



Dr K Gyngell
Chair, Prisons and Addiction Forum
Centre for Policy Studies
57 Tufton Street
London, SW1P 3QL

30th September 2011

Dear Dr Gyngell,

Freedom of information request on MRC N-ALIVE study

Thank you for the Freedom of information request you submitted on 31st August 2011 where you have asked for the following information relating to the N-ALIVE pilot trial:

1. The monetary value (size) of the MRC grant awarded for the above trial
2. The value of the associated grant given by the Scottish Government
3. To whom (what institution and to what individual) was the award granted
4. The conflicts of interests declared by the applicants for the grant and those employed in the conduct of the research
5. The names of the scientists who peer reviewed this application
6. Full details of the 'ethics' approval/procedure and transcripts that the application passed
7. What stage of completion the trial is at.

The study, N-ALIVE (NALoxone InVEstigation) is a pilot, prison-based, randomised controlled trial. The ultimate aim of the main randomised trial (should it go ahead) is to assess the number of lives that could be saved by giving people who have a history of injecting heroin a take-home emergency dose of the drug Naloxone to carry around with them when they leave prison. Naloxone is an antidote to the effects of heroin and other opiates and the take-home dose would be given to ex-prisoners to be administered by family or others in the event of an overdose as part of emergency management whilst awaiting an ambulance. Heroin overdose is one of the main causes of death for young adults, and people in prison who have a history of injecting heroin stand a much greater chance of dying from a heroin overdose soon after they leave prison – for every 200 prisoners with a history of heroin injection who leave prison, one may die within two to four weeks because of an overdose.

You have asked for information relating to the award of the pilot trial, including the *value of the grant, funding from the Scottish Government and award holder/institution.*

Information on MRC grants is routinely published on our website, a summary of the information requested and the link to further details about the study on the main MRC website are provided below:

Medical Research Council, One Kemble Street,
London WC2B 4AN
www.mrc.ac.uk

tel: (direct) +44 (0)20 7395 2283 email: rosa.parker@headoffice.mrc.ac.uk

Project title: N-ALIVE: Prison-based Naloxone-on-release RCT to reduce drugs-related deaths

Host institution: MRC Clinical Trials Unit, London

Principal investigator: Professor Mahesh Parmar, MRC Clinical Trials Unit

Co-investigators: Professor Sheila Bird, MRC Biostatistics Unit and Professor John Strang, Institute of Psychiatry

Award value: £984k over 32 months

MRC Portfolio link: <http://www.mrc.ac.uk/ResearchPortfolio/Grant/Record.htm?GrantRef=G0800012&CaseId=11763>

The study is currently in the set-up phase, and recruitment is expected to commence shortly.

The N-ALIVE study is not being undertaken in Scotland and no funding has been provided by the Scottish Government. The recent policy decision, in Scotland, for drug services to provide take-home naloxone and the provision of on-release naloxone for eligible prisoners with a history of heroin injection, means it would not be possible to include Scotland in the trial. However, this policy in Scotland, and related public policy in Wales, makes it all the more important for an effective evaluation of naloxone on release.

As with all clinical trials undertaken by the MRC Clinical Trials Unit, information relating to the study is available on the unit website, the link for the N-ALIVE study is as follows: www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=80. Additional information, including more details such as the inclusion criteria and outcome measures, is available from the register of randomised controlled trials, www.controlled-trials.com/ISRCTN34044390. Both of these pages will be updated as the study progresses.

You have asked about *'any conflicts of interests declared by the applicants for the grant and those employed in the conduct of the research'*.

No material conflicts of interest have been declared relating to the N-ALIVE study, all potential conflicts will be reviewed on a regular basis and will be updated as necessary and published on the study web pages.

When proposals are submitted to the MRC, applicants are required to assure the MRC that they have not entered into any obligations which would conflict with the Terms and Conditions of MRC grants and fellowships. These terms and conditions require that all host institutions have processes which ensure that any potential conflicts of interest in research are declared and subsequently managed. Within the MRC, staff are required to declare all real, potential or apparent conflicts of interest to the unit Director, or (including in the case of Unit Directors) to the MRC Chief Executive Officer or Chief Operating Officer.

You have asked for *'the names of the scientists who peer reviewed this application'*.

All proposals for MRC grant funding are assessed through a two-stage process involving independent expert reviewers and the MRC research boards or panels.

The decision to fund the N-ALIVE study was made by the MRC Health Services and Public Health Research Board in March 2008; a paper showing the membership of the Board for this period is provided and can also be accessed on the archived MRC website available at www.webarchive.org.uk. You will notice that Professor Parmar, who is the principal investigator for

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the study, was a member of the Board at this time. However, in line with the MRC's usual policy for managing conflicts relating to specific proposals, Professor Parmar was not present during the Board's discussion of the item and did not participate in any way in the decision to fund it.

In considering proposals, the Boards take account of the comments from independent expert reviewers. These comments are provided to the MRC in confidence to allow reviewers to provide a full and frank assessment of the proposal. While comments are provided to the applicants as part of the process, this is in an anonymised form and reviewers expect the MRC to maintain their anonymity. Therefore the MRC considers this information to be exempt under section 41 of the Freedom of Information Act, as information provided in confidence, and that to release the identities of reviewers into the public domain would constitute a breach of this duty of confidence.

Finally, you have asked for *'full details of the 'ethics' approval/procedure and transcripts that the application passed'*.

Ethical approval for the study was granted by the Essex 2 Research Ethics Committee in May 2010 under the National Research Ethics Service (NRES) process. A copy of the approval letter is attached. You will notice that some information has been redacted, this comprises the names of junior staff which we consider to be exempt under section 40 of the Freedom of Information Act, as personal information.

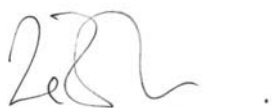
NRES routinely publishes details of the research which has been approved on their website, a summary of the approval of the N-ALIVE pilot study can be found at the following link:
www.nres.npsa.nhs.uk/researchsummaries/?entryid29=84609&q=0%7en-alive%7e.

I hope that you are satisfied that we have handled your request appropriately; if not, you may appeal using the MRC's complaints procedure. Details are on the MRC website at:
www.mrc.ac.uk/index/about/about-contact/about-complaints_procedure.htm. You may contact the MRC Complaints Officer by email at customer.service@headoffice.mrc.ac.uk or write to:

The Complaints Officer
Medical Research Council
14th Floor
One Kemble Street
London WC2B 4AN

If, following the Complaints Officer's reply, you remain dissatisfied; you may contact the Information Commissioner. Details of how to take your complaint further are at
www.informationcommissioner.gov.uk.

Yours sincerely



Rosa Parker
**Corporate Policy
and Information**

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