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Development of an integrated electronic platform for patient self-report and management of adverse events during cancer treatment.

P. Holch, *[1,2] L. Warrington [2,] L. Bamforth,[2,7] A. Keding,[3] L. Ziegler,[4] K. Absolom,[2] C.Hector, [1] C. Harley,[5] Johnson, O,[6,9] G.Hall, G, [7] C.Morris,[8] & G. Velikova, [2].

1 Psychology Group, School of Social Sciences, Faculty of Health and Social Sciences, City Campus, Leeds Beckett University, Leeds, UK; 2 Patient Reported Outcomes Group: Leeds Institute of Cancer Studies and Pathology, Bexley Wing, St James's Hospital, Beckett Street, University of Leeds, Leeds UK; 3 Department of Health Sciences, Heslington, University of York, York, UK, 4 Institute of Health Sciences, 101 Clarendon Rd, University of Leeds, Leeds UK; 5 School of Healthcare: Baines Wing, University of Leeds, UK; 6 School of Computing, University of Leeds, Leeds, UK; 7 Leeds Teaching Hospitals NHS Trust, St James's Institute of Oncology, Bexley Wing, St James's Hospital, Beckett Street, Leeds, UK. 8 Patient Representative eRAPID Project Management Group. 9 X-Lab limited, 10C Joseph's Well, Hanover Walk, Leeds, UK.

Corresponding author Dr Patricia Holch Psychology Group, School of Social Sciences, Faculty of Health and Social Sciences, Leeds Beckett University, Room 815 Calverley Building, Leeds, LS1 3HE, UK; Tel: +44 (0)113 812 4950; Email: T.Holch@leedsbeckett.ac.uk

**This work was completed at the Patient Reported Outcomes Group: Leeds Institute of Cancer Studies and Pathology, Bexley Wing, St James's Hospital, Beckett Street, Leeds, LS9 7TF: University of Leeds UK*

Key message

This paper describes the secure real-time integration of electronic patient reported adverse event (AE) data into the electronic patient record system (EPR) in a leading UK Cancer Centre. eRAPID (electronic patient self-Reporting of Adverse-events): Patient Information and aDvice) allows AE reporting from home and generates self-management advice for low or moderate AE and for severe AE immediate advice to contact the hospital. Clinicians view patient AE data in the EPR and receive email notification of severe AE.

Abstract

Background

Significant adverse events (AE) during cancer therapy disrupt treatment and escalate to emergency admissions. Approaches to improve the timeliness and accuracy of AE reporting may improve safety and reduce health service costs.

Reporting AE via Patient Reported Outcomes (PROs), can improve clinician-patient communication and making data available to clinicians in 'real time' using electronic PROs (ePROs) could potentially transform clinical practice by providing easily-accessible records to guide treatment decisions. This manuscript describes the development of eRAPID (electronic patient self-Reporting of Adverse-events: Patient Information and aDvice) is a National Institute for Health Research (NIHR) funded programme,a system for patients to self-report and manage AE online during and after cancer treatment.

Materials and methods

A multi-disciplinary team of IT experts, staff and patients developed using agile principles a secure web application interface (QStore) between an existing online questionnaire builder (QTool) displaying real-time ePRO data to clinicians in the electronic patient record (EPR) at Leeds Teaching Hospitals NHS Trust (LTHT). Hierarchical algorithms were developed corresponding to Common Terminology Criteria for Adverse Events (CTCAE) grading using the QTool question dependency function. Patient advocates (*N*=9), patients (*N*=13) and staff (*N*=19) usability tested the system reporting combinations of AE.

Results

The eRAPID system allows patients to report AE from home on PC, tablet or any web enabled device securely during treatment. The system generates immediate self-management advice for low or moderate AE and for severe AE advice to contact the hospital immediately. Clinicians can view patient AE data in the EPR and receive email notifications when patients report severe AE.

Conclusions

Evaluation of the system in a Randomised Controlled Trial in breast, gynaecological and colorectal cancer patients undergoing systemic therapy is currently underway. To adapt eRAPID for different treatment groups pilot studies are being undertaken with patients receiving pelvic radiotherapy and upper gastrointestinal surgery.

Clinical trials numbers ISCTRN CCT-NAPN-21338 and ISRCTN88520246.

Key words: Cancer Adverse Events; Patient Reported Outcome Measures(PROMs); Electronic Patient Reported Outcomes (ePROs), Electronic Patient Records (EPR); Internet Intervention: Self-management

Introduction

Significant adverse events (AE) during cancer therapy can disrupt treatment and impair quality of life (QOL) [1, 2]. In the UK The National Confidential Enquiry Report into Patient Outcome and Death (NCEPOD) highlighted increased emergency department admissions and limited support for patients experiencing chemotherapy-related AE [1]. An audit of the acute oncology service in Leeds Hospitals NHS Trust (LTHT) found patients often delay reporting even severe symptoms [3]. Approaches to improve care and avoid preventable emergency admissions may contribute to improving cancer patients' safety and QOL and reduce health costs.

Reporting symptoms and side effects via Patient Reported Outcomes (PROs), can improve clinician-patient communication and the accuracy of clinician-reported AE [4-6]. The last 20 years has seen an increase in electronic PRO systems [7] providing timely and effective solutions to capture and utilise PRO data in a range of clinical contexts [7, 8].

Patients can report QOL and chemotherapy AE via PROs in clinical practice using home internet [9] or mobile phones (ASyMS) [10]. Successful implementation of electronic PRO systems include: PatientViewpoint, [11], the Computer-based Health Evaluation Software (CHES) [12], and the Symptom Tracking and Reporting System (STAR) for PRO AE

reporting during chemotherapy [13]. To support online reporting patient education is also recommended [14] along with an ethical responsibility to provide patients with clear guidance on managing severe AE and alerting their clinical team [15].

Making data available to clinicians in 'real time' using electronic PRO (ePRO) could have the most transformative effect on clinical practice by providing easily-accessible records to guide treatment decisions [16]. The increased use of Electronic Patient Records (EPRs) and patient access to health records has created opportunities for the integration of PRO systems with clinical data.

A challenge of linkage to an internet based ePRO system is to maintain the security of sensitive patient data in the EPR. In the UK NHS, the single secure N3 network connects all NHS organisations [17]. Approved third parties (e.g. prescribing systems) access to the NHS is subject to strict governance.

Previously, in Leeds Cancer Centre a highly scalable electronic online questionnaire management software QTool was developed by X-lab (a private software company) for ePRO data collection. QTool facilitates building and scheduling of flexible questionnaires to match clinical needs. When complete, the PRO data is instantly accessible and downloadable for analysis. QTool was used in a study of 600 cancer survivors [18] successfully linking group PRO data to the cancer registry. However, PRO responses were not integrated into the EPR.

The Leeds Cancer Centre EPR (PPM-Patient Pathway Manager) is used in NHS trusts across the Yorkshire region [19] to coordinate the care of over 2 million patients. PPM has an integrated clinical trials module enabling allocation of patients to research studies, management of trial documents and correlation of demographic and clinical information with trial data.

Building on these platforms we initiated the National Institute for Health Research (NIHR) funded eRAPID programme (electronic patient self-Reporting of Adverse-events: Patient Information and aDvice) [20]. eRAPID aimed to design and evaluate a system for patients to self-report and manage AE during and after cancer treatment. To support the programme we developed an innovative, secure interface between the QTool system and the existing Leeds Cancer Centre EPR known as Patient Pathway Manager (PPM).

The aims of this project were to develop:

1. Secure real-time integration of the online questionnaire system (QTool) with the EPR in Leeds Cancer Centre (within N3 network restrictions) including a user-friendly and easily-accessible display of PRO data for clinicians.

2. Clinically-based algorithms providing patients with immediate, automated tailored advice on managing AE, and notification via email for severe AE to clinicians.

3. Improved usability and functionality of the QTool patient interface to support patients to login securely and easily report and manage AE from web enabled devices

Theoretical foundations and rationale for approach of the eRAPID system

Following recommended Criteria for Reporting the Development and Evaluation of Complex Interventions in Healthcare [21] we have described the theoretical underpinnings of eRAPID and the aims, essential functions and rationale for selection of the individual components (S1).

Methodological approach and procedures

A Multi-disciplinary project team (MDPT) led the development which included researchers, lead oncology clinicians, health informatics professionals (X-Lab), a patient advocate group and lay members from the National Cancer Research Institute (NCRI) patient and public involvement group. Key roles included a technical lead working within a disciplined agile framework [22] to enhance the software to fit stakeholder specifications. A researcher in a liaison role translated the research and clinical needs to the IT team and led system usability testing.

A wider stakeholder group of clinical staff (*N*=19), Patient advocates (*N*=9) and patients (*N*=13) administrators and researchers was continuously consulted throughout to: 1) elicit initially the requirements of the system; 2) validate the content and design by reviewing each iteration of the eRAPID platform. This was achieved either via direct interviews, meetings participation or, telephone contacts. Responses were charted thematically [23] and if required changes made to the next iteration.

An overview of the work in chronological order is provided in Figure 1. Below, we report the methods and results for each aim.

Insert Figure 1

1. Secure real-time integration of the online questionnaire system (QTool) with the EPR including a user-friendly and easily-accessible display of PRO data for clinicians.

Method

Stakeholder requirements were elicited via interviews and summarised to inform the technical specifications (S2). A key challenge when integrating PRO data into the EPR was to develop a scalable way to display PRO results to clinicians whilst maintaining the security of patient data. QStore, a web application, was developed (hosted within the NHS network) to access the QTool secure anonymised interface and retrieve and store PRO data utilising the existing clinical trials module in PPM. QStore was developed using ASP.NET MVC and SQL Server. Using Task Scheduler, a .NET windows application retrieves and stores PRO data from QTool every 5 minutes.

Results

The resulting data flow through the system is illustrated in Figure 2 with descriptions of how the system meets the needs of the key stakeholders. Identifiable and sensitive patient data is held securely in the EPR database behind the NHS firewall. QStore links each patient EPR record to QTool and allocates a unique QTool login name.

Insert figure 2

Patients are given a postcard with their login details which allows access to eRAPID via the website portal (Figure 3) from home, hospital kiosks or any web-enabled device. On completion of the AE items patients can view their own data (over time) in tabular or graphical formats, and may receive severity-dependent advice (see aim 2). They have the facility to print or email the results. eRAPID generates weekly text message or email reminders to encourage completion. Adherence is monitored though system tracking (website visits and questionnaire completion) and evaluated by the number of appropriate contacts with the hospital, alerts and admissions. QStore pulls PRO data every few minutes and displays it to clinicians in tabular or graphical format with level 3 symptoms highlighted in red (figure 3)

Insert figure 3

2. Clinically-based algorithms providing patients with immediate, automated tailored advice on managing AE, and notification via email for severe AE to clinicians

Methods. The existing question scoring dependency function in QTool was utilised to construct hierarchical algorithms triggering immediate severity dependent advice based on AE grading dependant on how the patient answers a question or combination of questions. The eRAPID symptom report questionnaires are patient reported AE adaptations (PRAE) [24] of the gold standard clinician reporting system (CTCAE version 4.0) [25]. The responses for each question are allocated a score from 0-3 corresponding to the CTCAE severity grades and the United Kingdom Oncology Nursing Society (UKONS) triage forms [26] (see table 1).

Insert table 1

Five hierarchical algorithms were developed corresponding to the UKONS severity levels 0-3 ranging from A1 (most severe) to D (least severe) (S3). For severe symptoms triggering A1 an email notification is automatically sent to one (or more) clinicians advising them to view the PRO report in the EPR. Corresponding AE advice was sourced from local and national guidelines accessible via QTool or a customised website [27]. Both the algorithms and patient advice were developed though iterative review with the stakeholder group: 19 clinicians, 9 patient advocates and 13 patients via face-to face or telephone interview, and though discussion at project management meetings, see (S4) for demographic detail. Additionally, we asked the clinicians to complete the eRAPID symptom report questionnaire (from the patient perspective) following two chemotherapy-related AE scenarios (S5) [23]. The scenarios were designed to test the algorithms to ensure relevant severity-dependent advice was triggered.

Results. The clinical algorithms, implemented in QTool via the scoring system and dependencies, allow patients to receive immediate targeted advice for low or moderate AE to help self-management with links to relevant webpages for more detailed information. For severe AE they are advised to contact the hospital immediately (see figure 3).

Clinicians receive an email notification for severe symptoms) detailing the patient's QTool username and the symptom(s) reported. A report corresponding to the notification was created in the EPR identifying the patient with the QTool username, allowing the clinician to open the medical records and respond to the notification. The scenario-based testing of the algorithms did not reveal any issues.

3. Improved usability and functionality of the QTool patient interface

Methods. To test the eRAPID symptom reports and algorithms we initially engaged 19 clinicians and 9 patient advocates who reported combinations of symptoms and severities. Comments were collated on: logging in, accessing the system, navigation through the questionnaire; accessing their results and self-management advice and printing or emailing results. Staff and patients responded verbally via semi structured audio-recorded interview and written comments. Data were charted and analysed thematically [23]. Changes were made and subsequently the full eRAPID system was tested in a convenience sample of 13 patients receiving chemotherapy using interviews and written comments for feedback for demographic details see (S4).

Results. Key points from staff and patient feedback included: patient safety, accessing the 24-hour hotline number within the QTool management advice, accessing and navigating through the system and patients viewing and accessing results. Significant improvements were to made see (S6).

Discussion

We have successfully developed an online system for PRO reporting of AE with an existing EPR in real-time whilst maintaining patient confidentiality and security and meeting the key stakeholder specifications.

Patients can now report AE from home on PC, tablet or smart phone securely during treatment and receive appropriate management advice via the severity dependent algorithmic questionnaire scoring. Clinicians can view patient AE data in the EPR and receive email notifications when patients report severe symptoms. The immediate severity-related guidance on how to manage AE is a unique feature of our system compared to other ePRO web-portals [11-13,16].

Key security concerns were addressed though development of QStore allowing non-identifiable questionnaire response data to be transferred through NHS firewalls. We have achieved this with the full support of, and in close collaboration with, the local EPR development team supported by LTHT thus ensuring the smooth integration of the system.

The content and design of the system was developed with the programmer, research liaison, clinicians and patient advocates on the project management team and validated through usability testing. We developed an accessible intuitive staff, researcher and patient interface by identifying and troubleshooting system errors and usability issues prior to introduction to patients/clinicians.

In future we will work with staff to determine the level of support needed to integrate the system into the care pathways of different treatment groups and provide extensive staff training to ensure smooth adoption of the system.

The system is functioning within the local EPR but we have adapted eRAPID to meet the needs of different patient groups in UK NHS settings. Implementation work is currently underway in Manchester and Bristol for pelvic radiotherapy and upper gastrointestinal surgery respectively.

Collection of large scale patient reported AE data poses challenges for data capture, storage, security and integration into patient care pathways. We do not underestimate the challenges of interfacing QTool with other NHS EPR as success is dependent on local system limitations. QTool was developed for web browsers of computers or tablets. Usability could be improved by developing smartphone apps but such approach would reduce the flexibility of changing patient questions and increase the development cost of apps for different smartphone platforms

Conclusion and Future challenges

We have successfully developed a secure interface between an online integrated electronic system for PRO data collection and an EPR in a single cancer centre. A remaining challenge is the implementation in busy hospitals considering the administrative procedures and resource requirements. To assess the staff and patient training needs and the acceptability of the system we plan to test the full eRAPID intervention in a sample of breast cancer patients on adjuvant chemotherapy. This will provide an opportunity to refine the system prior to its full evaluation in a Randomised Controlled Trial in breast, gynaecological and colorectal cancer patients undergoing systemic therapy.

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Patient advocates

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Project management team

Professors Jenny Hewison; Peter Selby; Julia Brown; Clare Hulme Jane Blazeby Norah Kearney and Rick Jones who sadly passed away in 2014; Doctors Lucy Ziegler; Clare Harley; Geoff Hall; Kevin Franks; Others: Martin Waugh and David Fox; Krystina Koslowska and Mrs Sue Kier who sadly passed away in 2012.

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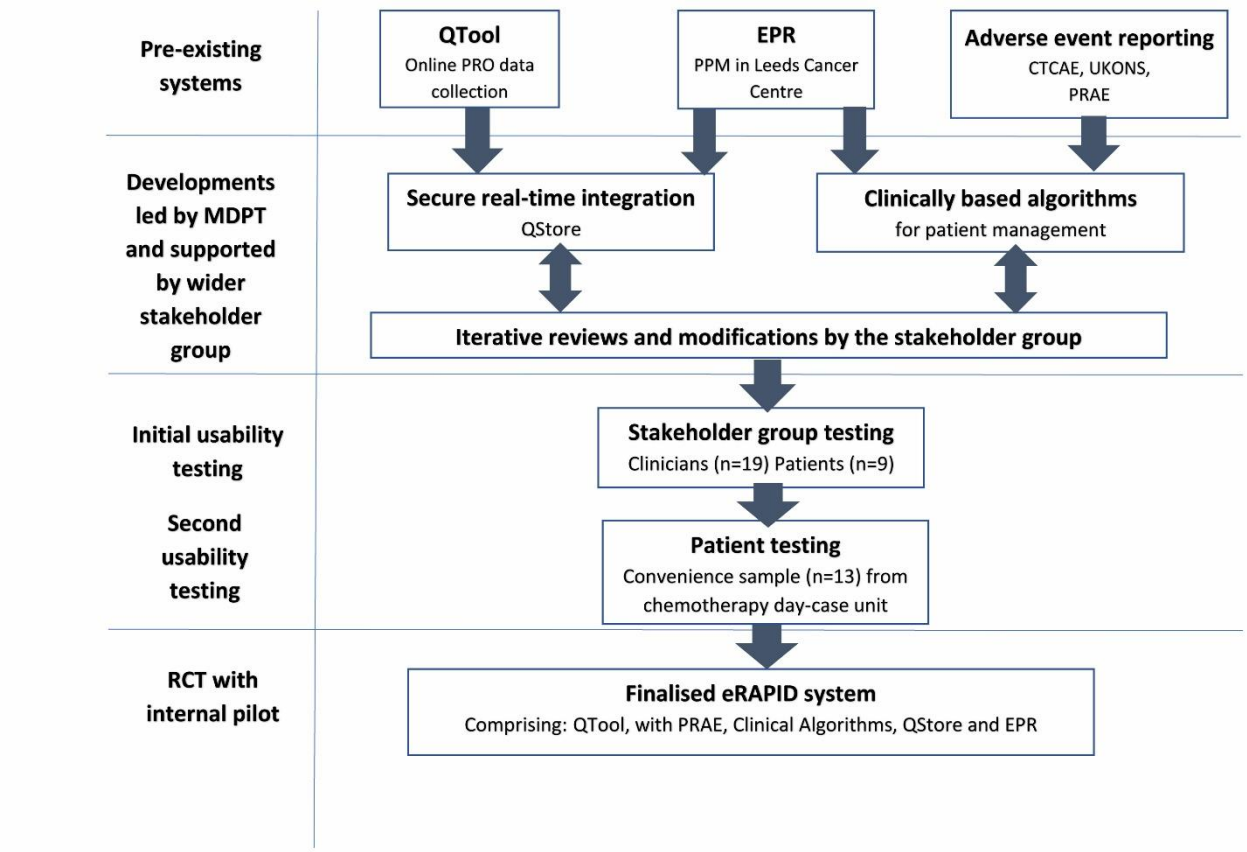
Table 1: CTCAE (version 4.0) vomiting item, corresponding patient reported version and CTCAE and UKONS severity grading (0-3)

CTCAE (version 4.0) Vomiting item	**PRAE item Have you been sick (vomited)?**	**CTCAE Grade**	**CTCAE Version 4.0 General description of severity grading**	**UKONS**
N/A	N/A	0	N/A	No problem reported and no advice needed.
1 - 2 episodes (separated by 5 minutes) in 24 hrs	I have vomited 1 - 2 times in a 24 hour period	1	Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.	Mild problem not requiring medical attention, self-management is appropriate.
3 - 5 episodes (separated by 5 minutes) in 24 hrs	I have vomited 3 - 5 times in a 24 hour period	2	Moderate; minimal, local or non-invasive intervention indicated; limiting age-appropriate instrumental ADL	Potentially serious problem, may require medical attention.
>=6 episodes (separated by 5 minutes) in 24 hrs; tube feeding, TPN or hospitalization indicated	I have vomited 6 or more times in a 24 hour period	3	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL.	Potential medical emergency, requires urgent medical review.

ADL: activities of daily living; Instrumental ADL (preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.), Self-care ADL (bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not bedridden)

Figure 1: Flow chart of timelines of the development of the eRAPID system



Legend: QTool online questionnaire builder; EPR: Electronic patient records; PPM: patient pathway manager; PRAE: Patient Reported Adverse Event Items; CTCAE: Common Terminology Adverse Events; UKONS, United Kingdom Oncology Nursing Society; QStore: Link between QTool and EPR; MDPT: Multidisciplinary Project Team.

Figure 2: eRAPID system diagram describing the data flow from public internet to hospital network

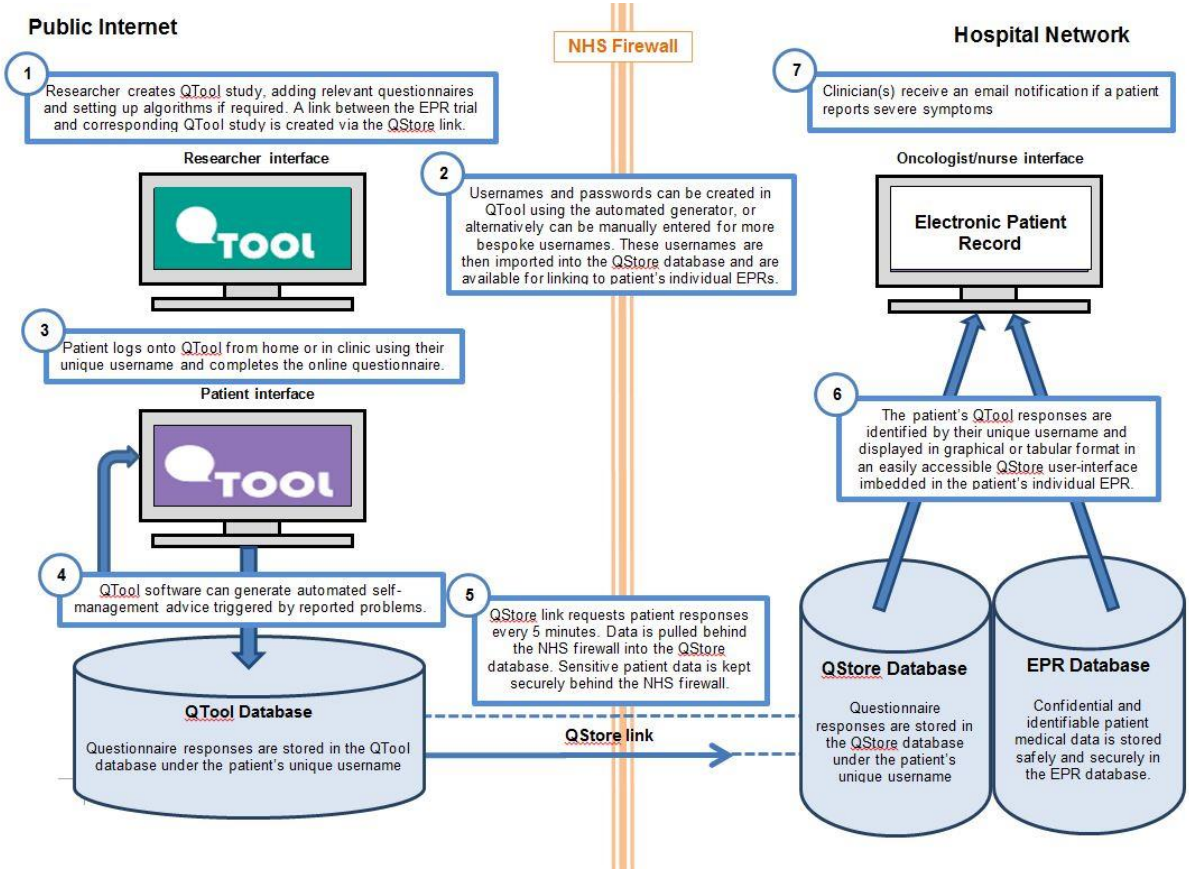
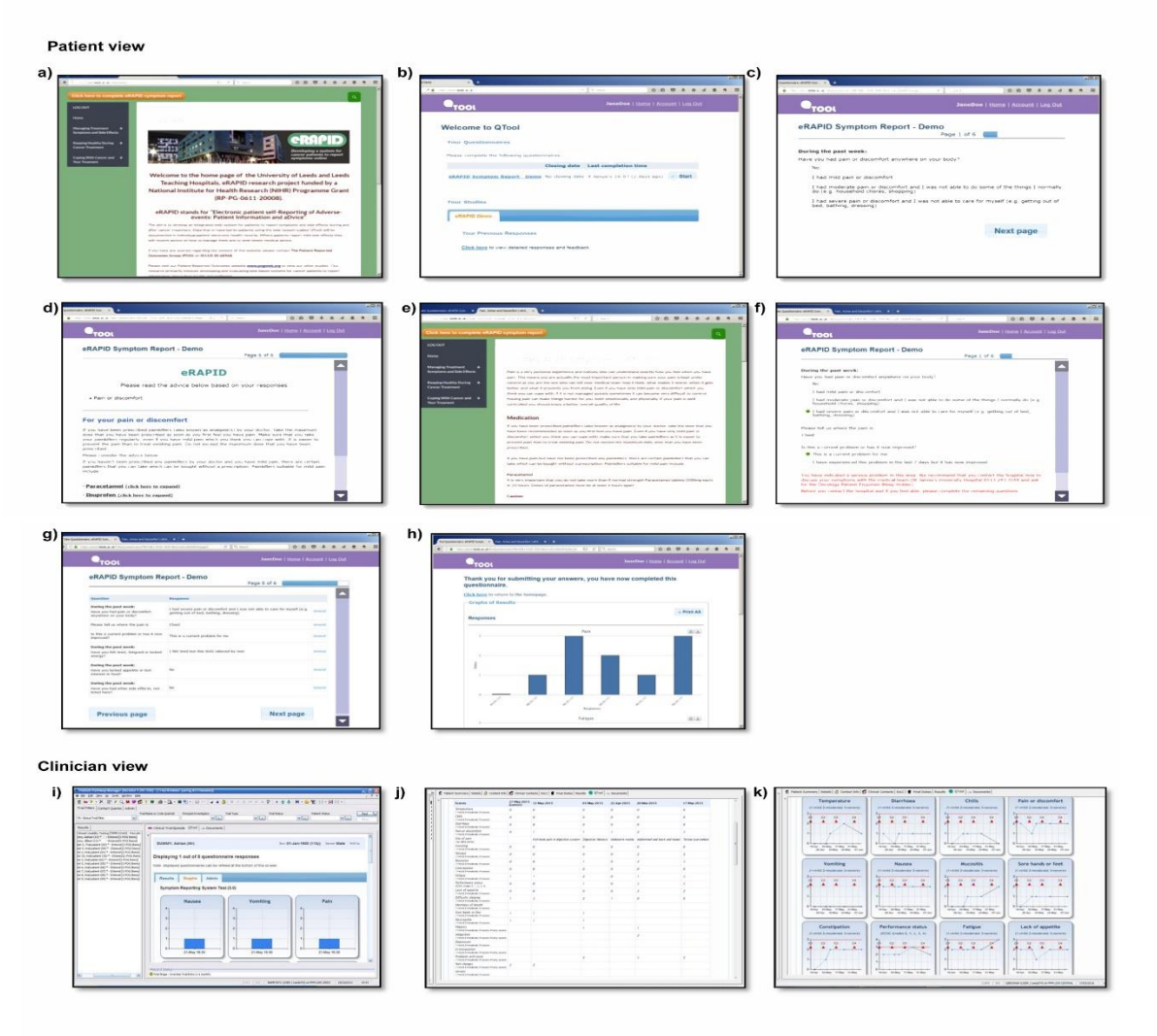


Figure 3: Screen shots of the Patient view: a) eRAPID website portal screen, b) QTool patient welcome page with links to questionnaires, previous responses and feedback, c) Example of the eRAPID symptom report ,d) AE Self-management advice generated from QTool when patient reports mild/moderate symptoms, e) If patients report low level AE they are directed to the eRAPID website for self-management advice, f) if patients report a severe AE and if it is a current problem advice (in red) to telephone the hospital is generated, g) patient view of the tabular summary of AE reported, h) Patient view of the graphical summary of their responses. Clinician view: i) graphical display of a one-time completion of PRO results, j) display of PRO reported results in the EPR in tabular form with severe symptoms indicated in red, k) graphical display of completion over time with red triangles indicating chemotherapy cycles.



Online supplementary material (S1-6)

S1: Theoretical underpinnings of the complex intervention and description of all the components and rationale for selection and functions

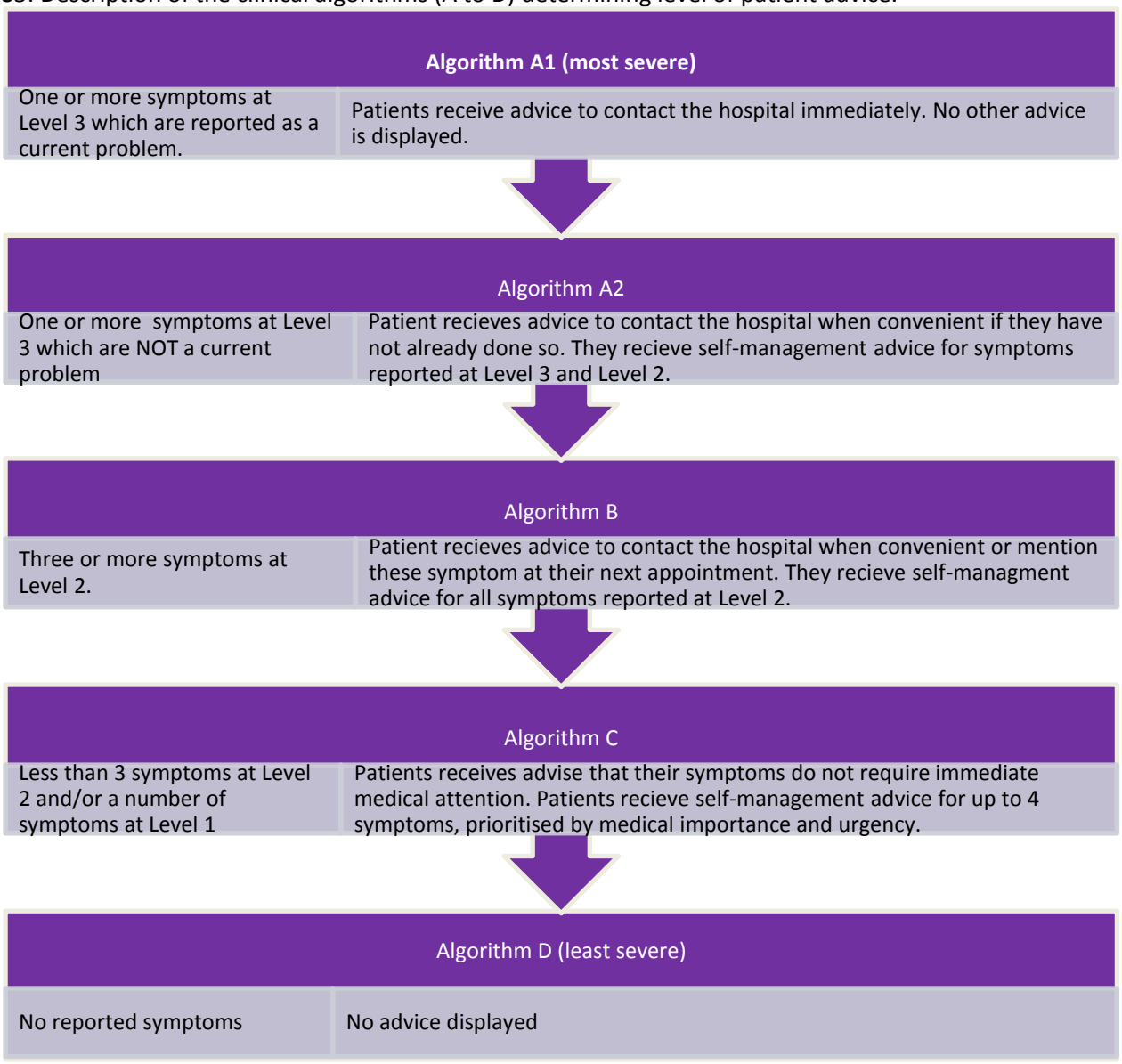
Intervention	Description	Basis of rationale	Theory	References
Secure ePRO interface	Patients can report AE from home via secure integrated electronic platform	Patients are happy and able to report AE symptoms online (Basch et al 2005). Making data available to clinicians in 'real time' using electronic PRO (ePRO) could have the most transformative effect on clinical practice by providing easily-accessible records to guide treatment decisions (Holzner et al 2015).	The theory of planned behaviour (Asjen et al 1991, (Armitage & Conner 2001) underpins the intervention. Reporting symptoms online will be mediated by cognitive representations of help seeking namely perceived behavioural control.	Ajzen, I. The theory of planned behaviour. Organizational Behavior and Human Decision Processes 1991, 50 (2): 179–211. Armitage, C.J. & Conner, M. Efficacy of the theory of planned behavior: a meta-analytic review. British Journal of Social Psychology 2000, 40: 471–499 Basch E, Artz D, Dulko D, et al. Patient Online Self-Reporting of Toxicity Symptoms During Chemotherapy. J Clin Oncol 2005, 23:3552-3561. Holzner B, Giesinger JM, Zabernigg A, et al. Patients' preferences regarding the setting of electronic patient-reported outcome assessments. Val Health 2015, 18 (7):A473.
Linkage of ePRO data within EPR	Staff and patients can view AE reports in tabular and graphic formats over time.	Using PROs in consultations have improved Dr -patient communication and QOL, When the results are fed back to the doctor this has more impact (Velikova et al 2004). However clinicians need to be trained in how to incorporate PROs successfully into consultations (Santana et al 2015).	The theoretical approach guiding the behavioural change needed from staff to access and utilise ePROs in consultations was the 'diffusions of innovation' theory (Rogers & Everett 1962) and the later translational research model (Titler 2001). Based on the idea that people will eventually adopt a system but there will be differences in people's ability to uptake new ideas or styles of working.	Rogers, E. M. (1962). Diffusion of innovations (1st ed.)1962, New York: Free Press of Glencoe. Santana MJ, Haverman L, Absolom K, Takeuchi E, Feeny D, Grootenhuis M, Velikova G. (2015). Training clinicians in how to use patient-reported outcome measures in routine clinical practice. Quality of Life Research, 24 (7):1707-1718. Titler MG, Everett LQ. Translating research into practice: considerations for critical care investigators. Crit Care Nurs Clin North Am 2001a;13(4):587-604. Velikova G, Booth L, Smith AB, et al. Measuring quality of life in routine oncology practice improves

			In future, we will identify key staff who can be influential 'opinion leaders' to ensure smooth adoption and staff training will provide appropriate support and encourage 'late adopters'.	communication and patient well-being: a randomized controlled trial. J Clin Oncol 2004, 22:714-724.
Severity appropriate management advice	Patients receive self-management for low level AE and advice to contact the hospital for severe AE.	The immediate severity-related guidance on how to manage AE is a unique feature of our system compared to other ePRO web-portals. Self-management is becoming an increasingly important way for patients to manage cancer related symptoms during and beyond treatment (Boger et al 2015).	The perceived behavioural control element of the TPB would enable the prediction of self-management intentions with setting of action plans and goals. Self-efficacy (Bandura 1977; Holman & Lorig 1992) can translate the behavioural intentions into action and determine patient competencies in management and coping with chronic disease. Self-efficacy is important for managing pain, symptoms, and function in patients and is related to QOL (Haugland et al 2016) and effective self-management can result in modest improvements in self-efficacy Boger 2015, Gao & Yuan 2011) self-efficacy will be monitored during the forthcoming eRAPID RCT.	Bandura, A. Self-efficacy: Toward a Unifying Theory of Behavioral Change. Psychological Review, 1977. 84 (2): 191–215. Boger E, Ellis J, Latter S, Foster C, Kennedy A, et al. Self-Management and Self-Management Support Outcomes: A Systematic Review and Mixed Research Synthesis of Stakeholder Views, PLOS ONE, 2015 10(7): e0130990. Gao W, Yuan C. Self-management programme for cancer patients: a literature review. International Nursing Review, 2011, 58, 288–295. Haugland, T, Klopstad Wahl, A, Hofoss, D and DeVon, H.A. et al. Association between general self-efficacy, social support, cancer-related stress and physical health-related quality of life: a path model study in patients with neuroendocrine tumors Health and Quality of Life Outcomes, 2016 14:11 Holman, H., & Lorig, K. Perceived self-efficacy in self-management of chronic disease. 1992, In R. Schwarzer (Ed.), Self-Efficacy: Thought control of action (pp. 305-323). Washington: Hemisphere Publishing Corporation.

S2: Specifications of stakeholder requirements from the eRAPID system

Patient • *User friendly system available to use from computer, tablet, smart phone and 'in house' hospital kiosks* • *Secure anonymous access via a unique username and password to report symptoms and side effects of treatment online* • *Assurance of security and confidentiality when reporting symptoms online* • *Ability to complete the questionnaire at different time points throughout their treatment and beyond* • *Can view responses in graphical and tabular format over time and can print and email this information* • *An option to have dependencies between questions, to allow skipping irrelevant questions or branching* • *Receives tailored on-screen self-management advice for mild symptoms with the ability to print and email* • *Hyperlink to more detailed advice available from a dedicated website* • *Immediate advice to call the hospital for severe symptoms*
Clinician • *Can access PRO data in the EPR in real time during the consultation without separate login* • *Has easily accessible PRO data in graphical and tabular format (ability to print and email this data)* • *Receives an email alert when patients have reported a severe AE* • *Has information about patient symptoms between clinic visits*
System administrator/Researcher • *Easy to follow procedure for setting up new studies and linking participants on QTool with their corresponding Electronic Patient Records* • *Can set up multiple questionnaire types with single and multiple response modalities* • *Can assign algorithms corresponding to current treatment guidelines/questionnaire scoring and disease group to provide tailored self management advice and alerts* • *Creates questionnaires by duplicating questions (copy/paste function)* • *Review item responses and graphical and tabular display (can email and print this)* • *Receives high quality PRO data over time with less missing data (patients cannot continue if questions are unanswered)* • *Customise questionnaire instructions* • *Access to a downloadable summary of questionnaire responses (by study/arm/group)* • *Export real time questionnaire completion data in a standardised format for statistical analysis* • *Access to real time daily reports of patients and their responses that triggered alerts*

S3: Description of the clinical algorithms (A to D) determining level of patient advice.



S4: Demographic details of staff (*N*=19), patient advocates (*N*=9) and patients (*N*=13) and who took part in iterative rounds of consensus discussion and usability testing.

Staff from St James's Institute of Oncology Leeds (*N*=19)		
Role	***n***	**Cancer speciality and hospital location**
Consultant medical oncologist	4	Gastrointestinal, lung, breast & gynaecology
Staff grade medical oncologist	1	Chemotherapy pre-assessment
Lead cancer nurse	1	Institute of oncology
Nursing sister	1	Chemotherapy day case unit, acute admissions unit
Clinical nurse specialist	4	Breast; gynaecological
Clinical psychologist	1	Wards and OPD in the institute of oncology
Dietician	1	Wards and OPD in the institute of oncology
Physiotherapist	1	Wards and OPD in the institute of oncology
Staff nurse	1	Chemotherapy pre-assessment (all tumours)
Macmillan information support worker	1	Support centre in the institute of oncology

Patient advocates from the patient reported outcomes group (POG) *N*=9 all had internet access			
Age group	***n***	**Gender**	***n***
41-50	4	Male	4
51-60	1	Female	5
>60	4		
Tumour group	**Treatment**		
Breast	3	Chemotherapy	5
Gynaecological	1	Radiotherapy	4
Gastrointestinal	1	Surgery	5
Urology	1	Hormone	
Blood/bone	1	Not currently on treatment	1
Head and Neck	1	Not currently on treatment	1
Melanoma	1	Not currently on treatment	1

Patients (*N*=13) from chemotherapy day case unit all had internet access			
Age	***n***	**Education**	***n***
Mean	53	University degree	11
Range	35-69	Basic school	1
		Missing	1
Tumour group			
Breast	2		
Gynaecological	3	**Agree to email storage for future contact**	
Colorectal	5	Yes	8
Lung	3	No	1
Gender		Missing	4
Male	4		
Female	9		

S5: Two chemotherapy related treatment AE scenarios designed to test the management algorithms for low, moderate and severe symptoms.

Scenario 1

- Patient 1 is receiving chemotherapy infusions once every 3 weeks. They are suffering from a number of symptoms relating to their treatment:
- Has suffered severe nausea and was not able to eat and drink as usual
- Has vomited 2 times in the last 24 hours
- Has had no pain
- Has had diarrhoea 8 times more a day compared to before treatment
- Has no constipation
- Mouth feels a bit sore
- Temperature is 37.8
- Has had chills with shaking but medication has helped
- Is short of breath when around the house, not able to do some things like household chores but only when climbing stairs
- Is up and about for half of the day. Can wash and dress themselves but cannot do much else.
- Has lacked appetite and has eaten and drank less than usual
- Has felt tired but this has not been relieved by rest. Had difficulty doing household chores and shopping .
- Occasionally finds it difficult to sleep
- Has a bit of tingling in fingertips when handling cold objects
- Feels quite low in mood and no longer enjoys things they used to, finds it difficult to carry out daily activities
- Occasionally experienced anxiety but this has passed when they have calmed themselves
- No other side effects to report

Scenario 2

- Patient 2 is receiving a weekly chemotherapy infusion. They are suffering from a number of symptoms relating to their treatment:
- Has felt a bit sick but was able to eat and drink as usual
- Has vomited 4 times in the last 24 hours
- Has severe pain in abdomen and not able to care for themselves
- Has had diarrhoea 2 times more a day compared to before treatment
- Has occasional constipation and sometimes uses laxatives or changes diet
- Mouth feels very sore and is not able to eat and drink
- Temperature is 38.1
- Has not suffered chills and is not shaking
- Has been short of breath but only when climbing stairs
- Is up and about almost all of the time. Cannot do heavy work but can do light household chores.
- Has lacked appetite and has been taking supplements
- Has felt tired but this has been relieved by rest. Able to carry out activities.
- Has no difficulty sleeping
- Has tingling in fingertips (problems with buttons on clothes)
- Feels occasionally low in mood but it passes
- Quite often feels anxious about prognosis and future treatment and this has interfered with daily activities
- No other side effects

S6: Feedback on the system and how usability issues were addressed from staff (*N*=19) patient advocates (*N*-9) and patients (*N*=13).

Patient & staff issues	Resolved by
Patient safety	
Staff	
❖ When patient gets a red warning (for a severe symptom) there should be a contact number of who to ring in clear bold font that is easy to see and read	❖ *A contact telephone number for the corresponding oncology team is listed on the system in a suitable font size*
❖ Use of the sentence "help your doctors/nurses to monitor your symptoms" might suggest that staff are actively monitoring each individual and the patient can sit back and wait for staff to act.	❖ *A disclaimer has been inserted informing patients that the information they report in the questionnaire will be reported to their medical team and can be discussed at their next appointment this effect*
❖ The phrase "Please note we cannot provide feedback for the other symptoms you have listed" currently sounds like the team behind the system aren't medically trained.	❖ *This has been changed to 'The system cannot provide feedback'*
❖ When viewing patient feedback from scenario 1 – (combination of severe symptoms) – temperature was not prioritised I suggest the feedback should list all of the reasons why the patient should contact the hospital	❖ *The algorithm now prioritises high temperature and lists all the severe symptoms why the patient should contact the hospital.*
Logging in to the system	
Patient	
❖ It is too troublesome to reset a forgotten password by contacting the research group	❖ *An email automatic reset function was made available*
❖ It was not immediately obvious where to go to change password	❖ *This process has been made more intuitive by emboldening text and simplifying the procedure*
❖ The usernames and passwords are difficult to remember as they are complex and not full words	❖ *Developed a different system for generating memorable usernames and passwords*
❖ Might need to add to info on how to log on to press (maximise) button to enlarge page	❖ *The instructions have been amended*
❖ Not clear how to start the questionnaire - needs to be more explicit, e.g.: "Click here to start the questionnaire."	❖ *A large 'Start' button has been added beside each questionnaire name; clicking the questionnaire will also launch the questionnaire.*
Navigating	
Patient	
❖ Difficulty in scrolling down and having to scroll down for next button	❖ *Scrolling function changed to be more obvious and scroll bar made larger*
❖ Needs to be made clear when text can be clicked on and expanded	❖ *A discrete designated instruction button has been installed for these instances*
❖ Some people may not be able to read the text	❖ *Font size has now been increased throughout*
❖ It would be nice to have a back button in order to review/change previous answers, or change an answer without using the button on explorer.	❖ *Back button now installed*
Staff	❖ *This function is now available*
❖ There should be an option to 'pause' the questionnaire and complete later	❖ *The 'take the questionnaire button' has been enlarged and patients are now issued with a user manual*
❖ Once logged in it isn't obvious where a patient should click next. A patient will need instructions to use QTool	❖ *This is now called 'my questionnaire' in the patient view*
❖ Symptom Report' in QTool could be called 'My Questionnaire'	

Questionnaire completion, viewing and exporting results	
Patient	
❖ I have forgotten what I have answered by the end of the questionnaire	❖ *Patients can now view a summary and severity of their responses after completion of the questionnaire*
❖ If you want to amend an answer it is annoying that you have to then go through all other answers to get to the end again	❖ *If amending an item, there is a link straight back to the review if no questions up to the review point depend on the outcome of the amended item*
❖ Graphical display did not make sense/not useful Didn't understand what I had to click on to get information	❖ *Installing new interactive software package to display graphs (Highcharts)*
❖ When emailing this was not validated with no warning of an invalid email address, lets you submit it anyway	❖ *Basic checks for invalid email and now integrated and the system now displays an error message if an invalid email is entered*
Staff	
❖ There is too much text to read at the end of the questions and the patient advice seems hidden	❖ *The advice was made more concise and accessible on the system*
❖ When navigating back to view feedback via the 'back' button the feedback box did not display the actual content just the 'Your Feedback' title. The feedback printed in a tiny font size which is not acceptable	❖ *This issue is now resolved and the feedback prints in a larger font size*