



Annual Report 2008-2009

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1. Introduction

Mental illness is an important public health problem:

“Mental illnesses and mental health problems cause a large and increasing burden that contributes to high costs to societies, long-lasting disability, increased mortality and enormous human suffering.”¹

“1 in 4 British adults experience at least one diagnosable mental health problem in any one year, and one in six experience this at any given time.”²

If we are to adequately address the problem of mental illness we need research. The Scottish Mental Health Research Network exists to create and develop sustainable cutting edge expertise and capacity for mental health research in Scotland. The Network was funded by the Chief Scientist Office of the Scottish Government Health Directorates for an initial period of three years. This annual report describes our achievements against the original objectives, process and activity and outlines our future plans. It also summarizes expenditure for the period 1st April 2008 – 31st March 2009.

2. Scottish Mental Health Research Network Objectives.

Data is presented below in respect of each of the Network’s objectives.

2.1 Establish a baseline of multicentre clinical trials activity in, and funding for, Scottish Mental Health research at the time of the inception of the Network.

Work to establish the baseline record of multicentre clinical trials in, and funding for mental health related studies was completed in June 2007.

2.2 Ensure at least six new UK multicentre clinical trials have been adopted by the Network within three years

This objective has been exceeded: Three UK Multicentre clinical trials were adopted in 2007 – 8 and a further four UK multicentre studies were adopted in 2008 – 2009.

¹ Scottish Public Health Observatory

² The Office for National Statistics Psychiatric Morbidity report (2001)

Table 1. UK/International Multicentre Trials adopted by the SMHRN

Trial	Lead Centre	Scottish lead	Total Funding	Scottish Recruitment Requirement	Year of Adoption
ProCEED: Evaluation of a system of structured, proactive care for chronic depression in primary care.	University College London	N/A	£374, 655 (The Big Lottery Fund)	21	2007/8
COBALT: Cognitive behavioural therapy as an adjunct to pharmacotherapy for treatment resistant depression in primary care	University of Bristol	Dr C Williams	£1, 260 000 (HTA)	160	2007/8
CEQUEL: Comparative Evaluation of QUetiapine-Lamotrigine combination versus quetiapine monotherapy (and folic acid versus placebo) in patients with bipolar disorder	University of Oxford	Dr M Taylor	£1, 626 468 (MRC)	27	2007/8
SMaRT Oncology-2³ A trial of depression management in patients with cancer	University of Edinburgh	Prof M Sharpe	£1 333 000 (CRUK programme grant)	500	2007/8
EDIE-2 Early detection and intervention evaluation for individuals at high risk of psychosis	Manchester	Prof A Gumley	£1 489 039 (MRC)	80	2008/9
iMANTRA-R A trial of an internet-based relapse prevention intervention for inpatients with Anorexia Nervosa	KCL/loP	Dr Cassar	£90 000 (NIHR programme grant)	14-20	2008/9
Commercial Study SMHRN_010		Prof S Lawrie		10	2008/9
Commercial Study SMHRN_011		Prof K Mathews		10	2008/9
SMaRT Oncology-3 Pilot trial	University of Edinburgh	Prof M Sharpe	(CRUK programme grant)	10	2008/9
SMaRT Oncology-3 Trial of intervention for patients with major depressive disorder and cancer	University of Edinburgh	Prof M Sharpe	£1 333 000 (CRUK programme grant)	200	2008/9
Bipolar Family Study – A descriptive study of brain function and structure in relatives of people with bipolar disorder	University of Edinburgh	Dr A McIntosh	£650 000 (Health Foundation)	30	2008/9

³ The SMaRT studies are funded from a £4m programme grant. For the purpose of this report funding has been apportioned between the studies.

2.3 Ensure that at least three new multicentre studies led from Scotland are adopted by the Network within three years

This objective has been exceeded; four Scottish-led multicentre studies have been adopted. Three Scottish-led multicentre studies were adopted in 2008 – 2009.

Table 2. Scottish multicentre trials adopted by the SMHRN

Trial	Chief Investigator	Funding	Scottish Recruitment Requirements	Year of Adoption
SMaRT Oncology-2 Trial. A trial of depression management in patients with cancer	Prof M Sharpe	£1 333 000 (CRUK programme grant)	500	2007/8
SMaRT Oncology-3 Pilot of intervention for patients with major depressive disorder and cancer	Prof M Sharpe	(CRUK programme grant)	10	2008/9
SMaRT Oncology-3 Trial of intervention for patients with major depressive disorder and cancer	Prof M Sharpe	£1 333 000 (CRUK programme grant)	200	2008/9
Bipolar Family Study - Brain function and structure in relatives of people with bipolar disorder	Dr A McIntosh	£650 000 (The Health Foundation)	30	2008/9

2.4 Ensure that the number of patients participating in multicentre studies in mental health in Scotland is increased by at least 20% of baseline every year.

During 2008 – 2009 studies adopted by the Network recruited 127 patients. This represents a 188 percent increase on 2007 – 2008 baseline.

Table 3. Patients participating in multicentre studies in mental health in Scotland

Year	Number of studies	Number of patients recruited	% increase
2007 – 2008⁴	4	44	Baseline
2008 – 2009⁵	11	127	188%

2.5 Ensure that the active grant funding for multicentre studies in mental health in Scotland is increased by at least 20% of baseline every year.

The number of Scottish-led studies adopted by the Network to date is small. For this reason only limited significance can be attached to annual percentage increases. However, the objective has been exceeded. Industry studies with

⁴ Includes only multicentre RCTs

⁵ Includes multicentre RCTs and other adopted studies

undisclosed funding are not included. Industry studies are adopted on a full cost recovery basis.

Table 4. Active grant funding for multicentre studies in mental health in Scotland.

Year	Number of Scottish led multi-centre studies with active grant funding adopted in year ⁶	Value of multi-centre studies adopted in year	% increase over baseline
Baseline 2006 – 7	0	£ 233, 353	n/a
2007-8	1	£1, 333, 000	471
2008-9	3	£1, 983, 000	750

3. Encouraging and Supporting Research

3.1 Scottish Mental Health Trials Service

The Network’s Trials Service provides support to investigators in study design. During 2008 -9 the following support was provided:-

- Regulatory advice for studies in pre-adoption stage (1 study)
- Advice and help with costs related to support for science and excess treatment costs (1 study)
- Site feasibility visits to ascertain likelihood of investigators recruiting to target (2 studies)
- Protocol development, advice and ongoing liaison with investigators (6 studies)
- Identification of sites and clinician investigators (1 study)

3.2 Other Support to Studies

- Liaison with Industry on pharmaceutical or device trials, coordination of confidentiality agreement sign-offs and discussion with clinical research associates (6 studies)
- Coordination of documentation and procedures with English MHRN to facilitate studies coming to Scotland (3 studies)
- Coordination with other Scottish topic specific networks to facilitate study start up (3 studies)
- Miscellaneous other contact and support (16 studies/investigators)

⁶ The baseline used reflects a thorough survey of Scottish led trials activity in the year prior to the Network’s inception (the single study identified, SMaRT Neurology, was not an adopted study since it pre-dates the Network).

3.3 Outcome Data Collection

The Network undertook independent collection of outcome data for 2 studies during the year. This involved:-

- Development of outcome data collection SOPs
- Development of outcome data storage systems
- Systems for quality control and quality assurance of outcome data
- Development of IT and phone systems for outcome interviews
- Recruitment and management of outcome data collection staff

4. Building the Network

4.1 Staff recruitment

As in previous years the progress of the Network has been hindered by delays and difficulties in staff recruitment, particularly for NHS staff. Delays of many months were experienced in getting NHS posts banded. Four rounds of recruitment concluding in November 2008 failed to identify candidates with the necessary experience for the Lead Nurse position and we then planned a new staffing structure. New recruitment rounds for Research Nurse posts in Glasgow and Edinburgh were initiated towards the end of the reporting period and we have just appointed our first nurse in Edinburgh.

The Network Statistician (Gillian McHugh) left in December 2008. This post was converted into a Trials Co-ordinator role and recruitment is ongoing with an interview planned for the near future.

The Network Manager (Lucy McCloughlan) left the Network in January 2009 to manage a CSO funded research programme. A replacement (Mark Hazelwood) was appointed and started work in February 2009

4.2 Staff Development

Staff undertook appropriate training and development activities during the year.

4.3 Network Governance and Management Structures

In 2008-9 the Management Board met 3 times and the core Implementation Group met 9 times.

During 2008-9 the Network's governance and management structures were reviewed and reconfigured. A new Operations Group met in February and March 09. The reconstituted Network Board will meet for the first time in 2009.

4.3.1 New Governance and Management Structures

The new management structures are:-

4.3.1.1 Network Board

The purpose of the Network Board is to provide strategic oversight and advisory functions to the Scottish Mental Health Research Network. Specifically the Board will:-

- assist in the development of strategic objectives for the Network
- provide advice on achieving those strategic objectives
- recommend which activities should be supported by the Network
- monitor and supervise the performance of the Network against its agreed performance measures
- provide advice on the development of new performance measures
- endorse three yearly funding bids to the Chief Scientist Office
- endorse annual and half yearly reports to the Chief Scientist Office

Membership of the Board will draw representation from the CSO, English MHRN, a major eligible funder, academia, NHS (including primary care), public health, NHS R&D, service users and will include an observer from industry.

4.3.1.2 Operations Group

The Operations Group was established in February 2009. The purpose of the Operations Group is to ensure the delivery of the Network's plans and objectives. Specifically the Network Operations Group will:-

- regularly receive and review progress against the network's plan, objectives and budget
- decide which studies will be adopted by the Network
- monitor the progress of adopted studies, and provide advice and practical support as required
- determine the unadoption of studies if they have failed despite all reasonable efforts to make them succeed
- advise and assist with the promotion of the Network to specific professional groups, disciplines, or geographical locations

The Membership of the Group is:-

- Director of the Network
- Associate Director, Psychosis & Imaging
- Associate Director, Operations
- Associate Director, Study Design and Statistics
- Clinical Lead (Grampian)
- Clinical Lead (Tayside)

- Clinical Lead (Glasgow & Clyde)
- Clinical Lead (Lothian)

4.4 Collaboration

The Scottish MHRN has actively collaborated with the corresponding English and Welsh Networks since its inception. The SMHRN also has representation on the following UK- wide Groups:

- UKMHRN Network Directors' Group,
- UKMHRN Network Leads Group;
- UKMHRN Adoptions Committee;
- UKMHRN Methodology Group;
- MHRN Devolved Nations Managers' Group;
- UKMHRN Hub Managers Group.

The Scottish Mental Health Research Network has also worked closely with the Scottish Topic Specific Research Networks and Primary Care Research Network, via the Scottish TCRN managers' group which meets quarterly. These meetings focus on developing strategies which cross-cut the topic specific divide such as staff training, the UKCRN portfolio database, patient involvement, working with industry, and reciprocal adoptions procedures for cross Network studies.

4.5 Communications

Network staff publicised the Network through presentations and stalls at:-

11/04/08	Edinburgh Clinical Trials Unit Launch
13/05/08	R&D Forum (Newcastle)
14/05/08	Royal College of Psychiatrists, Old Age Psychiatrists Meeting
06/06/08	Royal College of Psychiatrists, Scottish Division Meeting
3-4/07/08	UK Clinical Research Facilities Annual Conference
25/09/08	Royal College of Psychiatrists, Celtic Meeting
16/10/08	Scottish Imaging Network, (SINAPSE) Launch meeting,
13/03/09	UK Clinical Research Facilities Open Day, (Edinburgh)
18/03/09	UK Primary Care Mental Health day
26/03/09	Scottish Personality Disorder Network conference

4.6 Engagement with Smaller Health Boards

Towards the beginning of the 08-09 year, a concerted effort was made by the Network to engage the smaller Health Boards. Every Health Board R&D Manager was contacted with the purpose of gathering relevant information as to what sort of mental health research was being done in their area and to establish who would be interested in being contacted by the Network with research opportunities - should a suitable study be adopted. From the responses received a contact list of

researchers who wished to be kept informed of Network activity, study opportunities and news was compiled.

5. Future Plans

5.1 Scope of the Network

During 2009 – 2010 the Network will broaden the scope of studies which it is prepared to adopt. In addition to multicentre clinical trials the Network will also be prepared to adopt imaging studies, observational studies and epidemiological studies. This will potentially increase the impact of the Network on Scottish research.

5.2 Staff Recruitment

At the time of writing we are optimistic that we will be able to recruit to Research Nurse and graduate Research Assistant posts and also to the Trials Co-ordinator post. This will greatly increase the capacity of the Network to support adopted studies.

5.3 Protocol Development Groups

2009 will see the establishment of a number of Protocol Development Groups (PDGs) facilitated by the Network. These groups will bring together researchers with a shared interest in specific research questions. Each group will focus on the production of high quality fundable research proposals and will receive high level methodological support.

5.4 Launch

The Network is planning a high profile launch and scientific meeting later in 2009.