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Absolom, K, Gibson, A and Velikova, G (2019) Engaging patients and clinicians in online reporting of adverse effects during chemotherapy for cancer. The eRAPID system (Electronic patient self-Reporting of Adverse-events: Patient Information and aDvice). Medical Care, 57 (5 Supplement 1). s59-s65. ISSN: 0025-7079

https://doi.org/10.1097/MLR.0000000000001085

Engaging patients and clinicians in online reporting of adverse effects during chemotherapy for cancer. The eRAPID system (Electronic patient self-Reporting of Adverse-events: Patient Information and aDvice)

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Funding

This paper presents independent research funded by the National Institute for Health Research (NIHR) under its Programme Grants for Applied Research Programme (Grant Reference Numbers RP-DG-1209-10031 and RP-PG-0611-20008). The

views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

This paper is part of the PRO-cision Medicine Methods Toolkit funded by Genentech. Kate Absolom received an honorarium payment for their contribution.

The PRO-cision Medicine Methods Toolkit paper series was presented during a symposium at the 2018 Annual Conference of the International Society for Quality of Life Research (Dublin, Ireland).

Acknowledgments

We would like to thank all patients, clinical staff and patient representatives from our Research Advisory Group who were involved in eRAPID development and usability testing and all the associated staff from the Patient Centred Outcomes Research team. Thanks also to the following eRAPID grant co-applicants for their expertise and guidance: Dr Clare Harley, Dr Liz Glidewell, Karen Henry, Professor Peter Selby, Professor Jane Blazeby, Dr Kevin Franks, Dr Geoff Hall, Martin Waugh and Dr Susan Davidson.

Conflicts of interest: None declared

Word count: 3241

Number of text pages: 20

Number of references: 21

Number of tables: 1

Number of figures: 2

Abstract

Introduction: During cancer treatment the timely detection and management of adverse events (AE) is essential for patient safety and maintaining quality of life. eRAPID was devised to support oncology practice, by allowing patients to self-report symptoms online at home during and beyond cancer treatment. Fundamentally the eRAPID intervention delivers immediate severity-tailored feedback directly to patients to guide self-management strategies or hospital contact. Patient data are available in electronic health records (EHR) for hospital staff to access and review as part of clinical assessments.

Methods for interpreting and addressing PRO scores: The eRAPID intervention has 5 main interconnecting components (clinical integration into standard care pathways, patient symptom reports, self-management advice, information technology and staff/patient training). Following guidance for the development of complex interventions and using a mixed methods approach, eRAPID was created through a number of stages and tested in a series of usability settings before undergoing systematic evaluation in an ongoing randomised controlled trial. These developmental stages are described here with a focus on how decisions were made to enhance patient and professional engagement with symptom reports and encourage interpretation and clinical utilisation of the data.

Discussion: Clinically embedded PRO interventions involve a number of elements and stakeholders with different requirements. Following extensive developmental work eRAPID was pragmatically designed to fit into current oncology practices for reviewing and managing chemotherapy-related toxicities.

Key Take-Home Points: Co-design with patient and professional stakeholders is vital. The adoption of a flexible and experiential approach is recommended.

Transparent use of PRO data is important to encourage ongoing patient and professional engagement with the intervention.

Key words: Patient Reported Outcomes (PROs); cancer; chemotherapy; online intervention; adverse events

Introduction

The toxic nature of many cancer therapies puts patients at risk of a diverse range of side effects from mild complications to potentially life threatening adverse events (AE).[1-3] Robust and comprehensive practices for monitoring patients are essential for the safe and successful delivery of treatment regimens and to optimise patient functioning and well-being. The task of assessing and recording AEs has traditionally been the responsibility of the treating clinical team. However, treatment toxicities are typically not well captured or conveniently accessible within medical records. In addition, with most therapeutic agents being administered in an outpatients setting, patients are largely responsible for monitoring their own symptoms when away from the hospital environment. Patients report challenges with understanding the clinical severity of particular symptoms and the appropriate options for self-management or clinical care.[4] In response to these challenges eRAPID was devised to allow online patient reporting during cancer treatment. Using eRAPID patients can report symptoms and side effects from home and patient data is available for oncology staff to access and utilise in clinical assessments with a central focus of the system being the provision of immediate severity-tailored patient feedback (based on PRO scores) to support self-management strategies or guide when hospital contact should be sought. Patient data are also accessible in electronic health records (EHR) for clinical staff to review and staff can also be emailed notification of severe symptoms.

Our aim with eRAPID was to encourage the delivery of timely and appropriate patient-centred clinical advice during cancer treatment to improve the management of adverse events. The overall research programme has three separate strands focussing on the

delivery of the intervention in systemic chemotherapy, radiotherapy[5] and surgical settings[6] **within cancer services in the National Health Service (NHS) in the UK**. A large single-centre randomised controlled trial (RCT) has been conducted to evaluate eRAPID with patients undergoing systemic cancer treatment[7], **results of which will be available in summer 2019**.[7] The main trial explores the potential benefit of the intervention on patient quality of life, and process of care outcomes (including number of emergency and hospital admissions and associated health economic implications). In addition patients and staff are being interviewed and asked to provide written feedback about their perceptions of how eRAPID has worked in practice and its impact on care.

From the outset of the eRAPID programme we recognised there were a range of important elements and challenges to the design and clinical integration of the system in order for the patient reported symptom data to lead to improved clinical management and patient outcomes. It was a primary goal that eRAPID should enhance current practice at the local cancer centre and be a valuable addition to clinical assessments performed by oncology staff. Here we provide an overview of the eRAPID developmental and usability work focussing on how the system was created in order to maximise how clinical staff and patients engage with, interpret and act upon the patient reported data.

Methods:

eRAPID can be divided into 5 main complementary components, all of which are integral for optimising the intervention and encouraging patient and professional interpretation and utilisation of PRO data.

1. **Clinical integration of eRAPID**: Documentation of routine oncology care pathways and workflows to optimise placement of a PRO intervention
2. **Patient symptom reports:** Use of clinically appropriate items complying with standard medical assessments of symptom toxicity
3. **Severity tailored self-management advice**: Delivery of timely and accurate advice to support patient management of mild, moderate and severe AE
4. **Information technology**: Use of robust and secure systems for capturing patient data, delivering self-management advice and making data accessible to clinical teams in electronic patient records
5. **User training:** The provision of flexible and sustainable patient and staff training to support the adoption and ongoing acceptance of the intervention

The development and evolution of these elements was directed by the Medical Research Council's complex intervention guidance.[8] Mixed methods have been adopted throughout all stages. At the heart this has been a co-design approach with the end-users of the system, both health professionals and patients to maximise the relevance and practical application of PRO data. **From project conception oncologists, nursing and hospital informatics leads at the local cancer centre were involved in the proposal as co-applicants and as workgroup members once funding was awarded.** Below we describe in more detail the methods used to address each of the elements underpinning eRAPID and provide a case study demonstrating how the intervention has worked to guide patient care in practice. We

highlight the main learning points derived to date for supporting eRAPID PRO interpretation and subsequent actions in this systemic cancer setting.

1. Clinical integration of eRAPID

Preliminary work focussed on understanding the clinical need for the eRAPID PRO intervention and mapping current oncology care pathways and workflows to ascertain where the system can be best be placed to support patient care. **The local NHS cancer hospital (Leeds Cancer Centre, Leeds, UK)** had reorganised the acute oncology service in 2010 to include a dedicated acute admissions ward and assessment unit. A nurse-led telephone triage system was adopted and patients receiving anti-cancer therapy are given an emergency contact number to call for AE related problems. A clinical audit was conducted to evaluate and understand this new service.[4] Data were collected in 2011 and again in 2013 to determine how the triage processes were being assimilated by assessing the integrity of triage data being routinely collected, a summary of AE issues patients were seeking help for and the clinical advice or management provided. In addition a subset of patients admitted to the acute admissions ward were interviewed about their understanding of AE and routes to admission. We also worked with clinical teams to map the standard pathways through which patients typically pass during their treatment and the staff involved with the routine treatment reviews. We conducted 12 interviews with staff involved in the delivery of chemotherapy pathways, exploring organisational issues and clinical decision making processes in relation to symptoms triggering admission and determined the patient's points of contact during and out-of-office hours.

There were a number of valuable learning points ascertained through this exercise. Importantly we discovered a significant proportion of the acute contacts were with breast, gastrointestinal and gynaecological patients; patients admitted during treatment frequently reported experiencing symptoms for a number of days before contacting the service and a considerable number of calls were for non-emergency problems.

We learned about pathway variation across the different cancer groups which highlighted the main health care professionals involved in clinical assessments. We discovered that in some pathways the clinical nurse specialists played a significant role in assessing patients. In other groups the oncologists were delivering more of the chemotherapy review consultations. Valuable insight into the main patient groups seeking acute oncology support guided the initial plan to design the intervention for use with breast, gynaecological and colorectal cancer patients. The common issues patients presented with to acute oncology services highlighted the range of support needs, demonstrating where and when patients could be encouraged to contact the hospital and how help for less medically concerning problems may be delivered with online informational support.

2. Patient symptom reports

The selection and development of items for patient self-report began with a review of the main systemic treatments prescribed for breast, colorectal and gynaecological cancers. Associated AE information was gathered via a) a literature review of AEs reported in clinical trials b) analysis of patient-reported symptoms collected from our

previous studies in Leeds c) collation of the symptoms recorded in the acute triage assessments (as described above).

A core set of AEs were identified including nausea, vomiting, diarrhoea, mucositis, fatigue, insomnia, palmar-plantar erythema, pain, peripheral neuropathy, appetite loss, constipation, rash, bleeding, anaemia, febrile neutropaenia and stoma problems. Clinical and nursing representatives from each tumour group provided input on the most clinically important AE for reviewing their patient group during treatment. The professionals also added physical activity/ performance status to the list of symptoms.

Working in line with the standard assessment procedures used by the oncology teams, we adopted the Common Terminology Criteria for Adverse Events (CTCAE) to guide the development of the patient reported AE items and ensure compatibility with current practice. The US National Cancer Institute's Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE)[9] were not fully validated at the time consequently a set of Patient Reported Adverse Event (PRAE) items were locally devised by converting the CTCAE descriptors into a patient friendly format with response options aligned to the standard severity grading (see Figure 1).[10] PRAE items were then presented to representatives from the care teams to determine the core clinically relevant items to be included in the eRAPID symptom report for each cancer group. Decisions were made with the clinical teams on the assignment of clinically significant symptom items and severity grades and an underlying algorithm was devised to determine the scoring of symptom reports and the level of advice generated (see Table 1). Following system testing in the breast service[11] an important

modification was made to the symptom report to accommodate patients reporting severe symptoms that may have already been resolved (questions ask about the last 7 days). An additional branching question was included to confirm current status and prevent unnecessary severe symptom notifications.

3. Severity tailored self-management advice

As mentioned above, a fundamental aspect of the eRAPID intervention is the delivery of immediate tailored feedback advice directly to patients to encourage appropriate and timely action. Advice was collated from a number of sources including national patient and clinical guidance documents resources and reputable cancer websites. We liaised closely with clinical staff and hospital information specialists. Due to the wealth of available information, advice for each symptom was developed for two formats 1) as a succinct summary to be presented immediately after online patient symptom reports were completed and 2) the eRAPID website where all the advice and wider information was collated. The website was structured around three themes '*Managing treatment symptoms and side effects'*, '*Keeping healthy during cancer*' and '*Coping with cancer and your treatment*'. Usability testing of the self-management advice and website was initially conducted with members of our local patient Research Advisory Group to ensure advice matched that provided by oncology staff.[12]

4. Information technology

The eRAPID system comprises a number of IT elements including a password protected patient facing website, a web-based questionnaire builder and a web applications interface for securely transferring and displaying PRO data within the local

EHR.[13] This is an example of a 'hybrid' system where a stand-alone PRO collection facility interfaces with an existing EHR through moderate levels of integration [14].

The eRAPID research team worked with a private software company (XLab [15]) to add the necessary functionality to QTool (an existing questionnaire management system).[16] Additions to QTool included enhancing the item scoring dependency function to implement the clinical algorithms described above to allow feedback of the tailored self-management advice (including a hyperlink capability leading patients to the eRAPID information website). Features to provide the option of reviewing previous responses and advice in written and graphical formats as well as printing and emailing advice were added to allow for practical patient engagement with data. Again, clinical and patient representatives played an integral role in usability testing of the online symptom reports in QTool providing feedback on system navigation and the user interface. [12, 13]

Making PRO data available from the local cancer centre's EHR was a prime objective of eRAPID. To encourage professional engagement with the patient reports we wanted the data to be easily accessed alongside the clinical information used during patient reviews. **Fundamentally the eRAPID programme grant funded the role of an Informatics Manager who was able to focus exclusively on making this possible. The Informatics Manager worked closely with the hospital EHR development team (the cancer centre utilises a bespoke in-house EHR called Patient Pathway Manager, PPM) and the X-Lab software developers. The research team and a wider stakeholder group of clinicians and patients also**

provided valuable feedback and usability testing.[13] A web application was created allowing the data flow of anonymised reports from QTool to be linked to individual patients and viewed in the local EHR. A separate tab in the patient EHR view was created so staff could move between medical data and symptom reports for an individual patient. The default view is a graphical depiction of each symptom severity level (1 = mild 2= moderate 3= severe) over time (see Figure 2 for example EHR screenshot). The display can be modified by the user to show data over different time periods. Results can also be viewed in a table alongside any free text items provided by the patient. Following staff feedback during a usability testing in the breast clinic, graphs were revised to include chemotherapy delivery dates to help guide interpretation of symptom trajectories. The option for a notification element was also added to QTool allowing health professionals to be emailed if clinically severe symptoms were reported. A report can be accessed in the EHR which summarises when the symptom was reported and by which patient. Although the notifications are in place in the ongoing RCT (with emails sent to selected key health professionals for each cancer group, e.g. gynaecology specialist nursing teams) an immediate response cannot be guaranteed therefore participating patients are aware of their responsibility to contact the hospital as needed and do not expect to be directly contacted by medical teams.

5. User training

The training of the key stakeholders in using a new PRO system is a fundamental aspect to intervention success. In the ongoing eRAPID evaluation studies the research team deliver face-to-face sessions with individual patients where the system is demonstrated and log in details and user manuals (developed with input from patient

representatives) are provided for supporting patients outside of the hospital setting. Staff training sessions have taken a number of forms. Initially, group sessions were arranged with all clinical staff (oncologists, specialist nurses and pre-assessment nursing teams) with responsibility for conducting routine chemotherapy review assessments with gynaecology, colorectal and breast patients. Training covered the background to eRAPID and provided practical demonstrations of locating the data in the EHR and the patient interface. In addition ad hoc one-to-one sessions have been required for individual new staff joining services. During eRAPID usability phases we observed a number of consultations to see how staff engaged with the data and incorporated it into clinical encounters and obtained feedback from staff on how they used PRO data in consultations.[11] We found there was a tendency for professionals to review data but not overtly refer to it. Subsequently, patients were unsure if their data were being used. Staff commented that data was more useful when patients had provided regular symptom reports over time. This reciprocal relationship between patients and staff both explicitly recognising the value of PRO data is likely to be important for maintaining engagement from both parties. eRAPID training now includes encouragement to professionals to acknowledge the PROs and for patients to mention they have data available to review. As the eRAPID systemic RCT has progressed it is apparent that the constraints of the controlled trial leads to staff only seeing a small number of patients every week with PRO data. Thus they can forget these data are available and limits opportunities to practice utilising patient reports. In a bid to create a sustainable approach to staff training in time pressured clinical settings and involve interactive elements (which we previously found to be useful in earlier studies [17]) we recently created an e-learning package accessed from a

hyperlink in the EHR which includes background information and clinical scenarios using example eRAPID PRO data.

eRAPID case study

Figure 2 summarises a case study from the ongoing eRAPID RCT of the experience of a patient with early breast cancer. In this instance the eRAPID symptom report and immediate patient advice supported an early diagnosis of metastatic disease.

Discussion

The successful monitoring and management of patients' physical symptoms and wider psychological well-being during cancer treatment is extremely important. With many patients being outside of the hospital when problems occur interventions that utilise online technology appear well-placed to help support patient care. A number of other electronic symptom reporting interventions in cancer settings have been developed [18-21] and there is a growing body of evidence supporting their clinical value. eRAPID is unique in that 1) a central function of the system is the delivery of immediate feedback for guiding patients to take an appropriate level of action for reported symptoms and 2) PRO data is directly accessible to health professionals from within the local hospital electronic system.

We have taken an experiential and pragmatic approach. Fundamentally we aimed to develop a PRO intervention that complemented the symptom monitoring strategies and the CTCAE grading systems already in place in routine care to enhance the likelihood of professional engagement. From our developmental and usability phases

(described in more detail elsewhere[10, 11, 13]) invaluable lessons were learned through patient and staff feedback about the design and content of the symptom reports, the scoring algorithms/self-management advice and the display of PRO data in the electronic health records. This led to a number of important refinements to the intervention before the RCT began and endorses the benefit of embracing a co-design approach with patient and professionals being equally recognised as active and integral stakeholders. **It is important to also note that practical aspects of the development work described here took place over a 4 year period and were conducted by a team of researchers (including research fellows, research assistants, research nurses and the Informatics Manager). Although much of what has been learned here (and from other teams) can be used to help support future application of similar PRO systems, staff resources are still required to establish and refine the integration of electronic PROs into clinical settings. As part of the eRAPID programme the IT system was established at two other hospitals in the UK for the radiotherapy[5] and surgical[6] work streams. This uncovered a variety of challenges and our team is currently exploring options to refine and streamline the process of PRO integration across different EHRs**.

Results from the eRAPID systemic RCT will be available in summer 2019. Anecdotally we can acknowledge that the randomised controlled trial methodology creates restrictions. Staff see a limited number of patients with eRAPID symptom reports, therefore engagement with the PRO data is not currently second nature. Training is important but if professionals only see a narrow patient group with PRO data then this element can lose impact. In the future broader implementation of the intervention into standard care would be beneficial to help staff hone use of PRO data.

This in turn would likely lead to positive implications for patient engagement if staff are seen commonly using data in practice.

With many health services under pressure to meet the needs of growing and ageing patient populations, strategies to support effective self-management continues to receive particular attention. More PRO interventions that support both patient and health professionals in clinical assessment and management are warranted. It is important we understand the elements that help keep patients engaged with personal symptom monitoring and support confidence in electronically based systems. As moves to develop robust clinically integrated technology for collecting and utilising patient reported data becomes commonplace it is important that experiences of developing and optimising the implementation of these systems be shared and a knowledge base generated to help guide expansion and utilisation moving forward.

Key take home points

- Clinically integrated PRO interventions are complex with a combination of overlapping elements.
- Patients and clinical staff can require different features and functions to encourage successful interpretation and use of the data. A co-design approach to optimise processes for effectively using PRO data is essential.
- Patients and health care professionals should be advised to actively acknowledge patient reported data in clinical encounters to encourage sustained engagement with the PRO interventions.

- Electronic PRO systems must be flexible and adaptable to changing user needs, emerging new treatments and technological advances.

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Figure and table legends

Figure 1: Example of Common Terminology Criteria for Adverse Event (CTCAE) and patient self-reporting item for oral mucositis

Figure 2: eRAPID case study

Table 1. Overview of scoring algorithm for symptom report and immediate patient advice

Figure 1: Example of Common Terminology Criteria for Adverse Event (CTCAE) and patient self-reporting item for oral mucositis

CTCAE item **Definition: A Disorder characterised by inflammation of the oral mucosal.** **Attributes: Severity, Interference**		**Patient reported adverse event (PRAE) item and advice** **Have you had a sore mouth or tongue?**	
Grade 1.	**Asymptomatic or mild symptoms; intervention not indicated**	**My mouth was a bit sore**	**Self- management advice:** • **Background information- why the mouth can be affected during cancer treatment** • **General good practices for helping mouth care during cancer treatment** • **Medications- advice on prescribed mouthwashes and when to use them and the availability of over the counter products** • **Types of drinks and food products that may be suitable to try and those to avoid**
Grade 2.	**Moderate pain; not interfering with oral intake; modified diet indicated**	**My mouth was quite sore but I was still able to drink and eat soft foods**	
Grade 3.	**Severe pain; interfering with oral intake**	**My mouth was very sore and I was not able to eat or drink**	***You have indicated a serious problem in this area. We recommend that you contact the hospital now to discuss your symptoms with the medical team (hospital contact telephone number XXXXX).***

Table 1. Overview of scoring algorithm for symptom report and immediate patient advice

Algorithm	Summary*	Immediate patient advice
A1	One or more Level 3 problem, current - contact the hospital now	You have indicated a serious problem in this area. We recommend that you contact the hospital now to discuss your symptoms with the medical team
A2	Level 3 problem(s) which have improved, contact the team when convenient	You have reported that you have been experiencing some serious problems which have now improved. If you have not already been in contact with your medical team, we recommend that you contact them to discuss your symptoms when convenient, or mention them at your next clinic appointment (if in the next 1-2 weeks). If you have already been in touch with your medical team regarding your symptoms, please follow the advice they have given you.
B	Three or more Level 2 medically important problems; contact the team when convenient	If your symptoms are new or have changed recently, please either contact the hospital when convenient to discuss your symptoms with the medical team or mention them at your next clinic appointment (if in the next 1-2 weeks).
C	Mild symptoms, do not require medical attention at present, self-management advice	Follow self-management advice
D	No problems reported	No advice

* Level 3= severe; Level 2= moderate; Level 1= mild

Figure 2: eRAPID case study