Medicines for Children Research Network

Consumer Strategy 2012 - 2015
**NIHR-MCRN Strategy for Consumer Involvement 2012 - 2015**

1. **Introduction and background**

Consumer involvement is a central thread running throughout the activities of the National Institute for Health Research Medicines for Children Research Network (NIHR-MCRN). High quality research, good accrual and attrition rates, and improved health outcomes for children, depend on listening to the voices of children and young people, as well as their families and carers, and taking account of their experiences, priorities and perspectives. All stages of the research process benefit from consultation and collaborations with users, and we know that children can make real contributions to decision-making in these areas.

This document sets out the NIHR-MCRN strategy for consumer involvement from 2012 to 2015. The strategy builds on the extensive work undertaken with consumers since 2005. Some of our key achievements to date have been:

- The meaningful engagement of children, young people and parents in all MCRN activities. These perspectives have been integrated into all other workstreams.
- Ensuring that consumer input is integral to all MCRN procedures and increases the quality and delivery of industry and publically-funded studies.
- External recognition that MCRN consumer engagement is a model for publicly-funded and industry studies.
- Consumers have communicated MCRN messages to professionals and the public more effectively than any other group.
- Won National Awards for Excellence.
- Increased the involvement of children and young people through the establishment of a National Young Persons’ Advisory Group
- Wider impact of the MCRN Consumer Involvement work-stream on National Research Ethics Programmes
- Provided guidance to researchers on how to involve children and parents effectively in research design and delivery, this has included supporting the set establishment of two young people’s advisory groups both in Scotland and Canada. We have also published a book chapter reflecting on how young people can be involved in the design of medicines for children research.

The strategy is informed by the following key documents:

- NIHR MCRN Consumer Involvement Strategy 2007-2012
- NIHR CRN’s The Way Forward Report¹
- NIHR CRN’s Higher Level Objectives/PPI Objectives²
- MCRN’s Strategy 2007-2012³
- MCRN Communications & Engagement Strategy 2012-2015

This document should be read in the wider context of the business case for Patient and Public Involvement (PPI) submitted to the Department of Health (DH) by the NIHR Clinical Research Network Coordinating Centre (NIHR CRN CC) on behalf of all the clinical research

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¹ *The Way Forward*: Making a difference in research by actively involving people: The Report, Stewart D (October 2010).
² See Appendix A:
³ MCRN’s 5 Year Strategy 2007-2012, MCRN Coordinating Centre, University of Liverpool
networks at the end of March 2011. The submission was part of the wider strategic review of PPI undertaken across all NIHR’s clinical research networks through The Way Forward process.

2. Terms

Public and Patient Involvement (PPI) and Consumer Involvement (CI) are often used interchangeably. In this document we use Consumer Involvement to refer to all such activities. In this context consumers refers to:

- Children aged 18 years or less, with experience of, or interest in, participating in clinical research, health conditions and/or health settings
- Parents/carers with experience of, or interest in, participating in clinical research, health conditions and/or health settings
- Organisations that represent children’s and young people’s interests.

3. Context and relationships

3.1 The NIHR MCRN

The vision of the MCRN is to improve the health of children through research. Its purpose is to provide the best infrastructure within England to support the development and delivery of world-class medicines for children research which is relevant and meaningful to children, families and other key stakeholders, and to contribute significantly to international medicines for children research.

The MCRN Coordinating Centre (MCRN CC) is based at the University of Liverpool’s Institute of Child Health at the Royal Liverpool Children’s Hospital to oversee and coordinate activities across the Network via Local Research Networks (LRNs) and Clinical Studies Groups (CSGs). It is led by a consortium comprising the University of Liverpool, Royal Liverpool Children’s Hospital, Imperial College London, National Perinatal Epidemiology Unit (NPEU; University of Oxford), Liverpool Women’s Hospital and the National Children’s Bureau (NCB). The MCRN is funded by the Department of Health and is part of the National Institute for Health Research (NIHR) Clinical Research Network.

3.2 The MCRN CI Workstream

The MCRN CI workstream is managed through the NIHR MCRN CC by a full time Consumer Liaison Manager with 0.2 administrative support. External funding was obtained in 2011 to employ a part-time youth participation officer to support and facilitate the young person’s advisory group in Liverpool and to work with young people’s groups across the network. The MCRN CI workstream supports the part time post of Associate Director for Consumer Involvement, who is employed by NCB, together with additional expertise in evaluation and involving children in research from NCB.

3.3 The MCRN Consumer Involvement Steering Group (CISG)

A key resource for delivery of the consumer involvement strategy across the NIHR MCRN is the Consumer Involvement Steering Group (CISG) which advises on the strategic direction of consumer involvement within the research Network and provides an impetus for action. The membership and terms of reference for the CISG are set out in Appendix B.
4. The MCRN Consumer Strategy

The following structure will be used to outline the MCRN consumer strategy in further detail using the following headers:

- **vision, principles and values**, informed by the NIHR CRN CC’s PPI framework (in development), MCRN organisational visions and principles
- **aim(s)**, stemming from the vision and informed by NIHR CRN, MCRN high level aims
- **objectives**, stemming from the aim(s)
- **priorities**, based on those stated in 5-year plan
- **delivery**, key activities relating to each objective

4.1 Vision, principles and values

MCRN supports the NIHR position that “involving patients and members of the public in research can lead to better research, clearer outcomes, and faster uptake of new evidence”. Involving children and their families helps to ensure that the issues researched are those of greatest importance and relevance, that the ways in which studies are conducted are appropriate, and that information about the research is accessible, thus enhancing the recruitment of fully informed participants to studies.

The UNCRC (Article 12) asserts that children have a right to have a say in matters that affect them; in this case, clinical research. In addition to upholding their rights, the involvement of children (and families) in research can bring direct benefits to participants in terms of knowledge, skills and confidence.

4.2 Aims

The MCRN Consumer Involvement strategy aims to:

- ensure that all aspects of the work of the MCRN are informed and enhanced by the involvement of children and their families
- continue to build capacity to enable consumers working locally to inform the national research agenda and vice versa
- systematically map and evaluate the impact of Consumer Involvement activity on the research process
- widely publicise and promote the benefits of Consumer Involvement

4.3 Strategic Objectives

In order to support the aims and priorities of the NIHR CRN and MCRN (See Appendix A), and to achieve our aims for Consumer Involvement, our key strategic objectives for 2012-2015 are as follows:

**Objective 1:** Implement an open and transparent system of involving consumers throughout MCRN

**Objective 2:** Ensure that consumers participate, or have their views represented, in all key national and local MCRN committees
**Objective 3:** Support and promote high quality and innovative consumer involvement in all stages of the research cycle, within MCRN and beyond

**Objective 4:** Provide training, mentoring, resources and other support to consumers, researchers and other professionals as required to enable effective and meaningful consumer involvement

**Objective 5:** Provide structures enabling capture, reporting and dissemination of the impact of consumer involvement on individual consumers, on researchers and other professionals, and on medicines for children research

### 4.4 Delivery

We will deliver our strategy as outlined below. Detailed annual plans will be developed outlining key tasks and responsibilities.

1. **Implement an open and transparent system of involving consumers throughout the MCRN**
   
   We will achieve this by:

   1.1 Ensuring that the Consumer Involvement Strategy, and linked documentation, is posted on the MCRN website and freely available elsewhere.
   1.2 Making the remit for, and activities of, all MCRN Committees fully accessible via the MCRN website.
   1.3 Regularly review and monitor the Consumer Involvement Strategy

2. **Ensure that consumers participate, or have their views represented, in all key national and local MCRN committees**

   We will achieve this by:

   2.1 Ensuring that children and/or parents/carers are represented on all national and local MCRN committees (CSGs, CISG, LRN Boards, National Young Person’s Advisory Group); if not represented in person, then we will ensure that mechanisms are developed for the representation of their views
   2.2 Developing structures to support sustainable consumer involvement across regional networks to inform and support national consumer structures
   2.3 Supporting regional consumer involvement roles through an operational group that will ensure activities are carried out to meet the requirements of the consumer strategy
   2.4 Developing systems to enable routine capture and sharing of learning between researchers, clinicians and patient groups about Consumer Involvement and its impact on children’s research. We will ensure this system supports reporting requirements from NIHR CRN CC
   2.5 Providing appropriate training and support for consumer members enabling their involvement in MCRN’s activities.

3. **Support and promote high quality and innovative consumer involvement in all stages of the research cycle, within MCRN and beyond**

   We will achieve this by:

   3.1 Building on our partnerships between pharmaceutical companies and consumers to enable involvement in study design at an early stage of development
   3.2 Working in partnership with Paediatric Clinical Research Facilities (CRFs) to increase capacity and supporting complex and early phase studies
3.3 Working in partnership with children and families to develop appropriate strategies for attracting participants to MCRN studies and activities
3.4 Continuing to develop mutually beneficial relationships with relevant external organisations and agencies (e.g., NRES, RCPCH, WellChild, EFGCP, etc.) for the purpose of developing and promoting high quality consumer involvement
3.5 Actively engaging with investigators to ensure research studies and protocols consider all consumer issues.
3.6 Work towards empowering consumers to play a key role in directing research teams to investigate research questions that are of importance to consumers/service users.

4 Provide training, mentoring, resources and other support to consumers, researchers and other professionals as required to enable effective and meaningful consumer involvement
We will achieve this by:

4.1 Providing members of the Young Person’s Advisory Group with appropriate training and mentoring to assist them in developing informed views on the clinical research process involving young people as well as the necessary skills to enable them to contribute to MCRN activities.
4.2 Providing young people in other settings with relevant support and training from consumer involvement leads and research teams across the network. This support will involve ensuring the young person is fully briefed on his/her role and the activity in question, providing ongoing support throughout the activity, de-briefing after the session, and providing feedback and follow-up information as appropriate.
4.3 Supporting ongoing delivery and evaluation of a core induction programme for newly recruited consumers working at a national level.
4.4 Identifying the training needs of consumers and meeting these through the identification of appropriate training opportunities and/or the provision of resources (e.g., toolkit for consumers)
4.5 Supporting development and uptake of further learning and development opportunities for consumers, researchers and clinicians that helps to optimise consumer impact on medicines for children research
4.6 Working collaboratively across the NIHR CRN with learning and development opportunities that are likely to increase engagement between researchers, clinicians and consumer groups within available resources.

5 Provide structures enabling capture, reporting and dissemination of the impact of consumer involvement on individual consumers, on researchers and other professionals, and on medicines for children research
We will achieve this by:

5.1 Developing a routine annual reporting system for consumer activities and their impact (from national and local research networks and groups), enabling local consumer activities to influence the national research agenda and vice versa
5.2 Developing and implementing systems to capture consumer activities enabling increased understanding of the processes, diversity, and impact across the research cycle
5.3 Working with MCRN Communications Team, develop and disseminate case studies, conference presentations, and relevant publications (across all NIHR CRNs)
5.4 Providing appropriate training and support for consumers to support their involvement in the development of research proposals likely to contribute to an evidence base on the impact of PPI in research, as well as involvement in MCRN’s Impact workstream
5.5 Support formal research initiatives which evaluate the impact of consumer involvement on research
Appendix A: NIHR and MCRN Objectives

The High Level Objectives of the NIHR CRN are to:

HLO 1 - Double the number of participants recruited into NIHR CRN Portfolio studies
HLO 2 - Increase proportion of NIHR CRN Portfolio studies delivering to recruitment target and time
HLO 3 - Increase percentage of commercial contract studies delivered through NIHR CRN
HLO 4 - Reduce time taken to achieve NHS permissions through CSP\(^4\) for NIHR studies
HLO 5 - Reduce time taken to recruit 1st participant into NIHR CRN Portfolio studies
HLO 6 - Increase percentage of NHS Trusts participating in NIHR CRN Portfolio studies

The PPI vision of the NIHR CRN is to:

Maximise the benefits of research to patients and the NHS through active, inclusive and co-ordinated Patient, Carer and Public Involvement (PPI).

The overall priorities of the PPI work programme through to 2015 are to empower individuals to make a contribution by:

- Bringing together the knowledge and experience of patients, carers, researchers, the wider public and the NHS, to generate and support high quality, timely recruitment to and delivery of research on the CRN Portfolio ensuring that PPI remains focused on these impacts and benefits
- Building on existing good practice and remaining at the forefront of thinking, we will develop effective and innovative methods of involvement, to meet the needs of the CRN
- Embedding a coordinated, collaborative and coherent approach to PPI in order to achieve demonstrable impact on the core business of the Clinical Research Network by working with key stakeholders along the research pathway and across organisations

The NIHR CRN’s themes for PPI are:

- Developing PPI as part of NIHR CRN’s core business, built into annual planning and reporting
- Supporting effective engagement, making it easier for patient/carers to be involved in the work of the NIHR CRN
- Sharing good practice, supporting innovation
- Supporting staff working in research to make best use of PPI in developing high quality patient friendly research studies
- Strengthening partnerships with organisations offering PPI opportunities where they can add value to the work of the NIHR CRN

MCRN Aims/key priorities

In order to deliver on its strategic aims to 2015 whilst supporting delivery on the higher level objectives of NIHR CRN, MCRN will prioritise delivery through the following 6 MCRN Priority areas

\(^4\) NIHR Coordinated System for gaining NHS permission (NIHR CSP)
KEY PRIORITIES

COMPREHENSIVE INFRASTRUCTURE - To provide a world-class NHS infrastructure across all of England to support the delivery of MCRN Portfolio studies to time and target, via our Local Research Networks and in partnership with the Comprehensive Local Research Networks (CLRNs), and with effective involvement of children and families.

SUPPORTING INDUSTRY - To increase the number of commercial contract medicines for children studies effectively delivered through the MCRN, utilising appropriate facilities including within clinical research facilities and district general hospitals.

RELEVANT PORTFOLIO - To generate a world-renowned portfolio of high-quality studies that is balanced, meaningful and meets the needs of children and families, clinicians, the pharmaceutical industry and other relevant stakeholders, via collaboration between our Clinical Studies Groups, Local Research Networks and Clinical Trials Units, and in partnership with children and families, and with other appropriate groups and organisations.

EFFICIENT WORKING - To reduce, in partnership with CLRNs, the time taken to achieve NHS permissions for MCRN Portfolio studies, to identify and influence strategies to overcome issues relating to children’s research which impact on these timelines, and to robustly performance manage portfolio activity and study set up and delivery.

OPEN AND INCLUSIVE - To ensure that children and families located across the whole of England have the opportunity to participate in MCRN Portfolio studies regardless of where they live or receive their care, and that all stakeholders have the opportunity to engage with, benefit from and influence MCRN activities and objectives.

INTERNATIONAL COLLABORATION - To foster strong and productive relationships with international groups and initiatives pertinent to, or associated with, medicines for children research in order to influence the improvement of children’s health through global research.
Appendix B – Remit and Terms of Reference of the Consumer Involvement Steering Group

Background

Consumer involvement is a key element of MCRN activities, as set out in its Consumer Strategy. Two members of MCRN have a specific brief to develop this strategy and encourage and oversee the involvement of children and parents/carers. These are the Associate Director (Consumer Involvement), and the Consumer Liaison Manager (Consumer Involvement). In addition, external funding was obtained in 2011 to employ a part-time youth participation officer to support and facilitate the young person’s advisory group in Liverpool and to work with young people’s groups across the network. The Consumer Involvement Steering Group was set up to support them in this role. In this capacity, it advises on the strategic direction of consumer involvement within the research network and provides an impetus for action.

Membership of the Group

The membership of this Group includes:

- MCRN Associate Director (Consumer Involvement) - Chair
- MCRN Consumer Liaison Manager (Consumer Involvement)
- Four parents/carers
- NCB representative
- INVOLVE member with a special interest in children and young people
- RCPCH Participation Involvement Manager
- MCRN LRN PPI Leads
- MCRN CSG representation
- Members of the MCRN Young Persons’ Group (when appropriate)

The remit of the group

The main purposes of the Consumer Involvement Steering Group are to:

- Ensure that the research interests and priorities of children, young people, parents and carers are fully taken into account within the work of the MCRN
- Bring together those with relevant interests and experiences to explore and discuss opportunities to enhance the consumer strategy
- Provide a forum for parents/carers and young people to be involved in the development and implementation of the Consumer Involvement Strategy
- Provide a mechanism to ensure that the ethos of consumer involvement is conveyed as widely as possible across the Network and externally

Responsibilities of the Group

Activities of the group would include:

- Reviewing and revising the remit of the Group as activities progress
- Providing an ongoing review of the consumer strategy and its aims, principles and objectives, linking to the NIHR Patient and Public Involvement (PPI) Strategy
- Reviewing and commenting on other MCRN documents as required (i.e. Communications Strategy; Annual Reports etc)
• Reviewing consumer involvement activities across the MCRN (e.g. Young Person’s Advisory Group, within Local Research Networks (LRNs), Clinical Studies Groups (CSGs))
• Ensuring systems are in place for analysing training needs of consumers involved in MCRN activities and identifying approaches to meeting those training needs
• Establishing good practice guidelines on the involvement of consumers in MCRN research activities
• Examining and discussing new opportunities for consumer involvement, particularly the involvement of children
• Contributing to the dissemination of good practice in consumer involvement through the collection of case studies of consumer activities and via data captured from evaluation forms
• Advising on the consumer involvement section on the MCRN website and other communication materials aimed at the public

Meetings and arrangements:

Frequency and format of meetings

The Group will meet twice a year at the MCRN Coordinating Centre in Liverpool from 11am - 4.30pm.

Members may also be asked to comment on documents by email and/or to take part in teleconferences between meetings.

All expenses for consumer members will be paid by the MCRN CC.

Accountability

The MCRN is responsible for the overall management of the Group on behalf of the UK Clinical Research Network. The Group is supported by the Medicines for Children Research Network Coordinating Centre, based at Institute of Child Health. The Group is ultimately accountable to the Medicines for Children Research Network, via its Executive Group and Board.

Payment and expenses

Parent members of the Group will be offered a fee for taking part in meetings and related activities. This will be based on current NIHR guidance. It is the individual’s responsibility to enquire to their own personal tax/benefits office about the effects of any such claims on their personal financial circumstances such as sickness and unemployment benefits etc and to report the income to relevant authorities in a timely fashion.

Parent members will also be offered travel and related expenses (e.g. care costs) for attending meetings. If required travel and accommodation can be booked in advance of the meetings so you are not out of pocket. Jenny Newman can organise this for members.
Further information about what can be claimed and how to claim it will be given to each member by Jenny Newman.

**Terms of Office for Members:**

4 years in the first instance. This can be extended by an additional two years at the discretion of the MCRN Associate Director for Consumer Involvement and the MCRN Consumer Liaison Manager.