BUILDING A SERVICE USER LED VISION OF MEDICAL RESEARCH AND INFORMATION

This report is the result of a roundtable of 10 cancer service users, chaired by Joanne Rule and Sarah Woolnough, head of policy at Cancer Research UK and facilitated by GlaxoSmithKline (GSK).

Summary recommendations

1. Embed quality assured information on research throughout the whole care pathway

    - Research should form an integral part of the commissioning pathway
    - All patients should be made aware of relevant research from the first point of presentation, whatever their route to diagnosis and throughout their care;
    - At the point of referral to diagnostic tests, there should be information and a consent form for donation of tissue to be banked for current and future research.
    - Opportunities for patient-to-patient information sharing about relevant research should be included in all stages of the care pathway.

2. Ensure that every patient hears about research directly from a health professional

    - Designate a clinician in the Multi-disciplinary Team to be responsible for talking with the patient about relevant research and whether or not to take part in a clinical study;
    - Consideration of patient eligibility for clinical studies should be routinely discussed at Multi-disciplinary meetings whether or not the hospital is conducting those studies.

3. Support patient accessibility to clinical studies

    - Make the necessary arrangements for patients to take part in a study being run by another hospital, if the patient is eligible and wants to take part;
    - Supporting patient preference will need the active support of commissioners and may require incentives for hospitals to refer patients to another hospital;

4. Bring accurate and up-to-date information resources closer to the patient and carer

    - Make accurate and up-to-date information about medical research available through different sources/media, including the creation of clinical study databases built from the perspective of the patient or carer searching for information;
    - Charities/patient groups of all sizes should be involved in ensuring key databases are accurate, up-to-date and patient friendly
    - Personalised information prescriptions for individual patients, currently being developed by the NHS, should also include information about relevant research;
    - Clinical study results should be published as early as possible and made readily available for patients, clinicians and commissioners.

5. Collect, collate and evaluate the right data at the right time

    - Multi-disciplinary Teams should record that patients have been told about relevant research and their eligibility and whether or not the patient chose to take part in the research; this data should be aggregated and disseminated by the National Cancer Intelligence Network for commissioners and the public;

    - Patient Reported Experience Measures (PREMs) should be introduced to explore patient experience of being informed and consulted about research opportunities;

    - The National Cancer Patient Survey should include a question on whether or not patients have been told about relevant research and the results by demographic group should be made available to commissioners and the public;

    - The quality assurance of cancer services through peer review should consider data relating to patient preference, access and involvement in research, as part of the overall assessment of cancer care and treatment.

Overview and background

This report has been co-produced by 11 services users working together as a 'roundtable.' In December 2010, an event for service users actively involved in oncology clinical studies in the UK was facilitated by GSK and subsequently this report has been drafted and amended using electronic discussion. The service users presented the report to Earl Howe, the Undersecretary of State for Health, in January 2011.

In light of the Department of Health's current consultations into information and choice, the roundtable explored the changes required to the provision of information for medical research from the unique perspective of the expert service user. This roundtable followed a successful workshop held in July 2010. This earlier workshop focussed upon the expert service user perspective to clinical studies and explored the changes participants felt were needed across the whole 'pathway' in order to improve medical research in the UK.

Clinical trials are essential to supporting innovation in medical science – providing some patients with opportunities to access potentially life-changing, innovative treatment and at the same time, allowing them to contribute to research into future treatments, ultimately benefiting the wider patient population. Without patient involvement, clinical studies simply cannot continue. Hospitals conducting research are also more likely to attract the best clinicians who will be keen to be involved in innovative medical research.

The workshop in July 2010 set out how expert service users can initiate and inform improvements in medical research. Participants considered that patient involvement would remove some of the barriers to participation in clinical studies and lead to service improvements. In particular, the workshop highlighted the need for all patients to have the opportunity to take part in medical research, so that there really is 'no decision about me, without me'. The workshop in July 2010 suggested that patients are too often made to feel like passive and insignificant participants of clinical trials rather than active partners in the process.

Recent initiatives from the Department of Health, most notably the Liberating the NHS Health White Paper and the key message of 'no decision about me without me', have rightly focussed on the need to place patients at the centre of shared decision-making with clinicians. Giving patients the right information, in the right way, at the right time can give them greater choice and enable them to feel more in 'control' of their own care. The provision of information also has a significant role to play in increasing awareness and supporting recruitment to clinical studies.

Sources of information, such as the National Cancer Research Network (NCRN), Cancer Research UK and patient groups, are valuable resources for all those interested in clinical studies. However, there are real concerns and difficulties in accessing useable and accurate information about medical research. This report identifies some of the solutions to these issues from the unique perspective of the service user and concludes that every person affected by cancer should hear about relevant research from a member of their health care team.

VISION FOR ACCESS AND AVAILABILITY

Recommendation 1: Embed quality assured information on research throughout the whole care pathway

1.1 How can access to and availability of information be improved?

Health Secretary Andrew Lansley launched his health reforms by saying he intended to bring about an 'NHS information revolution', in which patients would be put 'at the heart of the NHS'. To help bring about truly patient-centred decision-making, this roundtable event set out to build a vision for medical research.

Central to the service user vision of medical research is the belief that the system must be open, transparent and accessible. In particular, equality of access to research should not be determined by an individual clinician's interest or disinterest in entering patients into clinical trials or by where the patient lives. To support service users' participation in research whole system and cultural change is needed. This systemic change should include:

- Raising the profile of research such that the NHS becomes a National Health and 'Research' Service, from GP practices to hospitals, clinics and hospices; from health education and awareness raising, to testing and diagnostics; and from treatment to follow-up, 'survivorship', palliative and end-of-life care. This demands a change of culture, not of structure.
- Fostering a climate in which research is the norm. This is further emphasised in the recently published Academy of Medical Sciences review which highlights the importance of 'embedding a culture that values research within the NHS'. [1]
- Building research into the capabilities and practices of all healthcare professionals.
- Raising the profile of research amongst wider society, not just within healthcare. Here there is an important role for the consumer in driving meaningful, systemic change. Patient power must be harnessed to influence clinicians and commissioners alike.
- Reducing professional protectionism, which 'shelters' patients from relevant research.
- Reducing many hospital trusts' risk aversion to research.

The provision of information does not equal understanding. Patients will require differing levels of support, in order to complete the journey from accessing raw data to gaining full understanding and being able to make decisions as a result. Awareness-raising, information and support should be available from a number of different sources and in a variety of ways, if we are to achieve the goal of providing accessible information about medical research. Active support should always be available from the healthcare professional – whether through the GP or through hospital care – rather than depending on the patient or carer's own information-seeking abilities.

[1] http://www.acmedsci.ac.uk/index.php?pid=99

VISION FOR CHOICE AND SUPPORT

Recommendation 2: Ensure that every patient hears about research directly from a health professional

2.1 How and by whom should people be told about relevant research?

- It is important that all patients are made aware of relevant research from the point of first presentation, whatever their route to diagnosis, for example, whether they enter the care system through their GP or as an emergency admission, and throughout their treatment. At the point of referral to diagnostic tests, there should be information and a consent form for donation of tissue for research so that if it is the patient's wish, their tissue can be banked for research purposes – it is important that this tissue is linked to outcomes data. Currently the Human Tissue Act requires specific consent be given for a specific study which is a barrier to tissue being used for other relevant research. More generic consent would greatly improve the productivity of tissue usage and we need to find a way forward here based on fully-informed consent from the patient donor.
- When considering treatment a patient should be told about relevant clinical studies that are currently taking place. This recommendation has been supported in the recently published I*mproving Outcomes: A Strategy for Cancer*.
- As a patient's treatment progresses, so the information made available to them about medical research should change and adapt to be relevant to their individual situation. Patients should be made aware of research opportunities, even if they decide not to take them.
- The information provided should not solely include clinical studies relevant to the condition but all relevant research on areas such as quality of life, patient related outcomes, diet and the long-term effects of treatment. Capturing research and information on the longer-term effects of treatment is of particular importance to patients themselves, especially as cancer survivors grow in number and longevity. Additionally, this information is important to health services in meeting the needs of this relatively new population group.
- Whilst patients need to be made aware of medical research early in their treatment, information should be given with skill in order to meet the needs and wishes of the potential participant, allowing them to make an informed choice when they feel ready to do so. All too often the wish to 'be sensitive' is experienced as paternalistic. The training of health care professionals should incorporate this subtle but important difference.
- It is essential that clinical research is anchored in Multi-disciplinary Teams (see below)

Recommendation 3: Support patient accessibility to clinical studies

3.1 Timely information from supportive Multi-disciplinary Teams

- A designated member of the Multi-disciplinary Team should be responsible for talking to patients about relevant research including access to clinical studies. The clinical nurse specialist is likely to be best placed to deliver this information and discuss research needs, as well as to champion patient research preferences within the Multi-disciplinary Team. However, the role of championing research for the patient needs to be taken up by the clinical lead in order to ensure that research issues receive sufficient attention during the Multi-disciplinary team meeting.

- There are still significant variations in access to a clinical nurse specialist. This is not to suggest that the clinical nurse specialist should take on the full role of a designated research nurse but rather that the patient's potential involvement in research is considered alongside other aspects of patient centred care and information-offering. These are both integral roles of the clinical nurse specialist and, for the benefit of both the patient and of research, it makes sense for the clinical nurse specialist to raise the issue of relevant research with the patient or carer.

- Every cancer patient should already have their care and treatment discussed at a Multi-disciplinary Team meeting. In future, Multi-disciplinary Team meetings should routinely consider studies for which a patient might be eligible, and include these as part of the care and treatment recommendations discussed with the patient and carer. To support this process, health professionals should have access to training about how to discuss medical research with patients. . However, there are some disease stages during which medical research is relevant, such as the metastatic stages, but when the patient's care and treatment is not routinely discussed at a Multi-disciplinary team meeting. We welcome greater emphasis given both to metastatic disease and to Multi-disciplinary team development in the recently published *Improving Outcomes: A Strategy for Cancer*

- In future, these meetings should routinely consider studies for which a patient might be eligible, and include these as part of the care and treatment recommendations discussed with the patient and carer. To support this process, health professionals should have access to training about how to discuss medical research with patients.
- When a patient is taking part in a clinical study, they should always be provided with a named contact to support them throughout their time on the trial and advise them on any future research that could be relevant to them.

"I was previously involved in a trial but found there was no named contact could get in touch with for further information or to talk through issues or concerns. Although NCRN protocol states that as soon as an expression of interest in a trial is made you should be assigned a named contact, such as a clinical nurse specialist, it is still the case that some patients, like me, are never provided with one". Expert service user experience

3.2 Patient preference

- Patients should be told about all medical research options which are available to them, even if the hospital they are being treated in is not involved in that research. Choice is essential both for the patient who wishes to take part in a clinical study and for the research community that wishes to improve trial recruitment figures. In order to guarantee this freedom to choose, the issue of patient preference must be carefully addressed in the Department of Health's guidance on commissioning. If a patient would like to take part in a trial at another hospital, that should be made possible without delay. Policy makers and commissioners will need to consider how the use of preference as a 'driver' can be achieved. Patient preference is likely to encourage hospitals to become more aware of their 'research profile' and thus more likely to become research active clinical units. Research active clinical units are likely to look to learn from others and undertake local research, thus driving evidence-based practice and service improvement. Patient perception is that they will receive optimum care at hospitals where medical research is conducted. Although not every hospital can undertake research, patients should have confidence that their hospital will refer them if they want to take part in a trial elsewhere. Hospitals may need to be incentivised to do this. *Improving Outcomes: A Strategy for Cancer* reemphasizes the importance of these cross-centre partnerships in offering choice to the patient stating that 'patients may prefer to travel but might face barriers which prevent them from doing so and some patients may prefer the benefits of the close working relationships developed between service providers within an area. Effective choice should not involve a series of one-off decisions but rather a process of continuous patient engagement with entitlements to revisit decisions provided it is clinically appropriate.'
- Transparency about treatment options is a central plank of the current reforms to increase patient choice. An integral part of these changes should be the provision of information about clinical studies at other centres.

VISION FOR EXCELLENT INFORMATION RESOURCES

Recommendation 4: Bring accurate and up-to-date information resources closer to the patient and carer

4.1 What does good information look like and from where is it to be accessed?

- The production of information should draw upon the experience, knowledge and expertise of service users who have been involved in research and consumer research panels should be invited to review patient material.
- As part of the government's Big Society agenda, the recently published *Improving Outcomes: A Strategy for Cancer* highlighted the importance of drawing upon the expertise of cancer charities in the production of information. Partnerships between cancer charities and service users will prove invaluable in the creation of the most up-to-date and relevant research information.
- It is important to ensure that patients and clinicians have access to the most up-to-date information on clinical studies. We consider that there should be no division between professional and patient information and that information should be accessible to all. However, a one size fits all approach may not be suitable because the level of education and understanding may vary considerably amongst patients and clinicians. Information can be graduated such that straightforward communication is offered, together with the opportunity to drill down to greater detail.
- Not all patients will be 'in clinic' when and where a relevant trial is available and thus information needs to be available at a range of cancer care facilities, including cancer information centres, cancer care centres and through cancer charities. To raise awareness, national posters and information about clinical studies from the National Institute for Health Research (NIHR) should be available in GP surgeries and short video clips could be available via online sites such as YouTube.
- Information about clinical trial protocols need to be easily accessible to everyone, including service users. Currently, this is not the case and protocols are usually only available if you agree to consider a trial. Although protocols are dense and difficult to read, we consider that access to their content is essential, as they include reasons behind why the primary/secondary outcomes were chosen, the full inclusion and exclusion criteria, dosage details, stopping rules, details of patient monitoring and information on treatment continuation post-trial.

> "I tried to obtain a clinical trial protocol when my niece was diagnosed with Hodgkin's Lymphoma but was told I couldn't have it because I wasn't a health professional."

- Before a patient can be introduced to condition specific trials, a simple information sheet should be provided to all new patients explaining what a clinical trial is. This should be included in the information given to the patient at diagnosis. This information sheet should include a web address to enable the patient to link through to an up-to-date source of information about the relevant study or studies.
- The publication of clinical study results is equally important. The availability of the results is important for learning and scrutiny, which are important drivers to change clinical practice. Reviews and results are also important for patients being offered a choice of treatment approaches. By increasing the availability of evidence, patients can be empowered to make informed evidence-based decisions about their care.
- Service users also urge the use of Patient Reported Outcomes Measures (PROMS) to capture patient focussed research outcomes. PROMS could assess the effectiveness of treatments and interventions used in clinical studies and could also embrace both clinical and well-being measures, for example, the quality of life and physical health of patients during and after clinical studies; the symptoms experienced and the effectiveness of symptom control; the emotional impact upon the service user and the societal impact of the research.
- Information prescriptions should support the process and act as a lever to personal, timely information. Information prescriptions depend on access to a national cancer information database which is being built by the National Cancer Action Team in partnership with cancer charities. We want that same system to be able to link current and future databases of clinical trials so that information about relevant clinical studies can be incorporated into personalised information prescriptions. This has to be the test of a fit for purpose clinical studies database.
- Patients should be enabled to participate in the training and education of researchers and clinicians. There are already examples of where this has been undertaken successfully: training days have been run by Cancer Research UK, Breakthrough Breast Cancer and other charities; the King's Fund has offered training for NHS managers and Independent Cancer Patient Voice has run study days.

4. 2 Clinical trial databases

- The National Cancer Research Network is an important portal for information about clinical research and essential to ensure patients are offered up to date and accurate information. In particular, the development of its searchable database, which is to be completed in 2013, will be an important tool for accessing information. It is essential that this piece of work is given priority. However, any future resource should be designed to meet patient needs and clearly indicate the studies for which they might be eligible. Importantly, it should have a user-oriented interface which has been thoroughly tested with lay people from different

demographic groups. New user-oriented databases are being developed, for example see https://www.breastcancertrials.org

- Pharmaceutical companies can support a national database by providing clear and transparent information relating to their ongoing studies and completed study results.
- Databases, such as that of the National Cancer Research Network should be easily accessible and navigable. In particular, acronyms and medical jargon should be avoided and simpler lay summaries containing key facts, such as those developed by the National Research Ethics Service, should be available to ensure patients do not have to digest large technical documents. Importantly, information should be presented in a simple format with studies having a single identifier rather than referenced as a name in one format and a number in others.
- Information on databases should be developed with the reader in mind. To increase its usability, the database should guide the user to information step by step. For example, it should take the user through a number of questions around their health situation or diagnosis so that it is able to highlight studies which may be of interest.
- It is important to quickly capture and coordinate data from NCRN's Clinical Studies Groups which meet three times a year. There is a significant amount of information currently co-ordinated by the NCRN and NCRI secretariats for regular reports to the NCRI Board and sub-groups and it is important to utilise this information more effectively.
- Despite the recognition that a central database is essential for access to information, there were significant concerns about the feasibility of keeping such a large database updated. Much of the material is already available; however it may be necessary to think of new ways of capturing this in one place. The challenges of this task further reinforce the importance of health care professionals offering patients the right information at the right time. Some service users suggests that a more 'bottom-up' approach with changes being directly uploaded by Clinical Trials Units who have the information directly to hand might provide a more practical solution to providing essential information quickly and accurately than working from 'top down.' Charities are already grappling with these issues.

The British Sarcoma Group (BSG) has attempted to collate all clinical trials taking place in sarcoma, including multi-centre trials which are not NCRN badged.

Despite this being one of the smallest portfolios in the NCRN portfolio, gathering information from clinical trial units and patient liaison services was incredibly time intensive and there were difficulties keeping the information up to date.

The BSG has only limited resources, yet in December 2010, the BSG website was more up-to-date than the NCRN database on NCRN badged studies – the most notable omission from the NCRN site being a new academically led Phase 3 randomised controlled trial (GEDDIS) which had been discussed at clinical studies group meetings for two years.

VISION FOR MEASURING, MONITORING AND EVALUATION

Recommendation 5: Collect, collate and evaluate the right data at the right time

During this period of fiscal constraint, increasing efficiency in the health service is paramount. As such, the data the NHS captures must provide meaningful information which can be utilised to drive service improvements. There should not be a 'box-ticking' exercise the information collected should be used which means it must be easily accessible and widely communicated.

In particular, information relating to patient preferences and access to and involvement in research should be collected in order to monitor outcomes and, in turn, implement a procedure for improvement if required. By doing so, if it becomes easier for patients to enter trials and if studies complete and report quicker, then it is of benefit to everyone.

Information should be collected to create a national picture of patient access to, and involvement in research, to measure the quality of UK based medical research. This will equip commissioners with information about variations in services and where there is a need to address inequalities.

5.1 Data capture and dissemination

- Multi-disciplinary Teams already collect data, increasingly in real time at their regular meetings. At the Multi-disciplinary Team meeting, the question of whether or not the patient has received research information should be addressed and recorded as part of the cancer dataset. This data should be made available both to the National Cancer Intelligence Network (NCIN) and the NCRN. This information gathering and sharing process should be embedded in Multi-disciplinary Team best practice through peer review standards.
- Data collected at a local level should be used to create national datasets, as is currently the case with the collection of information through cancer registries and the forthcoming launch of the NCIN national agreed dataset.
- A number of ways in which to capture relevant research information should be introduced. These include:
    - Aggregated Multi-disciplinary Team data should be made available to commissioners through the NCIN.
    - Patient reported Experience Measures (PREMs) should be used to explore the patient's experience of being informed and consulted about research opportunities.
    - The National Cancer Patient Survey could ask whether or not patients have been told about research which is relevant to them and also record their views about how research information is conveyed.

5. 2 Monitoring and evaluation

- In order to understand the impact of the changes suggested and to gather information to make improvements, quantitative data must be recorded and correlated. How many people received information about clinical research? How many people were eligible to be entered into a trial; and how many of those chose to join a trial? What does this picture look like when data is 'cut' by gender, age, ethnicity and recruitment to time and target?
- For monitoring and evaluation to be meaningful, information needs to be triangulated, for example, peer review of an institution should look at the national cancer survey outcomes for the institution, as well as other data from NCIN and NCRN. All of this together should act as the snapshot for that hospital, as does the Ofsted methodology for schools.
- Multi-disciplinary Teams should audit their team practices for discussing and recording research and implement changes based on this self-reflective process.
- It is important to assure the quality of the information provided. This could be achieved through the process of DH Information Accreditation.

When David was asked to go on a trial, I had to obtain the six monthly results from a different place, as we were unable to get them from the centre where he was being treated. This information is vital for patients considering clinical studies. In the end, David did not enter the trial as 51% of patients had dropped out due to toxicity. However, this information should have been provided to him with the protocol as it would have saved a lot of time and worry, and provided a straight answer as to whether the trial was suitable for David.

Conclusion

Working together, service users have built a picture of how the information revolution can help relevant research to become part of the way the NHS carries out its core business, to the benefit of patients and to the enterprise of UK clinical research. For these benefits to come about, increased awareness and access to high quality information is needed; and, perhaps most importantly, every person affected by cancer should be told by a health care professional about the research which is relevant to them. Recording whether and how this is actually done will underpin improvement and enable commissioning for best practice.

Appendix

Participants

Christine Allmark	Member of the NCRI CLG, Head and Neck Clinical Studies Group, NCIN Site Specific Clinical Reference Group, NCAT Peer Review North Zone panel team; NCRN Cancer Networks review panel, NIHR Research for Patient Benefit Research Grant funding applications lay reviewer; and involved in partnership and research work primarily in Yorkshire.
Hugh Butcher	Co-chair, Service User Partnership Group, Yorkshire Cancer Network
Monica Jefford	NCRI CLG member and Chair of SWLCRN Consumer Research Panel
Adrienne Morgan	Research scientist and metastatic breast cancer patient. Chair of Independent Cancer Patients' Voice, member of Cancer52 strategy group and Breast Cancer Campaign Tissue Bank Board
Marek Plaskota	Research Nurse, Princess Alice Hospice
Lesley Roberts	Member of the Programme Grants for Applied Research funding committee, the Clinical Translational Radiography and Radiology Working Group, Advisory Panel for End of Life Care and member of the Consumer Liaison Group
Richard Stephens	Member of the NCRI Consumer Liaison Group (CLG) and Consumer Involvement Steering Group, the NCIN Site-specific Clinical Reference Group on Haematology and the NCIN Scientific Advisory group
Anthony Webber	Chaired research projects with North Trent CRP and an advisor on a study of myeloma at Christie Hospital
Maggie Wilcox	Founder member of SWSH Cancer Partnership Research Group and Independent Cancer Patients' Voice and member of NCRI CLG, NCRI Breast CSG and Breast Cancer Campaign Tissue Bank Board
Roger Wilson, CBE	Director of Sarcoma UK and former Chair of the NCRI Consumer Liaison Group

Facilitators

Joanne Rule	Independent facilitator, former consumer member of the NCRI Board and currently Co-chair of the National Cancer Equalities Initiative
Sarah Woolnough	Head of Policy at Cancer Research UK

In attendance

Sheila Fisher	Associate Director for PPI, NCRI/NIHR-NCRN

About GSK

GSK is one of the world's leading research-based pharmaceutical and healthcare companies with a wide range of products across a number of therapy areas namely oncology, neuroscience, cardiovascular and metabolic, infectious diseases, respiratory and vaccines. In the field of cancer care, we are dedicated to researching and developing treatments that will make a difference to the lives of patients.

All of GSK's products undergo robust regulatory testing through clinical trials. Clinical trials are essential to furthering medical science and conducting clinical research in the UK will increase the expertise of the country's clinicians, bringing new treatment options to patients. Four members of GSK also attended the roundtable as facilitators and observers.

Useful links

Cancer Research UK: http://www.cancerresearchuk.org

Clinical Research Network Coordinating Centre: http://www.crncc.nihr.ac.uk

Clinical Trials Toolkit: http://www.ct-toolkit.ac.uk

Department of Health Live Consultations:

http://www.dh.gov.uk/en/Consultations/Liveconsultations/index.htm

Independent Cancer Patients' Voice http://www.independentcancerpatientsvoice.org.uk

Medical Research Council: www.mrc.ac.uk

National Cancer Research Network: http://www.ncrn.org.uk

NCRI Consumer Liaison Group

http://ncrndev.org.uk/index.php?option=com_content&task=view&id=68&Itemid=115