitrary depth. This allows forms to re-use sections or sub-sections which are commonly used in various scenarios.

There is one further special feature in Amplitude forms – inherited answers. Where a question is marked as “inheriting” its value – the initial value for the question will be provided by looking up the most recent answer given to the same question on another form for the same patient. If the question has not previously been asked/answered, then obviously there will be no pre-population of the result. An example might be “Smoker Y/N?” where any previous

response would inherit into the current form. Even where there are inherited values the user may select or input an alternative where they don't agree with the previously entered data. Subsequent inherited values will then take from the later entry.

3.3 Pathways and Triggers

Pathways and Triggers are not user-configurable but are built as part of system deployment following a design phase with the customer. In most cases Amplitude's standard Pathways and Triggers will, without modification, meet customer requirements.

Once the necessary forms have been defined they are "attached" to the Pathway(s) to which they belong.

Pathways have key progressions or phases which are referred to in Amplitude as milestones. Depending on which stage within the pathway a patient is at there are various forms which might be required or available to complete.

The relationship between Pathways and Forms is configured in the Amplitude Clinical Content Administrator.

The key configuration undertaken in Amplitude is to set the triggers which generate the periodic requests of severity scores, patient satisfaction complication queries or simply follow up reviews at designated time, e.g. 2 weeks, at 3, 6 and 12 months following procedure.

These timings are designated by the registry steering groups and can be set at a fixed number of weeks or months following specific procedures. Amplitude makes these changes on behalf of the registries.

The Triggers ensure that reminders are generated to complete certain patient reporting tasks.

A special feature of Amplitude is its' configured bundling of requests together to consolidate requests rather than generate multiple forms for completion on the same date/anniversary or within a short period of time e.g. 2 weeks. So, for example, if a patient is expected to complete EQ-5D and Oxford Hip Score and VAS at 6 months following surgery – the request will appear to the patient as a single request and all three forms will be captured in a single session when the patient logs on to the Patient Portal. This is a significant factor in reducing the overhead and increasing compliance for patient feedback.

It is a relatively straightforward process for a customer (Enterprise or Registry version) to request the building or tailoring of new or amended Forms or Pathways. Any such work is conducted on a time and materials basis and Amplitude is happy to engage to complete such requests.

4. Configuration

4.1 System Configuration

Certain users within an organisation can be nominated as super users. These users are able to perform certain **admin functions** e.g. managing the user profiles and managing the user accounts. Super users may also be given rights to manage the content of the emails sent to users and the consent messaging displayed to patients. This level of access is different according to whether the system is a *pro one*TM, *enterprise* or *registry* system and the level of control and access which the licence holders wish their super users to have.

4.2 Clinical Configuration

The **clinical configuration** is carried out by Amplitude clinical staff.

The systems basic format involves creation of pathways that have a series of forms on them with a series of questions and answers on the forms.

Configuration involves building of forms that contain the questions that contain the data items that are important to the pathway. Step one is to configure questions using the tools described below. These questions are then laid out into a form using conditional rules to optimise the functionality so that minimal data clicks are necessary.

Each Pathway has a series of forms that require completion and as the forms are completed so further tasks are triggered at designated times. The system can be configured so that the completion of a form will trigger the required tasks, or perhaps just a specific answer within the form may trigger a further task or even just the creation of a pathway can trigger a task. The tasks can be set as reminders that remain outstanding for some time in the future when their completion is possible. (For example the retrieving of a blood result that is triggered when the user records that the blood test has been completed). They can be set as an immediate form that needs completion at the point that the preceding form has been completed and they can be set as a task that needs carrying out at a set point in the future. 3 month, 6 month, 1 year outcomes scores for example, are triggered on completion of the procedure form. These tasks remain greyed out under a heading of future tasks but pop onto the front dashboard in red when they are due. This configuration is highly flexible and is agreed at the outset of creation of the pathway.

In the case of an *enterprise* or *registry* customer, should they make subsequent refinements to configuration, these will only apply from the time of change, going forward. If a licence holder wishes for changes to be applied retrospectively then there may be a development charge by Amplitude for this service.

At the point of sign-off and into the Live registry system, these changes are then scheduled for implementation across all other systems.

4.2.1 Pathways

It is anticipated that each user will only make use of a small percentage of the pathways available within the system. E.g., Spinal surgeons not needing foot and ankle pathways for example. The initial set up therefore enables each clinician to select from the "Master

list” of pathways those pathways that will be relevant to their individual practice (including registry pathways where the Master List is defined by the Registry Lead). This means that when the clinician uses the system, only those pathways relevant to that user will be presented during use of the system.

4.2.2 Procedure Forms

Each user can configure the procedure forms according to their personal preference. A basic default answer set up system allows them to “pre-answer” standard items like position, approach, incision etc. where their standard practice is the same with each procedure. This means that the completion of a precise and complete operation note needs only take a few minutes as they simply enter or validate data that is not standard.

There is additional functionality that enables the users to modify the questions and answers on each form. Where a user does not want to see a particular question on the form, this can be turned off in their default settings. (Provided it is not a mandatory question as determined by the registry steering committee or the Amplitude designers where it is a key data item for potentially influencing outcome – like the diagnosis or name of the procedure for instance.) Where a question contains a number of answers that the user knows to be additional to their needs, these answers can be inactivated and so will not be presented to the user when completing their operation form.

Users are unable to change the order of the questions but these follow the recognised standards of: Preparation, Incision, Approach, Findings etc.

4.2.3 Clinical scores

Where users have personal preferences to ask additional outcomes scores over and above the standard inclusive outcome scores, they have the ability to customise their pathways to trigger these scores at their personal preferred time scales.

5. Data Exchange

The Amplitude *pro*TM series products can be configured to syndicate or share data. This is to eliminate duplication of data entry and to ensure consistency across all platforms.

- A procedure entered into *pro-enterprise*TM in a hospital (e.g. public) scenario may be forwarded to the clinician *pro-one*TM
- A procedure entered into *pro-one*TM may be forwarded to the relevant *pro-registry*TM

Thus a *pro-enterprise*TM will forward all PROMs for a given surgeon to his/her *pro-one*TM account. This transfer is of anonymised data (except where a private patient switches to NHS or vice versa). This function gives the surgeon “whole practice” regardless of where the patient was treated and how they were funded.

Likewise, *pro-one*TM and *pro-enterprise*TM can be configured to automatically upload all registry pathway data to the relevant registry, subject to appropriate agreements being in place with the registry and in accordance with any specific requirements of the registry.

Data Syndication Process

The data syndication features of Amplitude reduces the need for data duplication and ensure that all parties with “shared interest” in PROMS can best share the information without overloading either practitioner or patients in duplicate data entry. These measures are designed to ensure better compliance for registries and lower administration overhead and duplication for clinicians.

5.1 Mechanism

Any systems activated for data exchange publish their API end point to a central Data Exchange Register (DXR) hosted by Amplitude Clinical Services. This contains no data other than the name, the API base URL, and the list of supported pathways.

This mechanism works the same regardless of which server infrastructure the *pro enterprise*TM installation is on.

All interactions between the source and destination is done over a secure HTTPS connection. That is to say that all traffic is encrypted in transit using the same level of protection employed when logging into online banking systems.

Any user wishing to upload data from their *pro-one*TM or *pro-enterprise*TM account to a registry, has to be a registered user of that target registry. To set up the transfer process, the user is required to log into the source system (e.g. *pro-one*TM or *enterprise*TM). They are offered a list of registries that support syncing of the pathways they have in their pathway list (sourced from the DXR), an example of this screen is shown below:

SYNC JOBS

SYNCABLE PATHWAY LIST

SYNC HISTORY

Knee (Osteotomy) Pathway (UKKOR)

Destination	Last Run Date
Authenticate The Generic Test Registry	N/A

Upon clicking Authenticate the user is sent to the target registry (via a URL crafted from the base URL received from the DXR that also includes a request ID) and prompted to login. The user account used at this stage will define the user who is marked as owning the pathways on the destination.

N.B. It is important to note that this authentication happens directly with the target registry – no username and password is collected and then passed; it is input directly to the registry:

AUTHENTICATE FOR THE GENERIC TEST REGISTRY

Please login to the destination system:

TEST INSTANCE

Welcome to the Generic Test Registry

For support, contact Amplitude on 0333 014 6363
or customer.support@amplitude-clinical.com

Log in

Username

Password

Once the authentication process is complete the source system makes another API call to the destination to query the outcome of the authentication attempt. If the attempt was successful then a token is returned for future use and the job is setup ready for activation and syncing:

SYNC JOBS

SYNCABLE PATHWAY LIST		SYNC HISTORY
Knee (Osteotomy) Pathway (UKKOR)		
Destination	Last Run Date	
ON The Generic Test Registry	N/A	View History

The actual sync can be triggered manually if necessary – or is triggered by the scheduler weekly. When it runs, it carries out a number of checks:

- Ensure the data exchange mechanism is active on the source
- Ensure the destination is still registered with the DXR and supports the sync'd pathway type(s)
- Ensure the user account is still valid on the source
- Ensure the authentication token is still valid on the destination (this covers ensuring the associated user is still active on the destination and that they are allowed to import data)

Assuming the checks are successful then the exchange is allowed to continue. A list of pending changes is constructed; this consists of any records that have changed since the last run, plus any previously pending records that did not complete successfully.

Once the pending changes are identified they are collated into small batches and sync'd to the destination via an API call.

At the destination the records are validated to ensure that if they do exist they are already associated with the sending system (if this is not the case the record is rejected). If it passes validation, each record is saved in isolation – so if a single record fails the batch can still succeed.

Once the destination has processed the records it returns an outcome for each record processed – this outcome is used to determine if the record is removed from the pending list (i.e. did it complete successfully) and is recorded in the source system.

The history of sent changes (including whether it succeeded and if relevant the errors that occurred) can be seen against the sync job via the 'View History' button.

Records are identified in the receiving system as being external and it identifies the source from which they came. This is displayed in all Search Results.

SYNC JOBS

SYNCABLE PATHWAY LIST
SYNC HISTORY

The Generic Test Registry
Knee (Osteotomy) Pathway (UKKOR)

No records found.

Over and above security, permission, and or communication failures there are a number of potential reasons that could cause a sync to fail:

Code	Description
0	An unknown error occurred
1	No/invalidly formatted patient data was sent
2	Patient already exists in destination (i.e. locally created)
3	Patient already exists in destination (not sourced from current sender or locally created i.e. sent from a different source)
4	Pathway already exists in destination (i.e. locally created)
5	Pathway already exists in destination (not sourced from current sender or locally created i.e. sent from a different source)
6	Pathway type not sync-able
8	No matching pre-defined list entry (blank)
9	No matching pre-defined list entry (value mismatch)
10	Multiple matching pre-defined list values
11	Pathway type mismatch
12	Form structure mismatch

The above errors are recorded at record level; that is to say, a single record might be rejected but the rest of the batch may succeed. This record level outcome is shown in the sync history. Where relevant the error message includes the problematic element (e.g. in the case of a form structure mismatch the offending form is identified).

These error messages are sent to the sending system/user for review and rectification. Amplitude also reviews all errors with the view of assessing how the system (or training) may be improved to reduce these errors.

5.2 Data Protection, Patient Confidentiality, Consent

Amplitude is NHS IG Toolkit certified achieving the maximum score (level 3, 100%, for v13 2015/16, organisation code: YGMXG).

All data processing is subject to the Data Protection Act (1998) as amended by the Data Protection Regulation (GDPR) 2015.

Back-ups of the database are taken hourly, daily and weekly to ensure that, if there was a system failure, all patient information is protected. The system undergoes regular penetration testing and has achieved a 'STRONG' security posture.

All Amplitude website traffic is encrypted using TSL/SSL (Transport Security Layer) and SSL Certificates (SHA2). Additionally, Amplitude enforces HTTPS encryption by default for increased security unless the trust otherwise specify.

Website logins are secured with a two-factor authentication, a user password (8 characters' minimum including at least 1 numeric & either 1 special character or uppercase) plus a secret question (all secret answers are encrypted in the database for extra security).

Amplitude is a data processor. The individuals and organisations entering data into any of the *pro series* systems are defined as data controllers. Patients are the data subject. Definitions of these terms are contained within the Amplitude license and Data Processing agreements.

Protection of patient confidentiality is a core tenant of the Amplitude *pro*TM series products. All patient data sharing is subject to an informed and explicit consent which is the responsibility of the data controller to obtain. This is warranted for by the Data Controller in the Amplitude License Agreements and Data Processing Agreements.

[S3]Amplitude has a base data collection consent field which indicates whether the user has consented to their data being held by the owning system. For non *pro one*TM systems this consent message is controlled at system level and is only editable by administrators. For *pro one*TM systems this message has some customization options available to the users.

If a patient withdraws this base consent, then their demographics are removed from the system but the detail of all data captured that does not contain any patient identifiers will be retained and will be used for the clinician's records. For example, the fact that a hip replacement was done for Osteoarthritis will be retained for the clinician's logbook and revalidation reports.

Patients can also separately consent (or otherwise) to the receipt of reminder emails from the system.

For registry pathways on *pro one*TM and *pro enterprise*TM, the process and functionality regarding patient consent for submission of data to the registries is under development and will be included in a future version of this document. No data transfer occur until this development has been signed off by the registries, unless Amplitude is specifically instructed to do so by an authorized registry lead. The current draft of the anticipated process is outlined below.

For data sharing consent, it is anticipated that once a data exchange ‘job’ for a new destination is created by a user of the system, the patients that have a new pathway will be prompted to consent to this sharing the next time they log into the patient portal. The message displayed to the user will be defined by the receiving registry and will be in addition to the base agreement for the source system which will have been previously shown to the patient (and to which they will be required to consent to in order to proceed using the patient portal).

The outcome of their consent choice will be persisted against their record and used to control whether their data is allowed to flow to the destination system according to the rules defined by the sending and receiving systems (see section 5.3).

5.3 Anonymisation (De-Personalisation)

The data exchange mechanism is configurable with regard to how the anonymisation of data is handled where consent is declined. The sender and receiver can both be configured to:

- Ignore the consent flag and always send the data
- Send anonymised data where consent is declined
- Do not send any data where consent is declined

These configurations are part of the system set-up by Amplitude on behalf of the licence holder, are set system wide (i.e. cannot be overridden on a user by user basis), and cannot be amended by anyone other than Amplitude. The system has been set up to allow either option and can be configured according to the legal position and requirements of each organisation/licence holder and the table below shows how the data is processed for the differing option settings between differing sources and destinations.

Sender Setting	Receiver Setting	Outcome
Ignore	Ignore	All data exchanged
Ignore	Anonymise	Anonymised data exchanged
Ignore	Do not send	Data is not exchanged
Anonymise	Ignore	Anonymised data exchanged
Anonymise	Anonymise	Anonymised data exchanged
Anonymise	Do not send	Data is not exchanged
Do not send	Ignore	Data is not exchanged
Do not send	Anonymise	Data is not exchanged
Do not send	Do not send	Data is not exchanged

N.B. Whilst the data exchange system technically supports the ability to ignore consent, this setting would never be used in a real production setting and is designed for use in testing and data migration scenarios.

In all cases, to enable future data to be attached to the correct record, an internal unique GUID is attached to each patient and pathway. There is no way for this data to be identified using only the receiving system (although obviously if you have access to the source system the demographics are retained there).

5.4 Data Import

It is possible to import historical data into any of the Amplitude products using a built in data import module. Almost any data can be imported provided it is provided in a readable format (Excel, CSV, XML) and can be mapped into appropriate Amplitude data structures i.e. patient, pathway, forms.

The structure and the content of the data to be imported is defined by the user, thus, anonymisation is also controlled and defined at this point, by the user. i.e. patient identifiable data can be provided or withheld at the point of data import as part of the schema/file of the data import.

6. Reporting

Since the function of the tool is to produce outcomes and to be able to analyse these in the context of the clinically rich data the reporting functionality has developed in 5 main streams.

6.1 User-Defined Reports

User-Defined Reports are a highly flexible tool that enables user to select any single patient data item they wish to include in their report. This can include patient demographic items and any single answer response within any form on any pathway as well as the outcomes scores for each patient. At the time of running the report, the user indicates a date range (this applies to the pathway date) and all data for the logged in surgeon is gathered and made available in an Excel download, where it can be filtered and manipulated using all the flexibility of excel.

When a user downloads a document, they receive a warning message about the confidential nature of the data. It is up to the user to accept this and manage data appropriately. Once data is downloaded, it is outside of the control of Amplitude and the responsibility of the data controller/user to manage this data appropriately. [JT4][S5]

It is possible to add charts and pivots and statistical analysis features into the downloaded spreadsheet and then upload that spreadsheet to the report definition and it will then use that as a template for future runs of the report. This is how many of the advanced registry reports have been created.

Amplitude also provides (using this report builder) a predefined report that captures all of the important metrics relative to the pathway that has pre-configured pivot tables in order to allow simple instant reports for the data across all users of the given environment. i.e. *pro-enterprise*TM *pro-registry*TM.

By using the predefined categories instant filtering enables the users to manipulate the data and alter the displays of the dashboard display. This report requires no set up and is instantly available but obviously requires the act of running the report and then altering the filters to reflect the desired metrics of the user. It does produce an instant dashboard that reflects these metrics once the user has selected their preferred filters. It is aimed at providing an over view of all data In across all users and its use is always restricted to super users or steering groups. Its use is **aimed at the registry “leads” for over view of all users and patients.**

6.2 Instant “Widget” Reports.

This reporting tool is a step on from 1a. but **aimed at the individual users** and designed to enable clinicians to achieve standard reports instantaneously without the need for any set up or intervention.

This provides a dashboard that produces instant visual graphics that displays to individual users an over-view of predefined metrics relevant to use of the system. These are categorised into 3 main types of metrics. (With a 4th evolving as a combination of the first 2)

1. Metrics that relate to how well the software is being used and how it is performing.
Simple graphics that depict how many patients on the system, how compliant the

patients are being in completing the patient based forms and how compliant the clinicians are being in completing their specific forms.

2. Metrics that relate to the Clinicians base of patients. How many males versus females, average age, numbers of patients on different pathways, the diagnosis of patients on the system, the type of procedures being performed and so on. Where relevant and possible these provide comparisons to the users in general.

In registries they compare to clinicians within the registry, in an enterprise or unit they compare to that enterprise or unit and in *pro one*TM they compare to all *pro one*TM users.

It is up to each of the various licence holders to decide their specific metrics i.e. registry Steering groups will decide their metrics and *pro enterprise*TM, their metrics.

So a bar graph that depicts the numbers that are specific to the individual viewing the dashboard, and a column alongside that represents the user group population's patients metrics that relate to the outcomes of the individual's patients and once again how these compare to the user group population.

A further subcategory has evolved that merges 1. and 2 by applying **filters to the widgets**. This enhancement of the widgets enables individual users to subcategorise their patients based on filters like diagnosis or procedure in order to return of a table of patients, (rather than pie chart or bar graph type graphic) with columns for outstanding tasks in order to hone down on any particular group of patients that may form a specific cohort for a research project or special interest which in turn provides simple graphic of those patients with outstanding tasks. The tabular format also enables simple hyperlink to the patient's individual dashboard where the missing items can be edit or amended.

6.3 Pre-written SQL Queries

A series of sequel reports is pre-written in the system that is available to super users and steering groups. These reports are inflexible but standard and provide a series of reports that relate to number of users on the system, number of forms being completed, and general demographic metrics relative to the user group as a whole and the patients on respective pathways as a whole and how the respective registries are performing. These reports also give an over view of outcomes scores across all patients within the system. These reports are used to produce standard "Annual reports" for registries.

6.4 Revalidation Reports

A series of reports are in development at the moment aimed at providing each individual user a simple and easy way of achieving reports necessary for their revalidation.

The aim is that at the end of the clinician's revalidation year they will be able to extract the reports needed for their revalidation, print them or download them electronically to their desired location.

This report will provide a simple logbook for the user, a complications report and an overall Revalidation Report that summarises the key metrics required for revalidation. One of the reports that will be included in this report will be the overview of the clinician's patient outcome scores.

In Amplitude's *pro-one*TM pathways (and some of the registry pathways) a Friends and Family questionnaire is sent out. This is an automated process and the returns remain anonymous to the clinician or organisation. A Friends and Family report that gives the clinician an overview of their patient's responses which is available as a widget will be included in the revalidation report.

Similarly, as part of revalidation, clinicians are required to have asked a minimum number of their patients to complete a patient experience questionnaire. For all *pro-one*TM accounts this is a simple task of triggering the questionnaire electronically to those selected patients. The returns on these responses will also be included in the revalidation report.

There are a number of key issues that need to be taken into consideration in designing of the revalidation report. Primarily the metrics must be appropriate and meaningful to each sub-specialty. Amplitude is working with a number of Specialist Societies to create their preferred measurement criteria to ensure the Revalidation Report is a true reflection of the clinician's activity during the previous period with case mix adjustment appropriate to the specialty, incorporated into that report.

6.5 Outstanding tasks

Since the purpose of the software is to provide a simple automated way of capturing data it is imperative to have a simple overview of which patients have not responded to requests for the follow up scores, and similarly act as a reminder to the clinicians whenever they (Or their data manager) log onto the system.

On the user's dashboard an Outstanding Tasks report is running real time and gives the user an instant graphic of the existence of outstanding tasks. The report is sub-categorised into Patients outstanding task and Clinicians outstanding tasks. Each table enables simple hyperlink access to the patient's dashboard in order to complete these tasks. This is an overview of all patients under the care of the clinician. (The widget described above allows the clinician to drill down onto a specific group.)

This theme of reminders runs throughout the system, so that any interaction with a patient, whether on the Worklist or in the patient dashboard, flags up outstanding tasks and alerts the clinician at the time when they are most likely to have direct contact with the patient and can remind them to complete their scores or questionnaires.

7. Application Security

Amplitude is deployed as a web application and is configured to only allow secure HTTPS connections using the industry standard SSL protocol (the same level of encryption used when logging onto personal banking services) with non-secure requests being rejected.

Individual users log in with a username, password and secret question/answer combination. Access within the system is role based with roles being configurable through the allocation of specific, atomic security privileges that allow access to a particular system function.

Passwords themselves are NOT stored in the system, instead we make use of a salted hash and the secret question responses are stored in the database in an encrypted format.

The system can be configured to lock accounts after repeated attempts to login with incorrect credentials (with the default behaviour being to lock an account after three unsuccessful attempts) and.

The secret question requirement can be switched off if required (which is useful in some enterprise environments where a SSO solution is in place).

Amplitude also has an audit trail which allows us to track user activity at a granular level, covering numerous actions such as Patient, Pathway, and Form CRUD. Super Users can view the audit trail at individual user level or by date.

The invocation API supported by Amplitude requires a message which is signed and encrypted using a pre-shared key. These invocation requests are authenticated and the resultant authentication token is subject to an expiry date and can only be consumed once. Additionally, the API also requires the data exchange to be over a HTTPS connection.

In order to maintain a strong security posture, the application is periodically penetration tested by a specialist IT Security company to ensure it maintains a strong security posture (last test was in May 2016 by Nettitude):

Customer Confidential Security Document

NETTITUDE

2 EXECUTIVE SUMMARY

Background

Amplitude engaged with Nettitude in May 2016 in order to assess the overall security posture of their Amplitude registry application.

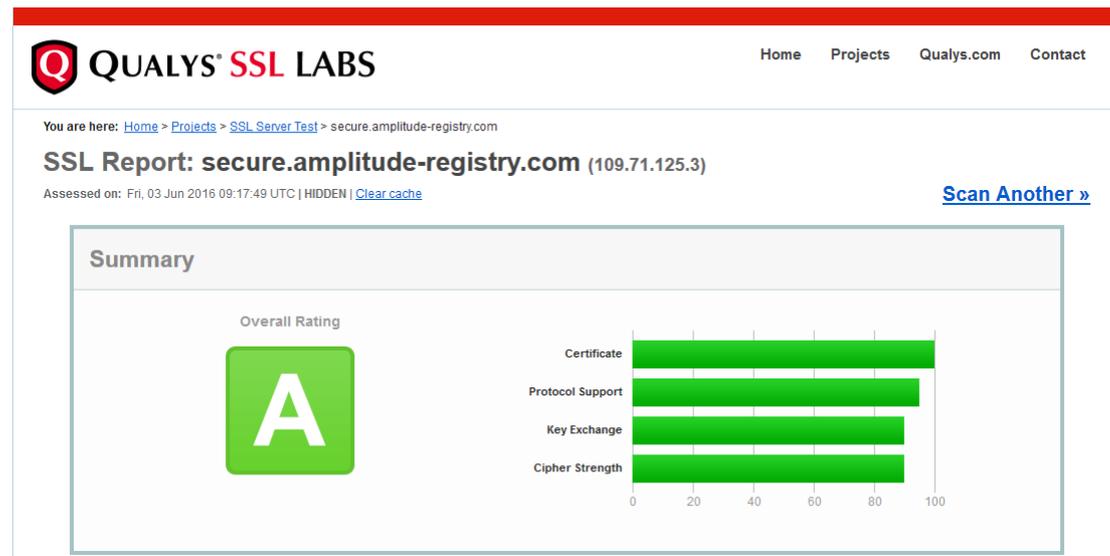
High Level Assessment

Based on the Amplitude's risk profile, primary security concerns and the vulnerabilities identified at the point of the engagement, Nettitude have found the application to be:

STRONG

The penetration test assesses the security controls configured on the access routers, firewalls, Intrusion Detection Systems (IDS) and Web Application Firewalls (WAFs), that protect the perimeter – in addition to assessing the strength of security for the application itself (including paying particular attention to exposed APIs).

Additionally, in between penetration tests Amplitude is regularly tested using industry tools such as SSL Labs' SSL Server Test to ensure Amplitude maintains good security ratings (currently an A rating which is what it has consistently maintained – secure.amplitude-registry.com shown below):



7.1 Data Exchange

The data exchange mechanism is covered in 5.1, but key points regarding security are as follows:

- All calls are made via HTTPS
- No credentials are shared between systems. Authentication is done directly against the destination and a token is generated and used for future communication
- At the point of each exchange, permissions are re-checked to confirm that the systems are still allowed to exchange data.
- At the point of each exchange the user's permissions are re-evaluated to ensure that the account is still active on the server and still has permission to import data.
- An audit trail of the data exchanged is maintained

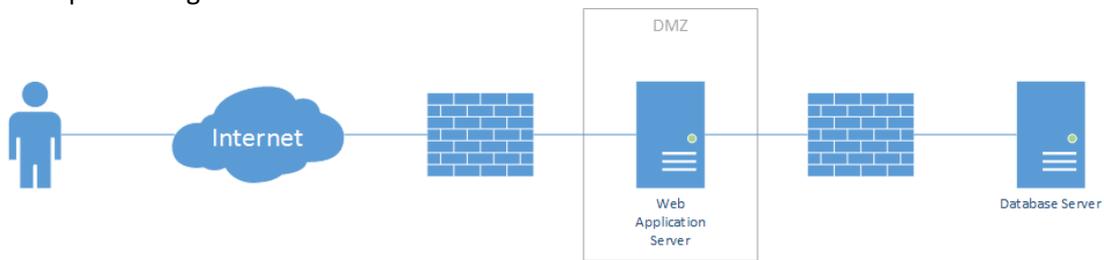
8. Technical

Amplitude is a web application developed using the latest Microsoft web technologies. It uses a combination of C#, ASP.NET (MVC), Javascript, HTML, and CSS. Additional windows services are also used which are also written using .NET (again in C#).

The back-end database is Microsoft SQL Server 2008 or above (at the time of writing the platform for the hosted solutions is 2012). The application server, reporting server and database server are deployed across several physical servers to maximise performance.

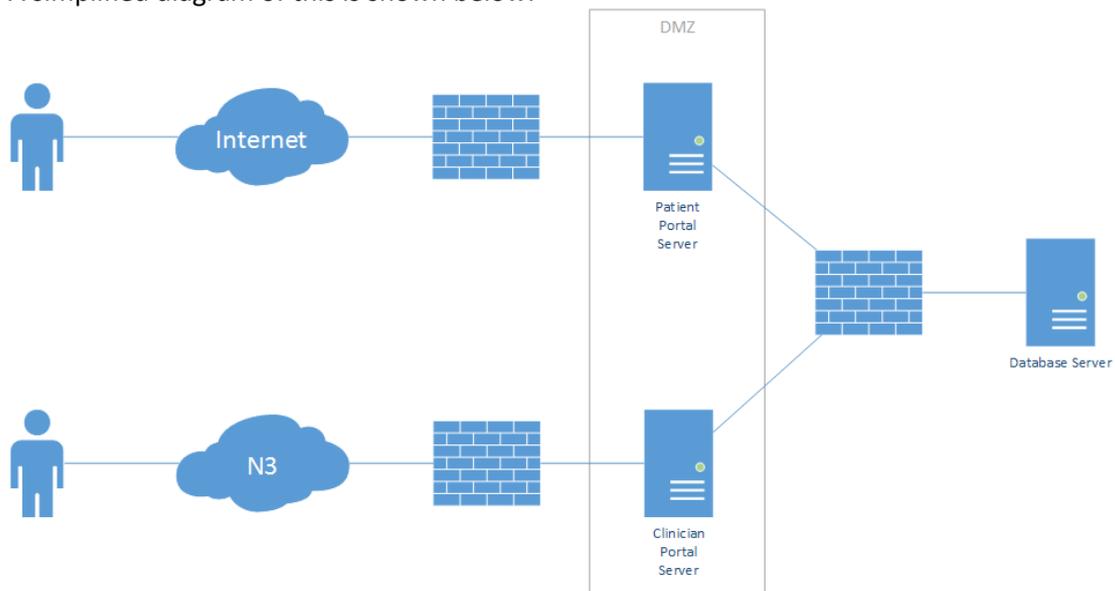
In the case of the hosted solutions, only the web server has any exposure to the internet and this exposure is limited to what is necessary, with the database server having an additional firewall between it and the web server.

A simplified diagram of this is shown below:



In the case of N3 hosted solutions the patient portal and clinician server are hosted on different servers, with only the patient portal server having any exposure to the internet (again the exposure is limited to what is necessary), with the database server having an additional firewall between it and the web server.

A simplified diagram of this is shown below:



Where an enterprise is hosting their own instance, the recommended deployment is similar to the above - although the Clinician Portal Server is generally only exposed to the local LAN

and a Web Application Firewall could be used to eliminate the need for the Patient Portal Server.

Backups are taken nightly, transactional backups during the day, with backups being replicated to alternative locations to provide data resilience. Disaster recover processes are in place internally and with the Amplitude Data Centre providers.

Whilst Amplitude will support most modern browsers – including recent versions of Android, iOS and Windows phones and tablets – it is strongly recommended to use the latest available version of your chosen browser family. Whilst the application is best operated on a PC, laptop or tablet, it is designed as a responsive application and will work with limited functionality on smaller platform devices such as smartphones

In the particular case of Internet Explorer, the application requires Microsoft IE9 or above – support for IE8 is deprecated in line with Microsoft’s support policy changes in Jan 2016 (a good overview of which – as they pertain to IE – is found here on the Mircrosoft IE teams blog: <https://blogs.msdn.microsoft.com/ie/2014/08/07/stay-up-to-date-with-internet-explorer/>).

Where required Mirth Connect is used to bridge gaps between a Customer’s existing interfacing capabilities and the Amplitude API. A typical example of this is to use one or more Mirth channels to receive HL7 messages within the Customer’s LAN and the convert those messages into secure, encrypted HTTPS calls to the Amplitude API.

Capacity

There is no capacity restriction in the software. Capacity is only restricted by the hardware on which it is hosted. As Amplitude runs almost exclusively on virtual hosted machines (apart from a very small number of customers) this hardware can be easily scaled as we incur capacity issues in whatever way they manifest themselves e.g. speed, storage space, bandwidth etc.

END