

# The role of an automated frailty score (electronic frailty index) in improving outcomes for cancer patients in chemotherapy

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| <b>Submission date</b><br>14/10/2020   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>18/01/2021 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>21/08/2023       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Diagnosis of cancer is a fearful event for most people. Adequate information and provision of the best treatment can not be underestimated. The treatment of many cancers involves major interventions such as surgery, chemotherapy and radiotherapy. Treatment of people who are frail is even more challenging. Our health can be affected by cancer itself and a range of other conditions and it is really important that we balance the side effects of cancer treatment against the harms it can cause. We know from several studies that clinicians struggle with adequate assessment of older people living with frailty and with cancer and offer less aggressive treatment even if they are not frail. We also know that many frail and older patients suffer multiple side effects of treatment and sometimes die as a result of the treatment itself. We need an improved way of assessing frail patients with cancer. We believe it is possible to use a score that can be calculated from medical records that will help us to better estimate the risks of chemotherapy. This score is known as electronic frailty index (EFI) and has been useful in general practice. EFI is now automatically calculated by GPs from electronic medical records. To validate this type of score in cancer we need to undertake a research project in 2 parts.

### Work-package 1 (Data analysis project):

Work-package 1 includes an analysis of historical systemic chemotherapy records (SACT). The SACT data will be obtained from Public Health England (PHE) and will include data for patients with stage II or III breast cancer, stage III colon cancer or stage IIIB-IV non-small-cell lung cancer (NSCLC) in England between January 1 2013 and December 31 2018. Patients with early breast cancer, stage III colon cancer as well as patients with NSCLC are considered for SACT and have improved survival as a result of SACT. We focus on this dataset as we have previously analysed these data and presented this at the NCRI conference . These data sets are already linked with some of the hospital records and survival data.

Data from SACT will be linked to Hospital Admissions statistics (HES data obtained from NHS-Digital) to calculate 30 day chemotherapy mortality for this cohort, hospital admissions during this time (starting day 1 cycle 1 to six months after day 1 cycle 1) as well as HES-EFI. HES-EFI will be calculated from the 35 fields that define EFI (full description in the attached protocol), with

the exception of polypharmacy. The NHS-digital data for linkage will be requested through Data Access Request Service online. Data will be pseudonymised and linked directly with researcher unable to access personal data of individual patients.

The data on EFI derived from GP records for the patients identified in the SACT dataset above will be obtained from the following databases:

- The Clinical Practice Research Datalink (CPRD)
- Royal College of General Practitioners (RCGP) Research and Surveillance Centre.

We have previously analysed 2013-2015 SACT data of patients with breast, lung and colorectal cancer and the results of this work have been presented at the NCRI conference. We plan to extend this analysis to include EFI, and compare the EFI derived from hospital data (HES-EFI) and the EFI derived from GP records (GP-EFI). This will be linked with 30-day chemotherapy mortality rates and hospital admissions during chemotherapy. 30-day chemotherapy mortality is an accepted measure of poor outcome from chemotherapy and similarly the need to be admitted during chemotherapy often reflects the side effects of chemotherapy and is accepted as a measure of chemotherapy toxicity.

#### Work-Package 2 (Qualitative study)

Alongside the data analysis we will conduct a qualitative study that will examine patients, carers and clinicians' attitudes to using an automated frailty score that can influence the cancer treatment decision making process.

#### Who can participate?

Recruitment will only take place for Work-Package 2 (25 participants in total). Patients must have received at least one cycle of chemotherapy.

Carers who are the partner or child of the patient.

Stakeholders: Medical and Clinical Oncologists, General Practitioners, Geriatricians; Chemotherapy and Specialist Nurses

All participants must speak/ understand English and be willing to participate in an interview that will last between 30 and 45 minutes.

#### What does the study involve?

All participants (except GPs) for the qualitative part of the study, will be approached at St Luke's Cancer Centre based at the Royal Surrey County Hospital. Information about the study will be provided and then individuals will be invited to participate.

The semi-structured interviews will be audio-recorded, last approximately 30 – 45 minutes and will explore:

- Acceptability of using an electronic score to help with the chemotherapy risk calculation
- Appropriateness and acceptability of outcome measures for the future prospective study
- Acceptability of the randomisation process and recruitment process to the future prospective study
- The stakeholders will also be asked for their views regarding the design of the future prospective study and their views on how a frailty score could impact their decision-making process.

#### What are the possible benefits and risks of participating?

The main possible benefit of taking part is voicing your opinion on using an automated frailty score to influence the decision making process. There are no risks of participating.

#### Where is the study run from?

St Luke's Cancer Centre at Royal Surrey County Hospital (UK)

When is the study starting and how is it expected to run for?  
March 2020 to August 2022

Who is funding the study?  
National Institute for Health Research (NIHR) Research for Patient Benefit Programme (UK)

Who is the main contact?  
Dr Agnieszka Michael, A.michael@surrey.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Agnieszka Michael

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Integrated Research Application System (IRAS)**  
279324

**Protocol serial number**  
20ONCN-279324, NIHR200517, CPMS 47050, IRAS 279324

## Study information

**Scientific Title**  
The role of Electronic Frailty Index in improving outcomes for newly diagnosed cancer patients undergoing systemic chemotherapy treatment

**Acronym**  
EFI in Cancer

## **Study objectives**

We believe that EFI can be successfully used as a tool to improve clinical decision making in frail cancer patients who undertake major anti-cancer treatment such as chemotherapy.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 01/12/2020, Wales REC 6 (Public Health Wales, Building 1, Jobswell Road, St David's Park, SA31 3HB, UK; +44 (0)1267 61 1164; Wales.REC6@wales.nhs.uk), ref: 20/WA/0284

## **Study design**

Mixed methods study containing a qualitative study and a retrospective data review

## **Primary study design**

Observational

## **Study type(s)**

Other

## **Health condition(s) or problem(s) studied**

Cancer

## **Interventions**

WP1 does not require patients' participation as the work undertaken will only relate to data obtained from electronic records. Anonymised medical records will be analysed to look for a link with electronic frailty index and poor outcomes from chemotherapy such as admission to hospital as a result of chemotherapy and dying as a result of chemotherapy.

Participants enrolled in the study described in work package 2 will be interviewed either in person or over the telephone and the interview will be recorded. Baseline information that will include the type of cancer, stage of cancer, age, gender, medical history and cancer treatment as well as social circumstances and for health professionals - job title and description of the role, as well as length of time working in oncology, will be recorded. This will be the only intervention and following the interview participants will be discharged

## **Intervention Type**

Other

## **Primary outcome(s)**

Work-package 1:

30 day chemotherapy mortality and hospital admissions during chemotherapy.

Information will be taken from historical systemic chemotherapy dataset (SACT) records 2013 - 2016 of patients with breast, lung and colorectal cancer. The data will be obtained from the following databases: The Clinical Practice Research Datalink (CPRD), ResearchOne database and Royal College of GPs (RCGP) Research and Surveillance Centre.

## **Key secondary outcome(s)**

Work-package 2:

1. The acceptability of eFI (electronic frailty index) will be measured using interview data collected at a single time point that will be analysed with Framework Analysis

2. The suitability of the endpoints for a future definitive study - this will be decided once the

data from WP1 shows the link between eFI and risk of dying from chemotherapy and risk of admission during chemotherapy. If eFI has a predictive power (the poorer the eFI score the higher the chance of complications) this will be deemed as a suitable endpoint for a future trial

3. The overall accuracy between hospital derived eFI and GP-medical records derived eFIGP-eFI) - the eFI and GP-eFI will be directly compared to assess the difference in score
4. The ease of access to GP-eFI and HES eFI - this will be a descriptive analysis of the time it takes to extract data and obtain relevant agreements

**Completion date**

31/08/2022

## Eligibility

**Key inclusion criteria**

1. Stakeholders (n=10)
  - 1.1. 5 Medical and Clinical Oncologists, General Practitioners, Geriatricians
  - 1.2. 5 Chemotherapy and Specialist Nurses
2. Patients (n=10)
  - 2.1. 2 patients aged 60 - 70 with newly diagnosed stage II or III breast cancer and 2 >70 years old
  - 2.2. 3 patients with stage 3 colon cancer (1 60 - 70 years old and 2 >70 years old)
  - 2.3. 3 patients with Stage IIIB-IV non-small cell lung cancer (1 - 60-70 years old and 2 >70 years old)
3. Carers (n=5) Purposely selected for gender (men =3, women =2) and relationship to the patient (partner =3 or child =2)

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

**Key exclusion criteria**

1. Stakeholders, patients or carers who do not fulfil the criteria described above
2. Are unable to participate in an interview
3. Do not speak/understand English

**Date of first enrolment**

01/05/2021

**Date of final enrolment**

02/05/2022

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**  
**Royal Surrey County Hospital**  
St Luke's Cancer Centre  
The Royal Hospital  
Egerton Road  
Guildford  
United Kingdom  
GU2 7XX

## Sponsor information

**Organisation**  
Royal Surrey County Hospital NHS Foundation Trust

**ROR**  
<https://ror.org/050bd8661>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
Research for Patient Benefit Programme

**Alternative Name(s)**  
NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**  
United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

| Output type                          | Details       | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|---------------|--------------|------------|----------------|-----------------|
| <a href="#">HRA research summary</a> |               |              | 26/07/2023 | No             | No              |
| <a href="#">Protocol file</a>        | version V4.0  | 23/11/2020   | 08/02/2021 | No             | No              |
| <a href="#">Study website</a>        | Study website | 11/11/2025   | 11/11/2025 | No             | Yes             |