NCRI
National
Cancer
Research
Institute

In partnership with

NHS England

Improving outcomes for older people with cancer

Workshop report

Partners in cancer research

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.

Improving outcomes for older people with cancer

In July 2015, the Independent Cancer Taskforce published a report 'Achieving world-class cancer outcomes: A strategy for England, 2015-2020' outlining a vision for the NHS to improve survival rates and achieve world class outcomes for those affected by cancer. Of the 96 recommendations outlined in the report, 11 were specific to research, including recommendation 42.

Recommendation 42: NHS England should ask NIHR and research charities to develop research protocols which enable a better understanding of how outcomes for older people could be improved.

This report outlines a workshop entitled 'Improving outcomes for older people with cancer' organised by NCRI and NHS England. The aim of the workshop was to define research questions to improve outcomes for older people with cancer, and agree the action steps to pursue these.

The day brought together a group of geriatricians, clinical academics, medical oncologists, consumers[1], and representatives from Macmillan, Cancer Research UK and Age UK, with specialist expertise in this area. The day was organised around an information-sharing session in the morning, followed by guided parallel breakout sessions in the afternoon, to develop recommendations in four key areas.

Professor Matt Seymour, NCRI Clinical Research Director, who was chairing the day, introduced the NCRI, emphasising that it is a research organisation and that the aim of the day was to ultimately develop a number of research questions. He gave an overview of the clinical research pathway, from identifying research questions right through to clinical impact, and highlighted that we need to focus on all stages of the pathway (Figure 1). Looking at the NIHR portfolio, out of 1117 studies, 43 are specifically addressing elderly or vulnerable patient issues. Age, frailty and comorbidity affect pharmacology and more research can be done in this area.

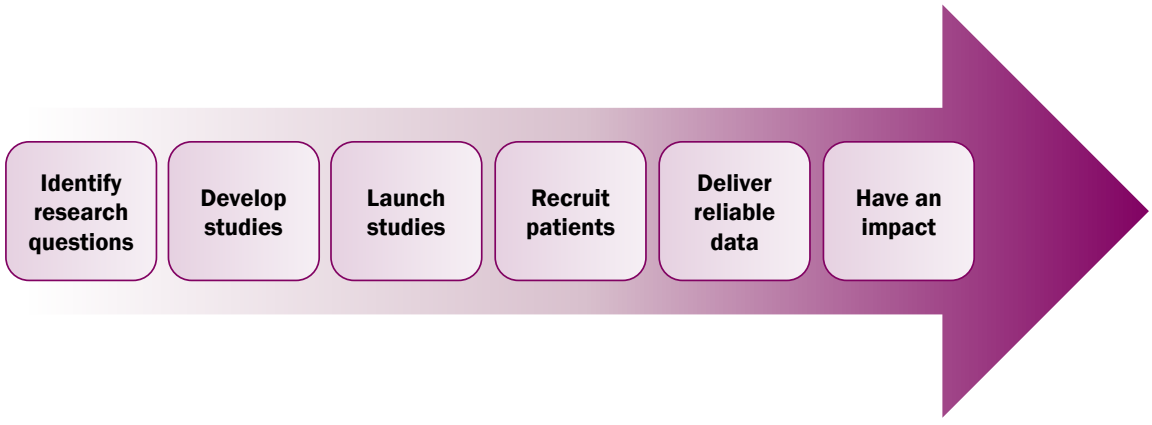

Figure 1. Schematic of the clinical research pathway, from identifying research questions through to having an impact.

[1] Patients, carers and others affected by cancer

Workshop presentations

Key issues in ageing

Dr Susan Davidson, Research Advisor for Age UK, talked through all the issues that need to be considered when looking at the outcomes of older patients, such as frailty, multimorbidity, dementia and cognitive impairment, end of life issues, nutrition and hydration, dignity, empathy, communication, and social care. She discussed ways to address these issues to improve the outcomes for older patients with cancer, such as mandatory training for clinicians. Dr Davidson finished her talk by reiterating that outside of drug development research and recruitment to trials, there are other important issues that need to be addressed.

Evidence on ageing and cancer treatment

Mr Emlyn Samuel, who leads the policy development team at Cancer Research UK gave an overview of Cancer Research UK, highlighting that their vision and strategy are grounded in patient outcomes. At present older patients are less likely to survive for the same amount of time as younger people, and there is evidence to suggest that later diagnosis and access to treatment are contributing factors. Mr Samuel presented comparisons across members of the International Cancer Benchmarking Partnership (ICBP), highlighting that UK survival rates for older people are behind other comparable countries. Routes to diagnosis also vary across age range with 42% of patients over the age of 85 years presenting through an emergency (22% of 70-79 year olds and 31% of 80-84 year olds diagnosed at emergency presentation). Emergency presentations have poorer outcomes as patients are more likely to be diagnosed at an advanced stage. Older patients are also less likely than younger patients to receive chemotherapy, radiotherapy and surgery. Cancer Research UK has commissioned research to look into the issues above by carrying out a literature review, UK-wide surveys and visits to UK sites. The emerging findings involve patient assessment, communication between primary and secondary care, importance of elderly-specialist roles, time given for specialist cases, clinical evidence of treatment effects on the older population and opportunities for new, kinder treatments which are more suitable for frail/ comorbid patients. A detailed report from Cancer Research UK is due to be published shortly.

Issues associated with clinical research with older people

Professor Jackie Bridges, Professor of Older People's Care at the University of Southampton, reiterated the importance of looking at the whole cancer journey, not just treatment, and supporting older people who have survived cancer, and at the end of life. Professor Bridges discussed topics that future research should focus on including treatment, patient perspectives and services delivery & organisation. The outcomes that we should be aiming to improve were also considered, including clinical endpoints, quality of life, and patient experiences during treatment/ receipt of services. Professor Bridges highlighted that we need to consider that in the older people population, there may be a shift in which outcomes are valued compared to younger patients and in the expectations of quality of life and good treatment experiences. She also discussed how cancer research design, recruitment and data collection methods need to be developed that are maximally inclusive of groups traditionally excluded from research, for instance, people living with dementia.

Breakout sessions

Following on from the information-sharing session, participants attended parallel breakout sessions to devise a series of recommendations.

1. Frailty, comprehensive geriatric assessment (CGA) and fitness, chaired by Dr Tania Kalsi

The 'Frailty, CGA and fitness' breakout group discussed a number of issues outlined below.

Inclusion of CGA frailty variables in trial datasets

The group agreed on the CGA variable domains that should be included in all trial datasets. These were measures of function, falls, social support/ activities/ living alone, nutrition, cognition/delirium, mood/ mental health, continence, comorbidities, polypharmacy and sensory impairment. In terms of whether we should be prescriptive in which tools trials and studies should measure these domains, it was deemed unnecessary as needs would differ depending on the study focus.

There is a need to think of providing appropriate support to any issues identified using CGA variable collection tools. In creating these datasets in clinical studies, vulnerable patients should not be left unprotected from issues that have been identified. Protocols should therefore include or should describe any relevant interventions for those who have needs identified through the collection of this data. For example, if someone has poor mobility/falls, have they had any physiotherapy? The group also agreed that geriatricians should be included in reviewing protocols which include or target older people.

Outcome measures

There was a strong feeling that we should be testing much broader patient-oriented outcome measures, like 'Did the trial/ treatment achieve its patient-orientated goal?' quality of life, wellbeing, and patient-reported overall health. CGA variables should be considered for being recorded at the start and considered as outcome measures if appropriate for that study. For example, changes in function from start to end of treatment. Involving patients in designing these measures is recommended, asking what outcome measures are important to older patients.

Industry intervention studies

In terms of CGA intervention studies, the group agreed that those involved in developing industry-sponsored trials should be encouraged to consider CGA intervention arms in their drug trials. There are examples of interesting two-arm drug trial designs with an extra layer created in the interventional trial in which a CGA intervention is tested. Geriatricians intervene in any issues that are identified. As well as comparing the two drugs, it also compares whether the added support further improves outcome. Funding towards CGA intervention studies should be encouraged and there should be economic evaluation, feasibility and outcomes evaluation.

Resources for advice on older people research

The group also discussed resources for getting advice on protocols and suggested assembling a panel of research-oriented geriatricians for the NCRI Clinical Studies Groups (CSGs) to call on for advice on protocols. The NCRI could be used as a base for creating this group, depending on resources within the NCRI. Patient representatives could also be tasked with reviewing general protocols from an older patient perspective so they can pick out issues that they are concerned about, such as being excluded from a trial. There was a suggestion to consider inviting geriatricians to the NCRI Cancer Conference and/or holding a "Cancer in the elderly" session at the Conference.

Finally, the group agreed there is a need to look at capacity building in terms of increasing number of geriatricians. NHS England will need to work with Health Education England to more broadly to look at the cancer workforce and skills mix required to develop the cancer workforce for the future. Further, there is need to look at specialty curriculum to ensure training needs of the workforce are met.

2. Interaction between clinicians and patients, chaired by Professor Jackie Bridges

The 'Interaction between clinicians and patients' breakout group focussed on the interaction between the health service and patients, the patient pathway through services and patient perspectives. The group also discussed in detail the issues around consultations between clinicians and patients and how it impacts on treatment decisions.

Outcome measures

In terms of outcome measures, the group queried what outcomes we are headed towards as we need to be thinking beyond survival. Survival is important but we need to think about quality of life including dimensions that represent older people issues such as independent living.

The safety of treatment and treatment experience was discussed and it was recommended that we should assess individuals' involvement in care and decision-making/ empowerment as these are as important to measure as patient experiences.

Barriers to patient-clinician interaction

Regarding barriers to patient-clinician interaction, the group recommended that there should be research into what's driving decisions made in a consultation between a clinician and a patient. There needs to be a better understanding of what goes on in a consultation and the factors that contribute to what the final decision is. The group also discussed how wider features of the treatment pathway influence what happens in the meeting between patient and clinician, including a clinician often meeting a patient for first time after the MDT meeting.

In terms of assessment, the group agreed that there is a need for more definitive evaluation of CGA for this patient group and its effectiveness, drawing on what other studies have used in terms of outcome measures to date.

There were discussions around the access clinicians have to research evidence and how that drives interactions with patients. There needs to be more evidence about what treatment works for older patients with cancer and there was a keenness to ensure that those with cognitive impairment are included in trials, so we understand the outcomes for that particular group. There needs to be a further understanding of the needs of those who never reach the stage of receiving treatment, and how to know the right decisions are being made depending on individual circumstances. It would be beneficial to have a better understanding of the factors involved leading to these issues.

A number of points in the discussion touched on workforce preparedness to deliver high quality care to older people with cancer, not just in terms of access to research evidence on treatment effectiveness but also a) clinician attitudes about cancer treatment for older people and knowledge of common conditions in old age e.g. dementia 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.

Comprehensive care pathway

Finally, the group discussed the comprehensive care pathway for older people, which is another recommendation in the Cancer Taskforce Report. The group recommended developing and testing a pathway that works so that people can have a predictable path through the system. A useful piece of research can be carried out to empower the patients, where patients are equipped with the right questions to ask, clinicians are equipped with all the information needed and where care is integrated when possible at point of patient contact so that burden of treatment is minimised and outcomes are optimised, not just in relation to the cancer. The research should include a means of assessing the benefit of having this type of pathway set up.

The group also discussed the need to use research to better understand family involvement and how best to support family involvement to help improve outcomes.

3. Designing research, chaired by Professor Matt Seymour

The 'Designing research' breakout group framed their discussions around potential recommendations to NCRI CSG Chairs.

Gap analysis of current trial portfolio

The first discussion was around gap analysis of the current status of, and feasibility of using the SACT, HES and radiotherapy databases to look at the age demographic in each cancer type of those receiving treatment, and then compare this to the demographic of those participating in each CSG's trial portfolio. This would be a useful scoping exercise to see if there is a mismatch between elderly patients receiving treatment and those participating in relevant trials for the same treatment modality. A coordinated approach is needed and the Data Access Officer at NCRI/ Public Health England could be approached to help with this.

Complementary trials for frailer patients

The group agreed that the CSGs should be encouraged to examine treatment intensity in relation to age. There was debate around whether clinical trials overall are currently targeted at fitter patients, and whether we should consider complementary trials for older, frailer patients. Once we have learned from these complementary trials, future trials could be designed which span the full spectrum using dose intensity-adapted treatment depending on fitness level, which is assessed at baseline.

Spectrum of equipoise

A key issue is equipoise. Within each spectrum of treatment, there will be an area of equipoise for each patient. Trials should be identified where clinicians can sit with patients and decide from a number of arms which area to be involved in. There was also discussion around trial processes such as hospital visits, information sheets and barriers to research. It was agreed that the CSGs should have responsibility to make sure trials are not overcomplicated and there are no barriers in the way of elderly patients taking part.

Endpoints were also discussed, such as the overall treatment utility and understanding what matters to patients. There is a need for qualitative research on what patients want which would allow a more refined composite endpoint

Translational research and industry trials

In terms of translational research, there are not only research questions for all ages, but also questions specific to older patients which could be incorporated. We need to ensure the protocols that are being developed get funded and are part of the mainstream portfolio.

Regarding interactions with industry, a lot of the issues raised are applicable to industry trial development as well as to CSGs. There needs to be more interaction with industry to make sure these same issues are considered.

Integration of geriatrics into oncology care

It was felt that geriatric assessment/ involvement should be integrated into oncology care, through direct involvement of geriatricians, geriatric assessment tools or specialist nurses. The health service systems that integrate geriatric care with oncology care should be scrutinised.

The attitude of clinicians may play a part in recruiting older patients to trials. Surveys should be carried out or consultations recorded to see what is happening on the ground and what people consider when making decisions.

Screening and early diagnosis

Research expediting the investigation of early symptomatic cancer and asymptomatic cancer screening in the older age group (e.g. bowel cancer screening which stops after 65 years) should be reviewed. The impact of screening pickup would be low in terms of life years gained, but screening pick up rate would be high as this population has a high incidence of disease.

The literature should also be scoped to understand what patients want in their cancer experience as this might drive what outcomes are important, and therefore what studies need to be developed.

4. Comorbidities, chaired by Professor David Melzer

The 'Comorbidities' breakout group discussed the issue of measuring comorbidities as this is not straightforward. Ideally dimensions such as cognition and functioning measures need to be measured and inputted into routine data systems and to be monitored.

The impact of comorbidities on diagnosis and treatment

The group discussed the impact of comorbidities on diagnosis and treatment, particularly how comorbidities can accelerate or impede diagnosis. At present, there is a lot of observational data in GP records, (Clinical Practice Research Datalink and MHRA engines which are linked to the cancer registries) which can answer questions such as which comorbidities impact on delayed diagnosis, and observationally on outcomes. This data can be used to work out what is driving a change in outcome.

Preparing patients for treatment

The issue of how to best prepare patients for treatment and pre-rehabilitation for patients with comorbidities was considered. A trial or exercise could be carried out on preparing patients who have comorbidities and this would run right through into survivorship. Would be good to investigate whether providing rehabilitation for people with comorbidities from the beginning will improve the functioning outcomes that matter in older people.

Issues about specific interventions, such as exercise and issues about optimising treatment were debated. Also considered was a review of prescription by a geriatric team or general medical team working with oncology, to decide whether all the medicines that an individual is taking are still relevant or required.

A trial for every older person

Every older person should be in a trial, like all other age groups and the longer-term outcomes that matter to people should be measured. More observational studies about drug availability in these older patients with comorbidities are needed. There are a lot of observational studies that

can be done first ahead of planning large, complex and expensive trials. It would be useful to develop a database that everyone can access online on what the prognosis is at any given age, cancer stage and comorbidity. Online tools are beginning to emerge. The UK has got the best observational data and best chance of doing organisational trials, e.g. randomising units or GP practices to do different interventions.

The group discussed the use of gadgets in trials, and getting patients to fill in functional data on tablets. We now have a generation of older people who are fairly tech-savvy. This will result in a newer and cheaper methods of data capture.

Utilising data

There are also research opportunities going back to the trials that have been done and finding out the long-term outcomes for the people who were included. For example, what are the 15 to 20-year functioning outcomes? It might be useful to follow this up with ageing measures.

It would also be interesting to develop a realistic life expectancy projection, factoring in comorbidity in an intelligent way. This could be used to estimate the cost-benefit analysis when a treatment is being considered. GP electronic record research systems such a CPRD run by the MHRA have linked up with cancer registries through the GP records. There is data on 13M people, including 3-4M older people in the datasets. Therefore, this is possible, but shortcomings need to be factored in, such as GP diagnoses not always being correct. There is data on approximately 11,000 centenarians in CPRD but this is not publicly available at present as it costs money to analyse.

Workshop 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

- Researchers should consider carrying out research into what drives decisions made in a consultation, to gain a better understanding of what goes on in a consultation and the factors that contribute to what the outcomes are in terms of decision making.
- Researchers should consider research into understanding of the factors involved for those patients who never reach the stage of receiving treatment.
- Research funders should consider commissioning research to support the development of the comprehensive cancer care pathway for older people (recommendation 41) by investigating:
    - how to empower older people to become active participants in their treatment decision making
    - how to equip clinicians with the information they need about individual patients and related research evidence
    - how integrated care can be provided for this client group so that burden of treatment is minimised and outcomes are optimised, not just in relation to the cancer.
- The NIHR should consider giving clinicians more access to research evidence for older people with cancer.

Appendix one – delegate list

Dr Seema Alexander	NCRI
Dr Kathyrn Almack	University of Hertfordshire
Dr Sally Appleyard	Brighton & Sussex Medical Schools
Dr Jo Armes	Kings College London
Dr Sue Bailey	Bristol Myers Squibb
Dr Susanna Banerjee	Royal Marsden NHS Foundation Trust
Ms Sarah Benger	NHS England
Professor Jackie Bridges	University of Southampton
Professor Janet Brown	Sheffield
Dr Lynn Calman	University of Southampton
Dr Helen Campbell	Department of Health
Mrs Laura Chambers	NCRI
Dr Pippa Corrie	University of Cambridge
Dr Susan Davidson	Age UK
Dr Lucy Dumas	Royal Marsden NHS Foundation Trust
Dr Carole Farrell	University of Manchester
Dr Caroline Forde	Queens University Belfast
Dr Ros Glasspool	NHS Greater Glasgow and Clyde
Professor Richard Gray	Oxford
Dr Stuart Griffiths	NCRI
Dr Sameena Hameed	Epsom and St Helier University Hospitals
Dr Mathew Hatton	University of Sheffield
Mr Dan Hughes-Morgan	NHS England
Mr Andrew Jazaerli	Macmillan
Dr Tania Kalsi	KCL/Guys & St Thomas'
Dr Karen Kennedy	NCRI
Dr Sue Maughn	Transforming Cancer service Team for London.
Dr Angela McCullagh	NCRI
Professor David Melzer	University of Exeter
Ms Kirstin Miller	NHS England
Dr Rob Morris	Nottingham University Hospitals NHS Trust
Ms Victoria Murphy	NCRI
Dr Richard Neal	Leeds
Dr Cassandra Ng	University Hospital of South Manchester
Professor Malcolm Reed	BSMS
Mrs Diana Robinson	NCRI Consumer Forum
Mr Emlyn Samuel	Cancer Research UK
Dr Rebekah Schiff	Guys & St Thomas' NHS Foundation Trust
Professor Matt Seymour	NIHR/NCRI
Ms Ellie Symonds-Lloyd	Royal Marsden NHS Foundation Trust
Mr Roger Wheelwright	Poole Hospital
Dr Juliet Wright	BSMS

Appendix two – workshop agenda

10.00	Arrival and registration	
10.30	**Information-sharing session**	
10.30	Introduction	Professor Matt Seymour, *NCRI*
10.50	Key issues in Ageing	Dr Susan Davidson, *Age UK*
11.05	Evidence on Ageing and Cancer Treatment	Mr Emlyn Samuel, *Cancer Research UK*
11.20	Issues associated with clinical research with older people	Professor Jackie Bridges, *University of Southampton*
11.40	Discussion	
12.00	Lunch	
13.00	**Guided parallel breakout discussions to develop one recommendation on each of the four key topics:** • Frailty, comprehensive geriatric assessment and fitness • Interaction between clinicians and patients • Designing research • Comorbidities	Dr Tania Kalsi, *Guy's and St Thomas' NHS Foundation Trust* Professor Jackie Bridges, *University of Southampton* Professor Matt Seymour, *NCRI* Professor David Melzer, *University of Exeter*
15.00	Coffee	
15.15	Report back to the group	
16.00	Agree next steps	
16.30	Close	

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