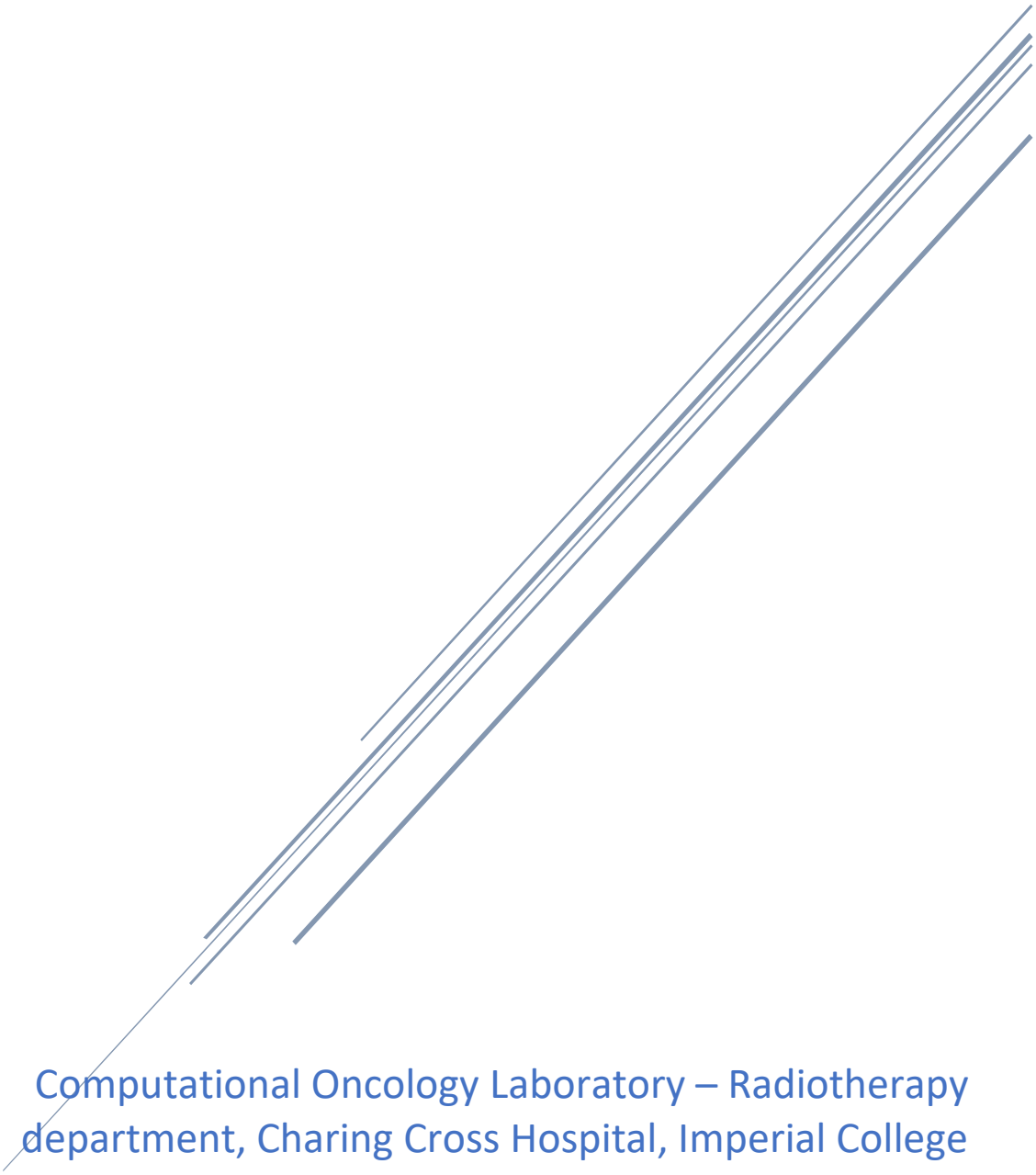
CURIE

Collecting, Understanding, Reporting, Interpreting and Exploring Patient-Reported Outcomes and Experience in adult cancer patients: a coordinated multi-centre quality improvement project



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Project Manual, version 1.6

Contents

Glossary

CNS	Clinical Nurse Specialist
CO	Clinical Oncologists
EBI	Even Better If
ePSS	Electronic Prescribed Specialised Services
ICHT	Imperial College Healthcare NHS Trust
NCRAS	National Cancer Registration and Analysis Service
ODN	Operational Delivery Networks
PRD	Patient-Reported Data
PREMs	Patient-Reported Experience Measures
PROMs	Patient-Reported Outcome Measures
SALT	Speech and Language Therapy
SLT	Senior Leadership Team
SMT	Senior Management Team
QI	Quality Improvement
VAS	Visual Analog Scale
WWW	What Went Well

Project management group

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Lay summary

Many patients with cancer have questions about quality of life associated with their treatment. However, this data is largely missing. Many patients and staff would also like to know more about how patients experience their treatment, but this data is also missing. All of these are potentially addressable by digital health approaches to provide scalable, robust, secure, close-to-patient data-capture and recording systems. However, the feasibility and acceptability of deploying these at scale remains unclear.

We do have some data from clinical trials. But patients in clinical trials tend to be younger and fitter than “standard” patients. Data on patient experience is also patchy and tend to under-represent patients with rarer cancers and those having palliative treatment.

Recent improvements in technology have allowed many cancer centres to offer patients access to their electronic records (or at least part of them) using a secure online platform, often called a “portal”. These portals often also allow patients to upload data on their quality of life or to answer other questionnaires (e.g., on service quality). We want to use these portals to capture Patient-Reported Outcome Measures (PROMs) and Patient-Reported Experience Measures (PREMs) which we define globally as “Patient Reported Data (PRD)”.

The aim of CURIE is to develop, deploy and test the effects of collecting PROMs and PREMs digitally in cancer patients starting a new line of treatment. It will allow us to collect this information at scale from multiple service providers across the UK, as well as understand how the results may vary across multiple parameters (i.e., patient groups, geography), and to work out how we feed this data back to patients and their treating teams in a useful and timely fashion.

Data collected may be shared with National Cancer Registration and Analysis Service (NCRAS) and therefore linked to patients’ clinical data on a national level. PRD might become available on the HDR UK Gateway website with the appropriate approvals and licenses.

Who is this manual for?

This manual has been written for staff interested in this project and keen to open it in their own centre. We do not and cannot force centres to run CURIE, we can only advertise this project and support teams motivated and interested by CURIE.

We do not expect patients to read and review this document as it is technical-oriented. This manual is a guide and does not have to be followed on a step-by-step basis. We recorded what we think worked across various centres, but the steps can be adapted.

Patients' testimonials

"When undergoing cancer treatment, patients often worry about side effects and the ability to carry on their lives. We want to find out what these worries are and how treatment affects their lives so the quality of cancer care can be improved even more. For the first time, a research project will try and find what those experiences and concerns are (PREMS), and what the effects of treatments are (PROMS), for cancer patients all over England, using modern methods of data collection. Patients will report their own concerns, their own outcomes.

We will be asking people of all colours and races, all ages, men and women, members of religious groups, and whatever their outlook on life, to gift their data to this study. It all matters.

The data will be used to guide individual treatment and be analysed for the benefit of future patients. We hope that care for cancer patients will become more personalised and add to quality of life as well as longevity." – Jacqui Gath

"I know from personal experience that cancer and its treatments can have impact both immediately and in the future on a patient's physical and mental health as well as economic impacts. Understandably, it is easier to collect data on the immediate physical impacts, but CURIE & INDIGO will help to paint a more holistic picture of the real-world impacts." – Pete Wheatstone

"When you are diagnosed with cancer it is easy to forget that before we are a patient, we are people. As a person, we are more resilient, more resourceful and better able to live our best possible day. This research, which focuses on the impact of treatment, will help people living with cancer to decide what is important to them, so that they can live the life they want as people, and not patients." – Dr Helen Bulbeck

Checklist

CURIE

Collecting, **U**nderstanding, **R**eporting, **I**nterpreting and **E**xploring Patient-Report Outcomes and Experience in adult cancer patients: A coordinated multi-centre **quality improvement (QI)** project

Making use of what patients tell us - Patient Reported Data (PRD) - to improve OUR cancer services

Prepare your service

- ☐ Engagement of senior leadership team (SLT) of your organisation
- ☐ Infrastruction to support CURIE
  - ☐ Exisiting PRD provider can be used
  - ☐ Other vendor / platform available within organisation
  - ☐ New vendor required
- ☐ Business case / QI plan
  - ☐ Budget / costing
  - ☐ GDPR concern / data ownership
  - ☐ Resources needed
    - ☐ Equipment
    - ☐ Staff
    - ☐ Wifi / IT infrastructure
    - ☐ Other supports needed
  - ☐ Interested parties
    - ☐ Clinical Oncologists (CO)
    - ☐ Secretaries of CO
    - ☐ Medical Oncologists
    - ☐ Service Managers
    - ☐ Senior management team (SMT)
    - ☐ Local cancer support services
      - ☐ CNS
      - ☐ SALT
      - ☐ Dietetian
      - ☐ Pharmacists
      - ☐ Physio
      - ☐ Others _____
    - ☐ Organisation
    - ☐ Cancer ODN / NHS
- ☐ Other cancer service / pathways within the organisation e.g. chemotherapy / radiotherapy / radionuclide therapy / radiosurgery / brachytherapy / intraoperative patients in theatre, etc.

- ☐ Local staff engagement
- ☐ How to maximise staff awareness to promote signup to CURIE
- ☐ Identify local champion(s) / team(s)
- ☐ Staffing requirement
- ☐ Protected time
- ☐ Local process mapping
- ☐ Resources e.g. printing facilities, tablets
- ☐ IT infrastructure in the department e.g., wifi access

Prepare the team

- ☐ Local team brief of CURIE
  - ☐ Background, purpose, resources related to CURIE e.g., website
  - ☐ Your local champion(s) – who? where? contact details?
  - ☐ Local core process
    - ☐ How organisation/service sign up
    - ☐ How patient sign up
    - ☐ What data CURIE collect
    - ☐ Collection time frame
    - ☐ Data flow
    - ☐ Use of local data for rapid improvement
    - ☐ How to use collected data
    - ☐ How local team respond to CURIE data – process, variations
    - ☐ How to measure and monitor improvement over time – tools
    - ☐ How to engage relevant interested parties and cascade progress / update
    - ☐ How to use quality management system to translate data into intelligent action at appropriate level?
    - ☐ Maintanance of project knowledge - change of contact / staff who has knowledge of the project
- ☐ Patient information leaflets
- ☐ CURIE poster (for staff)
- ☐ Make team(s) / staff aware of CURIE
- ☐ How to promote / encourage sign up
- ☐ Increase awareness within organisation
- ☐ Consider local dry run on small group of patients

Prepare the patients

- ☐ Core team to promote CURIE to patients
- ☐ Timely reminder for patients at all stage of data collection
- ☐ Opportunities to complete ePSS while waiting in the department if tablets available
- ☐ Promotional materials
  - ☐ Patient information leaflet / manual
  - ☐ Poster (for patients) display

Communication

- ☐ Share info with all interested parties
  - ☐ Interested parties are?
    - ☐ SLT
    - ☐ SMT
    - ☐ Staff – Nurses
    - ☐ Staff – Radiographers
  - ☐ Background
  - ☐ Purpose
  - ☐ Resources related to CURIE e.g., website, QR code
  - ☐ Ongoing developments
- ☐ Regular update / feedback provided at different meetings / forum to increase awareness
- ☐ Powerpoint to introduce CURIE

Rapid learning cycle

- ☐ Regular catch up with other participating services – peer support
  - ☐ Agree on frequency
  - ☐ Share challenges
  - ☐ Share learning
    - ☐ Sign up rate vs foot fall (activities)
    - ☐ Patient feedback on CURIE process
    - ☐ CURIE champion (staff) feedback on CURIE process
  - ☐ Share What Went Well (WWW)
  - ☐ Share Even Better If… (EBI)
  - ☐ Continuous learning of how best to 'CURIE'
- ☐ Adapt CURIE specification and put learning into action – rapid and adaptive improvement cycle
- ☐ Ask ourself
  - ☐ Who are the group we wish to hear from more / less?
  - ☐ What we need to excel at next?
  - ☐ Is the purpose still fit for purpose?
  - ☐ Are we anticipating the needs of all interested parties?
  - ☐ Are we meeting the short / medium / long term needs?

Le Calvez, Kerlann

I. Background

Much of the current focus for cancer research is on cure, and survival (almost 200,000 articles on treatment and survival but less than 10,000 articles on cancer and quality of life[1–3]). However, even as cure rates improve, there remains a substantial number of patients who have incurable disease, or those who are cured, but have long-term side effects from treatment[4,5]. It is also important to note that many patients and carers would rather focus on quality of life than survival[6], even though data to support their choice may be largely missing[7].

Because of this, there has been an increasing focus on developing Patient-Reported Outcome Measures (PROMs)[8]. These are standardised questionnaires that collect information on symptoms or side-effects of treatment from patients. At the same time, there is a growing interest in patients' experience of treatment and their care, collected via Patient-reported Experience Measures (PREMs) (in the span of ten years, the number of publications that included PREMS doubled[9,10]). In this project, we will use the catch-all term "Patient Reported Data" (PRD) to capture PROMs and PREMs.

Despite growing interest, there is very little robust evidence to support the use of PRD, although there are some randomised trials that show an improvement in quality of life and survival with use of PROMs[11–13]. Nonetheless, there is even less work on how to use PRD to improve services.

Our aim is to develop a robust way of collecting and using PRD in oncology departments in the UK. We have developed this project through a series of meetings, phone calls and email exchanges; in particular, we have held two face-to-face meetings, both of which had substantial patient & public involvement (PPI), one of which acted as an incubator day for the project.

The difference between this project, clinical trials and other PROMs projects is mainly on the patients recruited and the time points when they complete their questionnaires. As stated in the lay summary, patients recruited in clinical trials are not representative of the "normal" cancer population in the UK (i.e., fitter, younger)[14–16]; whereas other PROMs projects (e.g., the English Cancer Patient Experience Survey, by NCRAS) tend to collect data several years post diagnosis and post treatment and on most common cancer types (i.e., breast, prostate, colorectal)[17–19]. The latter rarely includes patients with rare tumours and a poor prognosis (e.g. brain, pancreas, lung)[20] and personal confidential data is commonly deleted by the data controller, preventing NCRAS from comprehensively linking the data and loosing information on sensitive characteristics (i.e., ethnicity). Furthermore, there is a delay (12-month back-log) between the data collection and its availability to the academics and researchers.

We have chosen a pragmatic approach, offering the project to all adult patients starting radiotherapy, chemotherapy (or both). This includes starting any new course of treatment (even if that is a change from an existing treatment) and is open to any patient aged 16+ who can manage simple written English and has minimal online access (via any device).

We will offer optional additional more detailed questionnaires for patients to complete - one of our outcomes will be measuring completeness of these additional questionnaires. CURIE is adaptive, in that as we learn how to do things better, we want to make those lessons standard: things we learn from it will change the "standard" approach.

i. Ethics and governance

The CURIE project is considered to be a Quality Improvement (QI) project, therefore formal ethical approval is not needed based on NRES guidance 'defining research' and the following statement[21]:

> *"3.1 For the purpose of this policy framework, research is defined as the attempt to derive generalisable or transferable new, knowledge to answer or refine relevant questions with scientifically sound methods. This excludes audits of practice and service evaluations. It includes activities that are carried out in preparation for or as a consequence of the interventional part of the research, such as screening potential participants for eligibility, obtaining participants' consent and publishing results. It also includes noninterventional health and social care research (i.e., projects that do not involve any change in standard treatment, care or other services), projects that aim to generate hypotheses, methodological research and descriptive research. Projects whose primary purpose is educational to the researcher, either in obtaining an educational qualification or in otherwise acquiring research skills, but which also fall into the definition of research, are in scope of this policy framework. Activities that are not research according to this definition should not be presented as research and need not be conducted or managed in accordance with this framework."*

The CURIE project uses validated questionnaires, supplied via an electronic platform at different NHS trusts. The aim is to develop the experience and evidence to understand how to do this better. Patient treatment is decided and delivered by their treating clinical team as usual, and there is no randomisation. Analysis of results will be based on interviews, take up and usability of the service, as well as reported results.

All confidential information will be securely held by each treating trust, using the secure platform. Anonymised data will be shared with the central co-ordinating centre (i.e., ICHT), and identifiable data will also be shared with NCRAS. Agreements are already in place between the NHS trust and NCRAS since the national cancer registry already collects identifiable information about any cancer patients diagnosed in England.

The project will report to the Imperial College Healthcare NHS trust audit committee 6 monthly to ensure oversight.

II. Aims

The primary aim of CURIE is defined by its acronym as we want to collect, to understand, to report, to interpreting and to exploring PRD. The second aim of CURIE is to demonstrate and assess whether we can deliver a broad, patient-driven online platform to measure PROMs and PREMs in cancer patients and feed this data back nearly instantly to relevant departments. Departments are encouraged to use SMART goals (Specific, Measurable, Achievable, Relevant and Time-based) to address patients' feedback.

The aims are broken down by different objectives as specified below.

i. Primary objectives

1. To assess uptake and use of a secure online platform to collect data on patient-reported data.
2. To assess the feasibility of providing rapid feedback to local services.

ii. Secondary objectives

1. To assess completion rates and predictors of completion rates.
2. To develop and improve ways of providing rapid feedback on PRD to treating departments.
3. To enable peer-to-peer data review and sharing of results, strategies, and developing work in under-represented communities.

By taking part in CURIE, we expect to help centres to improve their patients' feedback to the relevant departments. We also hope to have a two-way feedback: "patients to department" and "department to patients". We expect that patients will feel heard and listened to, even if the department cannot improve the patients' experiences. Departments should be able to rapidly acknowledge issues raised by patients, but also raise awareness when necessary. Developing the processes to enable rapid feedback in each department is part of the project.

iii. Milestones

New centres can join the project at any time they want to. However, we expect them to contact us first to set up a few meetings to explain the project in detail and answer any questions they may have. This step is crucial as we can set up common standard practices regarding the key stakeholders (detailed on page 11), the question around the platform (does the Trust already use a platform or do they need one provided by a vendor?), and local approvals that must be in place prior to the launch for the project.

After a few rounds of meetings between ICHT, the local team and its key stakeholders, CURIE can be opened in the new Trust. ICHT will send leaflets and poster a few weeks before the start, to give time to the local team to print the documents out in the correct size (A3 and A5 sizes).

As explained later in this document (page 14), we expect to have regular meetings between the participating Trusts and ICHT to share what actions work in the patients' enrolment, the progress in enrolment, what could be improved, etc.

The implementation of CURIE in a new centre can take a few weeks to a few months, depending on various parameters (i.e., teams' leaders, local approvals, platform set up, local process mapping, meetings set up).

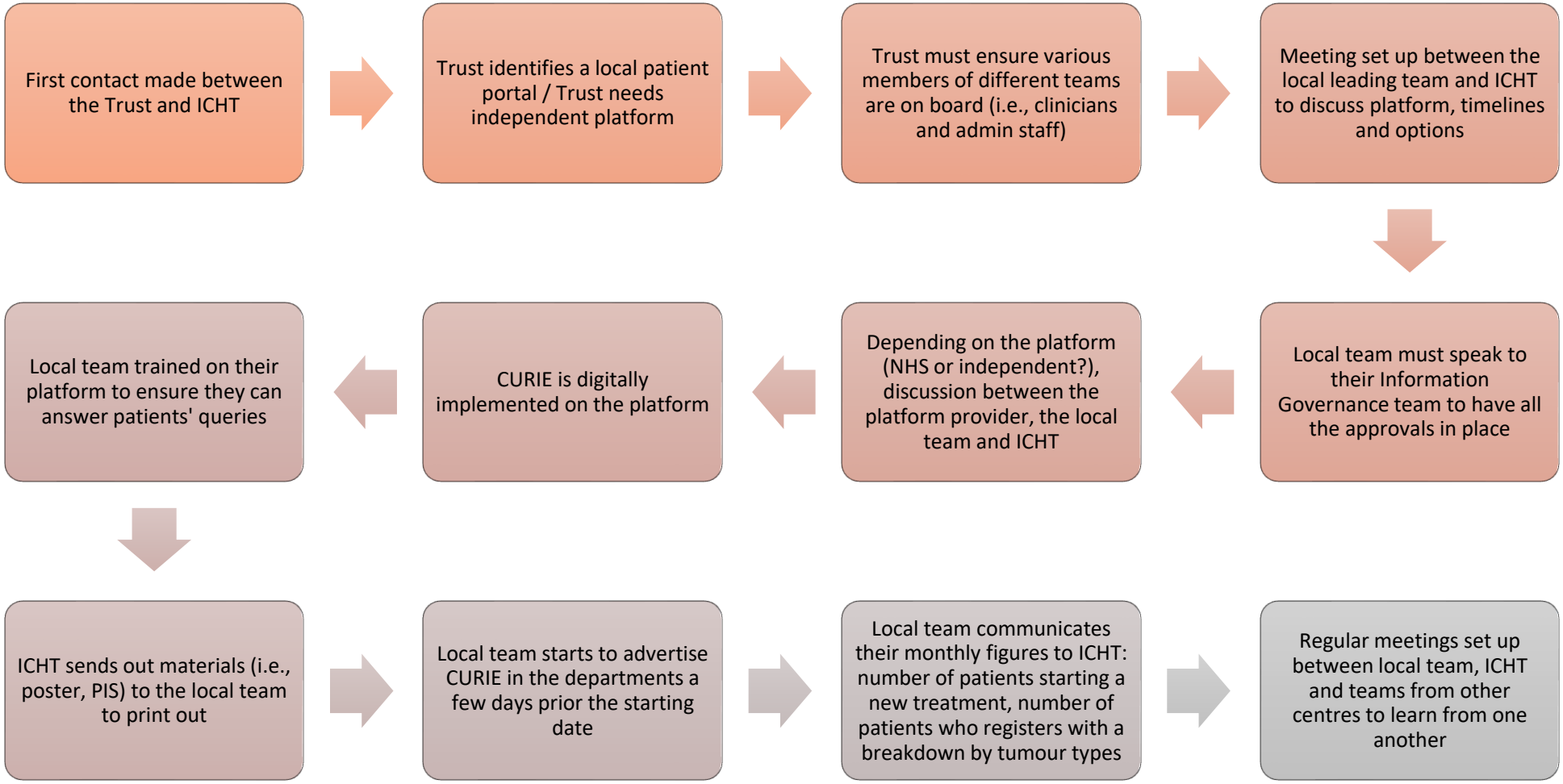

Figure 1: Steps summarised to join in and launch the CURIE project

III. Implementation of the CURIE project

Since the aim of the project is to understand enrolment, and to incrementally improve enrolment and data completion, we adopt an iterative approach, trying to understand how to improve enrolment over time. The methodology below demonstrates how we plan to generate improvement via the CURIE project.

1. Patients are exposed to information about CURIE as part of their routine care with posters and leaflets in clinic; clinical team mentions it to patients.
2. Patients attend for radiotherapy planning or pre-chemotherapy talk.
3. Patients are given information sheet to read, including details of who and how to contact if they have questions.
4. If the patients want to, they self-enrol into the project, using the Trust secure online platform, including permission for data sharing (with local teams, with central CURIE team (pseudonymised data) and with NCRAS). It is acceptable to use staff to help patients' sign-up, using computers in clinic, etc. although not mandatory.
5. Patients enter personal information and details of their illness and treatment.
6. Patients are asked to complete core CURIE data items at baseline (before treatment) and two timepoints afterwards – 4 and 8 weeks, and every 3 months after that. Patients are free to complete questionnaires at additional timepoints if they want to. (We are aware the timepoints chosen may not be in accordance with their treatment or not suit patients with a condition which progress rapidly, but the time frames can be reviewed if the change proves to be beneficial for patients and their treating team.)
7. Patients belonging to specific subgroups are offered additional questionnaires.
8. Data is fed back to treating departments on a regular basis.
9. Patients may continue on the project for as long as they chose too and are free to leave the project at any timepoint.

The exact nature of the online platforms can vary between sites and may vary over time as long as the secure online platform has been approved by the relevant Trust boards (Information Governance, etc). Sites that do not have an existing platform may be able to access one through an existing vendor, but this will still require local approval; and it needs to meet some key criteria – it needs to be secure, user-friendly and able to capture a variety of data from patients in a variety of patients (e.g., numbers, scale, free-text, etc.).

The core team of CURIE will handle any problem occurring on the platform provided by an existing vendor. If necessary, the local team will need to participate in meetings between the core team and the vendor when technicalities and improvement will be discussed.

i. Resources needed

A. LOCAL TEAMS

Teams interested in joining this project need to think about whether staff members involved in the project will need to take extra time off their current work and how this might be organised at the local centre.

They must think if any patients/ service users/members of the public involved in the study need to have access to quality improvement training if this could be provided to them and how would they

plan for it. They must also think if they have sufficient resources (i.e., time and money) for stakeholder engagement and patient and public involvement.

Project team members may need additional equipment to run CURIE locally (e.g., tablets in the waiting rooms, a computer dedicated solely to patients). One of the eligibility criteria is for patients to have minimal internet access and an email address, but some patients may want to register on-site and continue their assessments at home.

The teams running CURIE locally should be able to print out CURIE patient information sheet (double sided A5) and CURIE poster (A3 size). More requirements are detailed in this section (page 14, section Requirements [From staff]).

B. PLATFORM

CURIE is a project to e-capture patients reported data; therefore, a platform is necessary to run this project. We encourage local teams to check with their Trust if a patient portal has already been implemented and used by other teams. If no platform has been identified, we are putting together a list of vendors interested by this project. The ideal requirements are described on page 14.

ii. Identification of key stakeholders

Prior to any new centre deploying CURIE locally, teams will need strong relationships between departments, clinical and admin staff, patients, and carers. This project enhances multi-disciplinary team works, between the patient facing their clinical team, clinical team getting feedback from the managers and admin staff being able to help patients when they connect onto the secure online platform.

C. LOCAL CURIE GROUPS

a. Main steering group

Each local centre is expected to establish a small steering group. Our advice is that this includes a mix of staff including oncologists, radiographers, and chemotherapy nursing staff, as well as patients and other staff as local practice suggests. This group is responsible for the management of CURIE at the local centre, for liaising with the central coordination team. Their main responsibility is to work with local patients and staff and act as CURIE champions within their departments – presenting the project at departmental meetings, ensuring posters and information sheets are displayed, and arranging for local approvals. It is the role of the local CURIE group to ensure that all staff groups are aware of the project and understand its general principles. These include both radiotherapy and chemotherapy staff, but also administrative staff in the department (e.g., receptionists) and other clinical staff groups (e.g., CNS teams).

Non-exhaustive to-do list to consider

When the main steering group is formed, they must think through the following items, regarding the project meetings:

- How frequently will the project team meet to discuss the project?
- How long will these meetings last and who is expected to attend?
- Are these arrangements suitable for all attendees, including patients, service users and public representatives?
- Where will the group meet and is the venue suitable for all attendees?

- Who will set meeting agendas, take minutes and chase on agreed action points?
- Is a larger advisory or reference group required to engage a wider number of stakeholders?
- Who will co-ordinate and service meetings?

This list is non-exhaustive, but the main team should have answers that each member is happy with.

b. Patients and caregivers

Patients and their caregivers should be part of the local group to advise clinical and admin teams on what works and does not work in promoting the project locally. If necessary, patients already enrolled in CURIE might be able to engage with other patients, promote this project and involve the minority communities. We do not expect patients to have a formal conversation about CURIE, more of an informal chat that the clinical team can then follow and guide the patients through the project. Caregivers are also important in this project as they may help the patients to register, complete the questionnaire if the patients do not feel well enough.

c. Local management teams

CURIE captures data on both PROMS and PREMs. Therefore, local centres must confirm that managers and heads of departments are aware of this project being introduced locally. Indeed, they are the ones who can change the patients' experience by supervising the estates, the clinical and admin teams. They might not be able to fix some problems (e.g., long waiting times during treatment) but they can find solution to improve the local experience (e.g. warn patients prior to their first appointment that they might wait longer than expected and they should bring something with them to distract them). They are also the budget holders, therefore if patients or staff suggest a few iPads may help patients to register, managers and head of departments will be the ones to approve and buy the materials and technology.

d. Local community

During multiple meetings with patients during the design of CURIE, we identified the need for patients to be able to talk to other patients, patients in remission, nurses, and charities. Each centre may need to have a ready list of local cancer community such as the nearest Macmillan service, Maggie's centre, or even resources to access an online community, if the patients live too far from the local services offered. The choice will be given to the patients to join these communities. This is sometimes referred to as "social prescribing".

Figure 2: "A standard model of social prescribing has been developed in partnership with stakeholders, which shows the key elements that need to be in place for effective social prescribing", source

Social prescribing does not aim to cure the patients, but more about support, collaboration, and relationships with the patients. It also helps to design a web of relationships across the communities, primary and secondary care, local authorities, and charities. Social prescribing does not have to relate to healthcare exclusively, it is provided to help patients whenever they need and on any matter that may cause them worries during their treatments (e.g., financial or housing matters).

D. CORE PROJECT MANAGEMENT GROUP

The project management group will consist of the core team from Imperial College Healthcare NHS Trust, three patient representatives and a representative from each centre. This group will mainly communicate by emails, phone, or virtual calls. It is not expected of them to come on-site to help the local team to set up CURIE. They will coordinate remotely and be virtually available as much as possible.

iii. Requirements

A. FROM PATIENTS

At enrolment, patient should complete the first core questionnaire. We have defined a core question set as quality of life – measured with EQ5D-5L, a pain score and a distress thermometer (both measured with a VAS). The core question set is asked before a new line of treatment (= at baseline), at 4 and 8 weeks and every 3 months following the end of their treatment. Each assessment should take less than 10 minute to complete.

Patients will also complete the demographic questionnaire and must fill their name and date of birth in to identify them in the clinical systems. Some of the demographic questions will be optional. Patients will need to complete this questionnaire only at enrolment and will be able to edit answers

directly on the platform if any information becomes inaccurate. This questionnaire should take less than 10 minutes to complete.

Furthermore, before a new line of treatment, patients will be able to share their understanding of their diagnosis and treatment, and their personal experience, besides the core questions set. At each follow-up time point, in addition to the core questions set, series of questions about their experience, hospital visits and admissions will be asked to the patients.

Throughout the project, optional additional questionnaires will be offered depending on the patients' diagnosis (e.g., possibility to answer the ALERT-B questionnaire for any patient with a pelvic cancer).

The core question set, the patient experience questions, the additional questionnaires available and the time points are detailed in the appendix A (pages **Error! Bookmark not defined.**).

B. FROM STAFF

As part of the secondary objectives, CURIE sets out to improve services over the duration of the project through a set of actions between the participating centres.

C. FROM THE PLATFORM

The platform must be online and paper-free (i.e., a patient cannot complete questionnaires on paper in the department and then a member of staff re-enters the data on the platform).

To have a project scalable, the platform should be able to handle basic tasks, sometimes automatically, such as:

- Auto-scheduling questionnaires to be sent out (based on dates, treatment, previous questionnaire completed),
- Choose which questionnaires patients are eligible to according to their cancer type / their treatment / their care,
- Randomisation of patients,
- Input masking to guide the patients on what we expect from them,
- Checks answers type (i.e., ensure a patient has entered a date or number when expected),
- For the free text boxes, display the number of character left / over,
- Controls on answers (i.e., if a patient ticks the answer "yes" for a certain question, a new question should appear to ask for further information),
- Controls on questions (i.e., mandatory, and optional questions)

Ideally, the platform should be link to the local clinical system so the treating teams do not have to connect to the platform to check the patients' answers when they come to their appointment.

a. Shared learning and bench sharing of results

One of the key aims of CURIE is to enable local teams to explore what works in their department, and then rapidly share that with other centres. Part of agreeing to take part in CURIE therefore involves agreeing to participate in regular online calls and discussions about the project, implementation, and barriers.

The second is to enable departments to share their results, and to place their results in the context of others. However, this is not meant to be a "ranking" exercise – instead, we will help centres

understand what other centres are doing, and then enable conversations between centres to help them develop their own practice.

b. *Developing, assessing, and improving data feedback loops*

Before we agree to initiate CURIE in a centre, we expect the local CURIE group to have developed and documented data feedback loops. As a minimum, this would consist of monthly reports on enrolment, summary of reported data, and any indication of a change implemented and the effect it had on the registration rates.

However, one of the aims of the CURIE is to improve this feedback. We therefore expect local CURIE groups to identify clinical teams particularly interested in using the data from CURIE and working with them to develop more timely feedback loops. We expect that these will vary from centre to centre, but part of CURIE is sharing lessons about what has worked and not worked in each centre (e.g., patients from centre A may want to hear about and enrol to CURIE at the beginning of their treatment; but for patients from centre B, it would be at the end of their treatment). At the beginning of the project, we will be open to any feedback that may have had a significant impact on the patients, the registration and completion rates.

c. *Patient confidentiality*

Even though treating teams from different centres may need to speak to one another, we will ensure teams discuss methodology and aggregate figures during the meetings. Patients' data will stay confidential, and no patient names will need be mentioned.

d. *Local approvals and safety*

CURIE is not a clinical trial; it is a QI project. This means that it does not require REC/ HRA approvals, but it does still require local approvals, and some initial local design, before you can begin the project. These approvals and procedures may vary slightly from centre to centre, but will typically include:

- Registering CURIE as an audit/ QI project.
- Ensuring you have Information Governance approvals.
- Ensuring that the local portal is available and has the required functionality.
- Designing a local route for data feedback (see below).

The central CURIE team can help with these, especially in terms of documentation, experience in other centres and analysis. However, it is the responsibility of the local CURIE team to ensure that all of these are in place.

e. *Changes influencing CURIE*

You need to identify any changes or activities that are happening in the service or organisation at the same time – for example, new IT systems, staff turnover, relocation of services, other relevant quality improvement projects or cost improvement initiatives that may either aid in CURIE implementation or hinder / delay the process. These changes may have a significant impact on CURIE (positive or negative) and other centres may be interested to know these as they might go through similar processes.

iv. Access to additional support

Day-to-day management within each trust is devolved to the local project lead, who is expected to liaise with their local QI lead and information governance departments, and other departments as required.

Central management will be based at Imperial College Healthcare NHS Trust, and led by Dr. Williams. The overall management of the project will reside with the project management group. The project management group will consist of the core team from Imperial College Healthcare NHS Trust, three patient representatives and a representative from each centre.

The project management team can help with the local set up of the project, especially in terms of documentation, ensuring local portal has required functionality, sharing experience from other centres and in the analysis process.

IV. Improvements in the future

i. Patient and public involvement plan

We have had extensive PPI as part of the development of this project, with more than 15 patients and caregivers involved in the development of the CURIE protocol.

We will continue to use ongoing PPI as the project progresses as they can provide insightful feedback on the quality of services – current and with CURIE in place, useful personal perspectives - from current services and with CURIE in place, as well as were there are gaps in service or room for improvement. The management board will have three patient representatives on to help manage this process. Our PPI lead will maintain in constant communication with patients and caregivers on study as well as the wider cancer population and ensure that their voice is heard and reflected in the trial running, management, and continuous development. She will address concerns with patients and publics and ensure that results are disseminated in a timely manner to patients and public. Patients and caregivers will be reimbursed appropriately and in line with the INVOLVE guidance for their time[22].

All involvement will be aligned to UK Standards for Public Involvement and we will also take into considerations how to adapt PPI sessions with COVID and its restrictions[23] by using the GRIPP2 reporting checklists.

ii. Quality Improvement approach

We will use the Plan-Do-Study-Act quality improvement method[24] as it allows us to assess the impact of CURIE on local departments before CURIE is implemented on a wider and more national scale. This is a safer and more efficient method to test quality improvement as it allows a sample of stakeholders (patients, caregivers, local CURIE groups etc) to be involved and assess proposed changes in action in an iterative manner.

We will implement this using a central steering group with implementation in each centre being led locally. This is because the specifics of how to implement CURIE will vary from centre to centre, and so the main focus needs to be on the local implementation. The role of the central steering group is to provide resources and documentation to make local implementation easier, and to make sure that all centres are collecting the same measures in the same way.

iii. Assessing improvement

Across all the participating centres, we will assess the CURIE project by the following three outcome measures:

1. Uptake, use and sustained completion rates.
2. Patient feedback and free-text comments.
3. Staff feedback and comments.

To evaluate these outcome measures, we will measure:

1. Number and proportion of eligible patients enrolling in project.
2. Number and proportion completing initial data entry.
3. Number and proportion completing baseline questions.
4. Number and proportion completing baseline and both initial follow-up timepoints.

5. Number and proportion electing to opt-in to extension elements.

We will also assess our ability to interpret and feedback data to individual treating units. This will consist of a technical assessment (i.e., turn-around, workload) and qualitative assessments performed by both the reporting and treating teams (utility, response).

iv. Analysis plan

Data will be collected directly from patients onto the secure portal. Summarised data will be extracted at regular intervals, analysed locally, and fed back to departments and teams. Local data will be linked with basic demographic information, pseudonymised and pooled for joint analysis to allow centres to understand their results when compared with other centres. This joint analysis will be conducted at Imperial College Healthcare NHS Trust. Trusts will directly supply patient-identifiable data to Public Health England, in line with consent obtained from patients, and in keeping with the existing section 251 provisions that PHE operate under.

The main aim of CURIE is to understand how to collect PRD and how to use it in clinical practice. We will track numbers and proportions of patients who sign-up. We hope to run the project for 3 years in the first instance. All data will be handled in accordance with data protection and information governance guidance. There is no formal statistical analysis or power calculation for this project.

v. Impact and sustainability

The impact and sustainability are subjective to a few parameters that we decided to define as the registration rates, the use of the platform by the patients, the impact patients had on the centres, the improvement of the patients' care, feedback from staff.

A. Registration rates

At the start of the project, each centre agrees to share their monthly figures (i.e., numbers of patients registered and eligible to CURIE) to the project core management team. Monthly meetings will take place to discuss what centres have put in place to encourage patients to enrol and participate in the project. Meetings minutes will record the actions undertaken by the centres and will be shared with other centres.

Along with the aggregated number of patients eligible and registered, we would expect the local team to inform us of any significant changes, when they occur. Monthly figures will be analysed and in the case of an increase (or decrease) of the registration rate, the project core management team will contact the concerned team to understand the reasons behind the change. All these changes will be recorded by the project core management team as part of the shared knowledge and its dissemination.

B. During and after the patients' treatments

Since the aim of CURIE is to collect patients' PROMs and PREMs data during and following their treatment, we will assess how often patients answer their questionnaires (e.g., do they answer when they are prompted? Do they answer before/ after a significant health incident? How long did it take them to complete the assessments?) and link with the treating team to understand how many patients requested an appointment to discuss symptoms or their quality of life. We will then compare the patients' answers before and after their clinic appointment to understand if the patients had access to tools, communities to improve their quality of life.

C. PATIENT EXPERIENCES

During the design of this project, it has been raised that patients should have access to free text boxes to express their experiences. We will plan to compare patient experience at different time points to understand if an issue (or positive experience) is experienced by other patients over time as well. We will link these results to the local department to understand how the issue got fixed, or how they enhanced a positive experience from one patient to others.

D. FEEDBACK FROM STAFF

Although CURIE has been designed for and by patients, it is also meant to help clinicians to optimise their care by focusing on what the patients desire or what they would like to improve. We hypothesise that if patients have access to online screening tools, they may have more regular meetings with their treating team and they might avoid unnecessary long and painful admissions.

We do not expect the treating team to spend a long time with patients with the burden of multiple questionnaires to read through, rather we expect patients to lead and facilitate the conversation. Patients will not be asked to perform this on their own, the central steering group may provide them with extensive explanation, a typical scenario, or a script to follow if patients who may not be comfortable. Furthermore, we will ask staff to assess the project, the impact on their workload and their thoughts regarding the care they give to patients.

vi. Disseminate shared knowledge and data

A. SHARE KNOWLEDGE

We would like to share our results and learning in various forms, including webinars, posters, and other publications. These will be co-ordinated through the management group. Any paper, poster, webinar will be sent around to the teams' leaders to get their feedback and approval before submission.

B. SHARE DATA

We proved the linkage of non-anonymised patients' data to national cancer registries was feasible with fairly accurate results. When patients enrol, they explicitly consent that their data may be shared with the main steering group at Imperial College Healthcare NHS Trust and national cancer registries. They also consent that their anonymised data may be shared with third parties. Our aim would be to make anonymised data available to other research teams who have an interest in digital health, and PRD. The data could be shared via the HDR UK Gateway website.

V. Any other information

In case you still have questions, feel free to visit the official website or contact us directly.

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