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An online tool for monitoring adverse events in cancer patients during treatment (eRAPID): Field testing in a clinical setting

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Abstract

Objectives: eRAPID is an online system developed to support patient care during cancer treatment by improving the detection and management of treatment-related symptoms. Patients can complete symptom reports from home and receive severity based self-management advice, including notifications to contact the hospital for severe symptoms. Patient data is available in electronic records for staff to review. Prior to the commencement of a randomised controlled trial, field testing of the intervention was undertaken to troubleshoot practical issues with intervention integration in clinical practice.

Design: Observational clinical field testing.

Setting: Medical oncology breast service in a UK cancer centre

Participants: 12 patients receiving chemotherapy for early breast cancer and 10 health professionals (oncologists and specialist nurses)

Intervention: Patients were asked to use the eRAPID intervention and complete weekly online symptom reports during 4 cycles of chemotherapy. Clinical staff were invited to access and utilise patient data in clinical assessments.

Analysis: Descriptive data on the frequency of online symptom report completion and severe symptom notifications were collated. Verbal and written feedback were collected from patients and staff and semi-structured interviews were conducted to explore patient experiences. Interviews were transcribed and analysed thematically.

Results: The testing ran from January-2014 to March-2014. Feedback from patients and staff was largely positive. Patients described eRAPID as *'reassuring'* and '*comforting'* and valued the tailored-management advice. Several changes were made to refine eRAPID. In particular, improvement of the clinical notification, patient reminder systems and changes to patient and staff training.

Conclusions: The field testing generated valuable results used to guide refinement of eRAPID prior to formal intervention evaluation. Feedback indicated that eRAPID has the potential to improve patients' self-efficacy, knowledge and confidence with managing symptoms during treatment. A large-scale RCT is underway with data collection due to finish in autumn 2018.

Strengths and limitations

- The strengths of this field usability testing include the mixed methodological approach (combining qualitative and observational data) and the involvement of both patient and staff representatives.
- This type of embedded clinical testing is vital for determining how new interventions work in practice.
- The results are limited by the focus on one cancer group.
- An ongoing randomised controlled trial will assess the impact of the eRAPID online intervention on cancer patients, oncology staff and health services.

Keywords: oncology, patient reported outcome measures (PROMs), chemotherapy, adverse events, online intervention

Introduction

Systemic cancer treatment is associated with a range of side-effects which can negatively impact patients' quality of life (QOL) and become life threatening.[1] As patients typically receive chemotherapy in outpatient settings they are largely required to self-monitor symptoms at home. Patients can lack confidence in making decisions between obtaining clinical support or self-managing [2] and can delay seeking medical advice,[3 4] heightening the risk of symptom escalation and hospital admissions. [5] Conversely subgroups of patients may routinely contact the hospital for reassurance in relation to mild side-effects.[2]

There is growing evidence that the utilisation of patient reported outcome measures (PROMs) during cancer treatment can aid the timely identification of physical and psychosocial needs, facilitate patient-doctor communication and assist decision-making. [6-10] There has been a drive to develop electronic systems to allow remote real-time patient monitoring during cancer. [11-13] Positive patient benefit (including QOL and survival) was recently reported in a US trial of an online system for metastatic cancer treatment.[14]

We developed an online intervention for supporting patient care during and after cancer treatment. eRAPID (Electronic patient self-Reporting of Adverse-events: Patient Information and aDvice) [15] is web-based and accessible from home or mobile device, for patients to complete symptom reports and receive severity based advice. Recommendations for self-management are provided for milder symptoms and advice for when to contact the hospital for severe issues. A graphing feature allows patients to review personal symptom data over time. The system includes a facility to

notify healthcare teams via email when a severe symptom is reported. Patient reported data is transferred in real-time to be accessed by health professionals through the hospital electronic patient records (EPR) for use in routine consultations and assessments.

Following recommended usability principles of agile development, [16] we involved staff and patient representatives throughout the eRAPID developmental processes, using an iterative design approach.[17] Results from the technical usability testing are reported elsewhere. [15 18] Here we describe the field usability testing phase where staff and patients utilised eRAPID in a real life clinical setting to troubleshoot practical issues not identified by standard usability testing [19 20] and allow streamlining of eRAPID clinical integration prior to commencing a formal RCT. [21]

Aims

For patients the aims were to ensure:

- System training was sufficient and feasible.
- Routine (weekly) online symptom report completions were acceptable.
- Self-management advice and severe symptom notifications were useful and appropriate

For clinical staff the aims were to ensure:

- System training provided was sufficient and feasible.
- Symptom report data was easy to access in the EPR and comprehensible.
- Severe symptom notifications were correctly activated.

In addition we wanted to assess the overall reliability of the IT underpinning eRAPID.

Methods

Patient and Public Involvement

The eRAPID research programme has involved patient representation and collaboration at each stage from conception, funding application (involvement of a PPI co-applicant) and research delivery (membership on project management and steering committees). The eRAPID intervention was designed with substantial input from patient representatives from our dedicated Research Advisory Group (RAG). RAG members contributed to initial usability testing of the patient facing aspects of the IT system and advised on the content of the self-management advice.[22] This paper describes the subsequent phase of usability work, where the intervention was taken for the first time for field testing in a clinical context with patients receiving chemotherapy and their associated care teams.

Clinical setting

The field usability testing was conducted in the breast medical oncology service at St James's University Hospital, Leeds, UK. The Leeds Teaching Hospitals NHS Trust Research & Innovation Department approved the exercise as service evaluation. Procedures were undertaken in line with Data Protection [23] and Good Clinical Practice guidelines.[24]

Patient eligibility and identification

Patient eligibility criteria were 1) early breast cancer diagnosis 2) starting at least 4 planned cycles of adjuvant/neo-adjuvant systemic treatment 3) internet access at home and 4) proficient English (to understand symptom assessments and self-management advice). Patients were identified by clinical staff and eRAPID was

introduced by an oncologist or Clinical Nurse Specialist (CNS). Interested patients were given an information sheet and passed to the eRAPID team for further information.

eRAPID demonstration and training

The eRAPID system is described in detail elsewhere [15]. See Figure 1 for a system overview.

Patient training

Participating patients received written information to take home and the researcher arranged to meet them at their first chemotherapy visit, where unique eRAPID login details were provided alongside a user manual. Patients were asked to complete the online eRAPID symptom report weekly (or more frequently if preferred) throughout 4 chemotherapy cycles (approximately 12 weeks). Patients were advised to contact their clinical team as usual if they had any concerns about symptoms or side-effects.

Clinical staff training

The breast CNSs were shown how to access eRAPID symptom report data in the EPR and given one-page instruction sheet. They were also added to a mailing list to receive severe symptom notifications and encouraged to contact patients where feasible. Oncologists were trained on a needs driven basis, receiving a demonstration and a one-page instruction sheet immediately prior to an eRAPID patient consultation.

Evaluation methods

Patient evaluation

Information on system acceptability and general feedback were collected through a number of methods:

- Number of symptom report completions, and adherence to the weekly completion schedule.
- Patients were provided with email and telephone contact details for the research team and a researcher met with the patient at their routine hospital appointments to check progress. The content of these communications were documented and collated.
- Patients were asked to complete brief feedback in the user manual covering ease of system use and general comments or recommendations.
- Patients were interviewed at the end of the testing. Semi-structured interviews explored views on the technical practicalities, relevance/impact of the self-management advice and staff use of the reports and impact on medical management.

Clinical staff evaluation

Testing of the eRAPID system from the professionals' perspective involved:

- Completion of brief written feedback forms to record use of the eRAPID data and any impact on the consultation.
- Direct observation of a subset of consultations where eRAPID information was available for staff. The researcher sat in the room and took field notes to describe how staff utilised eRAPID data.

- Details of any severe symptom notifications sent to staff during the 12-week assessment were documented along with any action taken.
- Ad-hoc verbal feedback from staff was also documented by researchers throughout the 12 week assessment.

Evaluating the reliability of IT processes

Any IT issues reported by researchers, patients or staff during the assessment period were logged along with the action taken.

Iterative refinement of eRAPID

Throughout testing the research team collated feedback and identified issues being regularly fed back to the eRAPID project management team (consisting of oncologists, nurses, health informatics experts, patient representatives and researchers). The team decided how issues should be resolved and where eRAPID could be improved for the future RCT. A full report was prepared at the end of the testing, documenting all identified issues and actions taken.

Analysis

Patient and clinical staff evaluation

Descriptive accounts of the number of completed eRAPID symptoms reports were created along with the frequency of severe symptom notifications. Verbal feedback, comments from the user manuals, written feedback and notes taken during clinic observations were assimilated and categorised into themes.

Interviews were audio-recorded, transcribed verbatim and managed in NViVO version 9. Initially a pragmatic approach was employed where any important issues raised in interviews were taken to the project management team to guide any immediate action. Interview data was subsequently fully coded and analysed thematically. [25]

Results

Participants

Patients

Testing took place between January-March 2014 with 12 patients (mean age = 47.5 years, SD=10.3, range 33-73 years). See Figure 2.

Clinical Staff

10 members of the breast care team participated including 2 adjuvant breast CNSs and 8 doctors (4 senior oncologist consultants, 4 oncology trainees). Patients typically saw a CNS routinely throughout the 12 weeks and had one appointment with an oncologist before their 3rd chemotherapy cycle.

Evaluation of eRAPID

Figure 3 shows a summary of data collected from staff and patients.

Compliance with weekly symptom reports

Over the 12-week period, 42% (5/12) of patients completed the report 11-13 times, 33% (4/12) completed 7-9 times and 25% (3/12) completed 4-6 times. Average adherence to weekly completion (i.e. actual/expected completions per patient) was 63% (range 33%-92%). In total n=104 full symptoms reports and 4 partial were completed.

Interviews revealed the most common reason for non-completion of the symptom report was simply forgetting. Most patients were in favour of a text or email reminder (N=8). Patients reported not completing the report when very unwell, stating it wasn't a priority. Others were unsure how often they should be completing. Feedback from the user manuals and interviews demonstrated that all the patients found eRAPID easy to use and did not report problems locating, logging in or using the system. A couple of minor suggestions were made for improvement, which were subsequently addressed (see Table 1).

Table 1. Summary of identified issues and actions taken to refine the intervention following field usability testing

Procedures for remote access and completion		
Theme/area	**Issue identified**	**Action taken**
Graphs	Patients have the option to report 'other' free text symptoms at the end of the symptom report. However, the graphs displaying these symptoms looked odd when symptoms were not reported regularly.	Decision made to remove these graphs as they did not add much value and were confusing for patients.
	The headings on the graphs (symptom names) did not always correspond with those on the questionnaire	The research team to ensure labelling kept consistent.
System usability	Patients have access to a link at the end of their symptom report ("email your feedback") to email their self-management advice to themselves. However, patients expected this link to enable them to provide the research team with feedback on the eRAPID system.	Wording changed this from "Email your feedback" to "Send this information to your email address".
Symptom report	Patients wanted to provide additional information about symptoms, such as when they experienced them or the type of pain they had.	Two changes were implemented: 1) If a patient reported 'severe' symptoms, they were then asked a branching question to determine if it was a current problem or a problem that had now resolved 2) A free text box was added to the pain question so that patients could provide information about the site of pain.
	One patient was felt there were too many questions and that they were not all relevant. She suggested that we should add an option for patients to say 'I feel fine' or 'My symptoms haven't changed'.	After discussion with the research team and wider project management team, we decided against implementing this, as it would not be as useful for clinical practice.
Practicalities of completion	The most common reasons for not completing were forgetting, feeling	Implementation of an automated reminder

	too unwell, not experiencing symptoms or not realising they should complete weekly.	system to send patients weekly reminders via text or email. In patient training, researchers will emphasise the importance of completing weekly, even if they are not experiencing symptoms.
Self-management advice	One patient queried what to do if symptoms are not improving when you are following the advice and suggested we encourage patients to talk to their clinical team if this is the case.	This advice was added to the self-management feedback
	Suggestion to add some additional links to well used external websites to make it a more complete resource.	After discussion, it was decided not to add links for external websites, as we would not be able to ensure that they were always up to date, and patients are directed to these sites by the clinical team.
	Add specific advice on achy veins and hot flushes	Self-management advice was added for these issues.
Notifications	Severe symptom notifications were being triggered for patients reporting retrospective problems.	A branching question was added to ask patients 'Is this a current problem' if a severe symptom was reported. A notification would then be sent only if patients answered yes to this question.
	Several alerts were triggered for low physical functioning where patients felt that this was not warranted.	The level was amended so that a notification was only sent if patients reported a higher level. In addition to the branching question regarding whether the symptom is current, a second branching question was added for this symptom to ask if patients had help at home.

Staff notifications		
Notifications	Clinical staff suggested that it may be helpful to have the facility to comment on a notification in the EPR to let other staff know it had been actioned (e.g. by phoning the patient).	This facility was added so patients could mark a notification as 'responded' and make an annotation.
Accessibility and interpretability of eRAPID symptom report data for staff		
User interface	Several clinical staff members commented that it would be very useful for them to be able to see chemotherapy cycles on patients' symptom report graphs.	Red triangle added on the graphs to denote date of chemotherapy cycle delivery.
	Where a patient score was 0, it looked like the item had not been completed the item.	This was only an issue for the patients' first completion (which showed as a bar graph, rather than a line graph), these were amended so that it was clearer when symptoms were scored as 0.
	The line graphs depicting patient symptom reports had a red line to show where symptoms became severe and a notification would be triggered. This was confusing for staff.	Red line showing severity levels was removed.
	Staff found the symptom reports less useful when patients were not completing regularly. Patients were not always aware if staff were using their symptom reports or not.	In future training staff were asked to encourage patients to complete regularly and explicitly refer to and use the results in consultations.

Severe symptom notifications

Eight severe symptom notifications were activated, 7 were not appropriate due to the framing of the symptom items which asked patients to report symptom experience within the last 7 days. This led to occasions where severe symptoms were being retrospectively reported with notifications activated for resolved problems. One patient found this experience alarming and stopped using eRAPID as a consequence.

> *"It brought the alert up, and the hospital rang and thought I might possibly need an admission, I must admit that scared me a little bit…I said well no actually, these symptoms were a few days ago and now I'm absolutely fine… it were fantastic that they rang so quickly and I think it's a great system for that, but I just thought oh no, I don't want to go to hospital" (Female, 44)*

In addition, patients sometimes felt that notifications were not warranted for the symptom severity experienced, in particular those for low physical functioning:

> *"It more or less panicked you a bit and said contact the hospital immediately… Because I still think I'd classed it correctly. It didn't warrant an ambulance at the door or anything like that." (Female, 47)*

However, the notifications worked well for the one patient who experienced an injection site reaction for several days. On completing the symptom report, she followed the advice to contact the hospital:

"I wasn't sure whether I should, so that advice was good. It will be good for people like that who are borderline." (Female, 73)

Following testing the symptom report was refined to accommodate the notification issues identified (see Table 1).

Thematic analysis of patient interviews

The following themes were identified:

Increasing knowledge and confidence

The self-management advice empowered patients by providing information and support to personally manage symptoms. Patients felt confident doing this, in the knowledge that the system provided a "safety net":

"It's like a life line when you feel isolated when you're at home and feeling poorly…you can have a lot of questions or problems regarding your illness and with one click they can be answered and absorbed within minutes." (Female, 49).

"I would recommend it to anyone. It's like a safety net for you and gives you the help to keep on going on through your treatment" (Female, 73)

"I think it does make you feel a bit happier – if you read something on there that says well, you will feel like this but you can do this, this and this… you're happy with that" (Female, 50)

Supporting decision making

Patients felt that using eRAPID helped reduce their worry by aiding decision-making helping them feel more knowledgeable about when to self-manage and when to contact the hospital:

> *"I'm a bit of a worrier and I think 'shall, shan't I, am I over-reacting?' But I think that then would confirm to people that yeah, you should really ring the hospital so... it's just like a little bit of extra home support isn't it really?" (Female, 33)*

Coping strategy

Some patients found the symptom graphing feature useful for understanding patterns and this could be both reassuring and motivating.

> *"For me personally, I just think I can't do this anymore, I don't like this, this is awful, and I find that I'm very disheartened and I can't see an end to it……But then when you look at the graphs, you can think, but I did get better…and my mouth has got better, and my diarrhoea has stopped and… you can see that there is a pattern and that it will get better. It makes me feel better." (Female, 60)*

Staff evaluation

Notifications for severe symptoms.

Clinical staff agreed that notifications for retrospectively reported severe symptoms were not relevant and that some of the notifications sent for low physical functioning

were unwarranted. When this issue was identified email notifications were re-directed to the eRAPID research nurse for the remainder of the field testing, who liaised with patients and clinical staff where needed.

eRAPID patient symptom report data

The staff feedback forms indicated that symptom report data was easy to access and interpret and useful for identifying issues/problems for discussion (N=6), confirming knowledge of the patient's problems, (N=5), providing additional information (N=5) and contributing to management (N=3). Several staff commented that it would assist interpretation of symptom reports if the EPR graphical displays included dates of chemotherapy delivery. In addition staff commented that symptom information was most useful where patients had routinely provided reports throughout treatment.

The consultation observations confirmed that staff could easily access the symptom reports in the EPR but there were variations in utilisation. Some staff viewed the data but did not explicitly mention this to patients whereas others used it as a point of reference to guide the consultation and made this clear to patients.

Reliability of IT processes

The IT processes were largely stable. The notification system was reliable, with the patient and staff severe symptom notifications activated as expected. The patient symptom reports became temporarily unavailable to staff at one point. The problem was reported to the team and was resolved by the IT manager that day.

Refinement of eRAPID intervention and processes for integration

Following feedback from staff and patients several improvements were made to streamline the integration of eRAPID into the clinical setting (Table 1).

Discussion

The aim of this field usability testing was to observe end users (staff and patients) use of eRAPID in a real life clinical setting in order to troubleshoot practical issues which may not be identified through standard usability testing [19 20]. Feedback received from both patients and staff was positive and demonstrated the system was well received but also led to important modifications and improvements. The process allowed streamlining of intervention integration into clinical practice prior to formal evaluation. [21]

The majority of the notifications triggered for severe symptoms were for resolved symptoms patients reported retrospectively. This finding enabled us to adjust the system prior to the RCT to avoid 'false' notifications and therefore avoid unnecessary patient worry and clinical burden. In addition, we were able to use information gathered to inform training for both patients and staff going forward into the RCT.

Patients found eRAPID easy to use and weekly completions manageable. They reported valuing the self-management advice, particularly specific advice about when to contact the hospital, and several patients described the system as 'reassuring' and a 'safety net'. The testing highlighted the reciprocal relationship between patient and staff engagement in the system. Although staff felt the symptom reports was most valuable when routinely completed by patients, they did not always

explicitly mention using the data in consultations. Moving forward in the RCT we have emphasised this aspect in staff training, encouraging overt reference to symptom reports to endorse the value of patient reported data and encourage ongoing completion. We also implemented a patient reminder system and made some changes to patient training.

The interviews revealed the intervention could have the potential to increase patient self-efficacy and engagement with the management of their care. A recent systematic review has demonstrated the importance of self-efficacy in managing pain, symptoms and function in cancer patients. [26] In addition, high levels of patient activation (how engaged a patient is in their own healthcare), are associated with an array of improved health behaviours and health outcomes [27-29] while lower levels of activation are associated with higher use of hospital resources [30].

In the large scale eRAPID RCT the main outcomes focus on patient quality of life and clinical process data (contacts with the hospital, emergency admissions) but we will also explore psychological variables that may help us more fully understand how patients can benefit from eRAPID. [21] Specifically we will explore the relationship between patients' self-efficacy, patient activation [31] and utilisation of the eRAPID system, self-management advice and symptom graphs. The WebChoice system in Norway has demonstrated that enabling patients to self-manage can be more beneficial for patients than symptom reporting alone [32].

This field usability testing had some limitations. We only had resources to evaluate the system with early breast cancer patients. This patient group are relatively young

compared to other adult cancer groups and are more likely to be digitally agile. However, internet access continues to increase [33] and previous work has indicated that electronic systems are acceptable in other cancer groups [11 15 34-36]. Our RCT will evaluate eRAPID in a broader range of patients receiving systemic therapy [21].

In summary, the field testing helped endorse the practical potential of eRAPID for supporting patient care but importantly uncovered issues which would not have been identified with standard usability testing alone. This was an invaluable exercise prior to commencement of the ongoing RCT (due to be completed in Autumn 2018) which will evaluate the potential benefits of eRAPID for patients, staff and the NHS.

Figure legends

Figure 1. Overview of eRAPID system illustrating the flow of data from inside and outside the hospital

Figure 2. Overview of patients approached and participating in the eRAPID field usability testing network.

Figure 3: Summary of evaluation data collected from patients and staff

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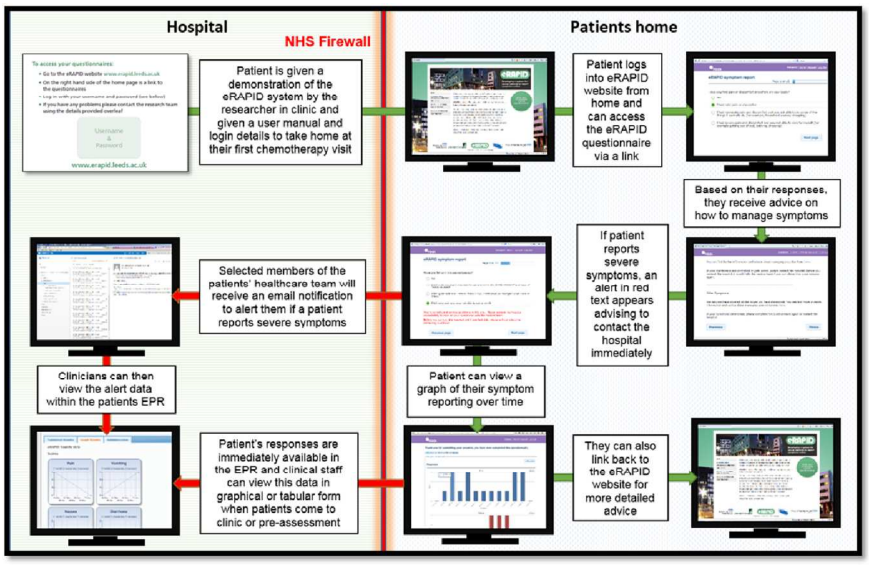

Figure 1. Overview of eRAPID system illustrating the flow of data from inside and outside the hospital network.

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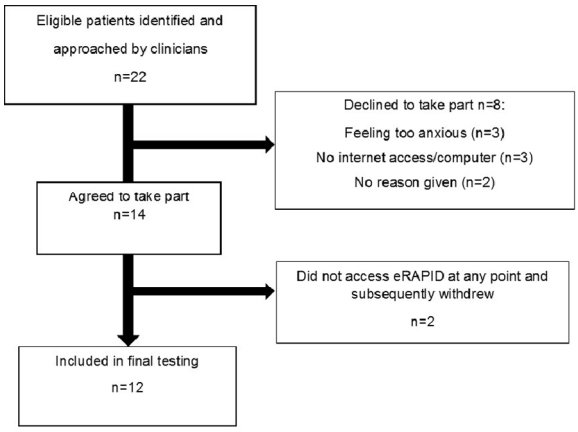

Figure 2. Overview of patients approached and participating in the eRAPID field usability testing

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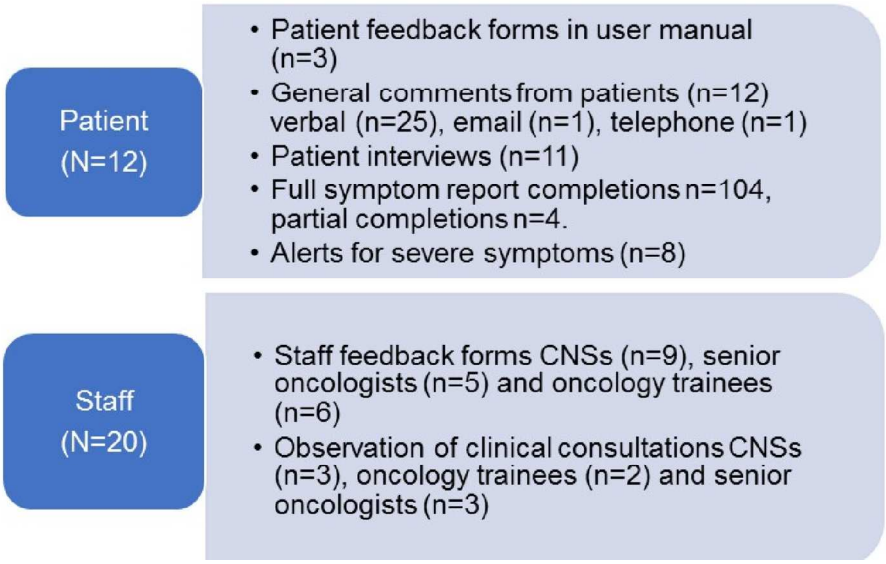

Figure 3: Summary of evaluation data collected from patients and staff

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An online tool for monitoring adverse events in cancer patients during treatment (eRAPID): Field testing in a clinical setting

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An online tool for monitoring adverse events in cancer patients during treatment (eRAPID): Field testing in a clinical setting

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Abstract

Objectives: eRAPID is an online system developed to support patient care during cancer treatment by improving the detection and management of treatment-related symptoms. Patients can complete symptom reports from home and receive severity based self-management advice, including notifications to contact the hospital for severe symptoms. Patient data is available in electronic records for staff to review. Prior to the commencement of a randomised controlled trial, field testing of the intervention was undertaken to troubleshoot practical issues with intervention integration in clinical practice.

Design: Observational clinical field testing.

Setting: Medical oncology breast service in a UK cancer centre

Participants: 12 patients receiving chemotherapy for early breast cancer and 10 health professionals (oncologists and specialist nurses)

Intervention: Patients were asked to use the eRAPID intervention and complete weekly online symptom reports during 4 cycles of chemotherapy. Clinical staff were invited to access and utilise patient data in clinical assessments.

Analysis: Descriptive data on the frequency of online symptom report completion and severe symptom notifications were collated. Verbal and written feedback were collected from patients and staff and semi-structured interviews were conducted to explore patient experiences. Interviews were transcribed and analysed thematically.

Results: The testing ran from January-2014 to March-2014. Feedback from patients and staff was largely positive. Patients described eRAPID as *'reassuring'* and '*comforting'* and valued the tailored-management advice. Several changes were made to refine eRAPID. In particular, improvement of the clinical notification, patient reminder systems and changes to patient and staff training.

Conclusions: The field testing generated valuable results used to guide refinement of eRAPID prior to formal intervention evaluation. Feedback indicated that eRAPID has the potential to improve patients' self-efficacy, knowledge and confidence with managing symptoms during treatment. A large-scale RCT is underway with data collection due to finish in October 2018.

Strengths and limitations

- The strengths of this field usability testing include the mixed methodological approach (combining qualitative and observational data) and the involvement of both patient and staff representatives.
- This type of embedded clinical testing is vital for determining how new interventions work in practice.
- The results are limited by the focus on one cancer group.
- An ongoing randomised controlled trial will assess the impact of the eRAPID online intervention on cancer patients, oncology staff and health services.

Keywords: oncology, patient reported outcome measures (PROMs), chemotherapy, adverse events, online intervention

Introduction

Systemic cancer treatment is associated with a range of side-effects which can negatively impact patients' quality of life (QOL) and become life threatening.[1] As patients typically receive chemotherapy in outpatient settings they are largely required to self-monitor symptoms at home. Patients can lack confidence in making decisions between obtaining clinical support or self-managing [2] and can delay seeking medical advice,[3 4] heightening the risk of symptom escalation and hospital admissions. [5] Conversely subgroups of patients may routinely contact the hospital for reassurance in relation to mild side-effects.[2]

There is growing evidence that the utilisation of patient reported outcome measures (PROMs) during cancer treatment can aid the timely identification of physical and psychosocial needs, facilitate patient-doctor communication and assist decision-making. [6-10] There has been a drive to develop electronic systems to allow remote real-time patient monitoring during cancer. [11-13] Positive patient benefit (including QOL and survival) was recently reported in a US trial of an online system for metastatic cancer treatment.[14]

We developed an online intervention for supporting patient care during and after cancer treatment. eRAPID (Electronic patient self-Reporting of Adverse-events: Patient Information and aDvice) [15] is web-based and accessible from home or mobile device, for patients to complete symptom reports and receive severity based advice. Recommendations for self-management are provided for milder symptoms and advice for when to contact the hospital for severe issues. A graphing feature allows patients to review personal symptom data over time. The system includes a facility to

notify healthcare teams via email when a severe symptom is reported. Patient reported data is transferred in real-time to be accessed by health professionals through the hospital electronic patient records (EPR) for use in routine consultations and assessments.

Following recommended usability principles of agile development, [16] we involved staff and patient representatives throughout the eRAPID developmental processes, using an iterative design approach.[17] Results from the technical usability testing are reported elsewhere. [15 18] Here we describe the field usability testing phase where staff and patients utilised eRAPID in a real life clinical setting to troubleshoot practical issues not identified by standard usability testing [19 20] and allow streamlining of eRAPID clinical integration prior to commencing a formal RCT. [21]

Aims

For patients the aims were to ensure:

- System training was sufficient and feasible.
- Routine (weekly) online symptom report completions were acceptable.
- Self-management advice and severe symptom notifications were useful and appropriate

For clinical staff the aims were to ensure:

- System training provided was sufficient and feasible.
- Symptom report data was easy to access in the EPR and comprehensible.
- Severe symptom notifications were correctly activated.

In addition we wanted to assess the overall reliability of the IT underpinning eRAPID.

Methods

Patient and Public Involvement

The eRAPID research programme has involved patient representation and collaboration at each stage from conception, funding application (involvement of a PPI co-applicant) and research delivery (membership on project management and steering committees). The eRAPID intervention was designed with substantial input from patient representatives from our dedicated Research Advisory Group (RAG). RAG members contributed to initial usability testing of the patient facing aspects of the IT system and advised on the content of the self-management advice.[22] This paper describes the subsequent phase of usability work, where the intervention was taken for the first time for field testing in a clinical context with patients receiving chemotherapy and their associated care teams.

Clinical setting

The field usability testing was conducted in the breast medical oncology service at St James's University Hospital, Leeds, UK. The Leeds Teaching Hospitals NHS Trust Research & Innovation Department approved the exercise as service evaluation. Procedures were undertaken in line with Data Protection [23] and Good Clinical Practice guidelines.[24]

Patient eligibility and identification

Patient eligibility criteria were 1) early breast cancer diagnosis 2) starting at least 4 planned cycles of adjuvant/neo-adjuvant systemic treatment 3) internet access at home and 4) proficient English (to understand symptom assessments and self-management advice). Patients were identified by clinical staff and eRAPID was

introduced by an oncologist or Clinical Nurse Specialist (CNS). Interested patients were given an information sheet and passed to the eRAPID team for further information.

eRAPID demonstration and training

The eRAPID system is described in detail elsewhere [15]. See Figure 1 for a system overview.

Patient symptom report and training

Participating patients received written information to take home and the researcher arranged to meet them at their first chemotherapy visit, where unique eRAPID login details were provided alongside a user manual. Patients were asked to complete the online eRAPID symptom report weekly (or more frequently if preferred) throughout 4 chemotherapy cycles (approximately 12 weeks). The online symptom report contained items from the locally devised Patient Reported Adverse Event (PRAE)[18] item bank based on the Common Terminology Criteria for Adverse Events (CTCAE) grading system. Working in collaboration with the breast oncology staff 12 core items were chosen for the main report (including pain, fatigue, physical activity, bowel function, sleep, temperature, chill, sore mouth and appetite). There was also the option for patients to add details on additional issues via a drop down list of further symptoms and a free text option.

Clinical staff training

The breast CNSs were shown how to access eRAPID symptom report data in the EPR and given one-page instruction sheet. They were also added to a mailing list to

receive severe symptom notifications and encouraged to contact patients where feasible. Oncologists were trained on a needs driven basis, receiving a demonstration and a one-page instruction sheet immediately prior to an eRAPID patient consultation.

Evaluation methods

Patient evaluation

Information on system acceptability and general feedback were collected through a number of methods:

- Number of full symptom report completions, and adherence to the weekly completion schedule.
- Patients were provided with email and telephone contact details for the research team and a researcher met with the patient at their routine hospital appointments to check progress. The content of these communications were documented and collated.
- Patients were asked to complete brief feedback in the user manual covering ease of system use and general comments or recommendations.
- Patients were interviewed at the end of the testing. Semi-structured interviews explored views on the technical practicalities, relevance/impact of the self-management advice and staff use of the reports and impact on medical management.

Clinical staff evaluation

Testing of the eRAPID system from the professionals' perspective involved:

- Completion of brief written feedback forms to record use of the eRAPID data and any impact on the consultation.
- Direct observation of a subset of consultations where eRAPID information was available for staff. The researcher sat in the room and took field notes to describe how staff utilised eRAPID data.
- Details of any severe symptom notifications sent to staff during the 12-week assessment were documented along with any action taken.
- Ad-hoc verbal feedback from staff was also documented by researchers throughout the 12 week assessment.

Evaluating the reliability of IT processes

Any IT issues reported by researchers, patients or staff during the assessment period were logged along with the action taken.

Iterative refinement of eRAPID

Throughout testing the research team collated feedback and identified issues being regularly fed back to the eRAPID project management team (consisting of oncologists, nurses, health informatics experts, patient representatives and researchers). The team decided how issues should be resolved and where eRAPID could be improved for the future RCT. A full report was prepared at the end of the testing, documenting all identified issues and actions taken.

Analysis

Patient and clinical staff evaluation

Descriptive accounts of the number of completed eRAPID symptoms reports were created along with the frequency of severe symptom notifications. Verbal feedback, comments from the user manuals, written feedback and notes taken during clinic observations were assimilated and categorised into themes.

Interviews were audio-recorded, transcribed verbatim and managed in NViVO version 9. Initially a pragmatic approach was employed where any important issues raised in interviews were taken to the project management team to guide any immediate action. Interview data was subsequently fully coded and analysed thematically. [25]

Results

Participants

Patients

Testing took place between January-March 2014 with 12 patients (mean age = 47.5 years, SD=10.3, range 33-73 years). See Figure 2.

Clinical Staff

10 members of the breast care team participated including 2 adjuvant breast CNSs and 8 doctors (4 senior oncologist consultants, 4 oncology trainees). Patients typically saw a CNS routinely throughout the 12 weeks and had one appointment with an oncologist before their 3rd chemotherapy cycle.

Evaluation of eRAPID

Figure 3 shows a summary of data collected from staff and patients.

Compliance with weekly symptom reports

Over the testing period n=104 full symptom reports were completed, 42% (5/12) of patients completed the report 11-13 times, 33% (4/12) completed 7-9 times and 25% (3/12) completed 4-6 times. Average adherence to weekly completion (i.e. actual/expected completions per patient) was 63% (range 33%-92%).

Interviews revealed the most common reason for non-completion of the symptom report was simply forgetting. Most patients were in favour of a text or email reminder (N=8). Patients reported not completing the report when very unwell, stating it wasn't a priority. Others were unsure how often they should be completing. Feedback from the user manuals and interviews demonstrated that all the patients found eRAPID easy to use and did not report problems locating, logging in or using the system. A couple of minor suggestions were made for improvement, which were subsequently addressed (see Table 1).

Severe symptom notifications

Eight severe symptom notifications were activated, 7 were not appropriate due to the framing of the symptom items which asked patients to report symptom experience within the last 7 days. This led to occasions where severe symptoms were being retrospectively reported with notifications activated for resolved problems. One patient found this experience alarming and stopped using eRAPID as a consequence.

> *"It brought the alert up, and the hospital rang and thought I might possibly need an admission, I must admit that scared me a little bit…I said well no actually, these symptoms were a few days ago and now I'm absolutely fine… it were fantastic that they rang so quickly and I think it's a great system for that, but I just thought oh no, I don't want to go to hospital" (Female, 44)*

In addition, patients sometimes felt that notifications were not warranted for the symptom severity experienced, in particular those for low physical activity:

> *"It more or less panicked you a bit and said contact the hospital immediately… Because I still think I'd classed it correctly. It didn't warrant an ambulance at the door or anything like that." (Female, 47)*

However, the notifications worked well for the one patient who experienced an injection site reaction for several days. On completing the symptom report, she followed the advice to contact the hospital:

> *"I wasn't sure whether I should, so that advice was good. It will be good for people like that who are borderline." (Female, 73)*

Following testing the symptom report was refined to accommodate the notification issues identified (see Table 1).

Thematic analysis of patient interviews

The following themes were identified:

Increasing knowledge and confidence

The self-management advice empowered patients by providing information and support to personally manage symptoms. Patients felt confident doing this, in the knowledge that the system provided a "safety net":

> *"It's like a life line when you feel isolated when you're at home and feeling poorly…you can have a lot of questions or problems regarding your illness and with one click they can be answered and absorbed within minutes." (Female, 49).*

> *"I would recommend it to anyone. It's like a safety net for you and gives you the help to keep on going on through your treatment" (Female, 73)*

> *"I think it does make you feel a bit happier – if you read something on there that says well, you will feel like this but you can do this, this and this… you're happy with that" (Female, 50)*

Supporting decision making

Patients felt that using eRAPID helped reduce their worry by aiding decision-making helping them feel more knowledgeable about when to self-manage and when to contact the hospital:

> *"I'm a bit of a worrier and I think 'shall, shan't I, am I over-reacting?' But I think that then would confirm to people that yeah, you should really ring the hospital so... it's just like a little bit of extra home support isn't it really?" (Female, 33)*

Coping strategy

Some patients found the symptom graphing feature useful for understanding patterns and this could be both reassuring and motivating.

> *"For me personally, I just think I can't do this anymore, I don't like this, this is awful, and I find that I'm very disheartened and I can't see an end to it……But then when you look at the graphs, you can think, but I did get better…and my mouth has got better, and my diarrhoea has stopped and… you can see that there is a pattern and that it will get better. It makes me feel better." (Female, 60)*

Staff evaluation

Notifications for severe symptoms.

Clinical staff agreed that notifications for retrospectively reported severe symptoms were not relevant and that some of the notifications sent for low physical activity were unwarranted. When this issue was identified email notifications were re-

directed to the eRAPID research nurse for the remainder of the field testing, who liaised with patients and clinical staff where needed.

eRAPID patient symptom report data

The staff feedback forms indicated that symptom report data was easy to access and interpret and useful for identifying issues/problems for discussion (N=6), confirming knowledge of the patient's problems, (N=5), providing additional information (N=5) and contributing to management (N=3). Several staff commented that it would assist interpretation of symptom reports if the EPR graphical displays included dates of chemotherapy delivery. In addition staff commented that symptom information was most useful where patients had routinely provided reports throughout treatment.

The consultation observations confirmed that staff could easily access the symptom reports in the EPR but there were variations in utilisation. Some staff viewed the data but did not explicitly mention this to patients whereas others used it as a point of reference to guide the consultation and made this clear to patients.

Reliability of IT processes

The IT processes were largely stable. The notification system was reliable, with the patient and staff severe symptom notifications activated as expected. The patient symptom reports became temporarily unavailable to staff at one point. The problem was reported to the team and was resolved by the IT manager that day.

Refinement of eRAPID intervention and processes for integration

Following feedback from staff and patients several improvements were made to streamline the integration of eRAPID into the clinical setting (Table 1).

Table 1. Summary of identified issues and actions taken to refine the intervention following field usability testing

Procedures for remote access and completion		
Theme/area	**Issue identified**	**Action taken**
Graphs	Patients have the option to report 'other' free text symptoms at the end of the symptom report. However, the graphs displaying these symptoms looked odd when symptoms were not reported regularly.	Decision made to remove these graphs as they did not add much value and were confusing for patients.
	The headings on the graphs (symptom names) did not always correspond with those on the questionnaire	The research team to ensure labelling kept consistent.
System usability	Patients have access to a link at the end of their symptom report ("email your feedback") to email their self-management advice to themselves. However, patients expected this link to enable them to provide the research team with feedback on the eRAPID system.	Wording changed this from "Email your feedback" to "Send this information to your email address".
Symptom report	Patients wanted to provide additional information about symptoms, such as when they experienced them or the type of pain they had.	Two changes were implemented: 1) If a patient reported 'severe' symptoms, they were then asked a branching question to determine if it was a current problem or a problem that had now resolved 2) A free text box was added to the pain question so that patients could provide information about the site of pain.
	One patient felt there were too many questions and that they were not all relevant. She suggested that we should add an option for patients to say 'I feel fine' or 'My symptoms haven't	After discussion with the research team and wider project management team, we decided against

	changed'.	implementing this, as it would not be as useful for clinical practice.
Practicalities of completion	The most common reasons for not completing were forgetting, feeling too unwell, not experiencing symptoms or not realising they should complete weekly.	Implementation of an automated reminder system to send patients weekly reminders via text or email. In patient training, researchers will emphasise the importance of completing weekly, even if they are not experiencing symptoms.
Self-management advice	One patient queried what to do if symptoms are not improving when you are following the advice and suggested we encourage patients to talk to their clinical team if this is the case.	This advice was added to the self-management feedback
	Suggestion to add some additional links to well used external websites to make it a more complete resource.	After discussion, it was decided not to add links for external websites, as we would not be able to ensure that they were always up to date, and patients are directed to these sites by the clinical team.
	Add specific advice on achy veins and hot flushes	Self-management advice was added for these issues.
Notifications	Severe symptom notifications were being triggered for patients reporting retrospective problems (due to item framing asking patients to report symptom experience within the last 7 days).	A branching question was added to ask patients 'Is this a current problem' if a severe symptom was reported. A notification would then be sent only if patients answered yes to this question.
	Several notifications were triggered for physical activity when patients felt it was not warranted.	Following discussion with clinical staff the threshold was increased for this item. In addition to the branching question regarding whether the symptom is current, a second branching question was added for this symptom

		to ask if patients had help at home.
Staff notifications		
Notifications	Clinical staff suggested that it may be helpful to have the facility to comment on a notification in the EPR to let other staff know it had been actioned (e.g. by phoning the patient).	This facility was added so staff could mark a notification as 'responded' and make an annotation.
Accessibility and interpretability of eRAPID symptom report data for staff		
User interface	Several clinical staff members commented that it would be very useful for them to be able to see chemotherapy cycles on patients' symptom report graphs.	Red triangle added on the graphs to denote date of chemotherapy cycle delivery.
	Where a patient score was 0, it looked like the item had not been completed the item.	This was only an issue for the patients' first completion (which showed as a bar graph, rather than a line graph), these were amended so that it was clearer when symptoms were scored as 0.
	The line graphs depicting patient symptom reports had a red line to show where symptoms became severe and a notification would be triggered. This was confusing for staff.	Red line showing severity levels was removed.
	Staff found the symptom reports less useful when patients were not completing regularly. Patients were not always aware if staff were using their symptom reports or not.	In future training staff were asked to encourage patients to complete regularly and explicitly refer to and use the results in consultations.

Discussion

The aim of this field usability testing was to observe end users (staff and patients) use of eRAPID in a real life clinical setting in order to troubleshoot practical issues

which may not be identified through standard usability testing [19 20]. Feedback received from both patients and staff was positive and demonstrated the system was well received but also led to important modifications and improvements. The process allowed streamlining of intervention integration into clinical practice prior to formal evaluation. [21]

The majority of the notifications triggered for severe symptoms were for resolved symptoms patients reported retrospectively. This led to two key adjustments to the system prior to the RCT to avoid 'false' notifications and limit unnecessary patient worry and clinical burden. First, we added a branching question to allow patients reporting symptoms to provide further clarification on whether the symptom was ongoing or had been resolved. Second, the physical activity severity threshold was raised as both patients and clinical staff felt the original setting was too low. This was off-putting to patients and encouraging unwarranted hospital contact. For additional safeguarding a further branching question was also added to this item to determine if patients reporting problems had help/support at home and assist with the identification of more vulnerable individuals.

Patients found eRAPID easy to use but many forgot to routinely complete the weekly report. As a consequence the proposed text message/email reminder system was subsequently established. Patients reported valuing the self-management advice, particularly specific advice about when to contact the hospital, and several patients described the system as 'reassuring' and a 'safety net'. The testing highlighted the reciprocal relationship between patient and staff engagement in the system. Although staff felt the symptom reports was most valuable when routinely completed

by patients, they did not always explicitly mention using the data in consultations. Moving forward in the RCT we conducted a series of one-to-one and group training sessions with relevant staff involved in chemotherapy delivery and assessments (oncologists, clinical nurse specialists, pre-assessment nursing teams). The sessions have included didactic elements (describing the eRAPID developmental work and the evidence supporting the use of using patient reported data in clinical practice) and practical demonstrations of how to access patient reported data. More recently an online training package was also created (accessible via a hyperlink in the electronic patient records) which allows staff to view information as required. This online resource includes practical refreshers on accessing patient symptom reports along with interactive case studies that demonstrate how the data can be interpreted and utilised. There is emphasis within all the training formats on the importance of making overt reference to symptom reports with patients in clinical encounters to endorse the value of patient reported data and encourage ongoing completions.

The interviews revealed the intervention could have the potential to increase patient self-efficacy and engagement with the management of their care. A recent systematic review has demonstrated the importance of self-efficacy in managing pain, symptoms and function in cancer patients. [26] In addition, high levels of patient activation (how engaged a patient is in their own healthcare), are associated with an array of improved health behaviours and health outcomes [27-29] while lower levels of activation are associated with higher use of hospital resources [30].

In the large scale eRAPID RCT the main outcomes focus on patient quality of life and clinical process data (contacts with the hospital, emergency admissions) but we

will also explore psychological variables that may help us more fully understand how patients can benefit from eRAPID. [21] Specifically we will explore the relationship between patients' self-efficacy, patient activation [31] and utilisation of the eRAPID system, self-management advice and symptom graphs. The WebChoice system in Norway has demonstrated that enabling patients to self-manage can be more beneficial for patients than symptom reporting alone [32].

This field usability testing had some limitations. We only had capacity (in terms of both staffing resources and time restrictions) to evaluate the system with early breast cancer patients. This patient group are relatively young compared to other adult cancer groups and are more likely to be digitally agile. However, internet access continues to increase [33] and previous work has indicated that electronic systems are acceptable in other cancer groups [11 15 34-36]. The RCT evaluates eRAPID in a broader population, specifically patients receiving chemotherapy for breast, gynaecology or colorectal cancer have been recruited from both adjuvant and metastatic treatment pathways [21].

In summary, the field testing helped endorse the practical potential of eRAPID for supporting patient care but importantly uncovered issues which would not have been identified with standard usability testing alone. This was an invaluable exercise prior to commencement of the ongoing RCT (data collection due to be completed in October 2018) which will evaluate the potential benefits of eRAPID for patients, staff and the NHS.

Figure legends

Figure 1. Overview of eRAPID system illustrating the flow of data from inside and outside the hospital

Figure 2. Overview of patients approached and participating in the eRAPID field usability testing network.

Figure 3: Summary of evaluation data collected from patients and staff

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Competing interests: None to declare

Approvals: The Leeds Teaching Hospitals NHS Trust Research & Innovation Department approved this field testing as service evaluation. Procedures were undertaken in line with Data Protection and Good Clinical Practice guidelines.

Data sharing statement: Requests for data sharing should be directed to Professor Galina Velikova. Full interview transcripts are not available to protect participant anonymity.

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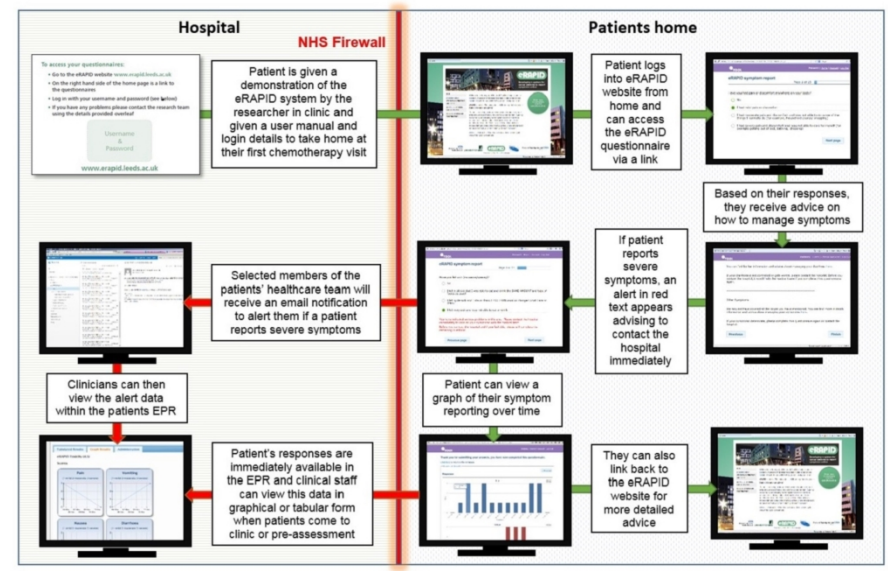

Figure 1 Overview of eRAPID system illustrating the flow of data from inside and outside the hospital

297x209mm (300 x 300 DPI)

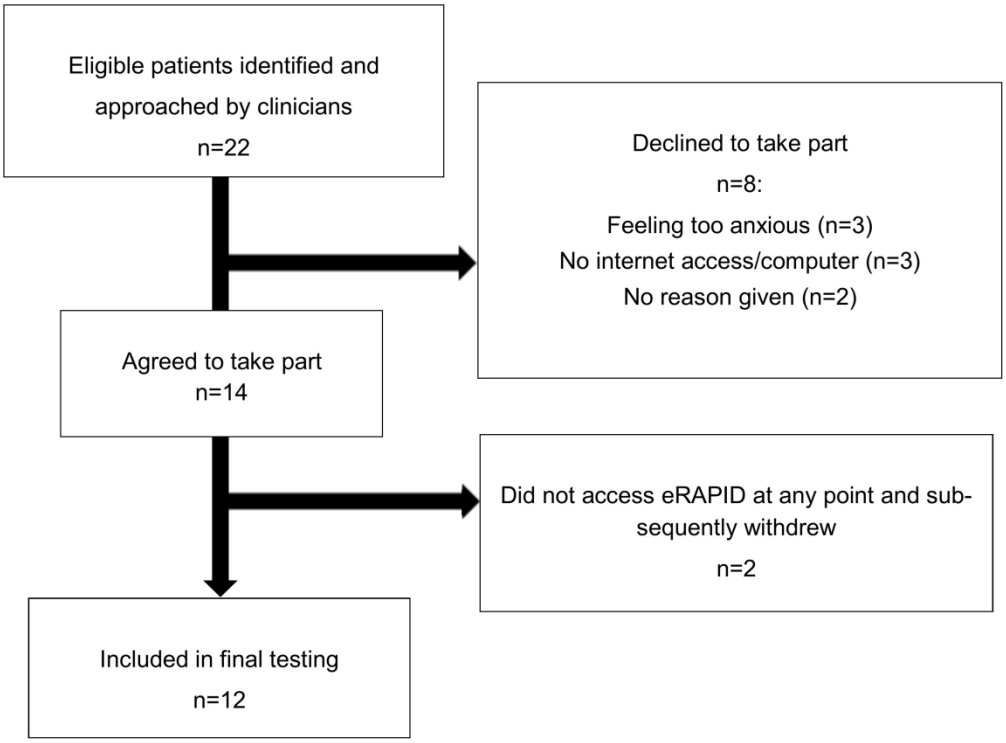

Figure 2. Overview of patients approached and participating in the eRAPID field usability testing network.

240x176mm (300 x 300 DPI)

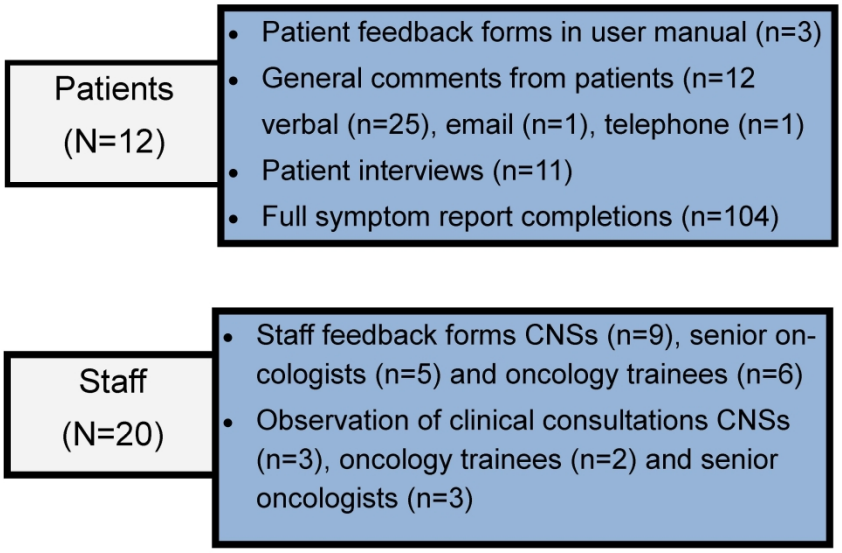

Figure 3: Summary of evaluation data collected from patients and staff

297x209mm (300 x 300 DPI)

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2	Observational clinical field testing.
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2-3	
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5	
Objectives	3	State specific objectives, including any prespecified hypotheses	5	
Methods				
Study design	4	Present key elements of study design early in the paper	5	
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-9	
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	6-7	
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case		
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-10	
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8-10	
Bias	9	Describe any efforts to address potential sources of bias	N/A	
Study size	10	Explain how the study size was arrived at	N/A	Clinical field usability testing,

				not set sample size requirements

Continued on next page

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10	
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	N/A	Descriptive summaries, no statistical analysis
		(*b*) Describe any methods used to examine subgroups and interactions	N/A	
		(*c*) Explain how missing data were addressed	N/A	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	N/A	
		(*e*) Describe any sensitivity analyses	N/A	
Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	10	Figure 2
		(b) Give reasons for non-participation at each stage	10	Figure 2
		(c) Consider use of a flow diagram		Figure 2
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	10	Results pages- 10-18
		(b) Indicate number of participants with missing data for each variable of interest	N/A	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	N/A	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	N/A	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure		
		Cross-sectional study—Report numbers of outcome events or summary measures		
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	N/A	
		(*b*) Report category boundaries when continuous variables were categorized	N/A	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time	N/A	

period

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	18-20
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	21
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	21
Generalisability	21	Discuss the generalisability (external validity) of the study results	21
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	22

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.