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Y Drindod Dewi Sant
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Trinity Saint David

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3. ABBREVIATIONS

Abbreviation	Meaning
APIs	Application Programming Interfaces
AQP	Assurance Quality Plan
AR	Adverse Reactions
CDR	Clinical Data Repository
CDS	Clinical Decision Support
DAL	Discharge Advice Letter
DHCW	Digital Health and Care Wales
ePMA	electronic Prescribing and Medicines Administration
FHIR	Fast Healthcare Interoperability Resources
FITT	Fit between Individuals, Task and Technology
GP	General Practitioner
HB	Health Board
HIT	Health Information Technology
IMTP	Integrated Medium Term Plan
IT	Information Technology
MVP	Minimum Viable Product
NHS	National Health Service
SNOMED CT	Systematized NOmenclature of MEDicine Clinical Terms
TAM	Technology Acceptance Model
TTF	Task-Technology-Fit model
UAT	User Acceptance Testing
UTAUT	Unified Theory of Acceptance and Use of Technology
UK	United Kingdom
WAO	World Allergy Organisation
WCP	Welsh Clinical Portal

WCRS	Welsh Care Records Service
WG	Welsh Government
WIAG	Wales Informatics Assurance Group
WRRS	Welsh Results Reports Service

4. INTRODUCTION

According to the World Allergy Organisation (WAO) the prevalence of allergy ranges from 10 to 40% in all the population, which means that allergies are a very common ailment (Pawankar, et al., 2013). The United Kingdom (UK) is among the most impacted countries with about 20% of its population affected by one or more allergic disorders (Levy, et al., 2004). Anaphylaxis is a life-threatening type of allergic reaction, with an annual incidence rate of 1.5 to 50 per 100,000 person-years (Yang, et al., 2017). The number of hospital admission due to anaphylactic shock has been steadily increasing; in the adult population in the period from 2013 to 2020 the figure has more than doubled, and in the same period, for paediatrics, there has been a 35% increase (Anaphylaxis UK, 2020). Of these, approximately 1% are fatal. Hence, the recording of allergies and adverse reactions within the patient's medical record is crucial.

In most countries, information on allergies and adverse reactions is stored in a variety of locations like paper records and across multiple systems. Wales is not the exception, however, there is a vision whereby data pertaining to adverse reactions (AR) is stored in a central repository that enables that information to become available across all the health information technology (HIT) systems. This way, in the future, structured data will be made available to be accessed and contributed to through every system, including AR (Welsh Government, 2017).

Digital Health and Care Wales (DHCW) is part of the National Health Service (NHS) Wales and it is in charge of delivering digital solutions that can transform health and care delivery. As part of its vision for a single record it has a portfolio that includes central repositories of information (documents, results, demographics, structured data) and portals to make that data accessible to clinicians anywhere in Wales. For example, the Welsh Clinical Portal (WCP) is the main point of contact for the clinician; at the same time, the WCP connects via Application Programming

Interfaces (APIs) to the different repositories like the Clinical Data Repository (CDR), Welsh Care Records Service (WCRS) or Welsh Results Reports Service (WRRS) (Digital Health and Care Wales, 2023a). This architecture/structure was designed to comply with the Welsh Government's (WG) policy to guarantee an Open data architecture, to which DHCW is committed in order to support seamless care and services across Wales. In essence, information should be available to share across Wales, subject to appropriate safeguards and governance, by interfacing with the APIs that DHCW provides (Williams & Williams, 2022).

The 'Adverse Reactions' (AR) functionality was created in the WCP with the aim to be the display of the allergies and adverse reactions that have been stored in a central repository in the national CDR (Figure 1). As well, this functionality is intended to be the place in the portal where clinicians can record new adverse reactions and allergies and write back/contribute to the central repository, in line with the vision described above. The CDR allows this data to be reused and retrieved by other systems that link to it, as this information is stored in a structured manner. The functionality is called Adverse Reactions because its intended use is not only to record allergies, but also intolerances and sensitivities (Sutton, 2020).

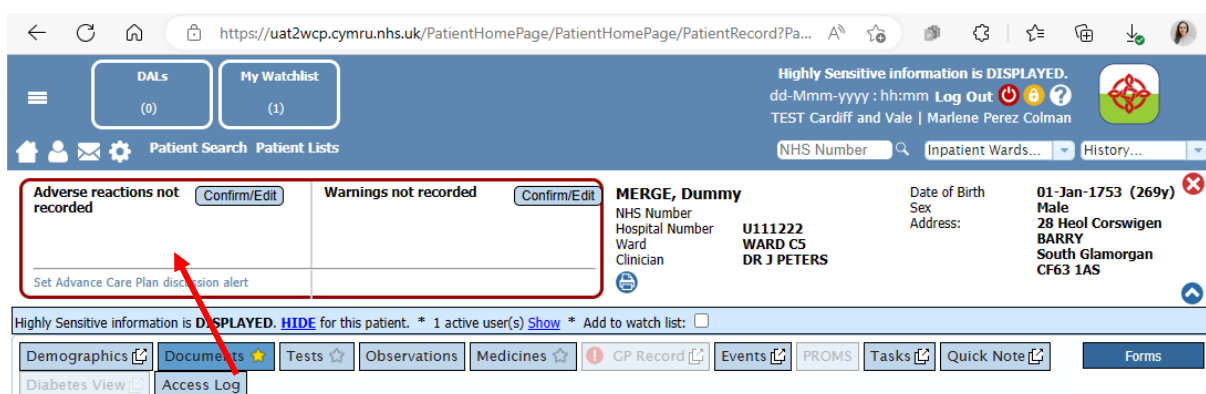


Figure 1: Welsh Clinical Portal (WCP) patient's banner. Arrow pointing at Adverse Reactions box. Image from user acceptance testing (UAT) environment with test patient named Dummy MERGE (Digital Health and Care Wales, 2023b).

The focus for delivering the AR software was to design, develop and implement a minimal viable product (MVP) that can then be enhanced iteratively once live. This workstream was included in the Integrated Medium-Term Plan (IMTP) for DHCW as early as 2016; however, due to COVID-19 response taking up the majority of resources, its release was postponed, and it was finally deployed into the live instance in the first health board (HB) in late 2021 (Sutton & James, 2023).

As stated above, the data that is captured when the clinician records an event in the AR box is intended to be structured and standardised via Systematized NOmenclature of MEDicine Clinical Terminology (SNOMED CT) code. This approach was adopted because SNOMED CT fulfils the desirable characteristics that a system to record adverse sensitivities requires, which includes the capacity to record '*no known adverse reactions*'; this negative finding is as equally as important to register as a positive one (Goss, et al., 2013). The use of SNOMED CT is a critical step to achieve semantic interoperability. As well, Welsh Government (WG) endorsed the use of SNOMED CT for HIT in a Welsh Health Circular in 2015, which was in turn, adopted by DHCW as a data standard (Welsh Information Standards Board, 2018).

The project was created following the standard fashion in DHCW. A request was presented to make this functionality available, and an Assurance Quality Plan (AQP) was presented. The initial version of this AQP dates from 2016, but it was updated and re-issued in 2020 when the development got funding and traction. The AQP was presented at the Wales Informatics Assurance Group (WIAG) for approval and identification of the requirements to build the software. In this process, the team members are identified and the group is built to fulfil the project; in this case, given that the functionality was planned to be built into an existing software – the WCP – the identified members for the project were the project manager (PM), a business analyst (BA), a

software architecture, a terminology specialist, an information governance (IG) lead, a clinical lead, and a patient safety manager (Sutton, 2020).

From a design perspective, after doing the relevant searches on the subject, the selected model to follow was that of HL7 as presented in Figure 2 (Goss, et al., 2013). The database was designed within the CDR, a system agnostic repository for structured data, so that future developments can link to it and become interoperable. The software design includes a full audit history trail of the adverse reaction record for transparency. During the project implementation, DHCW were asked to provide national guidance for recording adverse reactions in WCP and to specify who takes ownership or responsibility for maintaining the allergy record. A review of the allergy record confirms the following roles are the main contributors: pharmacists, junior doctors, and pharmacy technicians.

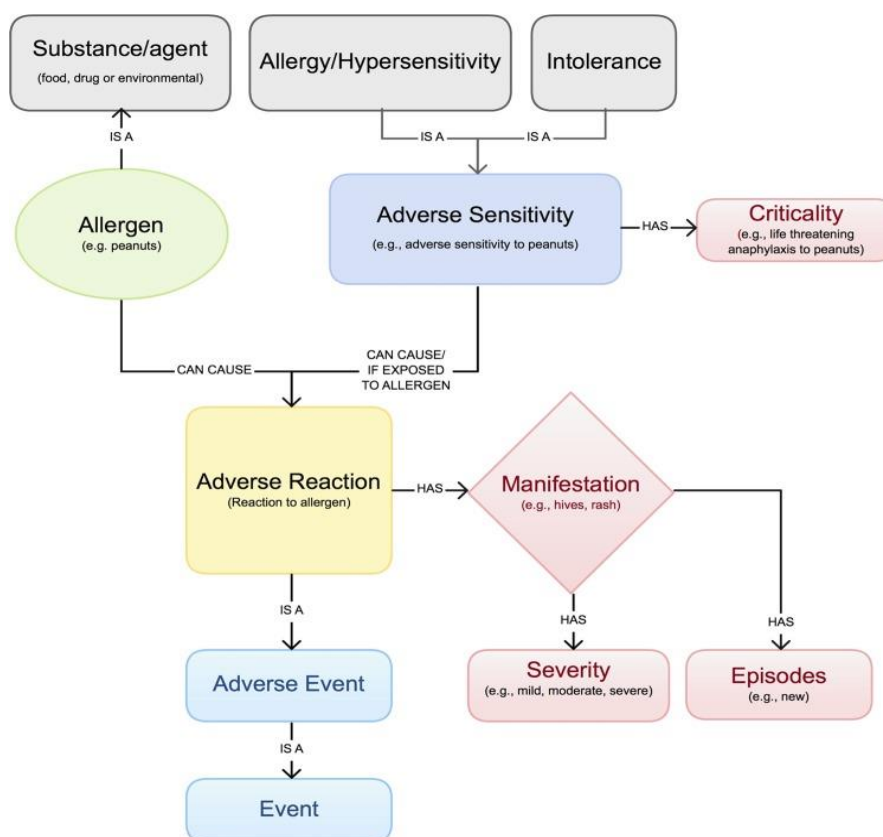


Figure 2: HL7 Diagram for allergies and intolerance model (adapted from HL7) (Goss, et al., 2013)

A business analyst gathered information in relation to the process and use-cases regarding the recording and uses of AR in the clinical environment. This included requests from the mentioned stakeholders and other clinicians – like dieticians – who would regularly read the AR from the paper chart. The clinical lead for this project is a doctor; he worked closely with the BA and the PM in the workshop for the requirements gathering and process mapping.

An analysis of this functionality is currently being undertaken by the DHCW team that delivered it. In this report, an alternate evaluation is presented, focusing on the factors that influence its adoption.

5. METHODS

A steady growth in development, implementation and use of HIT has been observed worldwide. These systems arise with the promise to solve issues like helping in cost reduction, improving access to data and improving the safety in the care provided. However, adoption of HIT system is varied, with a wide percentage of failure. Different studies have tried to establish which are the factors that contribute to a successful implementation of a new system – several frameworks evaluate the adoption of HIT systems and the factors influencing it (Han, et al., 2020).

The initial approach was to review existing frameworks that evaluate HIT adoption in the literature. From this review, the factors that influence the incorporation and use of a new system (or feature within a system) were assessed to establish which traits were relevant to consider to evaluate the AR implementation. So, note was taken of the attributes that the HIT system should have to be fit for use, to be able to do a valid evaluation of the AR software. The term ‘fit’ denotes that the characteristic or aspect is met or fulfilled in a way that it can achieve its aim (Yusof, et al., 2007) (Castillo, et al., 2010) (Joseph, et al., 2022).

Out of the array of available models evaluating the factors that influence adoption, only some have been used and implemented more frequently to study the success of the implementation of HIT (Park, 2019). Examples of the most commonly used frameworks are the 'Information success model' (DeLone & McLean, 1992), the 'Technology Acceptance Model' (TAM) (Davis, 1993), the 'Task-technology-fit' model (TTF) (Goodhue, et al., 2000) and the FITT framework (Ammenwerth, et al., 2006).

The latter framework, described by Ammenwerth in 2006, was chosen for the present evaluation. FITT stands for "*Fit between Individuals, Task and Technology*", and it is used to describe three types of relationships – the fit between individuals (users) and tasks and processes, the fit between individuals and technology and the fit between tasks and technology – to comprehend the factors that influence the adoption of HIT. The analysis is done for factors that facilitate the adoption and those that act as barriers and need to be optimised.

The benefit of using the FITT framework for the analysis is that it incorporates the relationship between the task and the user which is neglected by other frameworks like TAM or TTF. In relation to the AR functionality, the elements of FITT framework are the following:

- User: consultants, junior doctors, nurse specialists, pharmacists, and any other clinician with access to the WCP.
- Task: read, record and edit allergies and adverse reactions in the WCP.
- Technology: Software: adverse reactions box in the WCP and storage in the CDR. Hardware: computers and tablets, internet connection.

The hardware, a component of the 'technology' aspect of this development, had been tackled by the deployment of the WCP into the different HBs. So, the AR functionality benefited from being implemented into an already existing solution that users are used to working with, helping in the fit between *user* and *technology*.

For the purpose of assessing the three spheres of fit as proposed in the FITT framework, three different methods were undertaken. The first one was to identify in the literature specific characteristics that could act as markers of the requirements that an AR functionality needs to possess in order to be fit for purpose (task and technology) and compare the existing functionality to those findings. The second approach was to coordinate meetings with users of the system that would allow to gain insight relating to the fit between user and task and user and technology. These meetings were held with users from different backgrounds and verbal consent was taken to record their profession, years in practice, and replies. No person identifiable information was recorded as anonymity was guaranteed to avoid bias. During these meetings, a semi-structured approach was taken with open-ended questions to limit any other bias on the replies. The guiding questionnaire is included in [Appendix 1](#). A qualitative analysis of the replies was done.

To complete the analysis, a comparison was done with the data extracted from a recent survey that the team in DHCW has undertaken in relation to the AR functionality. This survey was anonymous and was sent out to a varied group of known users of the system, across different HBs. The data extracted from it has not been published yet and will be presented as part of the 'Evaluation Report' that is being completed for the AR workstream (Sutton & James, 2023).

6. RESULTS

As stated above, an initial examination of literature was undertaken to identify frameworks that assess the factors influencing adoption of a HIT system. From this review, the FITT framework was selected. From the FITT framework, the second analysis of the literature was oriented at identifying characteristics that the adverse reactions functionality needed to possess to be considered fit (Goss, et al., 2018).

In this search, the HL7 FHIR *AllergyIntolerance* resource (HL7 FHIR: Release 4B, 2022) and the openEHR Clinical Knowledge Manager *Adverse reaction risk* archetype (openEHR, 2021) were used as main sources of essential characteristics that the software needed to represent to be fit for recording adverse reactions. These two representations of an adverse reaction are detailed and comprehensive, considering all the component parts that the functionality requires. The openEHR archetype mind-map view is particularly helpful to visualise the elements that make up the adverse reactions recording (openEHR, 2021).

In the AR functionality the key characteristics presented in both, the FHIR resource and openEHR archetype, are present. In relation to the attribution, who recorded the AR, when it was last updated and who did the last update, are recorded (Figures 3 and 4). With regard to the allergen, the substance is visible, and so is the reaction that the patient had. The criticality and severity are left to interpretation of the user from the presented information.

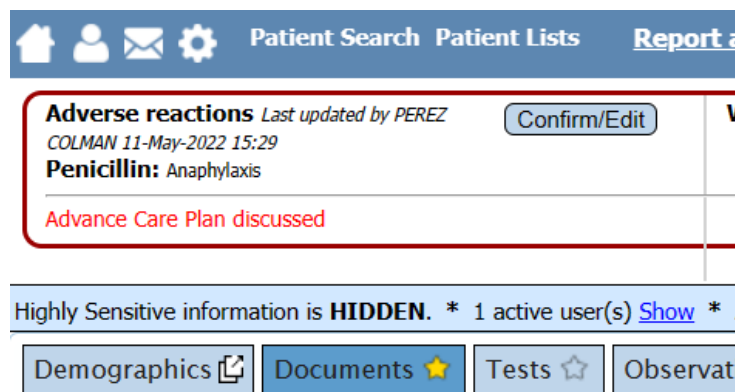
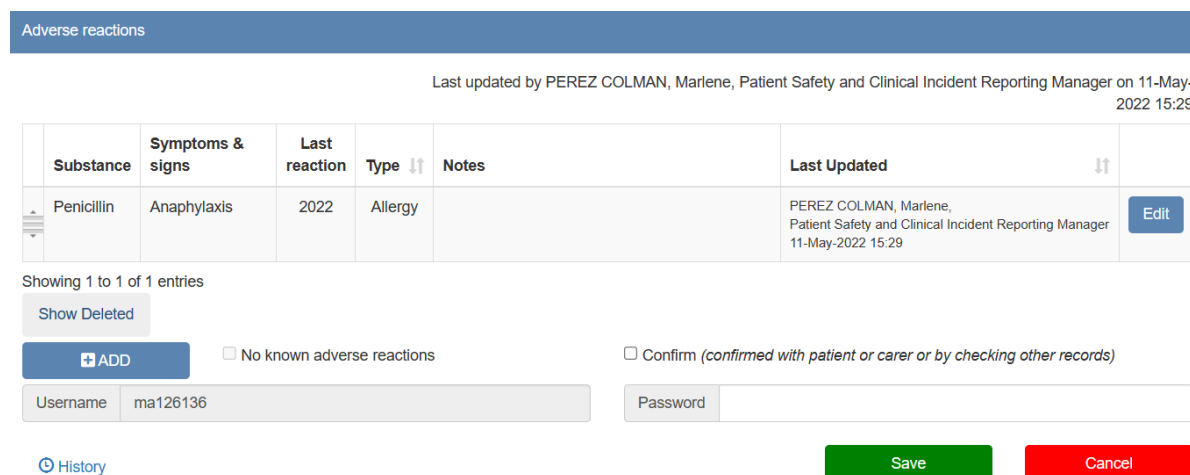


Figure 3 (left): Adverse Reactions box with a recorded adverse reaction (snippet of the box only to focus on the content). The allergen and reaction are visible, as well as the last user who updated the box and the date of the last update (Digital Health and Care Wales, 2023b).

As well, the date and time of the last reaction and if the event was witnessed by a clinician can be recorded in the entry when adding a new event or editing an existing one. In addition, a free text box is available for any supplementary information that the user would like to register as part

of their evaluation (Figure 5). One of uses that has been identified is to state that the patient reported the adverse reaction occurring in their infancy.



Adverse reactions

Last updated by PEREZ COLMAN, Marlene, Patient Safety and Clinical Incident Reporting Manager on 11-May-2022 15:29

Substance	Symptoms & signs	Last reaction	Type	Notes	Last Updated	
Penicillin	Anaphylaxis	2022	Allergy		PEREZ COLMAN, Marlene, Patient Safety and Clinical Incident Reporting Manager 11-May-2022 15:29	Edit

Showing 1 to 1 of 1 entries

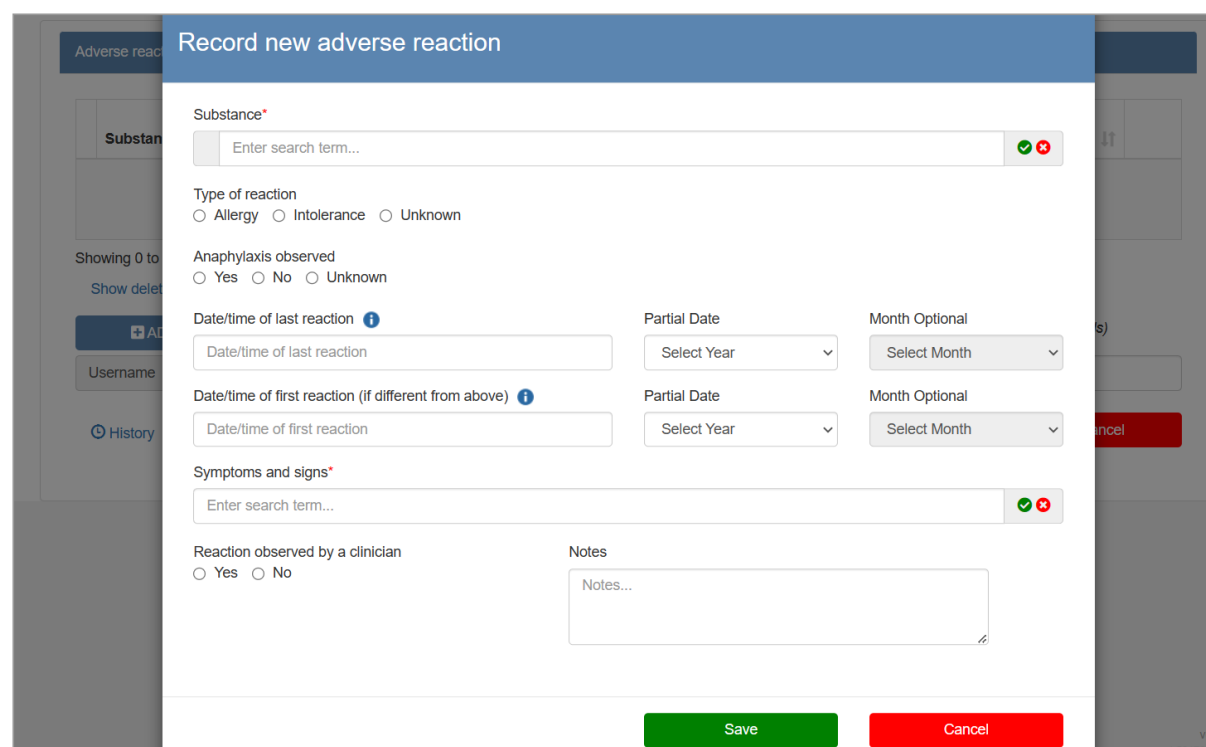
Show Deleted

☐ No known adverse reactions ☐ Confirm (confirmed with patient or carer or by checking other records)

Username: ma126136 Password:

[History](#)

Figure 4: Adverse Reactions functionality, after clicking the 'Confirm/Edit' button (snippet to focus on the content). The allergen and reaction are visible, as well as the last user who updated the box and the date of the last update. Other visible functionality are the 'Edit' of the existing record, 'Add' for a new record, and 'Show deleted' to view misfiled entries, and 'No known adverse reactions' tickbox to simplify the recording of that scenario. (Digital Health and Care Wales, 2023b).



Record new adverse reaction

Substance*
Enter search term... ✓ ✕

Type of reaction
☐ Allergy ☐ Intolerance ☐ Unknown

Anaphylaxis observed
☐ Yes ☐ No ☐ Unknown

Date/time of last reaction ⓘ
 Date/time of last reaction Partial Date: Select Year Month Optional: Select Month

Date/time of first reaction (if different from above) ⓘ
 Date/time of first reaction Partial Date: Select Year Month Optional: Select Month

Symptoms and signs*
 Enter search term... ✓ ✕

Reaction observed by a clinician
☐ Yes ☐ No

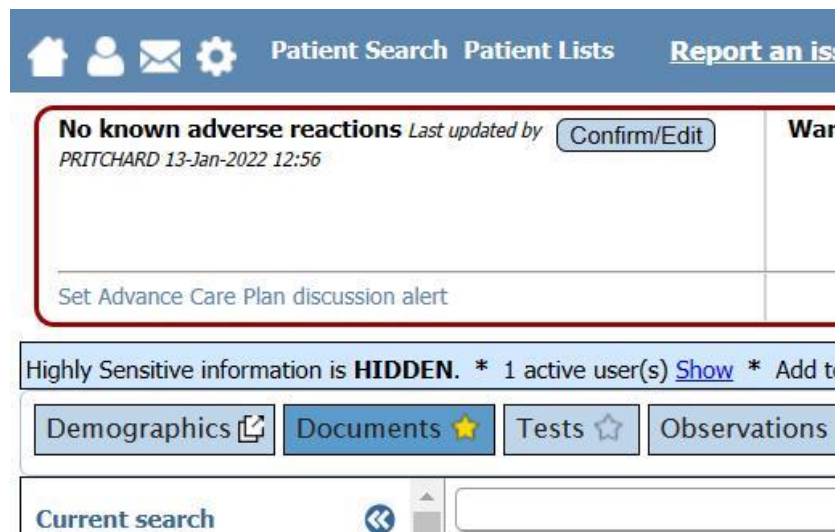
Notes
 Notes...

Figure 5: Pop-up writing the AR functionality, after clicking the 'Add' button (snippet to focus on the content). Mandatory fields - 'Substance' and 'Symptoms and signs' - are marked with a red asterisk. These two fields are SNOMED CT coded, as a search is performed on Ontoserver (Digital Health and Care Wales, 2023b).

The only mandatory fields are the ‘substance’ (allergen) and ‘symptoms and signs’ (reaction) that is the minimum set required for safety when assessing an adverse reaction. The ‘author’ of the entry – another essential feature – is automatically populated from the log-in details (NadEx account) and is fully auditable. At the same time, these two mandatory fields have the particularity that when typing, a search is performed on a specific group of SNOMED CT values as determined by the terminology specialist; this search produces a list based on the preferred term within SNOMED CT for a given entry. For example, if the user enters the word *acetaminophen* in the substance box, the first result to appear will be *paracetamol*, that is the preferred term. The same would happen if the user searches for *rash*, in which case the preferred term is *eruption*, guiding the user to select the preferred term. At the same time, these values get coded (not visible to the end-user) which would allow this information to be shared and reused, for example, as part of a clinical decision support (CDS) tool.

SNOMED CT has been chosen in the model because of several factors. The first, as mentioned, is to allow structured data to be entered and coded, to facilitate information exchange with other systems. Given that the recorded data is stored in the CDR, having structured data is a key element so that, when other systems link to this repository the information that is held can be shared without losing meaning, a basic requirement to achieve semantic interoperability. SNOMED CT has also been established as the standard terminology that fulfils the most desirable characteristics to record adverse reactions by Goss et al (2013). These desirable characteristics include content coverage, formal definition, concept orientation and vocabulary structure, amongst others. But the most salient characteristic from SNOMED CT, that has made it the ideal terminology standard, is the fact that it is the only one capable of encoding ‘*No known allergies*’ which in the AR functionality is called ‘*No known adverse reactions*’ (Figure 6). This is particularly relevant given that the absence of the finding has clinical implications too, and aids in delivering safer care which improves the fit between task and technology (Goss, et al., 2013). In figure 4, the

tick box to select that there are '*no known adverse reactions*' can be seen, and is used to simplify the task and avoid the need to search for 'not known' and increase the recording of this finding.



The screenshot shows a web interface for patient records. At the top is a navigation bar with icons for home, user, mail, and settings, and links for 'Patient Search', 'Patient Lists', and 'Report an is...'. Below this is a red-bordered box containing the text 'No known adverse reactions' followed by 'Last updated by PRITCHARD 13-Jan-2022 12:56'. To the right of this text is a 'Confirm/Edit' button. Below the text is a link 'Set Advance Care Plan discussion alert'. Below the red box is a blue bar with the text 'Highly Sensitive information is HIDDEN. * 1 active user(s) Show * Add to'. Below this bar are four buttons: 'Demographics' with a folder icon, 'Documents' with a star icon, 'Tests' with a star icon, and 'Observations'. At the bottom is a 'Current search' section with a search bar and navigation arrows.

Figure 6: Adverse Reactions box with 'No known adverse reactions' recorded (snippet of the box) (Digital Health and Care Wales, 2023b).

Updating data is one of the actions included in the CRUD basic operations. CRUD stands for *create, read, update* and *delete*, and describes the four essential user interface conventions, and as such these need to be attainable to determine that the user-task relationship is fit. In the AR box, the modification of a recorded entry can be easily done through the 'Confirm/Edit' button. Editing an entry includes adding new information, for example, if the reaction reoccurred or updating the signs and symptoms, as sometimes in immune-mediated reactions the severity can increase with repeated exposure, a very frequent event in latex allergies (MedlinePlus, 2022).

Finally, an adverse reaction can also be deleted, though it is not permanently deleted from the record and can be found if clicking on 'Show deleted' button. When deleting an entry, a reason to delete it must be entered. This includes the opportunity to register if an adverse reaction has been refuted, as depicted in Figure 7. Figure 8 demonstrates that the deleted entry is only hidden from view but can be found, following the principles of good record keeping. Every modification performed in the AR box is fully auditable.

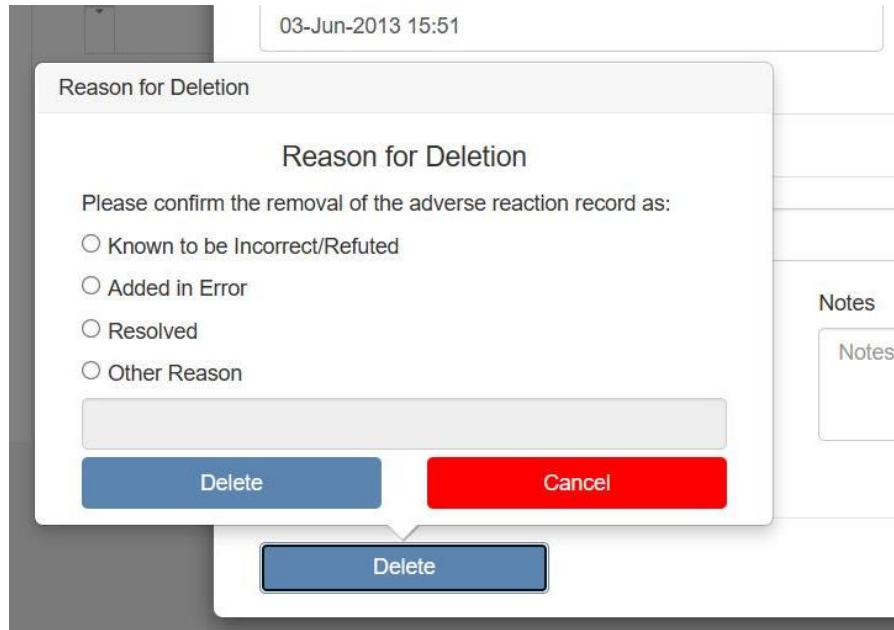


Figure 7: Pop-up to register a reason for deleting an entry which includes Refuted as an option. If 'Other reason' is selected, the free text box becomes mandatory (Digital Health and Care Wales, 2023b).

Adverse reactions

Last updated by PRITCHARD, Patricia, Business Analyst, Dermatology on 19-Jul-2022 15:58

Substance	Symptoms & signs	Last reaction	Type	Notes	Last Updated	Reason for deletion	
Solgar Vegetarian Multiple capsules (Solgar Vitamin and Herb) 100 capsule	Peripheral neuropathy with sensorineural hearing impairment syndrome	2020	Unknown		PRITCHARD, Patricia, Business Analyst, Dermatology 14-Jul-2022 12:58		Edit
Joint-Flex Daily 750mg tablets (Optima Consumer Health Ltd) 60 tablet 4 x 15 tablets	Swelling of oral cavity structure	2018	Intolerance		PRITCHARD, Patricia, Business Analyst, Gastroenterology 07-Apr-2022 15:16		Edit
Natural rubber latex	Anaphylaxis	Mar-2018	Allergy	Other Reason: gfdgfdgfggfd	PRITCHARD, Patricia, Business Analyst, Dermatology 14-Jul-2022 12:55		Edit
Brazil-nut	Anaphylaxis	2014	Unknown	Other Reason: deleted as on the wrong patient	PRITCHARD, Patricia, Business Analyst, Dermatology 19-Jul-2022 15:58	Added in Error	⛔
paracetamol	rash:gfgf		Allergy	bbfgfd	PRITCHARD, Patricia, Business Analyst, Dermatology 14-Jul-2022 12:58	Known to be Incorrect/Refuted	⛔

Showing 1 to 11 of 11 entries

[Hide Deleted](#)

☒ ADD ☐ No known adverse reactions ☐ Confirm (confirmed with patient or carer or by checking other records)

Username: ma126136 Password:

[History](#)

Figure 8: View of entries after clicking on 'Show deleted' in which the deleted entries and the reason to delete can be seen (Digital Health and Care Wales, 2023b).

However, certain qualities presented in the HL7 resource and the openEHR archetype have not been included in the design for the WCP. For instance, the route of exposure, which is a component of the two standards, is not represented in the AR functionality. This could be

included, if considered necessary, in the free text box. The reaction mechanism (immune mediated or non-immune mediated) is not available either. There is, however, an option to flag the reaction as allergy/intolerance/unknown, that can orient the user to understand the mechanism by which the reaction has occurred.

It can be established that there is a fit between task and technology if we assume that the hardware aspect of the technology was implemented by delivering the WCP into the HBs, and by the elements mentioned above that the software possesses to record an adverse reaction effectively and efficiently. These characteristics also influence in the fit between task and user, facilitating it.

To evaluate the individual's factors, 9 meetings were held to discuss this with users of the functionality. The identified users were one junior doctor, one consultant, two nurses (one based in the emergency department and another in an intensive care unit), two pharmacists, one pharmacy technician, one physiotherapist, and one dietician. The users were from different HBs to assess potential differences.

The information obtained in the meetings varied greatly, given that each user focused on their area of practice. The pharmacists and the pharmacy technician were the ones who mentioned using the software on a regular basis. Given that all of them work with inpatients most of the time, and that the inpatient journey is not digitalised, the general consensus was that allergies and adverse reactions for inpatients were usually checked from the paper chart rather than the red box in the WCP. However, while working in the outpatient secondary care setting, they did check the AR box. A benefit that was pointed out by six of the interviewees is the fact that the AR that are recorded in the red box get sent to the general practitioners (GP) via the Discharge advice letter (DAL).

Both pharmacists and the pharmacy technician claim to use the functionality to register AR during the 'medicines reconciliation' and 'discharge verification' processes, and they voiced the concern that junior doctors do not usually complete this section in the WCP. One of the pharmacists raised the issue that in one of the HBs, where an electronic prescribing and medicines administration (ePMA) system is implemented, the storage of AR was separated, and the ePMA system was considered the 'source of truth' for inpatients, and the WCP AR box for outpatients. There is no interoperability between these data bases, so there is a duplication of work if the AR identified during an inpatient stay, recorded in the ePMA system, and then requires a transcription to the AR box.

Another identified issue was that in the last HB that adopted the solution, in which the WCP is not regularly used as the main portal, there was little to no training provided and, because of this, the functionality is rarely used. The fact that the main portal in use is different to the WCP has created a gap in the provision of training as there is no project manager in charge of the deployment from the HB's perspective, hence training is rarely supplied for new functionality.

In all of the conversations, users stated that they knew how to create a new entry and read existing registers, however, only 44% said they knew how to update and delete records, and only one member confirmed that they had checked if a patient had a deleted record. In spite of knowing how to create an entry, it was suggested that training should be reinforced to increase completion rates of the AR box; one of the pharmacists mentioned that she had provided training to consultants and when junior doctors join the workforce (in August), but continued reinforcement was needed.

Another frequent complaint was the time it took to load the results from the search, nevertheless everyone mentioned that the term that they were searching appeared in the list from SNOMED CT. This sometimes slow response, associated to the presence of a green tick as

seen in Figure 5 whereby, if clicked, the term as typed by the user is selected, have created a number of un-coded entries that go in detriment of the quality of the data registered and the ability of this data to be reused. It is because of this, that the functionality of the green tick has been modified so that it is made available to click and select the entry only after an item from the list of SNOMED CT terms has been selected, improving the fit between user and task.

These findings were compared to those obtained from the survey sent by the AR project team (which have not been published yet) to 55 clinicians that have been registered as using the system as part of the project evaluation (Sutton & James, 2023). This survey was a qualitative assessment of the software with rating-scales with linguistic variable-type questions (ie: 'Highly recommend' to 'Would not recommend') to qualify the system and had a 64% response rate.

Graphs that form part of the AR evaluation survey from Sutton and James (2023) are presented in figures 9 and 10. One bias of this survey is that it was only sent to clinicians who were known users of the system, so there is a partiality in the fact that it does not capture the reasons why those who have not used the AR red box have not done so. It is the missing data that sometimes gives us more relevant information than the one we had in sight. For example, the low percentage of 'no known adverse reactions' could be attributed to a general lack of completion of the AR or to the fact that the tick box may not be in the expected place or failure to understand how it is used. Another example, as stated above, is that it has been alluded by a pharmacist, who is a frequent user, that junior clinicians may not have been properly trained regarding the functionality, hence this group tends to use it less frequently.

The following are some of the relevant findings from the survey. The first question was '*How likely are you to recommend the WCP Adverse Reactions software to a colleague?*' followed by a Likert scale from 1 to 10 to reply. An interesting result was obtained: as shown in figure 9, there is

an almost evenly distributed number of replies, with a trend towards the 'Recommend' represented by the '10'.

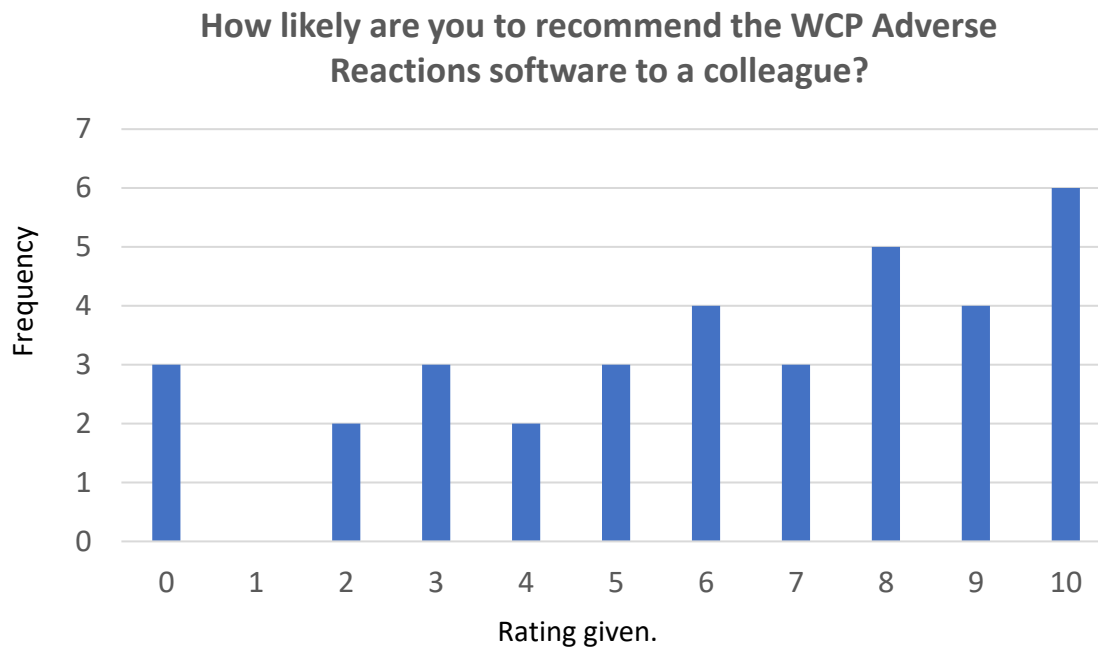


Figure 9: Bar chart showing the frequency of rating given to the AR functionality.

In addition to this, 66% of the users Agree or Strongly agrees that the software has all the required capabilities (as shown in figure 10), and over a quarter replied that they were very satisfied and 40% somewhat satisfied with the software (figure 11). In line with the recommendation, these results demonstrate that the users recognise the value of this functionality and are willing to endorse its use.

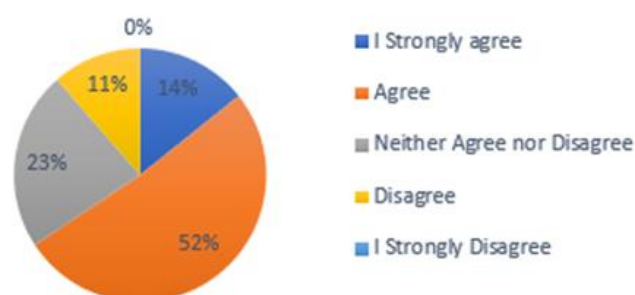


Figure 10: Pie chart depicting the percentage of the replies from the second item in the survey: 'The WCP AR software has all the functions and capabilities I would expect' (Sutton & James, 2023).

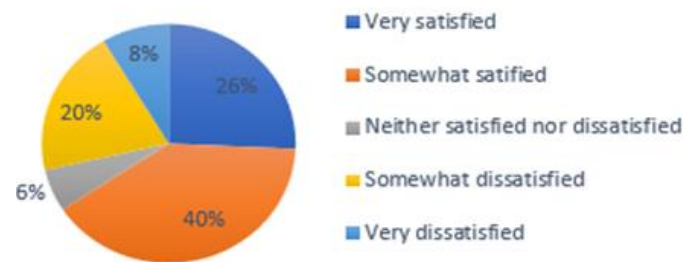


Figure 11: Pie chart of percentage of replies to the question 'Overall, how satisfied or dissatisfied are you with the Adverse Reactions software in the Welsh Clinical Portal?' (Sutton & James, 2023).

Finally, from my personal experience as patient safety manager using different systems and their recording of adverse reactions, I can identify that the main benefit from the software is its potential, given that it records the allergen in a structured/coded manner and in a database that is independent of the EHR and can become interoperable with other portals. At the same time, the fact that it is coded will allow the reuse of this information when CDS tools become available and in the implementation of ePMA systems.

7. DISCUSSION

Delivering the adverse reactions capability, with the supporting technical architecture, is the first step in unifying adverse reaction information in a digital format for NHS Wales. The adverse reactions software has been designed to enable users with appropriate access (role-based) to the WCP to read, contribute and edit the AR records (CRUD functionality). This is in line with the ministerial objective of *Once for Wales* that aims to provide access to structured electronic records based on common standards and interoperability associated to a central repository that forms the basis of the *Single Patient Record* (Digital Health and Care Wales, 2020).

In order for an organisation to be able to reap the benefits of an IT solution, there needs to be a clear understanding of the stakeholders involved and their capacities, government funding

(costs, availability of resource to implement new technology), end-users, patients and tasks (Han, et al., 2020). In addition, there needs to be a correlation called 'fit', between these stakeholders, the user's expectations and abilities, the task that the software aids or provides, and the information system (Joseph, et al., 2022).

Several frameworks have been used to assess how fit an IT solution is. In this report, we used the FITT framework by Ammenwerth et al. (2006) as the base of the analysis and have exposed how the AR functionality is fit between the three aspects that this framework considers which are individual, task and technology. From the analysis it can be established that the main areas of improvement are in relation to the user. The fit between the individual and the technology is the main focus, as training on how to use the system and the overall usability are at the centre of the grievances during the use of AR functionality.

Educating the users on the functionality should be a mandatory step prior to delivering the software, as otherwise this can hinder the implementation (Jeyakumar, et al., 2021). Even if DHCW does not have a direct involvement in the implementation, business change facilitators could ease the transition to a new functionality. At the same time, to encourage all WCP users to review and update the allergy record when interacting with the patient, DHCW could promote the use of the "message of the day" at log-in to WCP to display a prompt to users to keep the record up to date. This feature could also be used to post the link to the training videos in relation to the functionality to achieve wider reach. Another strategy could be to use the 'Allergy Awareness Week' that takes place at the end of April, as a moment to reinforce the importance of the recording of allergies and adverse reactions, by working in collaboration with the HBs.

Another improvement area for the functionality is the search in ontoserver via a FHIR API, to retrieve the desired SNOMED CT result and be able to code the term and making the fit between the user and technology (and in turn with the task) easier. This influences what is known as

‘performance expectancy’ as proposed in the unified theory of acceptance and use of technology (UTAUT) framework (Venkatesh, et al., 2003). Currently, the search can sometimes be slow or retrieve a large number of results, taking longer times to present the user with the list of preferred terms to select from.

Regarding the chosen framework, a major drawback is the analysis of the HIT system as a silo, and not considering the importance of interoperability in assessing the fit. Interoperability could be included in the technology aspect of the FITT framework, but it is not directly mentioned by the authors. In order to provide seamless care, considering the patient as a whole and independent of the EHR in use, interoperability is essential, and it aligns with the aim of providing a single record. Where HIT is developed and deployed as a silo, without taking into consideration the ecosystem of HIT that is in place across the health and care sectors, interoperability is harder to achieve, if not virtually impossible. The architecture that makes each of these is difficult to integrate and manage (Han, et al., 2020), hence the importance of taking into consideration the national architecture and infrastructure provided by DHCW, the use of messaging standards (like the FHIR API), and common terminology in the design of new software.

In line with WG policy to ensure an open architecture, the API to link to the CDR has been assured such that is secure and robust enough to conform with the safety and governance obligations and allow the user to read and write in the national repository. This API complies with patient safety, information governance and cyber security requirements (Williams & Williams, 2022).

In this regard, the AR functionality looks at the future and aims to be able to link to other systems by providing a data base that is system agnostic in the CDR and ensuring that a structured format is used to register the AR, so that the information can be reused, and eventually others can also write back information into the same data base. Currently, the *as-is state* of the CDR as the

central repository only holds the AR data that is being input via the WCP. However, the *to-be state* – as described by da Silva Serapião Leal et al. (2019) – is an interoperable central source of AR data to which systems connect via an API. To achieve this, the Better platform was procured as central repository (Better, 2021).

One future scope to consider is the use of AR in CDS tools. For example, alerts can be created to warn a clinician that a patient is allergic to a substance when doing a prescription. In Wales, the ePMA programme has been established and soon roll out of these systems will commence. AR will become more relevant in this use-case, and the benefit of collecting all the information in a central repository will be incorporated in this tool. However, care should be taken on the quality of the data that is stored and the types of alerts that are presented to the user, as it has been shown that override of these can be as high as 90% (Topaz, et al., 2017).

Other CDS in which AR can be incorporated are in the creation of order sets of medications, protocols, multipatient monitors and dashboards and relevant data summaries (Partnership for Health IT Patient Safety, 2019a). It is known that even with CDS alerting clinicians, adverse events still occur, that is why improving digital allergy documentation is one of the safe practices recommended. The implementation of CDS will be favoured by the structured data that is collected, and use of the same terminology, and harvesting the benefits of using SNOMED CT and the multiple levels in which information is connected (e.g.: components of a drug, or a specific brand of tablets) (Partnership for Health IT Patient Safety, 2019b).

To conclude, a multi-dimensional approach to the evaluation of an IT system can better capture the complexity that involves the implementation and use of a software and the maintenance of it in a manner that permits data persistence independent of the IT system. In that respect the repository and the data modelling are fundamental to permit semantic interoperability and

conceptual coherence. The focus for health-care organizations should shift from information systems' adoption to adopting a digital transformation paradigm (Crisan & Mihaila , 2023).

8. APPENDIX

8.1. Appendix 1 – Guideline questionnaire for meetings with users.

1. Could you tell me about your experience using the Adverse Reactions functionality?
2. If not covered in the above reply: Does the software allow you to Create, Read, Update and Delete (CRUD) adverse reactions?
3. Could you describe the advantages that this software provides?
4. Could you describe the disadvantages of this software?
5. How would you describe the Adverse Reactions functionality in one word or short phrase?

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