

Priority Setting and Patient and Public Involvement in Priority Setting in Clinical Research

A web review of UKCRN Topic Specific Research Networks

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1. Context

The James Lind Alliance (JLA) is developing, piloting, and describing methods for shared priority setting in research that addresses treatment uncertainties. The JLA considers the UKCRN to be a key partner in raising awareness regarding the lack of shared research priorities. Members of the UKCRN have been involved in the strategic direction of the JLA since its inception.

In early 2008, the JLA commissioned TwoCan Associates to scope research priority setting with a wide range of research funding organisations in the UK. This work comprises a web review, followed by telephone interviews with research managers in a sample of UK clinical research funding organisations. The UKCRN was not included in the scope of this project because a) the networks are not funding research and b) the resources available for the project would not cover the complex nature of the networks.

Whilst the UKCRN is not a funder of clinical research, it does influence and support the nature and scope of clinical research in the UK. Clinical Studies Groups “provide the primary route through which new clinical research ideas are developed”. The JLA was interested in how the Topic Specific Research Networks developed their research ideas and set their priorities for their respective clinical research programmes, and whether/how patients and the public are involved in this work.

A web review was undertaken of the Topic Specific Research Networks in parallel with the larger scoping project, with a view to comparing and contrasting the findings. As the Comprehensive network was still under construction at the time of the review it was decided to omit this network.

2. Method

Over a period of three days in June/July 2008 – the relevant websites of the Topic Specific Research Networks were reviewed using the same format as the TwoCan project. About 2 – 3 hours was spent on each site exploring pages that related to any aspect of priority setting and patient and public involvement. This included Annual Reports (where available), minutes of meetings and topic specific information. In December 2008 the content of this report was verified by Katherine Cowan of the JLA, so this report reflects the information available at this time.

3. About the UKCRN

The UK Clinical Research Network (UKCRN) was established to support clinical research and to facilitate the conduct of trials and other well-designed studies across the UK. As part of the UK Clinical Research Collaboration (UKCRC), it works towards the development of a world class infrastructure to support clinical research in the UK. The UKCRN is working to develop and strengthen NHS infrastructure to support the delivery of clinical research in the UK via Topic Specific Research Networks and a Comprehensive Research Network. The UKCRN is currently undergoing a rebranding exercise – due to launch in Jan 2009 – some areas of the website were not operational at the time of final reviewing.

3.1 About the Topic Specific Research Networks

The Topic Specific Research Networks (known as TSRNs) provide the structure for adopting and recommending clinical research studies that relate to these topics/settings, which currently include Mental Health, Diabetes, Stroke, Medicines for Children, Dementias and Neurodegenerative Diseases, Cancer and Primary Care.

Their budget is allocated to support the network administration, structure and Patient and Public Involvement (PPI) activity.

4. Summary of findings

4.1 UKCRN websites as a 'public window' to clinical research in the UK

- There was much variation between the currency of information generally, level of detail and ease of navigation between the TSRN sites.
- There is a tendency to report what the network aspires to and is planning, rather than what it is doing and has achieved.

NB. These factors place limitations on how some of the results of this review can be interpreted.

4.2 Patient and Public Involvement generally and in priority setting

- The review shows that the UKCRN has invested time and resources developing a structure and support system to enable patients, carers and the public to become involved in some UKCRN activities.
- These activities tend to be more focused on awareness raising, process issues of involvement and recruitment to trials, rather than the research portfolio/agenda.
- The National Cancer Research Network has a large and organised approach to PPI in the Clinical Studies Groups – but it is difficult to see from the website how far this involvement extends to priority setting activity.
- There is one example that describes both the priorities and methods to reach them, from a patient/carer perspective.

4.3 Priority Setting

- Most of the sites make statements about an intention to identify gaps and prioritise topics/areas for clinical research.
- Most sites state some clinical research priorities, but do not describe the source of these or how they were developed.
- The Mental Health Research Network has the most input from a wide range of stakeholders on priorities in four key areas (Scoping Groups).
- The Medicines for Children Network has an overarching priority setting project underway that will involve a wide range of stakeholders.
- The UKCRN's success appears to be measured by accrual and recruitment to existing or adopted trials within the portfolio. This is what is reported most in Annual Reports and Statements of Clinical Studies Groups. It is difficult to see where prioritisation processes and outcomes would fit into this model despite the make up of TSRN's and CSG's being well suited to this sort of activity.

5. Summary of findings of review

Topic Specific Research Network	Clinical Studies Groups (CSG's) /Sub Groups	Priorities stated?	Method stated?	Source of priorities?
Mental Health	32 CSG's 4 x Scoping Groups on topic areas (from Dept of Health) SURGE FACTOR	Broad areas Yes Yes Yes	 Yes Yes Yes	 Wide range of stakeholders Service users Carers
Diabetes	1 x CSG	Yes	No	D/K
Stroke	8 x CSG's covering topics and settings Focus groups	No DK	No No	DK People affected by stroke
Dementias and Neuro-degenerative Diseases	7 x CSG's 4 in specific disease areas 1 Primary Care 2 Special interests	Yes Yes Yes	1 Yes, 3 No No No	NICE Guidelines, otherwise D/K D/K D/K
Medicines for Children	13 x CSG's covering broad topic areas	Examples found: Gastrology, Hepatology and Nutrition PRIOMED CHILD Project	Yes Yes	Professional Organisations Patient Support Groups, Charities Wide range of stakeholders
Primary Care.		No	N/A	N/A
Cancer	23 CSG's 15 of these cancer 'site specific' 8 others 72 Subgroups	Examples found: Comp' Therapies Teenagers and Young Adults Lymphoma Renal No	 Yes Broad areas Yes Broad areas N/A	 Wide range of stakeholders Teenagers and Young Adults By proxy – stakeholders D/K N/A

6. Detailed summary of web review findings by TSRN

6.1 Mental Health Research Network (MHRN)

<http://www.mhrn.info/index.html>

Health conditions covered	<p>All mental health related – adults and children</p> <p>No distinctions found in web structure for particular disease areas</p>
Info relating to CSG's and priority setting	<p>MHRN structure consists of 8 x Clinical Research 'Hubs' by region across England that are collaborations of academic and clinical organisations and user and carer networks to support the MHRN adopted research.</p> <p>To “add creative drive and increase research capacity” the MHRN has created groups of clinical academics, clinicians, researchers and service users and carers to come together to “identify areas of strength and weakness in mental health research, pinpointing suitable topics and producing research proposals”.</p> <p>Since 2003, 32 Clinical Research Groups have been established to address particular areas of mental health e.g. treatment of depression, early intervention in psychosis. There is no mention of priority setting.</p> <p>Scoping Groups have been established in response to Department of Health priorities in broad topic areas. Each group conducts a horizon scanning exercise and is responsible for investigating the gaps, opportunities and range of research topics within that broad area. They cover:</p> <ul style="list-style-type: none"> ❑ Children's Mental Health ❑ Families and Carers of People with Mental Illness ❑ Older Age ❑ Social Care
PPI	<p><i>SURGE – Service Users Research Group for England</i></p> <p>SURGE plays an important part in making sure research across the MHRN is valuable for and makes sense to service users. SURGE supports service user input to the MHRN through service user involvement in local hub committees, research project teams and at a national level as described above.</p> <p><i>An important output of SURGE activity is the paper 'Service Users' Priorities for Research (December 07), which examines the latest evidence on service user priorities in current literature in order to inform the next call for research groups. This is available in the Service User Involvement section of the website, under publications.</i></p> <p>The MHRN's <i>Guidance for Good Practice</i> (November 2006) for service user involvement makes reference to the potential differences between the research priorities of service users and researchers or Trusts, and offers basic guidance on consulting with service users about their priorities.</p>

	<p><i>FACTOR</i> – Families/Friends And Carers Together in Research FACTOR has been set up to involve carers in research, and to make research information available to carers, by raising of the profile of carer research interests at networking events and research functions.</p> <p>As at June 2008 FACTOR was putting together a document on carers' research priorities, drawing together conference findings, input from the FACTOR network members, a review of existing literature and a forthcoming survey. Further information is in the June 2008 Newsletter (http://www.mhrn.info/index/library/factor-docs/mainColumnParagraphs/00/document/FACTOR%20newsletter%20June%202008.pdf)</p>
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6.2 Diabetes Research Network (DRN)

<http://www.ukdrn.org/>

Health conditions covered	Type 1 and Type 2 Diabetes
Info relating to CSG's and priority setting	<p>The DRN has 1 Clinical Studies Advisory Group (CSAG) with a "remit of overseeing the portfolio, working with the Department of Health and funders groups, to set research strategy and addressing any gaps in the portfolio with input from members of the new research groups".</p> <p>There are 9 broad priority areas for research with specific questions within these areas. No priority setting methods stated</p> <p>Feeding into the CSAG are 8 Research Groups, which have a particular research focus. One has patient representation within its membership and one has stated its link to a consumer panel. It is not clear how these specific areas were decided, they are:</p> <ul style="list-style-type: none"> • Neurodegenerative Diseases • Telemedicine in Self-Management of Diabetes Mellitus • Diabetes and Pregnancy • Use of neuro imaging to investigate metabolic disorders related to diabetes • Detection and prevention of diabetic complications in children and adolescents with Type I diabetes • Developing a structured education programme for people with diabetes • Prevention of type II diabetes • Developing a programme of work for black and ethnic minority groups with diabetes with a focus on South Asian populations. <p>There are 8 Local Research Networks whose aim is to increase research into diabetes.</p>
PPI	There appear to be clear support mechanisms in place for

	<p>involving patients and public in DRN activity. Those who become Patient Advocates can join a “Reference Panel” and “help set research priorities”</p> <p>There is no information about how this is done.</p>
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6.3 DeNDRoN

<http://www.dendron.org.uk/>

Diseases	Dementias, Huntingdon’s Disease, Parkinson’s Disease, Motor Neurone Disease.
Setting	Primary Care
Special Interest	Clinical Research Methodology, Neuropathology & Brain Banking
Info relating to CSG’s and priority setting	<p>There is a Clinical Studies Group for each of the specific areas in the box above. Each “work to a broad, but common remit that includes overseeing existing studies, considering new research questions, developing proposals and securing funding from CRC partners, as well as providing expert advice.”</p> <p>All specific disease areas state their research themes and priorities – it is less clear how they reach these, although NICE guidance and Cochrane Collaborative groups are mentioned on some of the CSG web pages.</p> <p>Two examples below:</p> <p>Research priorities for Dementias:</p> <ul style="list-style-type: none"> • Empowering patients and carers from diagnosis and treatment • Treatment of dementia in Parkinson’s disease • Cardiovascular risk factors and management in Alzheimer’s disease • Medication compliance in dementia • The cost effectiveness of specialist home care schemes • The impact of assisted technologies in care and diagnosis • Depression in primary carers and cost effectiveness of early intervention with AChIEs <p>Research priorities for <i>Parkinson’s Disease</i></p> <ul style="list-style-type: none"> □ Further examination of the effects of cholinomimetics on PD dementia and visual hallucinations in PD, as highlighted in the NICE guidelines. Which diagnostic investigations for PD and potential biomarkers of its progression are clinically useful and cost-effective? □ Are there ways to improve early accurate diagnosis of PD in a primary care setting? □ Which of the currently available therapeutic strategies to deal with refractory motor fluctuations and dyskinesias is most efficacious?

	<ul style="list-style-type: none"> ❑ What are the causes for disturbed balance and speech in PD and related disorders, and what treatment programmes can be considered? ❑ What types of PD research are considered important by patients – to be led by the patient experts on the panel <p>In the Primary Care Clinical Studies Groups “the debate in the CSG is now about refining and prioritising themes, and focusing on specific research questions that could be the basis of future research proposals, or that could inform calls for research from major funders”.</p> <p>The Special Interest Group on Clinical Trials Methodology also has 5 priority areas of interest.</p> <p>With the exception of the Parkinsons Disease CSG, which embraces some of the research priorities published in June 2006 in the NICE guidelines for the management of PD, there is no information on how these priorities were reached.</p>
PPI	<p>The website has links to pages that address involvement in network activity. Here is it stated that “The adoption of clinical studies to the Network will be done in partnership, between people affected by these conditions, and the clinical researchers and healthcare professionals working in this field. Both groups will contribute to the prioritisation, design, conduct, reporting and dissemination of research.” How patient involvement in research prioritisation will happen is not described.</p> <p>PPI activities include:</p> <ul style="list-style-type: none"> ❑ PPI Working Group that has identified priority areas where they can “<i>have a real impact on DeNDRon</i>”, these objectives focus on PPI ‘adding to processes within the network’, (but no explicit mention of priority setting) ❑ A wider ‘PPI Forum’ ❑ Focus Groups (to discuss barriers to participation in Dementia, Huntingdon’s research) ❑ Recruitment to steering committees

6. 3 Stroke Research Network

<https://www.uksrn.ac.uk/>

Health conditions covered	Stroke
Info relating to CSG’s and priority setting	<p>Clinical Studies Groups, (CSGs) are responsible for the development of stroke studies within their strand (see below) including “identifying gaps and proposing or developing new studies”. Some CSGs state likely broad priority areas and inclusion and exclusion criteria.</p> <p>8 CSGs on:</p>

	<ul style="list-style-type: none"> ❑ Acute ❑ Prevention ❑ Rehabilitation ❑ Primary care ❑ Translational research ❑ Biostatistics and informatics ❑ Service development and training ❑ Patient, carer and public involvement. <p>Site describes study adoption, and research portfolio, but no indication on areas of priority.</p>
PPI	<p>PPI activity appears to be mostly concerned with process of PPI, such as:</p> <ul style="list-style-type: none"> ❑ Help to design studies ❑ Become a member of a clinical studies group ❑ Contribute to newsletters or articles <p>However there are also indications of activity in research development, where patients have the opportunity to:</p> <ul style="list-style-type: none"> ❑ Identify research questions ❑ Contribute to discussions about new research in a focus group

6.4 Medicines for Children

<http://mcrn.org.uk/>

Health conditions covered	<p>Not condition-specific, but has a remit to improve the co-ordination, speed and quality of randomised controlled trials and other well designed studies of medicines for children and adolescents, including those for prevention, diagnosis and treatment.</p>
Info relating to CSG's and priority setting	<p>13 CSGs plus one CSG Chairs Forum.</p> <p>Each CSG was asked to produce a list of research priorities to be presented to the UKCRC Funders Forum in March 2007. Some Chairs approached members of the research community beyond the CSG using established working groups to compose their lists whilst others discussed the issue with the CSG via email or meetings. It appeared that some, but not all, CSGs involved patient organisations and carers in that process.</p> <ul style="list-style-type: none"> ❑ Anaesthesia, Pain, Intensive Care and Cardiology ❑ Diabetes, Endocrinology and Metabolic Medicine ❑ Gastroenterology, Hepatology and Nutrition <ul style="list-style-type: none"> ○ CSG wrote to all 400 members of the British Society of Paediatric Gastroenterology Hepatology & Nutrition, British Dietetic Association and patient support groups and charities. Asked these organisations to suggest key areas where clinical studies were a high priority. Invited investigators to make contact with the CSG to discuss specific research proposals. This consultation identified some key areas for clinical studies including;

	<p>inflammatory bowel disease, management of functional bowel disorders in children, and liver disease (including the management of obesity related non-alcoholic steatohepatitis).</p> <ul style="list-style-type: none"> □ General Paediatrics <ul style="list-style-type: none"> ○ states in their scope that their work will include “liaison with the research community to identify research priorities” and “prioritisation, in a timely fashion, of research priorities presented to the network”. However in last Annual Report on the web, priority setting “outside the scope of the group given the time and resources, further discussions with the RCPCH are suggested”. □ Methodology <ul style="list-style-type: none"> ○ The CSG’s scope includes liaison with the MCRN research community and the wider research community to identify research priorities and any organisational difficulties that are impacting negatively on the research agenda. However, priority areas for research were deferred until 2007. CSG agreed that identifying gaps in the existing evidence base for methodological research is important but acknowledge that such an exercise is going to be difficult. Accepted that identification of gaps would be undertaken by members of the CSG in consultation with colleagues in the various relevant disciplines/research areas (e.g. health economics, views of participants etc). □ Neurosciences <ul style="list-style-type: none"> ○ in their ‘scoping document, “developing consumer involvement in prioritising” through liaison with the wider paediatric neurology community. □ Neonatal <ul style="list-style-type: none"> ○ CSG has “future plans to run a Delphi exercise to seek a professional consensus on research priorities” □ Pharmacy and Pharmacology □ RANII <ul style="list-style-type: none"> ○ Rheumatology, Allergy, Nephrology, Infectious Diseases and Immunity – “plan to seek research priorities led by CSG members for specific areas”. □ Respiratory and Cystic Fibrosis <ul style="list-style-type: none"> ○ The group has been working closely with all members of the British Paediatric Respiratory Society to identify key unanswered clinical questions and prioritising topics for research. It has interrogated the Cochrane Database, used documentation from Asthma UK. It has responded to the first HTA call for Medicines for Children by submitting 7 topics for research funding. Four of these 7 studies have been progressed to the full proposal stage and we await the outcomes in June 2006. Following these they will plan and re-group their priorities for future funding opportunities.
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	<ul style="list-style-type: none"> ❑ Children's Cancer and Leukaemia Group (CCLG) <ul style="list-style-type: none"> ○ part of the NCRN. ❑ Paediatric Nephrology <ul style="list-style-type: none"> ○ The remit document states that “the CSG will both develop the clinical research portfolio and help to define research priorities in paediatric nephrology”. <p>ERA-NET PRIOMEDCHILD – this European funded project aims to set a Europe wide research agenda for medicines for children, working with children’s groups and charities as well as professionals. A Delphi approach will identify gaps and priorities.</p>
PPI	<p>All CSGs must “ensure consumer involvement in all activities”.</p> <ul style="list-style-type: none"> ❑ Neurosciences – “developing consumer involvement in scoping, selection of out-comes, recruitment, consenting and retention strategies, participant information, dissemination, and implementation”. Members include a consumer representative. ❑ Neonatal - work with BLISS to develop understanding of parents’ research priorities ❑ Pharmacy and Pharmacology - Members include a consumer representative.

6.5 Primary Care

<http://www.ukcrn.org.uk/>

Health conditions covered	All, with special interest in chronic long term conditions such as arthritis, asthma and heart disease, and with interest in disease prevention and early diagnosis
Info relating to CSG’s and priority setting	<p>The main goal of this network is to increase the number of patients recruited or involved in clinical trials, and other well designed primary care studies.</p> <p>The network comprises eight clinician-led Local Research Networks that include a Network Manager and staff from nursing and other health professions, or life sciences backgrounds, data managers and support staff.</p> <p>Each network works with GP practices, health centres, and dental practices and in other community locations to facilitate the involvement of staff and patients in clinical studies.</p> <p>No indication of priority setting of studies/adoptions/recommendations, other than the mission statement.</p>
PPI	No apparent infrastructures described or referred to

6.6 National Cancer Research Network

www.ncrn.org.uk

Health conditions covered	All cancers. Aim is to "improve the speed, quality and integration of research resulting in improved patient care".
Info relating to CSG's and priority setting	<ul style="list-style-type: none"> ❑ 33 regional cancer research networks exist in England. ❑ 23 NCRI Clinical Studies Groups, these include: ❑ 15 cancer 'site specific' groups <p>Other groups are; Consumer Liaison, Primary Care, Psychosocial Oncology, Complementary Therapies, Teenagers and Young Adults, Translational, Radiotherapy, and Palliative Care.</p> <ul style="list-style-type: none"> ❑ Each CSG aims to identify gaps in current research and develops new trials to address these. ❑ Approx 72 Subgroups (some with working groups as well) focus on more specific types, and sites of cancer. <i>This is an approximate figure because some annual reports hint at mergers of some groups and the development of new groups</i> <p>Evidence was sought for explicit descriptions of methods of priority setting and PPI in that priority setting. The following examples were taken from the web pages of the NCRN site:</p> <ul style="list-style-type: none"> ❑ The Complimentary Therapies CSG has undertaken surveys with cancer patients on aspects of their care and treatment to help scope out areas for research ❑ The Lymphoma CSG has used the recent NICE Review of Evidence in Haematological Malignancy to inform its' priorities. This review incorporated a range of stakeholder input including cancer patients. ❑ The Renal CSG facilitated a symposium whereby 5 areas of research priorities were established. It is not stated who participated. ❑ The Teenage and Young Adult CSG works with the Teenage Cancer Trust – particularly on a "Find your sense of tumour conference" an annual event which includes electronic surveys of participants views of clinical research.
PPI	<ul style="list-style-type: none"> ❑ Consumer Liaison Group with large membership ❑ Each CSG has at least two consumer representatives ❑ 6 Consumer Research Panels (geographical) ❑ In 2006 an independent panel reviewed the structure and how the rest of network viewed the value and impact of involvement. This includes a critique as well as positive benefits of consumer involvement – one of the consumer priorities was "input into the larger dialogue in regard to portfolio balance and direction" The report is available in Consumer Research Panel page, part of the PPI section of the website.