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**CURIE/INDIGO Project – some more information**

Thank you for asking for some more information about the CURIE/INDIGO project. Our initial letter was deliberately brief. This document is designed to give you some more detailed information.

As before, please let me know if you have any questions and drop me an email at matthew.williams@imperial.ac.uk

**What is CURIE/INDIGO?**

CURIE/INDIGO is an attempt to try and work out how to measure patient-reported outcome measures (PROMS) and patient-reported experience measures (PREMS) in adult cancer patients in the UK.

The main focus is on feasibility, and developing and testing feedback loops (i.e. feeding back data from patients to their treating teams/ departments/ etc.).

The central idea of CURIE is that patients self-enrol onto a secure website, enter some details about themselves and their illness and treatment, and complete a short set of questions at enrolment, 4 and 8 weeks after enrolment, and then every 3 months. The set of enrolment and assessment questions is shown in printed form in the associated “Paper Question Set Demo” document. CURIE/INDIGO is open to any adult cancer patient starting a new course of radiotherapy or chemotherapy at a participating centre. In addition, patients can be offered additional questions e.g. those patients having pelvic radiotherapy or palliative chemotherapy can be given more relevant questionnaires. We are also looking at including wider groups of patients, but this is dependent on further discussions.

Where possible, we will use existing patient portals already implemented in your hospital. These are secure websites that allow patients to look at their data, and often allow for messaging, completing questionnaires, etc. Many GP surgeries now have them, and an increasing number of hospitals have them. However, there are different systems, made by different companies, and implemented and used in different ways (see the later section Specification vs. Product).

**Previous experience with TRIGGER**

We have previously developed and implemented the use of a similar project – the TRIGGER project. This uses a secure online portal to collect the ALERT-B PROMS questions every 3 months in adult patients having radical pelvic radiotherapy. The project uses a secure online portal, and is dependent on patient-led sign-up and data entry. TRIGGER has now been running for 3 years in four centres in the UK, and we have learned a lot from it. There are some references at the end of this document if you are interested.

**Development of CURIE/INDIGO**

CURIE/INDIGO has been developed through a series of repeated meetings with patients, staff and carers over the last 9 months. In addition to meetings (both face-to-face and online) we have also hosted an early draft of the protocol online and asked for comments on that. We engaged with a wide variety of people through a combination of telephone calls, emails and twitter.

This outreach has continued as we have finalised the first version of the protocol. It has been developed with ongoing patient, caregiver and staff input, and will continue to be developed and refined in a collaborative manner.

**Patient benefit & the value of CURIE/INDIGO**

One of the areas we have worked on with CURIE/INDIGO is to try and make the process of contributing their data both easy for patients, but also worthwhile. There are several other projects that have looked at collecting PROMS data in cancer patients, most notably a large NHS England project and, at a smaller scale, the TRIGGER project. However, one of the problems with approaches such as these is, while we might find it useful to have the data, there is little direct benefit to patients. In CURIE, therefore, we have tried to increase the value to patients by providing shorter feedback loops from data entry to providing the data to hospital staff, providing more support links on the platform, and making sure that departments acknowledge the commonest problems raised in the PREM questions.

**Why are there two words in CURIE/INDIGO?**

CURIE is a Quality Improvement (QI) project. It aims to collect outcomes in patients undergoing routine cancer treatment, and feed those results back to the treating centre. In that sense, it is no different to any other data collection/ QI project that a department might run. The role of the co-ordinating centre in CURIE is about reducing barriers to entry (we will talk to the platform vendors), to provide co-ordination between centres, and enable sharing of learning and data.

However, even though we expect to learn a lot from CURIE, it cannot answer all of our questions. For that, we have developed INDIGO. INDIGO is the clinical trial counterpart of CURIE. It uses the same broad approach (patient-led sign up, secure platform, core questions with optional subsets), but because it is a clinical trial, it allows us more flexibility. For example, we can randomise patients to different assessments (e.g. EQ5D vs. QLQ C30) and begin to assess the possible impact of simple interventions, such as providing online advice to patients.

Because INDIGO is a clinical trial, we require informed consent from patients - this can be given electronically online (in line with HRA guidance), using the same portal as patients use for CURIE/INDIGO. Centres can opt to open either CURIE or INDIGO, depending on resources and local infrastructure. Because INDIGO is an NCRN-badged clinical trial, it attracts money for ever patient recruited, but it also requires more input and infrastructure, and someone locally needs to manage the local digital infrastructure (e.g. manage randomisation). However, if your centre is keen to take part in INDIGO, please let us know and we will explore what we can do to support you.

**Ongoing Development**

We are clear that the first version of CURIE/INDIGO is just that. Part of the aim of the project is to learn what works, and how we can better measures PROMS, and then adapt CURIE/INDIGO to that.

We will learn directly from CURIE, but we also hope that lessons we learn from the INDIGO trial will then become part of the routine approach in CURIE - e.g. if we learn that questionnaire A has much better response rates that B (from INDIGO) then we will look at making A routine within CURIE.

**Adding new question sets**

One area where we know we will need to update CURIE/INDIGO is the addition of new question sets. For example, we expect interested parties to come along with possible questions sets that might be applicable to all/ most/ a few of the patients who take part in CURIE/INDIGO.

This process will be managed through the central co-ordinating group. Briefly, centres that are part of CURIE/INDIGO can suggest a new set of questions/ assessments; we will discuss these centrally for technical feasibility and permissions, and then discuss with all other centres and our patient and carer advisors. If enough centres and patients think it is worthwhile, we will conduct as provisional implementation (typically for three months) and assess uptake. If uptake is reasonable, it becomes part of CURIE/INDIGO until we decide to remove/ replace/ improve. All questions are reviewed annually to ensure that they are both relevant and completed.

**Specification vs. Product**

Earlier, we talked about the fact that there are multiple different patient portals. These are made by different companies, and have slightly different technical abilities, although most offer a core set of common functionalities. We cannot insist that sites should use a particular platform, and nor do we want to. Where centres already have existing portal, we should use that portal.

However, because of this, CURIE/INDIGO is a *specification* (i.e. a list of what to do and how) rather than an actual software product. CURIE/INDIGO specifies *what* to measure, *in whom*, *when* and using *which measures*, and also suggests some ways in which teams should work and collaborate. This is a subtle point, and may not matter to many people – but it explains why we do not offer a software product directly. Instead, we work with vendors to develop a product (i.e. to turn the specification into a product) and then users access that product.

The key aims of CURIE are to see how feasible this is, to develop ways of sharing data back to centres quickly, and to allow centres to share results and experience. CURIE is a Quality Improvement project. INDIGO is the associated trial - using the principles and questions used in CURIE, but in the form as a clinical trial, with on-line electronic consent.

Centres can opt to take part in either CURIE or INDIGO. Centres are expected to use their hospital's existing secure portal to implement the project, although we can assist with paperwork, and we are discussing options with vendors who can supply a ready-built platform for those centres that don't have one. As part of the project, centres must agree to join monthly telecons with other centres, and to share their anonymised data with other centres in accordance with each centre’s Information Governance team guidance.

CURIE has been developed through very wide-ranging consultation and collaboration, including patients, carers, radiographers and oncologists, and will continue to evolve as we learn from the project. It is co-ordinated through a group in the Radiotherapy Dept at Charing Cross Hospital, but has been developed and is run in a collaborative manner. The role of the steering group is to make sure that all the centres are measuring the same things at the same time, to provide administrative and technical support, and to help centres talk to one another.

**Project governance & publications**

The project is led by a small multi-disciplinary core team, consisting of patients, carers, doctors, radiographers and technical staff, and is based in the Radiotherapy Department at Charing Cross Hospital in London.

However, the majority of the work and decisions are made by the steering group. This includes the project core team, additional patients and charity representatives, and two staff members from each site. That group is responsible for reviewing requests for new sites to join, discussing and reviewing opportunities for adding new questions, and planning publications.

Many of our ‘publications’ will be very informal: we will produce a monthly newsletter, for example. However, we expect to produce some peer-reviewed journal papers, and authorship will be discussed at the steering group.

If you would like to be involved please drop me an email at matthew.williams@imperial.ac.uk

**References:**

The Trigger Project: The Challenge of Introducing Electronic Patient-Reported Outcome Measures Into a Radiotherapy Service A. Macnair et al. [https://www.clinicaloncologyonline.net/article/S0936-6555(19)30415-7/pdf](https://www.clinicaloncologyonline.net/article/S0936-6555%2819%2930415-7/pdf)

TRIGGER Website: <https://www.radiotherapyoutcomes.org/>

NHSE Cancer PROMS: <https://www.england.nhs.uk/publication/patient-reported-outcomes-of-cancer-survivors-in-england-1-5-years-after-diagnosis-a-cross-sectional-survey/>