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Improving outcomes for older people with cancer - a Workshop of the UK National Cancer Research Institute

In July 2015, an Independent Taskforce commissioned by NHS England published [‘Achieving world-class cancer outcomes: A strategy for England, 2015-2020’](#). One recommendation was to ask the UK’s National Institute for Health Research (NIHR) and research charities *“to develop research protocols which enable a better understanding of how outcomes for older people could be improved”*. In May 2017, the UK National Cancer Research Institute (NCRI) hosted a workshop - *‘Improving outcomes for older people with cancer’*, bringing together key stakeholders (see Appendix) to agree on strategic research approaches and questions needed to address the Taskforce challenge and so to improve outcomes for older people with cancer.

Speaking for Cancer Research UK, Emlyn Samuel described International Cancer Benchmarking Partnership (ICBP) data showing that cancer survival deteriorates with age in most countries, but particularly so in the UK. This appears linked to later diagnosis and reduced use of active treatment in older people. An ongoing Cancer Research UK study is elucidating these findings.

Speaking for NCRI and NIHR, Matt Seymour outlined the UK cancer clinical research environment: a nationally coordinated system with opportunities for strategic research initiatives. The NCRI, a partnership of cancer research funders, clinicians, scientists and patients, runs Clinical Studies Groups (CSGs) which are the engine-room of the national portfolio of clinical studies (<https://csg.ncri.org.uk/>). Their remit is to develop, improve and coordinate the portfolio, including both academic and industry partnership studies. These are delivered at National Health Service hospital sites, supported by the NIHR Clinical Research Network in England and equivalent structures in the other UK nations. During 2017-18, this portfolio included 1,385 cancer studies and recruited 97,485 patients, equivalent to 27% of the UK’s annual cancer incidence.

Of this large national portfolio, 43 studies were designed specifically to address issues of older and vulnerable patients. Among the remainder, although there is rarely a formal upper age limit, older patients are frequently under-represented compared with the population demographic profile. There is evidence that older patients are just as likely to give consent if approached, but are less likely to be approached for research. Often, clinicians do not offer trial participation if this would require rigid adherence to a standard protocol, preventing prospective adaptations in recognition of frailty, comorbidity or age. More inclusive research is feasible, with some good examples, but more evidence on age- and comorbidity-related pharmacokinetics, pharmacodynamics and radiobiology is needed, together with sophisticated methodology to allow evidence-based individualised treatment adaptation within trials without compromise to the research question.

For Age UK, Susan Davidson described the many areas requiring more research, including assessment and management of frailty, multi-morbidity and cognitive impairment; optimum end of life care, nutrition and hydration; improving dignity, empathy, communication, and social care. In all these areas, there are opportunities to integrate research with service development and training. Jackie Bridges (University of Southampton) continued this theme, proposing that research should focus on the patient perspective in treatment, service delivery & organisation. This requires re-evaluation of

research outcome measures and appreciation that the most relevant outcomes may be different to those valued by younger patients. She also discussed how design, recruitment and data collection methods need to be developed that engage people who are currently under-represented or even excluded from cancer research, such as those with dementia.

Workshop participants attended parallel breakout sessions to generate recommendations.

1. Frailty, comprehensive geriatric assessment (CGA) and fitness

The group discussed the issues below.

CGA and frailty variables in trial datasets

The components of CGA to include in trial datasets was agreed. These were:

- comorbidities
- polypharmacy
- function
- falls
- social support
- activities of daily living
- living alone
- nutrition
- cognition/delirium
- mood/mental health
- continence
- sensory impairment

It was deemed unnecessary to be prescriptive on which tools to use as needs would differ depending on study focus. Providing appropriate support to issues identified using tools was considered critical to avoid vulnerable patients being left unmanaged. Protocols should describe relevant interventions for problems identified through collecting this data. Geriatricians should review protocols where older people are targeted/included.

Outcome measures

The group agreed that broader patient-oriented outcome measures should be sought e.g. Did treatment achieve its patient-orientated goal? (quality of life, wellbeing, patient-reported overall health etc). CGA variables could be outcome measures, not only measures of patient characteristics, e.g. change in functional status after treatment. Involving older patients in designing outcome measures was recommended.

Industry intervention studies

Industry-sponsored trials should be encouraged to consider CGA intervention arms in drug trials. Not only to compare two drugs, but also compare whether adding on CGA interventions further improve outcome. Funding towards CGA intervention studies should be encouraged with economic, feasibility and outcomes evaluation.

Resources for advice on older people research

Assembling a panel of geriatricians for NCRI Clinical Studies Groups (CSGs) to advice on protocols was recommended. Older patient representatives should review protocols from their perspective. Finally, NHS England should work with Health Education England to look at the cancer workforce and skills required to manage complex older people. Specialty

curriculum should evolve to meet training needs and capacity of geriatricians needs to be built.

2. Interaction between clinicians and patients

Studies that elucidate older patients' preferences for cancer treatment and care processes and outcomes could inform the design of evaluations of treatment/care effectiveness. Preferred outcomes are likely to include survival and quality of life, with a focus on independent living, but preferences at this life stage are not homogenous and science needs to develop to reflect this. Experiences of treatment and care are also important dimensions to evaluation. The evaluation of patient involvement in decisions made about treatment and care processes and goals is particularly relevant to this group.

Studies are also needed that develop our understanding of current practice of how cancer treatment and care is negotiated with older patients and what factors at individual and/or system level influence these practices. This research would enable identification of opportunities to improve the quality of patient involvement. Evaluation of the impact of interventions developed as a result would be an important next step. Research could also inform how best to support family involvement to help improve outcomes.

More evidence about what cancer treatment works for older people, including people with cognitive impairment, would improve the quality of clinician recommendations to patients. Evidence also needs developing about the needs of those who never reach the stage of receiving treatment, and older people's needs after cancer treatment has ended.

More research is needed on workforce preparedness to deliver high quality care to older people with cancer, including a) clinician attitudes to cancer treatment for older people and knowledge of common conditions in old age and impact on cancer treatment/toxicity, b) availability of older people's specialists to support cancer teams, c) the role of specialist nurses in supporting a more comprehensive assessment and enabling continuity of care, d) links between primary care and hospital teams.

3. Designing research

The group agreed several ways in which NCRI could improve research for older patients:

- Research gap analysis. The UK's National Cancer Data Repository (NCDR) links population-level data for diagnosis, survival, chemotherapy, radiotherapy and hospital events including surgery. This provides the potential to establish age-related demographics and current treatment practices and use this information to identify gaps in the scope and reach of the NCRI research portfolio.
- Treatment intensity. More trials are needed to establish the evidence-base for personalising cancer treatment in response to frailty, comorbidity and age. CSGs should either design adaptive which can include most/all patients, or parallel complementary trials suitable for less fit patients.
- Patient engagement. CSGs are well placed as research leaders to promote trials which encourage clinician/patient dialogue about equipoise, and avoid trial processes (frequent hospital visits, investigations, information sheets, etc) which deter participation of older and vulnerable groups.
- Clinician engagement. Qualitative research might contribute to an understanding of clinicians' willingness to approach older patients as potential research participants.

- Outcome measures. Conventional measures of treatment efficacy and adverse effects may poorly reflect what matters to all patients, and especially older patients. Qualitative research is needed to develop better endpoints, including composites such as Overall Treatment Utility.
- Translational research. Research is needed to explore predictive biomarkers of specific value in patients with advanced age, frailty and comorbidity
- Screening, Prevention & Early Diagnosis (SPED). Upper age limits for SPED programmes need to be examined in the context of lengthening non-cancer life-expectancy, together with the high cancer incidence and relatively poor symptomatic diagnosis pick-up rate in older patients.
- Working with industry. NCRI and NIHR should use their many interactions with industry to ensure that the focus on older people with cancer is reflected in industry as well as academic research.

4. Comorbidities

The ‘Comorbidities’ breakout group initially discussed challenges in measuring comorbidity status and outcomes, as older people with cancer often have complex sets of other diagnoses. Cognitive and physical functioning (e.g. ability to do activities of daily living) needs to be included alongside diagnoses in assessment and treatment planning.

The impact of comorbidities on diagnosis and treatment

Specific comorbidities can accelerate or impede cancer diagnosis. Cancer care planning requires good estimates of prognosis with the various complex co-morbidities seen in older people. Online tools are emerging to calculate prognosis and could include data by age, cancer stage and comorbidity. Existing largescale UK databases of linked electronic health records across primary care, hospital admissions and the cancer registry could help identify the comorbidities that most delay cancer diagnosis, and for calculating prognoses with comorbidities.

Preparing patients for treatment

Optimising treatment could include inter-specialty prescription reviews to decide whether all medications taken for comorbidities are still helpful. A trial of e.g. exercise could test ways of preparing patients with relevant comorbidities before cancer treatment and continuing into survivorship. Providing rehabilitation from the beginning may improve everyday functioning outcomes that are important to older people.

More trials in older groups

Ideally every older person with cancer should be in a trial. Outcome assessment should include longer-term cognitive and physical functioning and should not just be focused on the cancer outcome in isolation. There are observational studies that could be done ahead of planning complex and expensive trials. More studies on dosing requirements in older patients with comorbidities are needed. The use of gadgets in trials, e.g. for self-recording of patient assessed outcomes on tablets, could reduce data capture costs. There may also be research opportunities in going back to existing trials and measuring relevant longer-term outcomes for the included older people.

Recommendations

Comprehensive Geriatric Assessment (CGA)

- Researchers should consider the following CGA variable domains to be included in all datasets: function, falls, social support, activities, living alone, nutrition, cognition, delirium, mood, mental health, continence, comorbidities, polypharmacy, sensory impairment.
- Researchers should consider that study protocols need to include solutions or interventions to any issues that are identified by CGA, e.g. physiotherapy for someone who has poor mobility and/or issues with falls.
- Researchers should consider evaluating the effectiveness of CGA interventions for older people with cancer.

Integration of geriatric involvement with oncology care

- NHS England should consider integrating geriatric assessment and geriatrician involvement into oncology care.
- Geriatric teams or general medical teams should consider working with oncology to review patients with comorbidities.

Patient involvement

- Researchers should consider involving patients when designing outcome measures, to ensure inclusion of what is important to them.
- The pharmaceutical industry should consider involving patients in reviewing patient information leaflets and consider including a summary section.
- Researchers should consider assessing the impact on patients when they are involved in decision-making around their care.

Industry trials

- The pharmaceutical industry should consider including CGA intervention in industry-sponsored drug trials.
- The pharmaceutical industry should encourage funding towards CGA intervention studies, including economic and service implementation evaluations.
- Researchers should interact with industry to ensure CGA issues are considered when developing industry trials.

Comorbidities

- The NIHR should consider using observational data from GP records to investigate the impact of comorbidities on diagnosis and treatment.
- NHS England should consider developing a web-based database informing on prognosis based on age, cancer stage and comorbidity. A realistic life-expectancy projection, factoring in comorbidities would be useful to assess the cost-benefit of any treatment.
- Researchers should consider investigating the impact of providing rehabilitation for people with comorbidities to see if it improves functioning outcomes.
- Researchers should consider designing observational studies about drug availability in older patients with comorbidities.

Research design

- The NCRI CSGs should consider performing a gap analysis scoping exercise using SACT, HES and RT databases to identify mismatches between elderly patients receiving treatment and those participating in trials.

- The NCRI CSGs should consider developing complementary trials for older patients where the trial is only open to fitter patients, with the ultimate aim of designing dose-intensity adapted treatment based on fitness level.
- The NCRI CSGs should consider direct involvement of geriatricians with trial design. Protocols which target older people should be reviewed by a geriatrician.
- Researchers should consider testing much broader patient-oriented outcome measures, and designing these with patients.

Other research priorities

- Research is needed into what drives decisions made in a clinical consultation.
- Research is needed to improve the understanding of the factors involved for those patients who never receiving active treatment for their cancer.
- Research funders should consider commissioning research to support the development of the comprehensive cancer care pathway for older people:
 - how to empower older people to participate in decision-making
 - how to equip clinicians with the information they need about individual patients and research evidence
 - how integrated care can be provided for this group to optimise overall outcomes, not just in relation to the cancer.
- The NIHR should improve clinicians' access to research evidence for older people with cancer.

Contributions

None of the authors have relevant conflicts of interest.

SA organised the workshop and wrote the first draft of the article

JB led the session on interactions between clinicians and patients

TK led the session on frailty and the comprehensive geriatric assessment

DM led the session on comorbidities

IL coordinated production and editing of the manuscript

MS convened and chaired the workshop, led the session on designing research and finalised the article.

Appendix 1 – delegate list

Dr Seema Alexander	Programme Manager, NCRI
Dr Kathryn Almack	Professor of Health, Young People and Family Lives, University of Hertfordshire
Dr Sally Appleyard	NCRI Bladder and Renal Clinical Studies Group
Dr Jo Armes	Chair, NCRI Psychosocial Oncology & Survivorship Clinical Studies Group
Dr Sue Bailey	Bristol Myers Squibb
Dr Susanna Banerjee	NCRI Gynaecological Cancer Clinical Studies Group
Ms Sarah Bengier	Senior Programme Manager, NHS England
Professor Jackie Bridges	Professor in Older People's Care, University of Southampton
Professor Janet Brown	NCRI Breast Cancer Clinical Studies Group
Dr Lynn Calman	Psychosocial Oncology & Survivorship Clinical Studies Group
Dr Helen Campbell	Portfolio Manager (Research), Department of Health and Social Care
Mrs Laura Chambers	Clinical Studies Groups Manager, NCRI
Dr Pippa Corrie	Chair, Skin Cancer Clinical Studies Group
Dr Susan Davidson	Research Manager, Age UK
Dr Lucy Dumas	Clinical Research Fellow, Royal Marsden NHS Foundation Trust
Dr Carole Farrell	Division of Nursing, University of Manchester
Dr Caroline Forde	Supportive and Palliative Care Clinical Studies Group
Dr Ros Glasspool	Gynaecological Cancer Clinical Studies Group
Professor Richard Gray	Professor of Medical Statistics, University of Oxford
Dr Stuart Griffiths	Head of Strategy and Initiatives, NCRI
Dr Sameena Hameed	Consultant Physician in Geriatrics, Epsom and St Helier University Hospitals
Dr Mathew Hatton	Chair, NCRI Lung Cancer Clinical Studies Group
Mr Dan Hughes-Morgan	Cancer Policy and Strategy Manager, NHS England

Mr Andrew Jazaerli	Macmillan Cancer Support
Dr Tania Kalsi	Consultant Geriatrician, Kings College London/Guys & St Thomas'
Dr Karen Kennedy	Director, NCRI
Dr Sue Maughn	Clinical Advisor, Transforming Cancer service Team for London.
Dr Angela McCullagh	Consumer Member, NCRI
Professor David Melzer	Professor of Epidemiology and Public Health, University of Exeter
Ms Kirstin Miller	Programme Support Manager, NHS England
Dr Rob Morris	Consultant Geriatrician, Nottingham University Hospitals NHS Trust
Ms Victoria Murphy	Programme Manager, NCRI
Dr Richard Neal	Chair, NCRI Primary Care Clinical Studies Group
Dr Cassandra Ng	Geriatrician, University Hospital of South Manchester
Professor Malcolm Reed	Professor of Surgical Oncology, Brighton and Sussex Medical School
Mrs Diana Robinson	Consumer Member, NCRI Consumer Forum
Mr Emlyn Samuel	Head of Policy Development, Cancer Research UK
Dr Rebekah Schiff	Consultant Geriatrician, Guys & St Thomas' NHS Foundation Trust
Professor Matt Seymour	NCRI Clinical Research Director; NIHR Clinical Research Network Specialty Cluster Lead
Ms Ellie Symonds-Lloyd	Advanced Nurse Practitioner and Cancer Nurse in Urology, Royal Marsden NHS Foundation Trust
Mr Roger Wheelwright	Advanced Nurse Practitioner and Cancer Nurse in Urology, Croydon Health Services NHS Trust
Professor Juliet Wright	Professor in Elderly Medicine, Brighton and Sussex Medical School

Appendix 2 – agenda

10.00	Arrival and registration	
10.30	Information-sharing session	
10.30	Introduction	Professor Matt Seymour, <i>NCRI</i>
10.50	Key issues in Ageing	Dr Susan Davidson, <i>Age UK</i>
11.05	Evidence on Ageing and Cancer Treatment	Mr Emlyn Samuel, <i>Cancer Research UK</i>
11.20	Issues associated with clinical research with older people	Professor Jackie Bridges, <i>University of Southampton</i>
11.40	Discussion	
12.00	Lunch	
13.00	Guided parallel breakout discussions to develop one recommendation on each of the four key topics:	
	<ul style="list-style-type: none"> Frailty, comprehensive geriatric assessment and fitness Interaction between clinicians and patients Designing research Comorbidities 	<p>Dr Tania Kalsi, <i>Guy's and St Thomas' NHS Foundation Trust</i></p> <p>Professor Jackie Bridges, <i>University of Southampton</i></p> <p>Professor Matt Seymour, <i>NCRI</i></p> <p>Professor David Melzer, <i>University of Exeter</i></p>
15.00	Coffee	
15.15	Report back to the group	
16.00	Agree next steps	
16.30	Close	

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Authorship Contributions

The *Journal of Geriatric Oncology* adheres to the guidelines adopted by the International Committee of Medical Journal Editors ("Uniform requirements for manuscripts submitted to biomedical journals", available from <http://www.icmje.org>). According to the guidelines, authorship should be based on: 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published.

Please indicate the contribution of each author to the following areas:

<i>Contribution</i>	<i>Name(s) of author(s)</i>
Study concepts	Seema Alexander, Matt Seymour
Study design	Seema Alexander, Matt Seymour
Data acquisition	Seema Alexander
Quality control of data and algorithms	n/a
Data analysis and interpretation	Seema Alexander, Matt Seymour, Jackie Bridges, Tania Kalsi, David Melzer
Statistical analysis	n/a
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Manuscript editing	Matt Seymour, Jackie Bridges, Tania Kalsi, David Melzer, Ian Lewis
Manuscript review	Matt Seymour, Jackie Bridges, Tania Kalsi, David Melzer, Ian Lewis

Corresponding Author Declaration

I confirm that all authors have made a significant contribution to this manuscript, have seen and approved the final manuscript, and agree to its submission to the *Journal of Geriatric Oncology*.

Corresponding Author Name: Professor Matt Seymour



Corresponding Author Signature:

Date: 17/01/19