



Joint Working Agreement

AN AGREEMENT FOR JOINT WORKING BETWEEN
Wessex Academic Health Science Network Limited
AND
Lundbeck Ltd
FOR
Reducing Harm from Alcohol across Wessex

This agreement is to set out the principles and values that should underpin the joint working arrangement, as well as the objectives and modus operandi for projects to develop and evaluate Brief treatment pathways to establish their feasibility and cost effectiveness.

1 Name and Members of the Joint Working Arrangement

The joint working arrangement is an agreement between:

- Wessex Academic Health Science Limited (Wessex AHSN)
- Lundbeck Ltd (Lundbeck)

The working members will be known as the Joint Working Group. The number of Joint Working Group members will be decided to enable decision making to be as effective as possible whilst ensuring inclusiveness. Joint Working Group members will be designated by the parties. No more than 2 core Joint Working Group members may be assigned to the joint working arrangement by any party, except by agreement of the parties. Joint Working Group members may be replaced by an individual from their organisation at any time by a party to ensure continuity. Ad hoc membership may be agreed by the parties from time to time. The Working Group will include the following members:

Keith Lincoln	Director for Quality and Improvement	Wessex AHSN
Cathy Rule	Project Manager, Reducing Harm from Alcohol	Wessex AHSN
Andy Roberts	Regional Account Director	Lundbeck
Steve Turley	Managing Director	Lundbeck
Dr Julia Sinclair	Senior Lecturer in Psychiatry	University of Southampton

Lundbeck may, from time to time, join the Wessex AHSN Steering Group for their Reducing Harm from Alcohol programme.

Joint Working Agreement Wessex AHSN Lundbeck v12

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UK/NAL/1407/0519(1)

2 Aims and Objectives

Alcohol consumption accounts for around 10% of the UK's burden of disease. It is one of the highest lifestyle risk factors for disease and death in the UK, after poor nutrition, smoking and obesity. Alcohol dependence in the UK is significantly under-diagnosed and under-treated with only 6% of alcohol dependent patients aged 16–65 years receiving treatment each year.

Alcohol related harm consumes nearly £2.7 Billion per year the NHS budget (The NHS Information Centreⁱ). This is broken down to nearly £238 Million across Dorset, Hampshire and Wiltshireⁱⁱ:

Local Authority Region	Total Alcohol Spend
Bournemouth UA	£13,824,000
Dorset	£33,042,000
Poole	£11,666,000
Wiltshire	£33,373,000
Hampshire	£90,600,000
Isle of Wight	£9,907,000
Portsmouth	£14,568,000
Southampton	£17,485,000
Fareham and Gosport	£13,378,000
Total	£237,843,000

Despite there being high level recognition that it causes a substantial burden to the health of the UK, there is little integrated commissioning across the health economy or service specification around integrating care and no coordinated focus to reduce alcohol related healthcare spend. Much of the above spend is in acute services in terms of hospital bed days, repeated unscheduled care, extended stays and poorer outcomes from other chronic health conditions. Primary care is also burdened by the non-recognition of comorbid alcohol use, and continuing to symptomatically treat the complications (hypertension, depression, anxiety, gastritis etc.) rather than the underlying alcohol misuse. Recognition is poor, estimated by the Alcohol Needs Assessment Research Project (ANARPⁱⁱⁱ) study to be approximately 1 in 70 of increasing risk drinkers and 1 in 20 of patients with alcohol dependence. As such, improving identification and early intervention in primary care may be effective at averting A&E attendances and alcohol-related hospital admissions. This is the rationale for Alcohol being included in a wide range of outcome indicators at a national level for 2014-15.

This joint working agreement proposes to provide a mechanism for the Joint Working Group to deliver and evaluate a Brief treatment pathway for patients with increasing and higher risk drinking levels not currently well catered for in the treatment system. The projects will encompass pathway development and service evaluation that could lead to service redesign for:

- Primary Care pathway for increasing and higher risk drinkers
- Secondary Care pathway for increasing and higher risk drinkers



Across:

- Southampton
- Portsmouth
- Isle of Wight

And with engagement of local commissioners:

- Bournemouth / Poole
- Basingstoke / Winchester

Delivering outcomes to:

- Reduce drinking for those drinking at Higher or Very High risk levels by up to two risk levels as recommended by the World Health Organisation
- Increased recognition in primary care of comorbid alcohol use
- Reduce GP attendances and prescribed medication
- Reduce A&E attendance and hospital admissions that are alcohol related

Leading to the following outline benefits (the numerical values for these benefits will be developed during the project initiation stage):

- Health benefits:
 - Exponential reduction in risk of death from alcohol related injury – for example, a 50% reduction in alcohol consumption from 100 g/day gives an eight-fold benefit in terms of harm reduction^{iv}
 - Increased numbers of individuals, who aren't currently engaged, to seek help for their increasing or higher risk drinking
- Wealth benefits:
 - Reduced NHS spend on:
 1. Hospital bed days in terms of fewer admissions and shorter stays
 2. Fewer repeated unscheduled care attendances
 3. GP attendances and prescribed medication costs
 - This Joint Working project will in part create more opportunities for the appropriate use of medicines, including not exclusively, nalmefene ▼ in suitable patients in line with its licence. Current national endorsement from
 1. Scottish Medicines Consortium (SMC) recently accepted nalmefene for use as per its licence October 2013. For SMC advice visit www.scottishmedicines.org.uk (for full guidance see Ref¹)
 2. All Wales Medicines Strategy Group (AWMSG) recently recommended nalmefene as an option in alcohol dependence as per its licence January



2014. For AWMSG advice visit www.awmsg.org.uk (for full guidance see Ref ²)

3. A NICE technology appraisal is underway with expected completion by November 2014.
 - Employment for a Research Assistant

This joint working proposal will include the following assignments:

1. Matched funding (£60k in total over 3 years, £10k per annum per organisation), between Wessex AHSN and Lundbeck, to provide a Research Assistant, on a three year studentship basis, supervised within the Faculty of Medicine, University of Southampton. The research assistant will work on the project to help establish a pathway that incorporates brief advice and reduction. This will include collating data and measuring outcomes from pathway redesign including the appropriate use of medicines as well as other projects identified by the Wessex AHSN Reducing Harm from Alcohol programme.
2. Availability of Cathy Rule, Wessex AHSN as Project Manager for the Joint Working Group.
3. Availability of Andy Roberts, Regional Account Director from Lundbeck to provide support to the Joint Working Group for a maximum of three days per month as required for a period of 6 months after which a decision by both parties will be made as to whether to extend based upon progress of the project or that the project has been completed and met its objectives.
4. The shared risk funding for the projects to establish a pathway that incorporates brief advice and reduction will be managed between Lundbeck and the local commissioners for each locality.
5. Lundbeck will make available the use of their alcohol dependence service evaluation tool to capture the agreed outcomes of any local service evaluations of the pharmacological management of alcohol dependence.
6. Lundbeck will make available access to a psychosocial online support tool called www.reduceyourdrinking.co.uk.
7. Lundbeck, Wessex AHSN and other local stakeholders will support the development of a care pathway for those patients at increasing and or higher risk of alcohol dependence for each of the Wessex local authorities participating (starting with Southampton, Isle of Wight and Portsmouth) area named above with the option to assist other areas that fall under the Wessex AHSN locality
8. Alcohol Impact Model will be provided as a service to Wessex AHSN by Lundbeck. This will be made available for the whole period but may not be updated by Lundbeck during the period



3 Values

The following values should underpin joint working:

- Transparency and trust
- Appropriateness of projects
- Patient focused
- Value for money
- Reasonable contact
- Responsibility
- Impartiality and honesty
- Truthfulness and fairness

4 Principles of Joint Working

The following principles will apply to joint working:

- All joint working must be for the benefit of patients;
- Joint working will be conducted in an open and transparent manner;
- Joint working will take place at a corporate, rather than an individual, level;
- Arrangements will be of mutual benefit, the principal beneficiary being the patient;
- Contract negotiations will be negotiated in line with NHS values;
- Confidentiality of information received in the course of the arrangement will be respected and never used outside the scope of the project;
- All patient identifiers will be removed from data to preserve and respect patient confidentiality in line with the Data Protection Act;
- Reports and information pertaining to the agreement / projects will not be used or published without explicit permission given by all parties;
- Joint working must not be used or seen as endorsement or promotion of any specific medicine or product;
- Pharmaceutical companies must comply with the ABPI Code of Practice for the Pharmaceutical Industry at all times;
- All NHS employed staff must comply with NHS, and relevant professional body, Codes of Conduct at all times, and be aware of DH Guidance relating to joint working with the pharmaceutical industry (Best Practice Guidance for Joint Working between the NHS and the Pharmaceutical Industry, February 2008).

5 Procedures at Joint Working Group Meetings

- All members should make every effort to be present at Joint Working Group meetings;
- The quorum for meetings will be at least 2 members from each party;

- All discussions taking place in meetings will be confidential, unless stated otherwise, and not disclosed to any unauthorised person. In particular no view or opinion expressed will be attributed to any member by name;
- Decisions will be made by consensus of the parties;
- If any members of the joint working project are not present at a Joint Working Group meeting, their views will be requested either prior to or after the meeting;
- In the event of no consensus being achieved, a majority agreement will be accepted based on at least 2 Joint Working Group members from each party supporting the decision.

6 Powers of the Joint Working Group

- The Joint Working Group will decide by consensus what projects and plans the parties wish to undertake;
- The Joint Working Group may set up sub-committees or working groups which can include ad hoc members or non-members. The Joint Working Group will ratify recommendations made by sub-committees or working groups;
- The Joint Working Group will meet to review the project once per month

7 Selection of Consultancies

Where any work requires the involvement of a selected external consultancy, this will be selected by the following process:

- Drafting and sign-off of Terms of Reference for the consultancy input required;
- Drafting and sign-off of quantitative and qualitative Evaluation Criteria for potential suppliers;
- Agreement of a List of Suppliers to be invited to tender for the work;
- Issuing of Terms of Reference and Evaluation Criteria to potential suppliers;
- Receipt and evaluation of proposals from suppliers against the Evaluation Criteria;
- Short-listing of potential suppliers;
- Presentations by potential suppliers to the Joint Working Group;
- Final selection of successful supplier(s).

Any selection process will be open and transparent, and if undertaken by an NHS organisation, will comply with the requirements of the relevant Standing Financial Instructions and Standing Orders.

Consultancies will comply with the relevant Codes of Conduct and Practice referred to in 4 above.

8 Finances

- The finance provided by each party will be limited to that agreed. Additional finance may be provided from other sources if agreed by the Parties;
- The finance being provided by Lundbeck as part of the joint working arrangement will be held by Lundbeck Ltd and paid against approved invoices;
- Payment of this amount will be made on an annual basis of £10k per annum paid to Wessex AHSN who are co-funding and matching this figure for the research assistant.
- The Joint Working Group will monitor finances and record costs incurred.

9 Outputs, Monitoring and Evaluation

The length of the arrangement, the potential implications for patients and the NHS, together with the perceived benefits for all parties, together with a mutually agreed exit strategy, will be clearly outlined before commencement of joint working.

The parties will agree arrangements for recording, monitoring and evaluating the joint working arrangement.

The project and the outcomes it delivers can be written up as a case study to share with other AHSNs.

10 Data Ownership

- All summary data generated by the project will be owned jointly and may be shared with other AHSNs to improve alcohol service specifications by both the parties as part of the health and wellbeing agenda;
- No data will be disclosed to any third party except on the explicit agreement of all parties;
- Patient confidentiality will be maintained at all times.

11 Communication

- All external communication regarding the joint working arrangement and associated projects will be agreed by the Joint Working Group;
- All internal communication will be deemed confidential except by the agreement of the Joint Working Group;
- Minutes will be taken of all Joint Working Group meetings for subsequent agreement at the following meeting.



12 Dissolution

- The joint working arrangement shall be dissolved at any time if any party wishes to withdraw; a notice period will be given of 1 months.
- Any outstanding matters must be wound up by all parties by agreement.

13 Change of the Joint Working Agreement

Changes may be made to the Joint Working Agreement by consensus of all parties at a meeting convened for the purpose.



14 Declaration of Interests

All declarations of interest must be declared by any working member. Declarations of interest will be recorded and filed by Wessex AHSN.

I have read the above Joint Working Agreement and commit to the Terms.

Signed: on behalf of:

Print Name: Date:

Signed: on behalf of:

Print Name: Date:

ⁱⁱ The NHS Information Centre, Lifestyles Statistics (2011). Statistics on Alcohol: England 2011. The Health and Social Care Information Centre.

ⁱⁱ Alcohol Impact Model - Lundbeck

ⁱⁱ Department of Health (2005). Alcohol Needs Assessment Research Project (ANARP).

ⁱⁱ Nutt, D.J. and Rehm, J. (2014). Doing it by numbers: A simple approach to reducing the harms of alcohol. Journal of Psychopharmacology 28:3.



Ref 1. Scottish Medicines Consortium recommendation. No. 917/13.
<http://www.scottishmedicines.org.uk/Home> last accessed March 2014.

ADVICE: following a full submission.

Nalmefene 18mg film-coated tablets (Selincro®) are accepted for use within NHS Scotland.

Indication under review: the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level (DRL), without physical withdrawal symptoms and who do not require immediate detoxification. Nalmefene should only be prescribed in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption. Nalmefene should be initiated only in patients who continue to have a high DRL two weeks after initial assessment.

In a post hoc analysis of two pivotal phase III studies representing the licensed population, nalmefene was shown to significantly reduce alcohol intake compared with placebo, measured as a reduction in heavy drinking days and total alcohol consumption over a six month period.

Ref 2. All Wales Medicines Strategy Group. Final Appraisal Recommendation – 0414: Nalmefene (Selincro®) 18mg film-coated tablets. January 2014.

All Wales Medicines Strategy (AWMSG) Group recently recommended Selincro as per its license – January 2014

Nalmefene (Selincro®) is recommended as an option for use within NHS Wales for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level (DRL) without physical withdrawal symptoms and who do not require immediate detoxification. Nalmefene should only be prescribed in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption. Nalmefene should be initiated only in patients who continue to have a high DRL two weeks after initial assessment.