

# NCRI Living With & Beyond Cancer Group

Annual Report 2020 - 2021



# NCRI Partners

NCRI is a UK-wide partnership between research funders working together to maximise the value and benefits of cancer research for the benefit of patients and the public. A key strength of the NCRI is our broad membership with representation across both charity and government funders as well as across all four nations in the United Kingdom.



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# NCRI Living With & Beyond Cancer Group

## Annual Report 2020-21

### 1. Top achievements in the reporting year (up to three)

#### **Achievement 1**

Completed two portfolio RCTs (eRAPID and eSMART) developed with input from the former Psychosocial Oncology and Survivorship Clinical Studies Group (CSG). eRAPID trial has been accepted as an oral presentation at ASCO 2020 and has been published in J Clin Oncology in January 2021, with an accompanying editorial. The press release by the University of Leeds received wide media coverage across the world in several languages and by 17 different countries.

This work rigorously evaluating online symptom and toxicity monitoring during chemotherapy. Providing evidence base for safe remote models of cancer care, extending the available evidence in the setting of curative adjuvant treatments. The evidence is particularly timely due to the rapid adoption of remote provision of health care due to COVID-19 restrictions.

#### **Achievement 2**

Providing methodological expertise in Patient Reported Outcomes Measures (PROMs). A Methodology AdVIsory Service (MAVIS) was established with online template for submission of new proposals for PROMs methodology review. This is an innovation for NCRI and is aimed to support all groups. Following this procedure, the Methodology Workstream conducted two formal proposals reviews in 2020 and 2021. Unfortunately, due to the launch of the new NCRI website, the material is currently not available online.

Methodology Workstream members contributed to the international PROTEUS consortium (Patient-Reported Outcomes Tools: Engaging Users & Stakeholders). PROTEUS promotes tools and resources to optimise the use of PROMs in clinical trials and cancer practice.

We wish to build on this success by finding better ways of marketing our PROMs methodology service among the other NCRI Groups.

#### **Achievement 3**

Active collaborations:

The continuity of membership from the previous Supportive & Palliative Care and Psychosocial Oncology CSGs has enabled us to continue previous collaborations. Close linkage with NIHR Cancer & Nutrition Collaboration leading to a wave of cancer and nutrition studies (Eat-CIT study (funded by Tenovus); reached round 2 of ENeRgise - Exercise and Nutrition-based Rehabilitation in life-limiting cancer (WCRF)).

Prehabilitation work is strong, stimulated by the NIHR prehabilitation call with leadership from Acute Care and Toxicity Workstream with a range of collaborators. A partnership with Vinehealth plus methodological advice via MAVIS led to a successful Innovate UK trial of a digital health solution.

The Late Consequences Workstream is collaborating on a project on cardio-oncology (Heart for Health) with members of the UK Cardiac Oncology and International Cardiac Oncology groups as well as linking with international researchers in the Netherlands and through ESTRO.

## 2. Structure of the Group

We had a few members of the workstreams dropping off or not filling positions requiring key skills. We have worked to seek and invite new members throughout the reporting period. Some key changes are outline below:

The Consumer input has been strengthened across all workstreams. There are now two NCRI Consumers on all five LWBC work streams and on the Executive Group following the latest round of recruitment. The four new Consumers who joined in early 2021 have therefore not been asked to make a contribution to this Annual Report. Our full Consumer membership is now as follows:

- Executive Group: Jim Elliott, Emily Travis (new in 2021)
- Acute Care & Toxicities: Elspeth Banks, Dave Chuter (new in 2021)
- Late Consequences (Julie Wolfarth, Tim Wright (new in 2021)
- Advanced Disease & End of Life Care: Susan Restorick-Banks, Margaret Johnson
- Methodology: Jim Elliott, Daksha Trivedi (new in 2021)
- Metastasis of Unknown Origin & Cancer of Unknown Primary: Janice Rose, John Symons

Late Consequences Workstream - had a 6-month absence for paternity leave for Josh Turner and replaced with Amy Taylor and she has stayed on the group.

Methodology Workstream: Derek Kyte stepped down as Chair in Nov 2021 and Alex Gilbert took over the role whilst appointing a replacement.

ADEL: Annemarie Nelson had a long-term sick leave. Marie Lloyd-Williams and Lynn Calman took the role of interim co-chairs for the group in late October 2020. Annemarie is stepping down now, and new chair/co-chairs to be appointed.

Multi-disciplinary collaborations: Active collaborations were instigated on the NIHR Prehabilitation call; NIHR Nutrition collaborative and with Vinehealth on a successful Innovate UK trial of a digital health solution.

### 3. Living With & Beyond Cancer Group & Workstream strategies

#### Living With & Beyond Cancer Group

##### Achievements

1. Developing MAVIS and proposals review to support other NCRI Groups and researchers (strategic aims 5 and 11).
2. Collaborations with industry and successful Innovate UK application with Vinehealth (aim 8)
3. Preparing grant applications for NIHR calls – late effects of cancer treatments, prehabilitation, nutrition and cachexia, managing fatigue in long-Covid in cancer patients (aim 6)
4. Completed two portfolio trials (eRAPID and eSMART). eRAPID trial was in J Clin Oncology with an accompanying editorial (aim 10). The press release by the University of Leeds received wide media coverage across the world in several languages and by 17 different countries.

A major **challenge** for our newly created, large and cross-cutting group was NOT having the first annual group meeting (March 2020) and therefore missing the opportunity for networking, getting to know the wider workstream members and the spontaneous generation of new ideas. We managed to establish remote working practices for all workstreams and the Executive committee. In order to ensure good co-ordination one of the co-chairs always aimed to be present at the workstream meetings.

There were opportunities for COVID-related grants in 2020-21. Several submissions were made in the area of end of life care and managing long-Covid, with one successful proposal (C Mayland)

A **challenge** for us is how to make ourselves better known to NCRI groups. We plan to be more pro-active and pursue collaborations related to funding calls. However, the information on our LWBC group on the new website is minimal. We have also lost the online proforma for proposal guidance, which we want to re-instate as soon as possible.

Furthermore, there is a potential for mixed messages with the NCRI LWBC Initiative being considered identical to our LWBC group.

**We would welcome a discussion with NCRI to help us address the above concerns and challenges, and ultimately improve our collaborations.**

#### Metastasis of Unknown Origin (MUO) and Cancer of Unknown Primary (CUP) Workstream (Chair, Dr Kai-Keen Shiu)

This Workstream has a somewhat different focus from the rest of LWBC group. Developing the strategy and establishing the working practices in a way that engages all members has been more challenging but ultimately successful. The impact of COVID-19 on the regular activities has also been bigger on this Workstream due to the larger number of active clinicians.

The Workstream continued to support the recruitment of patients into ongoing CUP trials (the International Phase 2 CUPISCO trial, CUPem, PEACE, CUP TCGA).

The Workstream continued to develop and test a patient decision aid - CUPPA (Cancer of Unknown Primary Patient Decision Aids) in collaboration with CUP Jo Foundation.

In April 2020 the Workstream supported a £1.5million programme grant via Innovate UK (CUP-COMP-A comparison across tissue and liquid biomarkers' where The Christie Hospital are sponsors, Dr Natalie Cook is Chief Investigator, many oncologists on the Workstream are co-

investigators, and Roche and CONCR are commercial collaborators. One of the main aims is to perform solid and liquid (blood) genome profiling on up to 150 patients with CUP.

MUO-CUP Workstream will host a session at NCRI Virtual Festival 2021 to showcase successful studies, increase awareness of the topic and provide an update on new approaches and strategies.

### **Acute Care and Toxicities Workstream (Co Chairs, Dr Gillian Prue and Dr Pauline Leonard)**

The Workstream leadership has been very active, driving the development of a range of projects.

NIHR Prehabilitation call: Gillian Prue collaborated with Professor Simon Stanworth (lead for the Supportive Care, Transfusion and Late effects portfolio of the NCRI Haematological Oncology Group) to submit PROPEL: PeRsOnalised PrEhabilitation in acute myeloid leukaemia.

Chloe Grimmett was a co-applicant on PreopFit: Complex Needs-Based Multimodal Prehabilitation Interventions in Patients Prior to Major Elective Cancer. The group is currently developing a study on the introduction of prehabilitation for people who are diagnosed via the emergency route in collaboration with the Advanced Disease and End of Life Workstream.

A number of other proposals were submitted during the reporting year (see table in section 5).

The **main challenge** has been the impact of COVID-19 on the ability of members to engage meaningfully with the Workstream due to increased pressure from work commitments. The Workstream also lost two key members, a GP and a clinical oncologist, and is without a trainee member.

#### **Opportunities**

- To engage with professional organisations to offer trainees opportunities to join the workstream to shape a relevant research agenda.
- To engage with established site-specific tumour groups to understand if they have any unfinished or incomplete research ideas
- To work with NHS England Cancer Drugs Fund to develop real world research
- To determine if a new service in one Trust can be replicated in other trusts for e.g., Radiologically detected asymptomatic venous thromboembolic embolism.

## Late Consequences Workstream (Chair, Professor Sara Faithfull)

During the year the group have been active with 8 meetings held virtually, including 2 observers from clinical practice, 1 student and 2 invited speakers providing updates into specific late consequences research. Trainees have been actively working with the teams, in project planning and publications and will carry over the planned project to review late consequences mapping within the NCRI portfolio. Dr Dispesh Gopal is leading a primary care publication on cardiac oncology pathways.

We submitted a proposal to the adverse effects NIHR call on risk prediction and intervention for **chemotherapy induced peripheral neuropathy** (CIPN), which was considered out of scope for the call and did not proceed to review.

We developed a bid for NIHR RfPB funding to develop the proof-of-concept work through secondary data analysis but were unable to submit due to NHS COVID-19 restrictions. This work has now received funding (University of Surrey funding) for a secondary data analysis study to explore patient reported outcomes for neurological symptoms, CIPN trajectories and predictive risks for late consequences in people treated as part of a clinical trial for colorectal cancer.

We are developing a proof-of-concept work for an intervention study on **heart health** for people undergoing chest radiotherapy and/ or chemotherapy to be submitted for NIHR RfPB feasibility funding. Feedback from this consumer event highlighted the significant need for clear pathways, confusion on risks and the challenges in communicating late consequences pre and post treatment and the significance of this late consequence for survivors. We have been working with members of the UK Cardiac Oncology and International Cardiac Oncology groups as well as linking with international researchers in the Netherlands and through ESTRO. The team will contribute to future European studies on this topic led by the Netherlands. Julie Walforth, our consumer representative, has contributed to all project work as well as supporting qualitative work with MSc students who are looking at the experience of heart problems for survivors after cancer treatment.. These proof-of-concept projects will be published in the next year authored by the group.

We have also advised researchers who were looking to submit NIHR bids with one successful submission. We held one dragon's den with 3 studies presented plus advised on 2 studies sent to the group for peer review during the year. Current publication is in draft stage "Prevention, monitoring and secondary care management of cardiac consequences during and after radiotherapy and/or chemotherapy for cancer: a scoping review protocol".

**Challenge** for the group during this year is the ability to engage with NHS trusts to submit grants for late consequences due to COVID research restrictions.

**Priorities** for next year are to publish "heart for health" proof of concept work, develop proposal for "heart for health" and work closely with researchers and consumers to support growth in late consequences research.

## Advanced Disease and End of Life Care Workstream (Interim Co-Chairs, Professor Mari Lloyd-Williams and Dr Lynn Calman)

The Workstream met two times in the reporting period (Dec 2020 and February 2021). The group has two very active and engaged consumer members who contribute significantly to meetings and setting the group agenda. The Workstream Chair Annemarie Nelson had to take a long leave of absence through illness, Mari Lloyd-Williams and Lynn Calman were asked to take the role of interim co-chairs for the workstream in late October 2020.



## Challenges

The pandemic has had an impact on the progress of the group. We had planned to work towards a grant application in 2020 but this has not proved possible. Our clinical/academic workloads have been unpredictable over the last year. This has significantly limited any opportunities to progress our strategy.

Due to the long break in the activity of the group the group has been re-establishing itself and considering how to refocus on priorities to address current clinical needs.

We have identified psychological wellbeing in advanced disease and end of life care as an additional priority for the group. We have formed a working group to develop a proposal focusing on psychological wellbeing of advanced cancer patients. This is an area of expertise in the group, a significant need in advanced disease and has been further impacted by the pandemic. This topic offers us opportunities for collaboration with other groups e.g. the methodology group to support us with the design but also tumour specific NCRI groups eg GI group (pancreatic cancer). Workstream members are also contributing to the growing agenda around prehabilitation, especially around the NIHR focus on psychological wellbeing as well as nutrition and physical activity.

We retained a significant interest in treatment decision making and we plan a second working group to focus on developing a proposal around how patients and carers be appropriately informed of cancer diagnosis, treatment, prognosis and how this affects their treatment choices?

As per our strategy we are building **collaborations with other NCRI groups**. Lynn Calman has been collaborating with the NCRI Lung group on the development of a trial of radiotherapy in advanced lung cancer and this will be submitted for a stage 2 NIHR HTA grant. The ADEL members are actively seeking further collaboration within the LWBC group and beyond and will bring in specialists as the working groups progress their ideas.

## Opportunities

The group have been **actively engaged in COVID- 19 research** not initially planned for this year. Catriona Mayland *et al* have published 3 papers on the impact of COVID on bereaved relatives' and health and social care professionals' end of life experiences during the COVID-19 pandemic. Lynn Calman has produced a report on the experience of patients and carers with treatable but not curable cancer during the pandemic. Mieke Van Hemelrijck has been leading work examining factors affecting COVID-19 outcomes in cancer patients through large datasets.

## Methodology Workstream (Chair, Dr Alexandra Gilbert)

The strategic aim of the Methodology workstream is to promote and support the use of best-practice research methodology across the NCRI, with a focus on projects within the LWBC remit.

The major achievement of the workstream was the development of a **Methodology Advisory Service (MAVIS)**. This included the online template for clinical and LWBC groups to access advice from the Methodology workstream and to have the opportunity to present at Methodology workstream meetings for adoption onto Methodology portfolio. Two formal proposal development meetings were held virtually.

- *May 2020 meeting and updates*  
Matt Williams: CURIE: <https://www.radiotherapyoutcomes.org/curie>  
Rayna Patel: Vinehealth: Feb 2021: Innovate UK grant (£1.8M, successful)  
Galina Velikova: eRAPID radiotherapy RCT – NIHR HTA application: not funded
- *May 2021 meeting*

Luke Hatton/Pete Hall: KERMIT: Key pERforMance Indicators in electronic paTient reported outcome measures – project adopted onto Methodology portfolio

Workstream members are involved on NCRI strategic panels and initiatives:

- Michelle Collins and Jim Elliott: LWBC NCRI Prehabilitation proposals guidance panel (March 2021);
- Debbie Cavers: NCRI Multidisciplinary Proposal Guidance panel (Oct 2020);
- Alex Gilbert: NCRI webinar: In conversation with Patricia Ganz (July 2020);
- Jim Elliott: NCRI Virtual Series event 'Brexit deal: what it really means for cancer research and innovation' (February 2021)

**Consumer activities.** Jim Elliott has successfully co-authored and published: **Who should I involve in my research and why? Patients, carers or the public?** Kristina Staley, Ph.D., Jim Elliott, Ph.D., Derek Stewart, OBE, Roger Wilson, CBE. Research Involvement and Engagement (2021) in press

**Trainee involvement.** Debbie Cavers was a Panel member for the NCRI Multidisciplinary Proposal Guidance Session in her capacity as trainee member of the Methodology group with expertise in qualitative research methods. Emily Harrop is a co-principal investigator on a cross-cutting grant with the advanced disease group from UKRI/ESRC

#### **Collaborations and links to key stakeholders**

- International groups: NCRI representation in PROTEUS consortium (multiple stakeholders including international researchers, regulators and industry) – Alex Gilbert and Derek Kyte (The PROTEUS Consortium promotes tools and resources to optimize the use of patient-reported outcomes (PROs) in clinical trials to ensure that patients, clinicians, and other decision-makers can make the best decisions about treatment options). DK and AG have recently co-authored a BMJ Research Methods and Reporting article (re-submitted following minor revisions): *Recommendations for Including or Reviewing Patient-Reported Outcome Endpoints in Grant Applications*.
- Alex Gilbert had an invited presentation: ESTRO 2020 (European Society for Radiation Oncology): PROMs versus Clinician scored toxicity: do we need both?
- Emily Harrop: co-PI on a COVID Research proposal developed in collaboration with the advanced disease and EoL group: Supporting people bereaved during COVID-19: a mixed methods study of bereaved people's experiences and the bereavement services supporting them. UKRI/ESRC. 2020-2022 [www.covidbereavement.com](http://www.covidbereavement.com)
- **Proposal for NCRI LWBC Methodology and British Psychosocial Oncology Society joint webinar** Adaptations to research with people LWBC in light of the Covid 19 pandemic drawing on adaptations during the pandemic and those likely to stay as a consequence (outcome awaited).

## 4. Cross-cutting research

Ongoing collaborative activities are listed under the workstream reports.

The LWBC Group (as with its predecessor the Supportive & Palliative Care CSG) has worked closely with the NIHR Cancer & Nutrition Collaboration. NCRI hosted a large physical and virtual workshop on nutrition at all stages of cancer at the start of the pandemic lockdown in Spring 2020. A further virtual only workshop was held in January 2021 jointly with the Cancer & Nutrition Collaboration specifically for the NIHR call on Prehabilitation. This joint working has led to several lines of new research with the NCRI Workstreams (Acute Care & Toxicities; ADEL), and with international collaborators including Prof Stephen Hursting in North Carolina and European researchers in Norway and Germany. Topics being developed include prehabilitation before cancer treatment and mechanisms and management of cancer cachexia.

## 5. Funding applications in last year

**Table 1 Funding submissions in the reporting year**

Study	Committee & application type	CI	Outcome	Level of Group input	Funding amount
<b>Cancer Research UK*</b>					
<b>March 2021</b>					
Radiotherapy Dose De-Escalation in HPV Positive Oropharyngeal Squamous Cell Cancers, Maintaining Outcomes and Reducing Toxicity – RESPECT trial	CRUK December 2020	Dr Claire Paterson E Banks and G Prue co-investigators	Not funded	Developed with input from Acute care and Toxicities WS	
<b>Other committees**</b>					
Study	Committee & application type	CI	Outcome	Level of Group input	Funding amount
Randomised controlled trial of Vinehealth digital health cancer solution	Innovate UK	Simon Skene University of Surrey Clinical trials unit ; P Leonard is NHS Trust PI	Funded	Developed with Acute care and Toxicities WS; Study design presented to the Methodology WS;	1.8 M
Engaging patients to improve the management of toxicity during and after pelvic radiotherapy for gynaecological and anorectal cancers. Randomised controlled trial of eHealth intervention: eRAPID	NIHR HTA	G Velikova	Not funded	Methodology WS - presentation and discussion of study design Collaboration with CTRad – proposal presented in 2019	2.4M
SafeFit: Virtual clinics to deliver a multimodal intervention to improve psychological and physical wellbeing in people with cancer CG co-investigator.	Wessex Cancer Alliance Covid-19 Innovation Fund.	Chloe Grimmett Co-I	Funded	Developed with Acute care and Toxicities WS	
Networked Safety for patients undergoing treatment for cancer: a multicentre randomised controlled trial of a patient held digital checklist, personalised for side	HSDR February 2021	Chris Subbe) P Leonard and G Prue co-investigators	Pending	Developed with Acute care and Toxicities WS	

effects of treatment for cancer and shared with the acute oncology team and a friend or family member					
BENEFIT: Behaviour, Exercise and Nutrition for Fatigue after COVID.	NIHR Oct 2020	G Prue Co-lead PI	Not funded	Developed with LWBC group members (G Prue, SH Ahmedzai, Mieke Van Hemelrijck and consumer member S Restorick-Banks)	£1,6M
Carib-Fit: Implementing diet, activity and psychological support to improve outcomes for patients with a diagnosis of cancer in the Caribbean	Applied Global Research Health Board Oct 2020	Chloe Grimmett Co-I	Not funded		
Risk prediction and intervention for chemotherapy induced peripheral neuropathy (CIPN)	MRC late effects call	S Faithfull	Considered out of scope	Developed by Late Consequences Workstream	
What factors should be considered when making a shared decision with patient and carers to commence and discontinue artificial nutrition at end of life?	Pan-London Research Fellowship	C Shaw (CI), J McCracken, J Hopkinson, SH Ahmedzai et al	Funded	Developed with two of LWBC group and former Supportive & Palliative Care CSG members.	
ENeRgise - a randomised trial of Exercise and Nutrition-based Rehabilitation versus standard care in people with life-limiting cancer	World Cancer Research Fund International	B Laird (CI), Tora Skeidsvoll Solheim, M Fallon, S Wootton, Annemie Schols, Peter Hall, Beth Stuart, Sam Ahmedzai, Richard Skipworth	Successful first round. Submitted for Round 2.	Developed with Sam Ahmedzai, LWBC group member	£350K

\*CRUK CRC applications for table 1 completed by NCRI Executive.

\*\*Other applications in the table to be completed by Group Chair.

## 6. Consumer involvement

There are now two NCRI Consumers on all five LWBC Workstreams and on the Executive Group following the latest round of recruitment. The four new Consumers who joined in early 2021 have therefore not been asked to contribute to this Annual Report. Our full Consumer membership is now as follows:

Reports from each of the groups are as follows:

### Executive Group

#### Jim Elliott

I have not been able to provide the degree of input to the Executive Group that I had wanted to during the reporting year due to pressures from my employed role at the Health Research Authority supporting the involvement of patients and the public in research to address COVID-19. I attended the full meetings at the end of March 2020, December 2020 and early March 2021 but missed the September 2020 full meeting and one of three other intermediate catch-up meetings.

The main thrust of what I have been able to contribute is in trying to ensure that the priorities from the LWBC Priority Setting Partnership remain a focus for the development of proposals from the wider group and in the review of proposals that come to the group for review. I have also been trying to ensure that all the Consumers across the different LWBC work streams have the opportunity to feed in ideas or issues to the Executive Group. I invited all the LWBC Consumers to meet just before the Executive Group meeting and we did that in March 2020. Unfortunately, I wasn't able to maintain that for the following meetings but have now reinstated it for June 2021 onwards.

I am delighted to welcome Emily Travis to join me as a fellow NCRI Consumer on the Executive Group and am looking forward to working with her.

### Metastasis of Unknown Origin & Cancer of Unknown Primary

#### John Symons

It has obviously been a very challenging year because of the Pandemic and it is a great tribute to the Chairman and other HCPs on the subgroup that some meetings have been held using Zoom and Teams. I would suggest that it is too early to determine the 'impact' of the group, or individual impact, at this stage.

Due to an administrative hiatus in the forming of the present group, I was initially omitted (I sat on the group in its previous existence and was told that I would be automatically transferred to the new LWBC subgroup; but this did not happen.) Whilst my primary role is as a patient advocate, I'm in a slightly unusual position in that my 'day job' is as Director of the CUP Foundation. Once I was in post, I have been able to share my knowledge of what is happening in the CUP arena in the UK and around the world. In the UK there are active trials that the CUP Foundation has either been contributing funds for, or has been involved with the trial design. Examples being:

- **CUPEM:** Imperial. 3 centres in London investigating the benefits of immunotherapy treatment (Pembrolizumab)
- **CUPISCO:** The worldwide *Roche* trial.
- **Circulating Tumour Cell research:** CRUK Manchester Institute. Investigating the viability of liquid biopsies in relation to CUP, and to characterise CUP tumours molecularly in order to gain greater understanding of their biology and behaviour.
- **CUP-COMP:** The Christie NHS Foundation Trust. A comparative study across tissue and liquid biomarkers for CUP.

I have introduced a prospective trial to the Group: 'Analysing the Intratumoral Microbiome in Cancer of Unknown Primary and exploring diagnostic and biomarker utility'. This is a trial which is to be run by Imperial and is funded by the CUP Foundation. Consideration is presently being given as to what help NCRI can give the project (eg badging, peer review, tissue access).

Carried over from its previous incarnation, the sub group has taken on the plan to evaluate **Cancer of Unknown Primary Patient Decision Making Aids (CUPPA)** and this has been discussed at all the meetings I have attended this year. The *CUP Foundation* with *Sue Ryder* have produced a series of 5 patient decision aids for patients with MUO/CUP, their families and carers (2019). The five decision aids include information about having standard tests, having genetic tests, taking part in research, having systemic treatment and supportive or palliative care. Obtaining feedback from patients, their carers/family and health care professions will help validate and guide the PDAs ongoing development for the maximum benefit of future patients with this difficult cancer. Members of the NCRI MUO/CUP group have agreed to participate in this project as part of quality improvement and service evaluation. The discussion this year have focused primarily on methodology and implementation issues in relation to questionnaires to be distributed in FY21/22.

### **Janice Rose**

Meetings for the MUO/CUP Workstream have taken place throughout the year via Zoom. Although they are not as good as seeing people face to face, meeting this way has enabled the group to make progress with its strategy. I am getting to know the members on the group, many of whom I did not know before joining the group.

I was asked to review the project, 'Cancer of Unknown Primary Bio Study: Prospective Bio sample and clinical data collection'. Ethics approval was required for this study to go ahead and it needed to be reviewed by a patient. The Chief Investigator is Dr Sally Clive at NHS Lothian is also Deputy Chair of the LWBC MUO/CUP Workstream. I gave feedback on the protocol, patient information sheet and consent form. The project received ethics approval and 28 patients have been recruited to date.

Before becoming a Consumer member on the MUO/CUP Workstream I contributed as a patient representative to the Patient Decision Aids for MUO/CUP patients, their carers and families which are now available to view on the CUP Foundation website. This work was supported by the CUP Foundation and health professionals at the Sue Ryder Hospice, Cheltenham and Gloucestershire Hospitals NHS Foundation Trust. Evaluation of the decision aids has been identified as a target by the MUO/CUP Workstream. We want to see if and how the decision aids help patients, carers and their families make decisions about their treatment and care and whether they can be improved in any way. The project is viewed as a service improvement project. It will be carried out at cancer centres where members of the workstream are employed. Good progress is being made in developing the questionnaires for patients, cares, health professionals, a patient information sheet and guidelines for obtaining approval for the study at the cancer centres. I am working with John Symons (Consumer Member), Richard Wagland (Senior Fellow), Gillian Knowles (Nurse Consultant )and Sally Clive (Medical Oncologist) on this project.

### **Acute Care & Toxicities**

#### **Elsbeth Banks**

I was able to participate in an early face to face workstream meeting ahead of the COVID-19 restrictions which was beneficial to me in building relationships with new colleagues. Since then we have had scheduled regular online meetings in which I have been encouraged to play a full and active part in all agenda items thanks to the inclusive approach of the workstream joint chairs.

Early contributions included reviewing and responding to the workstream strategy and supporting the development of an Idea Scoping survey which would serve both to raise awareness of the new strategy group and explore new ideas for research. The survey is on hold during the pandemic and will be revisited.

Included in the range of studies that have been presented to the workstream for review and support was the Respect Trial - Radiotherapy Dose De-Escalation in HPV Positive Oropharyngeal Squamous Cell Cancers, Maintaining Outcomes and Reducing Toxicity. I am one of two workstream members who are co-applicants in this study.

I am also a member of the workstream subgroup that is currently developing a study that will focus on the introduction of prehabilitation for people who are diagnosed via the emergency route.

Together with other LWBC Consumer representatives, I received an invitation to review the BENEFIT Study and provided detailed feedback on this proposal to study the problem of fatigue in not just cancer patients, but also previously healthy people and those with long-term inflammatory conditions.

I have offered to represent both workstream and consumers on the proposed Immunotherapy and Toxicities Working Party.

In March 2021 I participated in an NCRI LWBC Prehabilitation Proposal Guidance session where two proposals were considered and then in April 2021 I was invited to contribute to an NCRI SPED Proposal Guidance session. The role of the consumer in such a forum is pivotal in both acknowledging good practice and in highlighting areas where PPI should be strengthened. NCRI places high value in the consumer voice in his context.

I was delighted recently to welcome my colleague Dave Chuter to the workstream following his appointment as a fellow consumer.

## **Late Consequences**

### **Julie Wolfarth**

Despite the problems of being unable to meet face-to-face, Zoom has worked exceptionally well for us. Our meetings have all been very well attended and we have benefitted from guest speakers who have brought a fresh perspective, increased our knowledge and stimulated lively discussions.

Following an inspiring presentation "Cardiac oncology: frontiers of research and potential collaboration", we have been working on a Heart4Health review which is focussed on late effects of radiotherapy on the heart. A Dragon's Den session in January 2021 resulted in good support and interest. The sub-group I'm involved in has met 8 times between July 2020 and March 2021 and what has been achieved in a short time is down to a strong level of commitment and enthusiasm. Breast Cancer NOW is fully on board. Next steps are mock interviews with consumers (already identified) and completion of clinical oncology questionnaires.

I have benefitted from having the Chair as my mentor. She has helped (probably without realising it) to keep me motivated, focussed and achieve 2 successes this year: being appointed as Patient Representative on East Midlands Radiotherapy ODN and re-establishing links with East Midlands NIHR Cancer Research Network. I continue to raise the importance of research at every opportunity. Two other potential research projects which I have been asked to support/advise on are Head & Neck Adaptive Radiotherapy, and the development of an app for lung cancer patients.

In a year where people's time has been stretched and communication has had to change, I feel we have had a successful year. Establishing a way of working with other LWBC and NCRI teams is something that needs to be progressed. I am a member of CTRad Workstream 4. Unfortunately,



meetings have been cancelled and I was unable to have a discussion on the H4H project. Hopefully things will improve in 2021.

Finally, this year we have been able to welcome a new consumer representative, Tim Wright onto the team.

## **Advanced Disease & End of Life Care**

### **Susan Restorick-Banks**

In these exceptional times three 'team' calls have occurred with the advanced diseases and end of life care workstream. The calls were looking at possible research for the workstream. As a consumer I have taken an active part in the discussions of what research we can undertake in our workstream bearing in mind our priorities. I believe my impact as a consumer has been to suggest ways forward on these calls and looking at ideas. I have been prepared for all the calls and will continue to support the workstream

My scientific mentor Dr Lynn Calman and I have had discussions and we have a very good working relationship, possibly as we have/are working together already on various research projects.

One thing highlighted to me as a consumer is the funding issue for any research. Most charities have stopped funding currently and this will be a barrier for any research in the future.

### **Margaret Johnson**

Group started by discussing projects we were each involved in and our specific interests.

Working very much as a team we have looked at under-researched areas that we could develop into worthwhile research topics that would bring the most benefit to patients.

My involvement in Primary Care research meant I could mention anticipatory prescribing and the need for guidelines, the lack of bereavement care generally and complicated grief. From my Paediatric involvement - research with rapid pain relief medications.

Psychological wellbeing and the support needs of patients led to thinking about whether patients are appropriately assessed and actually offered appropriate psycho-social interventions, also the inequity of access to such help anyway.

Was able to talk about a first – paediatrics usually have to use the experience of adult medications to work out appropriate dosage for children. With COVID and the lack of district nurses to administer rapid pain relief, usually by injection, there was a huge need for a safe way for carers to administer rapid pain relief, a topic very close to the hearts of parents of children with life limiting illnesses and the subject of present research into transmucosal pain relief meds in which I am involved. Clinicians turned to paediatrics for experience over using buccal and nasal sprays.

## **Methodology**

### **Jim Elliott**

I was able to attend all three work stream meetings during the reporting year (May 2020, November 2020 and February 2021). Because much of the focus of the group has been on establishing its ways of working to provide methodological advice on proposals across all areas of the LWBC agenda but also more widely because it is the only NCRI methodology group (at the moment) my input has mainly been to ensure that the need is recognised and acted on to involve Consumers from the earliest stage in the development of new studies.

The group developed a template for researchers to complete in order to submit a request for methodological advice from its 'Methodology AdVIsory Service' (MAVIS) and I ensured that this included a section on Consumer involvement. Unfortunately, due to work pressures I was unable to provide input in time for the assessment of the initial round of applications that used the template but on reviewing them later it was clear that the Consumer involvement section had had an impact in that there was evidence of Consumer involvement for most of them and a clear intention to involve Consumers in the rest.

The Workstream Chair had to stand down towards the end of the reporting year and as part of our discussions about the appointment of new chair I have suggested that the group consider having a Consumer co-chair, an approach which has been adopted by one of the Breast Group sub-groups. This was supported in principle and should help to ensure the involvement of Consumers early in the development of new studies.

I am delighted to welcome Daksha Trivedi to join me as a fellow NCRI Consumer on the Methodology Workstream and am looking forward to working with her.

## 7. Collaborative partnership studies with industry

These partnerships are described under each Workstream. Notably, one new collaboration with Vinehealth, a digital health company, resulted in a successful Innovate UK funding for a multicentre RCT.

Sam Ahmedzai is working with CBD Science Group on a cannabis-based medicine trial for cancer-related pain. This study is being developed with input from ACT and ADEL Workstreams.

Sam Ahmedzai is also working with NCRI Gynae Group and GSK to develop a 'real world evidence' study of holistic outcomes in patients with ovarian cancer on PARP inhibitors.

## 8. Priorities and challenges for the forthcoming year

<p><b><u>Priority 1</u></b></p> <p>Increase our collaboration with other NCRI Groups.</p>
<p><b><u>Priority 2</u></b></p> <p>Workstreams to engage more proactively in supporting proposals generated by the other NCRI groups.</p>
<p><b><u>Priority 3</u></b></p> <p>We need to pro-actively market in NCRI our methodology support via MAVIS</p>
<p><b><u>Challenge 1</u></b></p> <p>How to streamline LWBC proposals reviews and the general NCRI-wide proposal guidance workshops?</p>
<p><b><u>Challenge 2</u></b></p> <p>LWBC members need to get involved early in discussions on funding calls to provide PROMs measurement and design expertise.</p>

**Challenge 3**

How to get back online MAVIS template for proposals?

**Challenge 4**

How to avoid the potential confusion between NCRI LWBC Initiative and the LWBC Group with its specific remit and activities?

**Professor Sam Ahmedzai and Professor Galina Velikova**

**(Living With & Beyond Cancer Group Co-Chairs)**

## Appendix 1

### Membership of the Living With & Beyond Cancer Group

Name	Specialism	Location
Ms. Emily Travis	Consumer	
Mr Jim Elliott	Consumer	Newport
Dr Lynn Calman	Health Services Researcher	Southampton
Prof. Mari Lloyd-Williams	Palliative Medicine	Liverpool
Prof Sam Ahmedzai (Co-Chair)	Palliative Medicine	Sheffield
Professor Galina Velikova (Co-Chair)	Medical Oncologist	Leeds
Dr Pauline Leonard	Medical Oncologist	London
Dr Kai-Keen Shiu	Medical Oncologist	London
Dr Gillian Prue	Nurse	Belfast
Prof. Sara Faithfull	Nurse	Surrey

### Membership of the Workstreams

Metastasis of Unknown Origin and Cancer of Unknown Primary Workstream		
Name	Specialism	Location
Dr Alicia-Marie Conway*	Clinical Fellow	Manchester
Dr Richard Wagland	Clinical Lecturer	Southampton
Ms Janice Rose	Consumer	Gloucester
Dr John Symons	Consumer	Cirencester
Dr Kai-Keen Shiu (Chair)	Medical Oncologist	London
Dr Claire Mitchell	Medical Oncologist	Manchester
Dr Sally Clive	Medical Oncologist	Edinburgh
Ms Gillian Knowles	Nurse	Edinburgh
Dr Manuel Rodriguez-Justo	Pathologist	London
Dr Ben Taylor	Radiologist	Manchester

Acute Care and Toxicities Workstream		
Name	Specialism	Location
Dr Tim Cooksley	Acute Medicine Consultant	Manchester
Dr Chloe Grimmett	Clinical Research Fellow	Southampton
Mr David Chuter	Consumer	West Sussex
Mrs Elspeth Banks	Consumer	Carlisle
Dr Andrew Stewart	Consultant Haematologist	Bristol
Dr Tania Kalsi	Geriatric Consultant	London
Dr Pauline Leonard (Co-Chair)	Medical Oncologist	London
Dr Louise Carter	Medical Oncologist	Manchester
Dr Susan Catt	Nurse	Sussex
Ms. Suriya Kirkpatrick	Nurse	Bristol
Dr Gillian Prue (Co-Chair)	Nurse	Belfast

<b>Late Consequences Workstream</b>		
<b>Name</b>	<b>Specialism</b>	<b>Location</b>
Dr Rebecca Shakir	Clinical Oncologist	Oxford
Mr. Tim Wright	Consumer	West Midlands
Mrs. Julie Wolfarth	Consumer	Lincolnshire
Professor Linda Sharp	Epidemiologist	Newcastle
Dr Dipesh Gopal*	General Practitioner	London
Prof. Eila Watson	Health Services Researcher	Oxford
Prof. John Radford	Medical Oncologist	Manchester
Dr Marianne Aznar	Medical Physicist	Manchester
Prof. Sara Faithfull (Chair)	Nurse	Surrey
Dr Sara MacLennan	Psychologist	Aberdeen
Miss Amy Taylor	Radiographer	Sheffield
Mr Peter Donnelly		London

<b>Advanced Disease and End of Life Care Workstream</b>		
<b>Name</b>	<b>Specialism</b>	<b>Location</b>
Ms. Sandra Prew	Clinical Research Nurse	Birmingham
Mrs Margaret Johnson	Consumer	Balsham
Mrs Susan Restorick-Banks	Consumer	Southampton
Dr Mieke Van Hemelrijck	Epidemiologist	London
Dr Andrew Carson-Stevens	General Practitioner	Cardiff
Dr Lynn Calman (Co-Chair)	Health Services Researcher	Southampton
Professor Mari Lloyd-Williams (Co-Chair)	Palliative Medicine	Liverpool
Dr Catriona Mayland	Palliative Medicine	Sheffield
Dr Donna Wakefield*	Palliative Medicine Consultant	Newcastle
Dr Andrew Dickman	Pharmacist	Blackpool
Dr Lisa Graham-Wisener*	Psychologist	Belfast
Ms Brooke Swash	Psychologist	Chester

<b>Methodology Workstream</b>		
<b>Name</b>	<b>Specialism</b>	<b>Location</b>
Dr Alexandra Gilbert	Clinical Oncologist	Leeds
Dr Daksha Trivedi	Consumer	Bedfordshire
Mr Jim Elliott	Consumer	Newport
Dr Derek Kyte (Chair)	Health Services Researcher	Worcester
Dr Lynn Calman**	Health Services Researcher	Southampton
Dr Peter Hall	Medical Oncologist	Edinburgh
Dr Nicola Gray	Project Manager	Dundee
Prof. Claire Foster	Psychologist	Southampton
Dr Emily Harrop*	Research Fellow	Cardiff
Dr Sally Wheelwright	Research Fellow	Southampton
Dr Mike Horton	Research Fellow	Leeds
Dr Debbie Cavers*	Research Fellow	Edinburgh
Mrs. Michelle Collinson	Statistician	Leeds

\* denotes trainee member

\*\*denotes non-core member

## Appendix 2

### Living With & Beyond Cancer Group & Workstream Strategies

**A – Living With & Beyond Cancer Group Strategy - Updates are in the last column. For the Workstreams, the updates are highlighted.**

Strategic area	Overall Group Strategy	Update for 2021
1. Overall aim	The LWBC Group aims to improve the quality, and increase the quantity, of multidisciplinary research into outcomes for people affected by cancer at all stages of disease; and for their carers.	Overall aim remains the same. We are a new Group and a formal strategy review will be planned for 2022 or even 2023
2. Objectives	<ul style="list-style-type: none"> <li>a. Raise awareness of research into outcomes for people with cancer at all stages of disease, including long-term survivorship and at end of life; and for their carers.</li> <li>b. Stimulate new studies using a range of current and innovative approaches, into improving and measuring outcomes.</li> <li>c. Design and secure funding for research supporting our aim.</li> <li>d. Collaborate with other research groups both in UK and abroad to achieve our aim.</li> <li>e. Seek new sources of funding for research meeting our aim.</li> <li>f. Increasing outputs of the Group with respect to publications and presentations.</li> <li>g. Advise and support other researchers in the NCRI to design their own studies into measuring and improving patient outcomes.</li> </ul>	Progress has been made on all objective, outlined below We will keep the same for next year New- To study the impact of COVID-19 illness and restrictions on experiences of cancer patients, including the expected delayed diagnoses and treatments.
3. Scope of work	The LWBC Group will cover all cancer types and patients at all stages of illness, including those without a current histological diagnosis. It will include all aspects of patient and carer wellbeing. It will cover physical, psychological, social, spiritual, cultural, and financial consequences of cancer illness. This broad spectrum of research will be covered through four workstreams focusing on different stages of cancer illness; and one workstream focusing on research methodologies applicable to all stages.	Ongoing. Workstreams were established and started working with regular virtual meetings.

4. Membership and expertise	The LWBC Group will consist of a multidisciplinary mix of healthcare professionals, researchers and patient/carer representatives. The Group will maintain a Directory of skills and areas of expertise of its members.	Ongoing. Multi-disciplinary membership is established with ongoing monitoring to identify gaps in the skills and recruit new members where appropriate. Interviews were conducted and additional consumer members were appointed (2 per WS and 2 on the EC)
5. Relationship with other groups	The LWBC Group will actively seek out liaisons with other NCRI Groups to design studies relevant to specific disease types and age groups. It will also work with other research organisations including charities, in UK and abroad.	May 2020 - Collaboration with CTRad on pelvic radiotherapy HTA application.
6. Development of studies and grant proposals	The LWBC Group will set targets for numbers of new studies and grant submissions in each of the Workstreams. In the first year, there will be at least one project grant submission per Workstream. By year 2 there will be at least programme grant from the Group per year.	
7. Translational research	The LWBC Group seeks to increase the amount of mechanistic research in understanding and predicting patient outcomes, as part of the drive towards 'personalised' or 'stratified' medicine in oncology. It will work towards including translational research questions in studies wherever relevant and seek additional funding to answer these accordingly.	Co-chairs are engaged with NCRI Immunotherapy toxicities working group- limited progress Several project of MUO/CUP WS have translational questions (CUP-COMP. A comparative study across tissue and liquid biomarkers for CUP; Cancer of Unknown Primary Bio Study: Prospective Bio sample and clinical data collection). Late consequences WS project on peripheral neuropathy and Heart health include translational components.
8. Industrial / commercial engagement	The LWBC Group will broaden the engagement with industry and increase the level of commercial support for this area of cancer research. Commercial engagement will include pharmaceutical, surgical, radiation therapy and medical devices industries; data collection devices and apps; and other relevant industrially supported research.	Collaborative project with Vinehealth – Oct 2020 Innovate UK application

9. New technologies and approaches	<p>The LWBC Group will actively develop new technologies and approaches for conducting studies in elucidating patient and carer outcomes in cancer.</p> <p>We will explore the applicability of approaches becoming established in oncology as 'personalised' or 'stratified' medicine, adapting them to the LWBC aims and objectives.</p> <p>This may be done as 'standalone' studies, or in conjunction with other NCRI Groups or outside organisations.</p>	Continued evaluation of eHealth approaches to symptom and side-effects monitoring. Example is the HTA application for symptom monitoring during and after pelvic radiotherapy for gynaecological cancers.
10. Outputs of work	<p>The LWBC Group will maintain a register of its outputs in terms of publications and presentations at national and international level.</p> <p>We will also seek to measure the impact of the published work, in terms of benefit to patients and to the NHS.</p>	See publications
11. Advising and supporting other NCRI groups (and others)	<p>The LWBC Group is a cross-cutting resource to not only all of its members in each Workstream, but also other NCRI Groups and eventually, other researchers.</p> <p>We will publish – initially within NCRI – a template for applications to the Group and its Workstreams for advice and comments on study design and grant applications; and for letters of support and endorsement.</p>	Establishing MAVIS service. Completed. Ongoing 6 monthly proposals review meetings with a focus on trial design and use of PROMs.



## B – Metastases of Unknown Origin (MUO) and Cancer of Unknown Primary (CUP) Workstream Strategy

Strategic area	Overall Group Strategy	Workstream Strategy	Milestones	Outputs
1. Overall aim	The LWBC Group aims to improve the quality, and increase the quantity, of multidisciplinary research into outcomes for people affected by cancer at all stages of disease; and for their carers.	The MUO-CUP Workstream aims to improve the quality, expertise and increase the quantity of multidisciplinary research into outcomes for people MUO, or presumed CUP or Confirmed CUP diagnosis	<ul style="list-style-type: none"> <li>Version 1.0 circulated before end Dec 2019</li> <li>Version 2.0 agreed by Annual Meeting March 2020</li> </ul>	<ul style="list-style-type: none"> <li>Draft 1.0 and circulated internally</li> <li>Version 2.0 published March 2020</li> </ul>
2. Objectives	<ol style="list-style-type: none"> <li>Raise awareness of research into outcomes for people with cancer at all stages of disease, including longterm survivorship and at end of life; and for their carers.</li> <li>Stimulate new studies using a range of current and innovative approaches, into improving and measuring outcomes.</li> <li>Design and secure funding for research supporting our aim.</li> <li>Collaborate with other research groups both in UK and abroad to achieve our aim.</li> <li>Seek new sources of funding for research meeting our aim.</li> </ol>	<ol style="list-style-type: none"> <li>National expertise in CUP/MUO Workstream aim to capture 90% of CUP and MUO clinical and nursing leads in all UK hospitals with a CUP MDT collated from Cancer Alliances, UKONS networks and other contacts which will be updated annually Design a questionnaire to discuss evolving future of the workforce and research capabilities in each hospital/region</li> <li>Workstream aim to stimulate studies in 3 main arenas 1) Develop tools to capture patient reported outcome and experience measures to enhance patient involvement decision making and satisfaction in their care in challenging diagnostic and therapeutic environment. We continue to develop and test CUPPA (Cancer of Unknown Primary Patient Decision Aids) in collaboration with CUP Jo Foundation</li> </ol>	<ol style="list-style-type: none"> <li>National leads database: Nov 2020</li> <li>CUPPA – ongoing with first test outputs by Nov 2020 Biomarkers – ongoing – see Innovate UK CUP-COMP programme Trials - ongoing</li> </ol>	

	<p>f. Increasing outputs of the Group with respect to publications and presentations.</p> <p>g. Advise and support other researchers in the NCRI to design their own studies into measuring and improving patient outcomes.</p>	<p>2) Prognostic and predictive biomarkers in CUP          Collaborations with academic sites/biobanks and pharmaceutical/commercial diagnostic companies to increase access for patients to</p> <ol style="list-style-type: none"> <li>1) Studies using existing clinical biomarkers</li> <li>2) Studies to access solid tissue molecular profiling</li> <li>3) Studies to access liquid/blood biomarker molecular profiling</li> </ol> <p>3) Supporting existing and develop new clinical studies or trials for patients with MUO-CUP.</p> <ol style="list-style-type: none"> <li>1) The Workstream fully support the recruitment of patients into the International Phase 2 CUPISCO trial, CUPem, PEACE, CUP TCGA and other studies.</li> <li>2) It will work to ensure not only primary but, exploratory objectives can be achieved for both commercial and academic studies.</li> <li>3) A network of tissue biobanks in the UK for CUP patients so that ideas and questions generated by board members and collaborators nationally and internationally can tested on existing and future tissue samples from patient with CUP</li> </ol> <p>c. All supported studies will have defined aims and outputs, have designated funding and plan to</p>		
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		be collaborative across the LWBC group to achieve their objectives.		
3. Scope of work	The LWBC Group will cover all cancer types and patients at all stages of illness, including those without a current histological diagnosis. It will include all aspects of patient and carer wellbeing. It will cover physical, psychological, social, spiritual, cultural, and financial consequences of cancer illness. This broad spectrum of research will be covered through four workstreams focusing on different stages of cancer illness; and one workstream focusing on research methodologies applicable to all stages.	The MUO-CUP work group will focus <ol style="list-style-type: none"> <li>1) the broad challenges that patients with MUO-CUP face in terms of accessing standard and novel diagnostics and holistic care/support they require.</li> <li>2) Biomarker testing</li> <li>3) Establishment of CUP Biobanks</li> <li>4) Support existing MUO-CUP studies or trials</li> <li>5) Develop new MUO-CUP studies or trials</li> </ol>	Ongoing	
4. Membership and expertise	The LWBC Group will consist of a multidisciplinary mix of healthcare professionals, researchers and patient/carer representatives. The Group will maintain a Directory of skills and areas of expertise of its members.	The MUO-CUP workstream consists multidisciplinary mix of healthcare professionals, researchers and patient/carer representatives. The Group will maintain a Directory of skills and areas of expertise of its members.	March 2020	
5. Relationship with other groups	The LWBC Group will actively seek out liaisons with other NCRI Groups to design studies relevant to specific disease types and age groups. It will also work with other research organisations including charities, in UK and abroad.	The MUO-CUP Group will actively seek out liaisons with other NCRI Groups to design studies relevant to specific disease types and age groups. It will also work with other research organisations including charities, in UK and abroad.	Ongoing	

<p>6. Development of studies and grant proposals</p>	<p>The LWBC Group will set targets for numbers of new studies and grant submissions in each of the Workstreams. In the first year, there will be at least one project grant submission per Workstream. By year 2 there will be at least programme grant from the Group per year.</p>	<p>In April 2020 the MUO-CUP group support a £1.5million programme grant via Innovate UK (CUP-COMP Carcinoma of Unknown Primary (CUP): A comparison across tissue and liquid biomarkers' where The Christie Hospital are sponsors, Dr Natalie Cook is Chief Investigator, many oncologists on the workstream are co-investigators, and Roche and CONCR are commercial collaborators. One of the main aims is to perform solid and liquid (blood) genome profiling on up to 150 patient with CUP. The objectives are the:</p> <ul style="list-style-type: none"> <li>• Assessment of genomic sequencing (both in tissue and blood) for the diagnosis and treatment stratification in patients with CUP including a comparison of the effectiveness of tissue and blood based biomarkers</li> <li>• Collection of evidence to further develop technology that predicts an individual's response to a treatment.</li> <li>• Development of innovative systems of clinical data capture in patients with CUP</li> </ul>	<p>Ongoing – CUP-COMP will aim to recruit first patients by Jan 2021</p>	
<p>7. Translational research</p>	<p>The LWBC Group seeks to increase the amount of mechanistic research in understanding and predicting patient outcomes, as part of the drive towards</p>	<p>The MUO-CUP work stream modus operandi is to ensure all studies have clinically relevant translational research questions and objectives, and will be flexible in the approach in</p>	<p>Ongoing</p>	

	<p>'personalised' or 'stratified' medicine in oncology. It will work towards including translational research questions in studies wherever relevant and seek additional funding to answer these accordingly.</p>	<p>funding different aspects of research within and between studies, especially if there shared/integrated outputs</p>		
8. Industrial / commercial engagement	<p>The LWBC Group will broaden the engagement with industry and increase the level of commercial support for this area of cancer research. Commercial engagement will include pharmaceutical, surgical, radiation therapy and medical devices industries; data collection devices and apps; and other relevant industrially supported research.</p>	<p>The MUO-CUP workstream have already good established links with industry and achieved commercial support for existing and future projects. The board will continue to seek further industry/commercial collaborators to benefit patients with CUP so we can answer relevant clinical and research questions.</p>	Ongoing	
9. New technologies and approaches	<p>The LWBC Group will actively develop new technologies and approaches for conducting studies in elucidating patient and carer outcomes in cancer. We will explore the applicability of approaches becoming established in oncology as 'personalised' or 'stratified' medicine, adapting them to the LWBC aims and objectives. This may be done as 'standalone' studies, or in conjunction with other NCRI</p>	<p>The MUO-CUP workstream are actively developing new technologies within existing academic centres and commercial and/or investigator led studies</p> <p>We are keen to do these studies in collaboration with other NCRI groups and international MUO-CUP consortiums</p>	Ongoing	

	Groups or outside organisations.			
10. Outputs of work	<p>The LWBC Group will maintain a register of its outputs in terms of publications and presentations at national and international level. We will also seek to measure the impact of the published work, in terms of benefit to patients and to the NHS.</p>	<p>All outputs of the MUO-CUP work group in terms of abstracts, posters, presentations and publications will be registered.</p> <p>MUO-CUP group were going to host a session at NCRI Annual meeting in Belfast November 2020. This was postponed due to COVID-19 outbreak but we aim still to showcase outputs of our groups virtually/Webinars of the next year.</p>	<p>Ongoing</p> <p>Title: A biobank analysis of prognostic biomarkers of the systemic inflammatory response in patients presenting with malignancy of undefined primary origin</p> <p>Authors: M Stares<sup>1,2*</sup>, R Patton<sup>1*</sup>, G Knowles<sup>1</sup>, R Haigh<sup>1</sup>, C Barrie<sup>1</sup>, L Dobbs<sup>1</sup>, D McMillan<sup>3</sup>, B Laird<sup>2</sup>, S Clive<sup>1</sup></p> <p>Submitted to European Journal of Cancer May 2020</p>	
11. Advising and supporting other NCRI groups (and others)	<p>The LWBC Group is a cross-cutting resource to not only all of its members in each Workstream, but also other NCRI Groups and eventually, other researchers. We will publish – initially within NCRI – a template for applications to the Group and its Workstreams for advice</p>	<p>The MUO-CUP subgroup will create and also accept proposals for collaborative cross-cutting studies from within the LWBC group, other NCRI groups, researchers and relevant national and international entities. It will also support and advise on other projects/grant applications</p>	<p>Ongoing</p>	

	and comments on study design and grant applications; and for letters of support and endorsement.	as required by the NCRI group chairs		
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## C – Acute Care and Toxicities Workstream Strategy

Strategic area	Overall LWBC Executive Group Strategy	Acute Care and Toxicities Workstream Strategy	Milestones	Outputs
1. Overall aim	The LWBC Group aims to improve the quality, and increase the quantity, of multidisciplinary research into outcomes for people affected by cancer at all stages of disease; and for their carers.	The Acute Care and Toxicities Workstream aims to improve the quality, and increase the quantity of multidisciplinary research into outcomes for people at all stages of disease to address their acute symptoms, the acute toxicities of their treatment as well as the psychosocial impacts of treatment, prehabilitation and challenges in the primary secondary care interface	<ul style="list-style-type: none"> <li>Version 1.0 circulated before end Dec 2019</li> <li>Version 2.0 agreed by April 2020</li> </ul>	<ul style="list-style-type: none"> <li>Draft 1.0 and circulated internally</li> <li>Version 2.0 published April 2020</li> </ul>
2. Objectives	<p>a. Raise awareness of research into outcomes for people with cancer at all stages of disease, including longterm survivorship and at end of life; and for their carers.</p> <p>b. Stimulate new studies using a range of current and innovative approaches, into improving and measuring outcomes.</p>	<p>2a. The Acute Care and Toxicities Workstream will develop for distribution a “who are we” and “what do we do” information leaflet and website to include a photo and short biography on all workstream members and co-chairs.</p> <p>2b. Hold initial brainstorming meeting for potential research topics at 1<sup>st</sup> workstream meeting Dec 2019</p> <p>2b. Design a short survey to be distributed to several key national speciality groups to scope ideas</p> <p>2b. Workstream to select a range of research proposals to pursue funding</p>	<ul style="list-style-type: none"> <li>Version 1.0 to be reviewed at TC on 27.1.2020</li> <li>Version 2.0 agreed by April 2020</li> <li>Proposed portfolio of research interests to be compiled by September 2020</li> <li>To agree research proposals to focus workstream expertise on optimising</li> </ul>	<ul style="list-style-type: none"> <li>Draft 1.0 to be circulated before TC on 27.1.2020</li> <li>Version 2 to be circulated to all other workstream leads and site-specific group leads</li> <li>Portfolio to be set up on dedicated Acute care and Toxicities Workstream page on the main NCRI website</li> </ul>



	<p>c. Design and secure funding for research supporting our aim.</p> <p>d. Collaborate with other research groups both in UK and abroad to achieve our aim.</p> <p>e. Seek new sources of funding for research.</p> <p>f. Increase outputs of the Group with respect to publications and presentations.</p> <p>g. Advise and support other researchers in the</p>	<p>2c. To submit research proposals to NCRI LWBC Annual Trials meeting</p> <p>2d. Raise awareness of workstream activity with other UK and international research groups. Examples include ACP, NCRI disease specific groups and Consumer Forum, BSH, SIOG,BSG, ACPOPC, RCR, ECMC, BPOS, MASCC, BOPA &amp; UKONS</p> <p>2e. To aim to submit at least one agreed proposal to the Efficacy and Mechanisms Evaluation (EME) programme: 19/139 mitigation of the adverse effects of health and social care interventions</p> <p>2f. Workstream to identify speciality conferences to submit proposed work as oral presentation or abstract Ensure proposals are submitted to NCRI Annual Conference for presentation Completed work to be submitted to the most appropriate journal with highest impact factor</p> <p>2g. For GP and PL to keep workstream informed and connected by regular TC's and e-mail flyers. GP and PL to</p>	<ul style="list-style-type: none"> <li>• Submit research proposals for consideration at Proposal Guidance meeting by 20<sup>th</sup> February 2020</li> <li>• A list of co-research groups approached will be presented by Annual Trials meeting 2021</li> <li>• For NIHR to shortlist at least one proposal in June 2020</li> </ul>	<ul style="list-style-type: none"> <li>• Have two complete research proposal templates ready for circulation and discussion at each NCRI LWBC Annual Trials meeting.</li> <li>• PL and GP to identify a list of research groups to approach</li> <li>• Workstream to collaborate to ensure two high quality proposals to be submitted to NIHR by 16<sup>th</sup> April 2020</li> <li>• GP and PL to agree key dates for</li> </ul>
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	NCRI to design their own studies into measuring and improving patient outcomes.	demonstrate approachability and encourage all workstream members to share their research ideas & to be able to ask for support		TCs and face to face meetings throughout 2020
3. Scope of work	<p>The LWBC Group will cover all cancer types and patients at all stages of illness, including those without a current histological diagnosis. All aspects of patient and carer wellbeing will be included. Physical, psychological, social, spiritual, cultural and financial consequences of cancer illness will be covered.</p> <p>This broad spectrum of research will be covered through four workstreams focusing on different stages of cancer illness; and one workstream focusing on research methodologies applicable to all stages.</p>	<p>The Workstream will aim to develop relevant research proposals to:</p> <ul style="list-style-type: none"> <li>• Improve acute oncology pathways of care</li> <li>• Improve care to patients with cancer who may experience acute toxicities of treatment,</li> <li>• Focus research to understand the predictive factors which may influence toxicities of treatment</li> <li>• Ameliorate the symptoms caused by their cancer, improving the care and support of patients who complete their treatment and need support with self-management in primary care setting</li> <li>• Extending prehab conditions to optimise all therapies and treatments</li> <li>• Studies to address the psychological impact of treatments or adjustment to surveillance post completing definite treatment.</li> </ul> <p>All workstream approved proposals will be discussed and shared with LWBC executive team prior to any submission for funding</p>	<ul style="list-style-type: none"> <li>• Agreed membership of Acute care and toxicities workstream by Dec 2019</li> <li>• All agreed research proposals will be sent to LWBC executive team by end March 2020 for comment and review</li> </ul>	<ul style="list-style-type: none"> <li>• GP and PL to go through all applications to workstream by end September 2019</li> <li>• GP and PL to discuss with SA and GV their preferred choices</li> <li>• CB to offer places to the successful selected applicants by end September 2019</li> <li>• CB to inform unsuccessful candidates by end Dec 2019</li> </ul>
4. Membership and expertise	The LWBC Group will consist of a multidisciplinary mix of healthcare professionals, researchers	The Acute Care and Toxicities Workstream will ensure the successful applicants appointed will be from broad backgrounds, providing a range of healthcare backgrounds and	<ul style="list-style-type: none"> <li>• Version 1.0 will be reviewed by all the workstream at the annual trials meeting in March 2020</li> </ul>	<ul style="list-style-type: none"> <li>• A blank template will be distributed to all workstream members and both co-chairs</li> </ul>

	and patient/carer/consumer representatives. The Group will maintain a Directory of skills and areas of expertise of its members.	professions together with a patient/consumer. A directory will be compiled and maintained by NCRI administration staff. This will describe the background and expertise of each workstream member. It will be updated annually.		for completion by end April 2020 <ul style="list-style-type: none"> <li>• CB to edit final version for review in April 2020.</li> </ul>
5. Relationship with other groups	The LWBC Group will actively seek out liaisons with other NCRI Groups to design studies relevant to specific disease types and age groups. It will also work with other research organisations including charities, in UK and abroad.	The Acute Care and Toxicities Workstream will work with NIHR & NCRI to scope the current clinical trials portfolio to identify potential areas for collaboration with other NCRI site specific groups The Workstream Co-Chairs will set up a meeting with a range of site-specific cancer charities to scope potential areas for research. Alliances and collaborations will be built with groups such as NCRI Consumer Forum and charities such as Independent Cancer Patients' Voice and NCRI Partner charities	<ul style="list-style-type: none"> <li>• A small working party including the trainee representatives on the workstream will be created to undertake this task</li> </ul>	<ul style="list-style-type: none"> <li>• NCRI to link the key stakeholders</li> </ul>
6. Development of studies and grant proposals	The LWBC Group will set targets for numbers of new studies and grant submissions in each of the Workstreams. In the first year, there will be at least one project grant submission per Workstream. By year 2 there will be at least one programme grant from the Group per year.	This new workstream will aim to develop at least one research proposal from the Acute Care and Toxicities Workstream. The successful bid that secures funding will then be further developed towards considering a bid for a programme grant by the end of year 2021	<ul style="list-style-type: none"> <li>• By end Dec 2020 the workstream will know which submitted proposals have successfully secured funding</li> </ul>	<ul style="list-style-type: none"> <li>• By June 2020 workstream to agree at least one research proposal per subgroup</li> </ul>
7. Translational research	The LWBC Group seeks to increase the amount of mechanistic research in understanding and	The Acute Care and Toxicities Workstream will seek opportunities for mechanistic research in understanding and predicting patient outcomes, as	<ul style="list-style-type: none"> <li>• By end of Year 2 the workstream will present opportunities for mechanistic or</li> </ul>	<ul style="list-style-type: none"> <li>• By end of year 1 to review successful research protocols to determine any</li> </ul>

	<p>predicting patient outcomes, as part of the drive towards 'personalised' or 'stratified' medicine in oncology. It will work towards including translational research questions in studies wherever relevant and seek additional funding to answer these accordingly.</p>	<p>part of the drive towards 'personalised' or 'stratified' medicine in oncology. It will work towards including translational research questions in studies wherever relevant and seek additional funding to answer these accordingly.</p>	<p>translational research</p>	<p>potential for a translational component</p>
<p>8. Industrial / commercial engagement</p>	<p>The LWBC Group will broaden the engagement with industry and increase the level of commercial support for this area of cancer research. Commercial engagement will include pharmaceutical, surgical, radiation therapy and medical devices industries; data collection devices and apps; and other relevant industrially supported research.</p>	<p>The Acute Care and Toxicities Workstream will develop an engagement with industry and look to secure commercial support for some of the proposed projects. Commercial engagement will include pharmaceutical, surgical, radiation therapy and medical devices industries; data collection devices and apps; and other relevant industrially supported research.</p>	<ul style="list-style-type: none"> <li>• By end of Y2 Co-chairs PL &amp; GP will present a list of companies that have been scoped for funding support</li> </ul>	<ul style="list-style-type: none"> <li>• PL&amp; GP to identify potential commercial partners to proposed research protocols</li> </ul>
<p>9. New technologies and approaches</p>	<p>The LWBC Group will actively develop new technologies and approaches for conducting studies in elucidating patient and carer outcomes in cancer. We will explore the applicability of approaches becoming established in oncology as 'personalised' or 'stratified' medicine, adapting them to the LWBC aims and objectives.</p>	<p>The Acute Care and Toxicities Workstream will work closely with the whole LWBC group &amp; executive team to ensure any identified new technologies for conducting research is reviewed for its applicability in this sub-group</p>	<ul style="list-style-type: none"> <li>• To understand the proposed timeline for this objective at the annual trials meeting in March 2020</li> </ul>	

	This may be done as 'standalone' studies, or in conjunction with other NCRI Groups or outside organisations.			
10. Outputs of work	The LWBC Group will maintain a register of its outputs in terms of publications and presentations at national and international level. We will also seek to measure the impact of the published work, in terms of benefit to patients and to the NHS.	The Acute Care and Toxicities Workstream will maintain a register on the LWBC home page of its outputs in terms of publications and presentations at national and international level. We will also seek to measure the impact of the published work, in terms of benefit to patients and to the NHS.	<ul style="list-style-type: none"> <li>By Y3 a review of all proposals will be undertaken, and any published abstracts or oral presentations collated</li> </ul>	
11. Advising and supporting other NCRI groups (and others)	The LWBC Group is a cross-cutting resource to not only all of its members in each Workstream, but also other NCRI Groups, and eventually, other researchers. We will publish – initially within NCRI – a template for applications to the Group and its Workstreams for advice and comments on study design and grant applications; and for letters of support and endorsement.	The Acute Care and Toxicities Workstream will adopt the NCRI template for applications to the Group and its Workstreams for advice and comments on study design and grant applications; and for letters of support and endorsement.	<ul style="list-style-type: none"> <li>To fill a standing item on the biannual face to face meeting with external groups looking for advice on study proposals</li> </ul>	<ul style="list-style-type: none"> <li>CB to share dates of agreed face to face meetings of the Acute Care and Toxicities Workstream with all national CRN leads with an invitation to present proposed research</li> </ul>

### Strategic aims

- To develop collaborative projects with other NCRI site specific groups.
- To recruit to the VineHealth app randomised controlled trial testing the utility of artificial intelligence & technology devices to improve the safety & experience of patient care

- To complete a feasibility pilot project to determine the research questions to address the specific needs of patients who present with a new metastatic cancer via the emergency route to improve their fitness for treatment using a prehabilitation intervention.

## D – Late Consequences Workstream Strategy

**1. Overall aim:** The late consequences work stream aims to improve the quality and quantity of research into late consequences and survivorship support for adults living with and beyond a cancer diagnosis

**2. Objectives:**

- a. Raise awareness of ongoing research into late consequences and grow the number of studies registered on the NCRI portfolio
- b. Design and secure funding for multidisciplinary studies on late consequences within mechanistic, translation, health services and research for patient benefit grants
- c. Improve networking and multidisciplinary collaboration in late consequences research
- d. Expand outcome reporting and harmonisation for future cross study comparisons
- e. Collaborate with other research groups both in the UK and abroad (MASCC, ESTRO, ESMO, WCRF)
- f. Seek new sources of funding for late consequences in priority areas
- g. Advise and support other researchers in the NCRI and in clinical academic groups to design their own studies

**3. Scope of work:**

Late consequences are defined as intermediate, persistent and late effects of cancer treatment that cause physical and psychosocial morbidity which may result in reduced quality of life. The advent of novel therapies has resulted in new symptoms and side-effects emerging. Late consequences are those including; second cancers, cardiovascular disease, bone and musculoskeletal disorders, gastrointestinal and bladder dysfunction and endocrine dyscrasias. The true impact of these is not clearly defined in clinical trials, which typically treat a highly-selected population.

Research on late consequences may start prior to start of therapy with; biomarkers and defining risk, epidemiology of late effects, stratifying patients at risk to therapies with less late consequences, basic science of symptoms, mitigating side-effects with novel interventions, as well as influencing late toxicity recording, management and safety profiling. Late consequences of cancer treatment overlaps with the concept of survivorship.

Cancer survivorship focuses on the distinct phase of cancer care that takes place after active treatment and includes, physical, mental health and social aspects of living with and after a cancer diagnosis. The translation of management of these into services is defined as survivorship care. We aim to focus on 3 areas: (i) prevention (ii) Identifying scale of problem through big data and (iii) what do we do when people have late-effects from cancer treatment.

**4. Membership and expertise:**

The late consequences work group team will reflect a multidisciplinary team with two trainee positions for those new into research as well as one consumer representative. The group will aim to provide diversity of gender, profession as well as a mix of NHS and academic roles. Additional consumer representatives will be invited into the group meetings where relevant to represent specific late consequences.

**5. Relationships with other groups:**

The Late consequences group will work actively with the acute toxicity group and seek out liaisons with other NCRI groups to design and contribute to studies. It will also work with other research groups (CRUK, MRC and Health Foundation)

**6. Development of studies and grant proposals:**

We will work to submit one collaborative grant per year into NIHR and support 1 smaller pilot or feasibility project proposal for submission into third sector research.

**7. Translational Research**

The late consequences group will map NCRI studies and portfolio for developing a database and network of research teams working in LWBC late consequences. We aim to increase the number and quality of mechanistic and translational studies in understanding and predicting patient late consequences. We aim to build a map of translational and basic science skills sites for developing networking and collaboration in late consequences research.

**8. Industrial/ commercial engagement**

We will work with commercial companies to improve late consequences research, data collection and measurement for current and future cancer therapies.

**9. New technologies and approaches**

The Late consequences group will actively develop new technologies and data approaches for conducting studies and work with NHS digital and NCRAS.

**10. Outputs of work**

We will maintain a register of its outputs in terms of publications and presentations at national and international level. We will endeavour to work collaboratively to produce a proposition paper on late consequences research being undertaken and guidance for those wishing to develop future studies (Could this be a joint trainee project also working with the methodology group?).

**11. Advising and supporting other NCRI groups**

The late consequences group will work across the LWBC groups and with clinical speciality groups to provide support and advice on late consequences research.



## E – Advanced Disease and End of Life Care Workstream Strategy

Strategic area	Overall Group Strategy	Workstream Strategy	Milestones	Outputs
1. Overall aim	The LWBC Group aims to improve the quality, and increase the quantity, of multidisciplinary research into outcomes for people affected by cancer at all stages of disease; and for their carers.	The Advanced Disease and End of Life (ADEL) Workstream aims to improve the quality and increase the quantity of multidisciplinary research into outcomes for people at advanced stage of disease with a focus on terminal disease and appropriate treatment and care.	<ul style="list-style-type: none"> <li>• Version 1.0 circulated before end Dec 2019</li> <li>• Version 2.0 agreed by Annual Meeting March 2020</li> </ul>	<ul style="list-style-type: none"> <li>• Draft 1.0 and circulated internally</li> <li>• Version 2.0 published March 2020</li> </ul>
2. Objectives	<p>a. Raise awareness of research into outcomes for people with cancer at all stages of disease, including longterm survivorship and at end of life; and for their carers.</p> <p>b. Stimulate new studies using a range of current and innovative approaches, into improving and measuring outcomes.</p> <p>c. Design and secure funding for research supporting our aim.</p> <p>d. Collaborate with other research groups both in UK and abroad to achieve our aim.</p> <p>e. Seek new sources of funding for research meeting our aim.</p>	<p>ADEL will focus the 2<sup>nd</sup> highest research priority from the 2019 JLA PSP for LWBC - <i>How can patients and carers be appropriately informed of cancer diagnosis, treatment, prognosis, long-term side-effects and late effects of treatments, and how does this affect their treatment choices?</i></p> <p>This will include treatment decisions during transitions of care in advanced cancer.</p> <p>Our group will combine internal and external expertise to develop a programme grant to develop guidelines for stopping treatments in advanced cancer.</p> <p>The group will act as/or invite expert leads, including PPI leads, to create work packages with integrated PhD fellowships to combine different aspects of enquiry and methodologies to address multiple disease types and treatment modalities.</p> <p>Additionally, the group will review and advise on new studies (e.g. commissioned calls, contacts with other groups etc) for some of the other JLA priorities.</p>		

	<p>f. Increasing outputs of the Group with respect to publications and presentations.</p> <p>g. Advise and support other researchers in the NCRI to design their own studies into measuring and improving patient outcomes.</p>			
3. Scope of work	<p>The LWBC Group will cover all cancer types and patients at all stages of illness, including those without a current histological diagnosis. It will include all aspects of patient and carer wellbeing. It will cover physical, psychological, social, spiritual, cultural, and financial consequences of cancer illness. This broad spectrum of research will be covered through four workstreams focusing on different stages of cancer illness; and one workstream focusing on research methodologies applicable to all stages.</p>	<p>ADEL will focus on patient and family experience of the transitions between aggressive treatments (SACT, RT and surgery) specialist palliative care and end of life care. Relevant outcomes to be used include, for example, 30-day mortality, treatment compliance, satisfaction with decision-making, and QoL.</p> <p>We will use the expertise and networking potential of the ADEL group towards further methodological perspectives and innovations to further develop this work including,</p> <ul style="list-style-type: none"> <li>a. Development of patient aids and clinical guidelines for stopping aggressive treatments</li> <li>b. To scope and work with research teams developing biomarker studies in this area</li> <li>c. To record specific aims and objectives to integrate PPI in all group studies and activities, and to measure and report the its impact</li> </ul>		
4. Membership and expertise	<p>The LWBC Group will consist of a multidisciplinary mix of healthcare professionals, researchers and</p>	<p>Current membership includes senior academics/clinical academics with expertise in psycho oncology, qualitative research, epidemiology, QoL, Stats, patient safety, Pharmacy, decision-making, communication research, service modelling (<i>more to be added</i>)</p>		

	<p>patient/carer representatives.</p> <p>The Group will maintain a Directory of skills and areas of expertise of its members.</p>			
5. Relationship with other groups	<p>The LWBC Group will actively seek out liaisons with other NCRI Groups to design studies relevant to specific disease types and age groups. It will also work with other research organisations including charities, in UK and abroad.</p>	<p>ADEL will seek to work with other NCRI groups working in advanced cancer and aim to co- design RCTs that integrate relevant outcomes, or SWATS, or embedded experiential participant assessment of interventions at potential transitions of care.</p> <p>ADEL will work with its extended networks including major charities, cancer organisations, funding organisations, commissioners, professional bodies, industry and national research groups to fund, promote, develop and implement its work.</p>		
6. Development of studies and grant proposals	<p>The LWBC Group will set targets for numbers of new studies and grant submissions in each of the Workstreams. In the first year, there will be at least one project grant submission per Workstream. By year 2 there will be at least programme grant from the Group per year.</p>	<p>One programme grant in year one</p> <p>Support for overarching multimorbidity programme.</p> <p>Develop proposals for QOL/patient experiences sub-studies in clinical RCTs testing new treatments in advanced disease</p>		
7. Translational research	<p>The LWBC Group seeks to increase the amount of mechanistic research in understanding and predicting patient outcomes, as part of the</p>	<p>ADEL will be particularly interested in biomarker studies that further support the evidence for discontinuation of treatment.</p> <p>ADEL will design studies with a clear PPI and dissemination plan, and a pathway to implementation.</p>		

	drive towards 'personalised' or 'stratified' medicine in oncology. It will work towards including translational research questions in studies wherever relevant and seek additional funding to answer these accordingly.			
8. Industrial / commercial engagement	The LWBC Group will broaden the engagement with industry and increase the level of commercial support for this area of cancer research. Commercial engagement will include pharmaceutical, surgical, radiation therapy and medical devices industries; data collection devices and apps; and other relevant industrially supported research.	ADEL will plan to scope and engage with commercial support from relevant areas. ADEL will work with industry to get QoL measures included in trial design. The group will look to develop apps for patient monitoring and devices for supporting patient care (stoma care, pressure sores).		
9. New technologies and approaches	The LWBC Group will actively develop new technologies and approaches for conducting studies in elucidating patient and carer outcomes in cancer. We will explore the applicability of approaches becoming established in oncology as 'personalised' or	ADEL will not rely on objective outcomes entirely but will apply cutting edge methodologies and innovative thinking to include the real time priorities and preferences of patients and families for true personalised care.  Other potential areas to be designed within programme grant work packages may include data collection via registry databases for tracking treatment compliance and 30 day mortality.  App development for patient and family information and guidance.		

	<p>'stratified' medicine, adapting them to the LWBC aims and objectives. This may be done as 'standalone' studies, or in conjunction with other NCRI Groups or outside organisations.</p>	<p>App development for clinical guidance.</p> <p>Improved IT systems to share information along patient pathways.</p>		
10. Outputs of work	<p>The LWBC Group will maintain a register of its outputs in terms of publications and presentations at national and international level. We will also seek to measure the impact of the published work, in terms of benefit to patients and to the NHS.</p>	<p>ADEL members will disseminate studies as academic papers, and disseminate progress or results to patient groups, clinical teams, and via social media.</p>		
11. Advising and supporting other NCRI groups (and others)	<p>The LWBC Group is a cross-cutting resource to not only all of its members in each Workstream, but also other NCRI Groups and eventually, other researchers. We will publish – initially within NCRI – a template for applications to the Group and its Workstreams for advice and comments on study design and grant applications; and for letters of support and endorsement.</p>	<p>The ADEL group aims to produce a concise directory of expertise and knowledge to support other researchers across the NCRI and beyond.</p>		

## F – Methodology Workstream Strategy

Strategic area	Overall Group Strategy	Workstream Strategy	Milestones	Outputs
1. Overall aim	The LWBC Group aims to improve the quality, and increase the quantity, of multidisciplinary research into outcomes for people affected by cancer at all stages of disease; and for their carers.	The Methodology Workstream aims to improve the quality of multidisciplinary research into outcomes for people living with and beyond cancer (LWBC) by promoting and supporting the use of best- practice research methodology across the NCRI membership.	<ul style="list-style-type: none"> <li>• Version 1.0 circulated to workstream before end Dec 2019</li> <li>• Version 2.1 agreed by Annual Meeting March 2020</li> </ul>	<ul style="list-style-type: none"> <li>• Draft 1.0 and circulated internally Dec 2019.</li> <li>• Version 2.1 published March 2020.</li> </ul>

<p>2. Objectives</p>	<ol style="list-style-type: none"> <li>1. Raise awareness of research into outcomes for people with cancer at all stages of disease, including long-term survivorship and at end of life; and for their carers.</li> <li>2. Stimulate new studies using a range of current and innovative approaches, into improving and measuring outcomes.</li> </ol>	<ol style="list-style-type: none"> <li>1. Promoting and supporting the use of best-practice research methodology across the NCRI, with a focus on projects within the LWBC remit. Incorporating:             <ol style="list-style-type: none"> <li>a. Advice and support around the optimal design of study methodology. Key strategic methodological areas of expertise will encompass: patient-reported outcomes, including</li> </ol> </li> </ol>	<ul style="list-style-type: none"> <li>• Version 1.0 circulated to workstream before end Dec 2019</li> <li>• Version 2.1 agreed by Annual Meeting March 2020</li> </ul>	<ul style="list-style-type: none"> <li>• Draft workstream objectives and circulate internally (Dec 2019) for approval prior to sharing with Exec Feb 2020.</li> <li>• Version 2.1 published March 2020</li> <li>• MAVIS online reinstatement agreed as key objective: May 2021</li> </ul>
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	<ol style="list-style-type: none"> <li>3. Design and secure funding for research supporting our aim.</li> <li>4. Collaborate with other research groups both in UK and abroad to achieve our aim.</li> <li>5. Seek new sources of funding for research meeting our aim.</li> <li>6. Increasing outputs of the Group with respect to publications and presentations.</li> <li>7. Advise and support other researchers in the NCRI to design their own studies into measuring and improving patient outcomes.</li> </ol>	<p>questionnaire development and validation; patient and public involvement; qualitative research; statistical methods; implementation research; health economics; health services research; complex interventions and methods of electronic data capture.</p> <ol style="list-style-type: none"> <li>b. Methodology- focused knowledge transfer/educational activities.</li> <li>2. Sharing cutting-edge methodological advances.</li> <li>3. Reviewing, providing advice and feedback, and where appropriate endorsing, grant proposals from a methodological standpoint.</li> <li>4. Designing and undertaking appropriate methodological research.</li> </ol>		
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<p>3. Scope of work</p>	<p>The LWBC Group will cover all cancer types and patients at all stages of illness, including those without a current histological diagnosis. It will include all aspects of patient and carer wellbeing. It will cover physical, psychological, social, spiritual, cultural, and financial consequences of cancer illness. This broad spectrum of research will be covered through four workstreams focusing on different stages of cancer illness; and one workstream focusing on research methodologies applicable to all stages.</p>	<p>Scope as per overall group strategy.</p>		
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<p>4. Membership and expertise</p>	<p>The LWBC Group will consist of a multidisciplinary mix of healthcare professionals, researchers and patient/carer representatives. The Group will maintain a Directory of skills and areas of expertise of its members.</p>	<p>The Methodology Workstream will consist of a multidisciplinary mix of healthcare professionals, researchers and patient/carer representatives with a broad range of methodological expertise and experience.</p> <p>Key strategic methodological areas of expertise encompass: patient- reported outcomes including questionnaire development and validation; patient and public involvement; qualitative research; statistical methods; implementation research; health economics; health services research; complex interventions and methods of electronic data capture.</p>	<ul style="list-style-type: none"> <li>• Membership agreed by Exec meeting November 2019</li> <li>• Derek Kyte had to step down as chair to a new position (Nov 2020)</li> <li>• To appoint new chair</li> </ul>	<ul style="list-style-type: none"> <li>• Final membership published in advance of initial workstream meeting Dec 2019.</li> </ul>
<p>5. Relationship with other groups</p>	<p>The LWBC Group will actively seek out liaisons with other NCRI Groups to design studies relevant to specific disease types and age groups. It will also work with other research organisations including charities, in UK and abroad.</p>	<p>Scope as per overall group strategy.</p>		

<p>6. Development of studies and grant proposals</p>	<p>The LWBC Group will set targets for numbers of new studies and grant submissions in each of the Workstreams. In the first year, there will be at least one project grant submission per Workstream. By year 2 there will be at least programme grant from the Group per year.</p>	<p>The Methodology Workstream will focus on educational/advisory/outreach support activity in years 1 and 2.</p> <p>This will include the development of a Methodology AdVisory Service (<b>MAVIS</b>) pathway based on the existing CTRad structure.</p> <p>In addition, the group will develop its strategy to support a project funding submission in year 2.</p>	<ul style="list-style-type: none"> <li>• Provide methodologic al outreach to other NCRI groups (year 1 onwards).</li> <li>• Support development of grant proposals (MAVIS) (year 1 onwards).</li> <li>• Develop educational resources: face- to-face, outreach and online (year 1-2).</li> <li>• Develop strategy to support project funding submissions (year 1)</li> <li>• Developed online process template for researchers to request methodologi cal support: MAVIS and trialled at May 2020 meeting with positive</li> </ul>	<ul style="list-style-type: none"> <li>• MAVIS soft launch March 2020, incorporating a 6-month pilot. Refinement and sign-off of final structure following Methodology Workstream meeting Q4 2020.</li> <li>• Annual summary of educational/advisory/outre ach support activity.</li> <li>• Funding strategy Q4 2020/Q1 2021.</li> <li>• Project funding submission 2021. MAVIS published online March 2020 with 3 requests to review grant applications (May 2020). Note: since website update MAVIS has not been linked and we have not had any requests to review projects (other than within the group)</li> <li>• NCRI panel presence at four events (2020-2021)</li> <li>• Funded cross-cutting project with advanced cancer group: Supporting people bereaved during COVID-19: a mixed methods study of bereaved people’s experiences and the bereavement services supporting them. UKRI/ESRC.</li> </ul>
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			<p>feedback from researchers</p> <p><b>Year 2:</b></p> <ul style="list-style-type: none"> <li>Project funding strategy agreed – for cross-cutting proposal work up with advanced cancer group submission on decision-making.</li> </ul> <p><b>Year 2:</b></p> <ul style="list-style-type: none"> <li>Project funding submission (year 2).</li> </ul>	
7. Translational research	The LWBC Group seeks to increase the amount	The Methodology Workstream will work to promote and support the	<ul style="list-style-type: none"> <li>Consideration to translational research options included within MAVIS template</li> </ul>	

	<p>of mechanistic research in understanding and predicting patient outcomes, as part of the drive towards 'personalised' or 'stratified' medicine in oncology. It will work towards including translational research questions in studies wherever relevant and seek additional funding to answer these accordingly.</p>	<p>use of best-practice methodology within translational LWBC research conducted across the NCRI.</p>		
<p>8. Industrial / commercial engagement</p>	<p>The LWBC Group will broaden the engagement with industry and increase the level of commercial support for this area of cancer research. Commercial engagement will include pharmaceutical, surgical, radiation therapy and medical devices industries; data collection devices and apps; and other relevant industrially supported research.</p>	<p>The Methodology Workstream will support the exec strategy underpinning industrial/commercial engagement.</p>	<ul style="list-style-type: none"> <li>• Vinehealth presented at May 2020 proposal meeting</li> </ul>	

<p>9. New technologies and approaches</p>	<p>The LWBC Group will actively develop new technologies and approaches for conducting studies in elucidating patient and carer outcomes in cancer. We will explore the applicability of approaches becoming established in oncology as 'personalised' or 'stratified' medicine, adapting them to the LWBC aims and objectives. This may be done as 'standalone' studies, or in conjunction with other NCRI Groups or outside organisations.</p>	<p>Scope as per overall group strategy.</p>		
<p>10. Outputs of work</p>	<p>The LWBC Group will maintain a register of its outputs in terms of publications and presentations at national and international level. We will also seek to measure the impact of the published work, in terms of benefit to patients and to the NHS.</p>	<p>Scope as per overall group strategy.</p>		
<p>11. Advising and supporting other NCRI groups (and others)</p>	<p>The LWBC Group is a cross-cutting resource to not only all of its members in each Workstream, but also other NCRI Groups and eventually, other researchers.</p>	<p>Scope as per overall group strategy.</p>		

	<p>We will publish – initially within NCRI – a template for applications to the Group and its Workstreams for advice and comments on study design and grant applications; and for letters of support and endorsement.</p>			
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## Appendix 3

### Top 5 publications in the reporting year

Trial name & publication reference	Impact of the trial	CSG involvement in the trial
<p>1. Absolom K, Warrington L, ...Velikova G. Phase III Randomized Controlled Trial of eRAPID: eHealth Intervention During Chemotherapy. J Clin Oncol. 2021 Mar 1;39(7):734-747. doi: 10.1200/JCO.20.02015. Epub 2021 Jan 8. PMID: 33417506</p>	<p>Published editorial in J Clin Oncol Basch E, Leahy AB, Dueck AC. Benefits of Digital Symptom Monitoring With Patient-Reported Outcomes During Adjuvant Cancer Treatment. J Clin Oncol. 2021 Mar 1;39(7):701-703. doi: 10.1200/JCO.20.03375. Epub 2021 Jan 28. PMID: 33507823</p>	<p>eRAPID trial and NIHR programme were developed with input from the former NCRI Psychosocial oncology and survivorship (POS) group; The trial was on the POS portfolio.</p>
<p>2. Derek Kyte, Alex Gilbert co-authors as part of PROTEUS consortium. Recommendations for Including or Reviewing Patient-Reported Outcome Endpoints in Grant Applications. BMJ Research Methods and Reporting -In press</p>	<p>International consensus guidelines; will improve the quality PROMs projects and trials</p>	<p>Alex Gilbert and Derek Kyte represented the methodology WS on PROTEUS consortium  <a href="https://www.jhsph.edu/research/centers-and-institutes/health-services-outcomes-research/research/PROTEUS-Patient-Reported-Outcomes-Tools.html">https://www.jhsph.edu/research/centers-and-institutes/health-services-outcomes-research/research/PROTEUS-Patient-Reported-Outcomes-Tools.html</a>  <a href="https://more.bham.ac.uk/proteus/about-proteus/">https://more.bham.ac.uk/proteus/about-proteus/</a></p>
<p>3. Slade AL, Retzer A, Ahmed K, Kyte D, Keeley T, Armes J, Brown JM, Calman L, Gavin A, Glaser AW, Greenfield DM, Lanceley A, Taylor RM, Velikova G, Turner G, Calvert MJ. Systematic review of the use of translated patient-reported outcome measures in cancer trials. Trials 22, 306 (2021). <a href="https://doi.org/10.1186/s13063-021-05255-z">https://doi.org/10.1186/s13063-021-05255-z</a></p>	<p>The main project on PRO methodology in cancer trials produced guidelines and training for researchers. This is a continuation project looking at the implementation of PROs in cancer trials.</p>	<p>Developed originally with the former POS group, with continuing input from methodology WS</p>
<p>4. Wheelwright, S., Permyakova, N. V., Calman, L., Din, A., Fenlon, D., Richardson, A., Sodergren, S., Smith, P. W. F., Winter, J., &amp; Foster, C. (2020). Does quality of life return to pre-treatment levels five years after curative intent surgery for colorectal cancer? Evidence from the ColoRECTal</p>	<p>Identified risk factors for poor outcome up to five years following colorectal cancer surgery to inform follow-up and support services</p>	<p>The cohort study of &gt;1000 patients was on POS portfolio, developed with the group's input. The results are from long-term follow-up</p>



<p>Wellbeing (CREW) study. PLoS ONE, 15(4), 1-21. [e0231332].  <a href="https://doi.org/10.1371/journal.pone.0231332">https://doi.org/10.1371/journal.pone.0231332</a></p>		
<p>5. Mayland CR, Gerlach C, Sigurdardottir K et al. Assessing quality of care for the dying from the bereaved relatives' perspective: using pre-testing survey methods across 7 countries to develop an international outcome measure. Palliative Medicine 2019; 33 (3): 357-368  <a href="https://doi.org/10.1177/0269216318818299">https://doi.org/10.1177/0269216318818299</a>  <a href="https://doi.org/10.1177%2F0269216318818299">https://doi.org/10.1177%2F0269216318818299</a></p>		



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