Shine 2012 final report

NEPTUNE-
Novel Psychoactive Treatment: UK Network

Central and North West London NHS Foundation Trust

2014

The Health Foundation
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About the report

Part 1.Abstract

Project title: NEPTUNE- Novel Psychoactive Treatment: UK Network

Lead organisation: Central and North West London NHS Foundation Trust

Partner organisation: NEPTUNE was designed by a national group of experts representing addiction psychiatry, psychology, sexual health, emergency medicine, urology, clinical and analytical toxicology, psychopharmacology and general practice. Patient representatives also sit on the group. All relevant government departments and Royal Colleges/professional associations hold observer status on the group.

The expert group includes NHS and non-profit voluntary organisations, including lesbian, gay, bisexual and transgender organisations, because of the high prevalence of club drugs among this population. The expert group developed a clinical network for sharing information and a clinical community

Specifically, members of the NEPTUNE Expert group are from the following organisations (see appendix 3 for full membership):

- Central and North West London NHS Foundation Trust (lead organisation)
- Antidote- London Friend
- Avon and Wiltshire Mental Health Partnership NHS Trust
- City of London Substance Misuse Partnership
- Chelsea and Westminster Hospital NHS Trust
- Crew 2000
- Guy's and St Thomas' NHS Foundation Trust and King's Health Partners
- Imperial College London
- Leeds Partnership NHS Trust
- South London and Maudsley NHS Trust
- St George's Hospital; University of London
- Substance Misuse Management in General Practice (RCGP)
- University College Hospital London
- University of Hertfordshire

- Observers: Department of Health (DH), Home Office (HO) and Public Health England (PHE). The Royal College of Psychiatrists, Royal College of General Practitioners, he British Psychological Society, British Association of Sexual Health and HIV

Lead Clinician: Dr Owen Bowden-Jones
Programme manager: Dr Dima Abdulrahim

Please describe your project as a narrative account (up to 800 words) that reflects the experience of the project team of implementing the project. You should include:

- *Background in brief including the local problem and intended improvement*
- *Description of innovation*
- *Methods used for testing / implementation so far including ethics, plans, measures, methods for evaluation & analysis*
- *What you achieved – (method, process, context, challenges)*
    - *What went well?*
    - *What have been the challenges and how have these been overcome?*

Background

Club drugs, including novel psychoactive substances (NPS), present a current challenge to clinicians. Half a million people in the UK used a club drug in 2012/13; whereas many will use them in a recreational manner that causes few problems, some will suffer from severe harms that are direct (overdose, psychosis and death) or indirect (e.g. sexual risk taking, HIV).

The clinical management of harms is taking place in a context of patient hazard and wide variations in care. This is due to:

1. The rapid proliferation and diversity of NPS. At a global level, the number of reported NPS rose from 166 in 2009 to 251 by mid-2012, an increase of more than 50%. One new substance was reported every 6 days in the UK in 2012.
2. These substances are untested and have unknown physical, psychological and toxicological effects. Office of National Statistics suggest that in 2012 there were 97 death related to amphetamine use (including 49 amphetamine, 31 MDMA and 20 PMA); 52 death associated with NPS (including 18 synthetic cathinones 13 GHB/GBL)
3. In comparison to death from other illicit substances, fatalities were:

a. Young people, with for example MDMA most commonly implicated in the death of the 15-24 age group (in comparison to opiate deaths in the 33-44 year group)
b. Typically less likely to have established problem drug use.

4. Very limited clinical experience of treatment of NPS and club drugs, with only a handful of clinicians and centres in the UK developing expertise. Drug treatment centres typically lack the knowledge to provide informed, safe and reliable responses. The evidence base remains very limited.

Description of project

NEPTUNE is a response to the current gap in experience and knowledge in the management of acute and chronic problems resulting from these drugs. Specifically, the objectives of the project were as follows:

- Convene a multi-disciplinary group of UK experts in the treatment of club drugs.

- Review the national and international evidence, using systematic methods.

- Develop treatment guidance based on best available research evidence. Where this is lacking, use of the expert groups' clinical consensus and patient experience.

- External peer review of the guidance.

- Develop care bundles as tools to support the implementation of the guidance in clinical situations and to promote reliability and consistency in the delivery of quality of care.

- Test the implementation of the bundles in clinical settings through a quality improvement methods.

- Address issues pertaining to the following clinical settings:
    - Emergency Departments
    - Drug treatment services
    - General practice
    - Sexual health clinics.

Aim of clinical guidance

The aim of the guidance and bundles is to increase confidence, competence and skills of clinicians in the following:

- Detection/Identification of club drugs and harms
- Assessment of acute and chronic harms
- Clinical management of harms
- Reduction of harms; Prevention of morbidity/mortality; Support recovery, well-being and public health
- Reduction in variations in care

Methods used for the project:

Guidance development:

The development of the guidance was based on the review of the international peer reviewed literature and a transparent review process.

Measuring impact

From the guidance we developed care bundles. The impact of the project was measured using bundle implementation across the different clinical settings to develop learning on how best to implement them on a wider scale. A contemporaneous analysis of data, using 'statistical control process' was used..

Specifically, Plan, Do, Study Act cycles were carried out to address

a. Bundle utilisation

- Utilization and completion of the bundle by clinical staff (all target settings; target 100%)
- Acceptability of bundles among clinical staff and views of their clinical utility

b. Impact on patients

We also looked at changes in outcomes (including proxi-outcomes) on patient care in a specialist drug treatment service resulting from the implementation of the bundles, using national validated tools.

What we achieved; what went well and challenges

- A clinical network of club drug experts. Buy-in from the field.
- It has been a great achievement that we have developed the first clinical guidance for club drugs in the UK and Europe and possibly in the world.
- Care bundles and lessons for implementation.

The main challenge we faced was time. The literature review was extensive and comprehensive especially as new drugs continued to emerge on the illicit market during the project.

Limited time affected the number of bundles that will be tested within the timeframe and it was decided to focus on the club drugs that cause most harm (Gamma-hydroxybutyrate – GHB and gamma- butyrolactone (GBL)..

Time constraints also affected the scale of the testing and measurement process, resulting in relatively small numbers participating in PDSA cycles. However, we were aware before the start of the project that this would be the case, as the number of patients presenting with for example GHB harms within the project timeframe is small, thus affecting the robustness of the data. In order to mitigate this, the project will continue beyond the life of SHINE, when we will also be testing additional bundles.

Part 2. Quality impact: outcomes

This section is intended to explain the measures of quality that you used and to detail the outcomes (up to 500 words). You should address the following points:

- *Nature of setting and innovation i.e. description of where*
- *Course of intervention, tests of change, adjustments*
- *Please describe the primary and secondary data that you used to demonstrate impact on quality, including:*
  a) The source of the data and how easy it was to access
  b) The validity and reliability of the data
  c) Changes made demonstrated by data (please summarise using run charts, bar charts, tables or any other format that best shows changes made)
- *Description of confidence; to what extent is the data on quality that you have collected clear and in line with original targets? How satisfactory are your baseline numbers in terms of data quality?*
- *What adjustments, if any, have you made to outcome measures from your original application?*
- *What is your assessment of the effect of your project on the quality of the service and the experience of patients?*

NEPTUNE was developed by clinicians from across the UK and with the explicit intentionof national dissemination.

Phase 1

A comprehensive review of the evidence was carried out to develop clinical guidance, using a transparent process[1] (see appendix 4)

A copy of *Club Drugs and Novel Psychoactive Substances: Guidance on Clinical Management* is attached. The copy attached is a draft, as the guidance awaits external peer review . A final peer reviewed copy will be sent to the Health Foundation.

Phase 2

From the guidance care bundles were developed. Due to the limited timescale, it was agreed to focus on bundles for the management of GHB/GBL harms due to the life threatening acute and chronic effects of this drug (attached; also to be peer reviewed)

We tested implementation of the bundles through PDSAs in:

[1] AR Lingford-Hughes, S Welch, L Peters and DJ Nutt et al: **BAP updated guidelines: evidence-based guidelines for the pharmacological management of substance abuse, harmful use, addiction and comorbidity: recommendations from BAP** *2012 Journal of Psychopharmacology* 26(7) 899–952

i. Bundles for emergency departments (ED) Chelsea and Westminster Hospital London
    1. GHB/GBL overdose and acute toxicity
    2. GHB/GBL withdrawal syndrome
ii. Bundles for specialist drug services (Club Drug Clinic CNWL)
    1. Elective, medically-assisted withdrawal

Results so far

We were aware before the start of NEPTUNE that within the timeframe of the project, the numbers presenting with GHB-related harms would be small. To mitigate this, measurement will continue after the end of the project in March 2014 with the aim of ensuring that data are robust enough to allow for robust findings.

Primary data

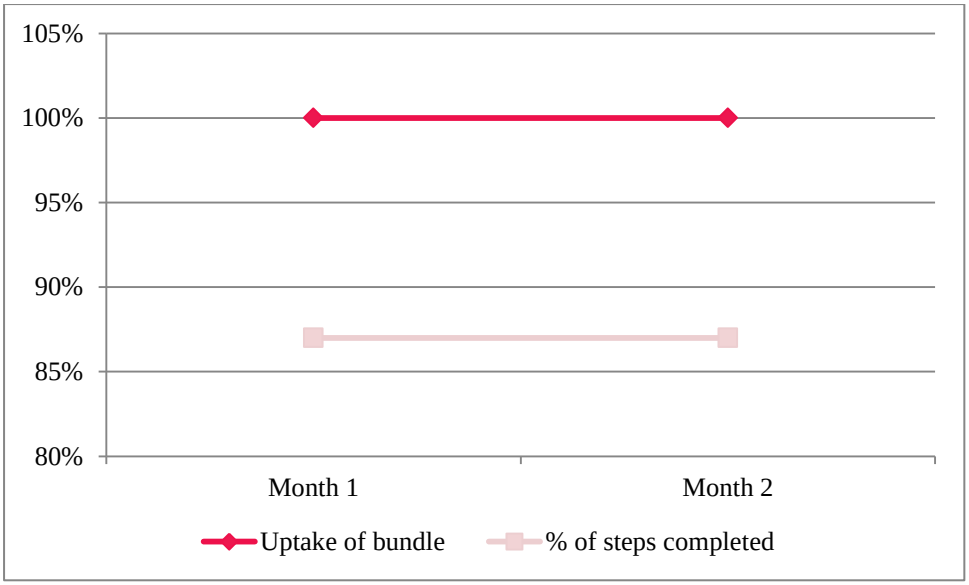
1. Bundle utilisation

The bundles were used as the primary data collection tool. Specifically measured:

- Utilization/uptake of the bundle (target 100%)
- Compliance with each element of the bundle (target 100%)

The graph below shows bundle uptake in the emergency department

- ED doctors utilised the bundle in 100% cases, reflecting its acceptability.
- There was adherence to the majority, but not all steps, of the bundle. Work continues to achieve 100%. Non-adherence was not associated with any specific step.
- Testing identified changes needed, including the need to focus on the management of those with very severe adverse effects.



Graph 1: Uptake and completion of bundle by emergency department staff

The clinical utility of the bundle was summarised by an ED consultant (see quote below p.12).

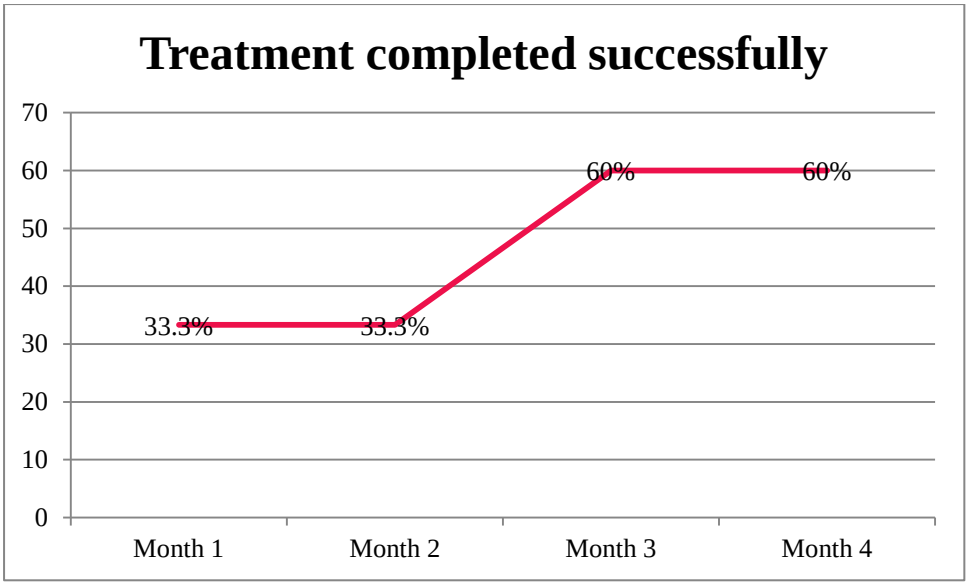
2. Bundle uptake specialist service

The bundle was utilised on the 26 patients who were eligible (Bundle uptake 100%).

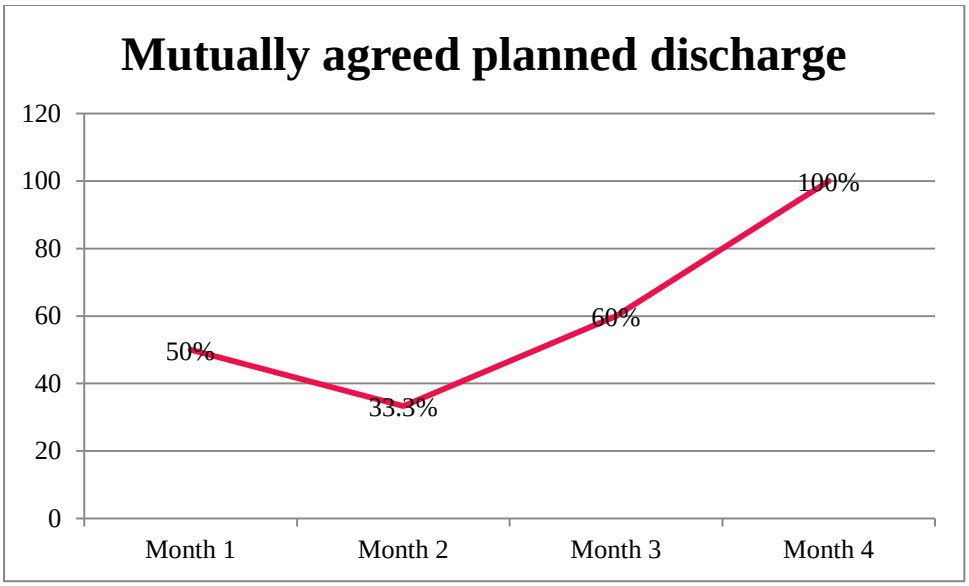
<u>Secondary data; Impact on patient care in specialist services</u>

We looked at patient outcome in specialist drug service since the introduction of the bundle, using the national Drug Treatment Monitoring System (NDTMS).

The graphs below show improvements in a) percentage of patients with successful treatment completion) and b) retention in treatment until mutually agreed discharge.



Graph 2: Percentage patients completing treatment successfully (NDTMS definition)



Graph 3: Percentage patients with agreed planned discharge (NDTMS definition)

Data validity and reliability

NEPTUNE measurement tools have been developed by staff with demonstrable experience of data analysis, improvement sciences and 'statistical control process'. National outcome measurement tools used are validated.[2]

[2](Marsden, J., et al. 2009 "National Drug Treatment Monitoring System Outcomes Study Group." ***Lancet*** 374).

Views of stakeholders

The impact of NEPTUNE on patient care is best summarised by stakeholders

The patient:

This work will be so valuable to improve outcomes of people, who like myself have struggled with addiction to these substances, when they present to GPs, A&E, mental and sexual health services to receive care. (SL; patient)

The doctor:

The bundles have given ED physicians confidence in managing NPS in a digestible and easy to use format and that promotes patient safety (Dr Sarah Finley. Consultant Physician Emergency Medicine. Chelsea and Westminster Hospital).

The policy maker:

"Public Health England strongly supports project NEPTUNE which we see as an important step towards improving national clinical standards and the lives of patients" (R O'Connor; Director of Delivery Drugs and Alcohol. Public Health England

Part 3. Cost impact

This section is intended explain the measures of cost you used and to detail outcomes (up to 500 words). You should address the following points

- *Please summarise your key cost measures and explain how your understanding of the financial impact has moved on since the beginning of your project.*
- *Describe how you have estimated the cost of existing services / pathways / packages of care. Are there any issues or limitations that need to be taken into account?*
- *How have you calculated the cost of the Shine intervention? Are there any issues or limitations that need to be taken into account?*
- *How have you accounted for the implementation costs (e.g. staff time for training and change management activity)?*
- *How have you demonstrated a cash-releasing saving from your Shine project? Has a benefit been realised and who has benefited financially?*

The cost impact of the project was outside the remit of the work, in line with the original application. However, although we do not have tangible evidence, there is the potential for the project to have a financial cost reduction impact, including savings from productivity / efficiency gains.

Cost saving impact

Potential light green dollars savings

- Savings made from improved patient safety (reliable and evidence-based care)

- Potential improvements in the productivity of services and outcome of patients, through increased knowledge and skills provided by NEPTUNE guidance and bundles.

- Savings made through the use of out-patient services for elective medically assisted GHB withdrawal based on the bundle instead of the more expensive in-patient admission. Unplanned detofication has high costs; a case series suggested that 50% of patients who present with acute withdrawal will require admission to intensive care units[3].

[3] D. M. Wood, P. I. Dargan. Development of a protocol for the management of acute gamma-hydroxybutyrate (GHB) and gamma-butyrolactone (GBL)withdrawal. *Clinical Toxicology* **2010**, *48*, 306.

- Staff time saved from improved in screening, assessment and management of acute and chronic harms.

  There was no systematic pathway for the management of GHB in ED, very little knowledge by doctors and other staff of what interventions are needed and no reliability of care. The NEPTUNE bundles provided a simple 12-step process from presentation to discharge and onward referral.

  One of the potential direct savings will be the impact of the bundle on patients not returning to treatment due to increased clinical skills. For example, the bundle prevents the discharge of a-symptomatic patients with GHB poisoning where there is a risk of a later presentation to hospital with late-onset acute withdrawal syndrome.

- Reduced length of stay in hospital and high-cost care, including intensive care. Compliance with all steps of the GHB withdrawal bundle will reduce the need for intensive care as a result of effective management and prescribing at ED

- Reduced mortality and morbidity.

<u>Potential dark green dollars reductions</u>

- Savings on unnecessary toxicology tests.

- Potentially, savings accrued by clients not returning to treatment due to the increased efficacy.

NEPTUNE costs

NEPTUNE had both direct and non-direct costs, which when added together show that the actual cost of this intervention exceeds the funding made available.

<u>Direct costs include:</u>

- Pay
- Non-pay (e.g. office costs, expenses of expert group meetings and travel expenses, copy of research evidence, technical support etc)

Indirect costs include:

The NEPTUNE project had a number of indirect costs for the development of tools and implementation of the project. This includes:

- Offices and related on-costs
- Supplementation of NEPTUNE budget by existing Trust monies for project manager pay (£7,625 additional to SHINE funding- also see mid-point report).
- Pro-rata work in project of clinical lead not covered by SHINE funding (1 to 2 sessions weekly)
- (Unpaid) pro-rata involvement of expert group members for the development of NEPTUNE guidance and bundles (from 18 NHS and voluntary sector organisations plus government departments)
    - 12 consultants psychiatrists and physicians
    - 6 senior managers (including directors and senior civil servants)
    - 5 nurses/other clinicians
    - An average of 6 full days each (12 sessions) in meeting attendance and remote work.
- Implementation costs: Indirect costs of sites where the PDSAs were carried out include:
    - Staff time for training
    - Cost of training venue
    - Staff time delivering the intervention and data collection

We have done all we can do within the SHINE budget and timeframe, but are actively looking for additional funding to expand this project.

Part 4: Learning from your project

This section is intended to summarise your achievements and the main changes observed in the quality of care (up to 850 words). Please address the following:

- *Did you achieve all of what you hoped to achieve at the start of the project? If so what helped you do so?*
    - *For example was it the contribution of a particular individual or group of people that made the difference? Why was this important?*
    - *How did you get staff buy-in to carry out this innovation? Were there any approaches more successful than others? Why do you think that was the case?*
    - *What have you learnt about how to collect financial information?*
    - *Was it an aspect of organisational culture, technology or policy (national or local) that helped you?*
- *Please tell us about the challenges and the things that didn't work out quite as planned*
    - *If you didn't achieve what you hoped for, what were the reasons for that?*
    - *Were there any aspects of organisational culture, technology or policy (national or local) that acted as a barrier?*
    - *Did staff change or leave? What impact did that have?*
    - *What did you do to try to overcome the challenges? How successful were these efforts?*
    - *Were your original ambitions realistic given available resources and timescales?*
- *What would you do differently next time when implementing an improvement project?*

What we achieved

We believe that we achieved what we set out to do:

- We believe that this is the first comprehensive clinical guidance and care bundles on the clinical management of club drugs and NPS in the world.

- The testing of the implementation of the bundles in clinical settings will inform the spread of the intervention across the UK.

- We have developed a clinical network and achieved stakeholder engagement as well as political engagement (ministers and government departments).

A number of factors contributed to the success of the project:

<u>Timeliness and importance of the project</u>

- First was the timeliness and importance of the project and the fact that the UK government, the EU and WHO, as well as clinicians, have been calling for the need to develop clinical guidance for club drugs as a matter of urgency. The project was welcomed by national and international bodies as well as clinicians and patients.

  This made recruitment, buy-in and engagement from the expert group very easy. This also secured buy-in and on-going commitment from Public Health England, Department of Health and Home Office and the Royal Colleges to support the work during the life of the project and beyond.

- Similarly, buy-in from staff where the project was implemented (bundle PDSA sites) was also easy to secure. Clinicians in those settings believed that they did not have the necessary knowledge and understanding. They welcomed the project.

Expert group membership

The membership of expert group of the NEPTUNE project was another important success factor.

- We were able to recruit all UK clinicians with expertise in the clinical management of club drugs as well as experts from the range of relevant professions (e.g. analytical toxicology). Many expert group members have high national and international standing and therefore provided significant credibility to the work

- We were able to recruit patient representation on the group and have involved voluntary sector organisation working with groups particularly affected by club drugs (e.g Lesbian, gay , bisexual and trangender organisations).

Project leadership and management

The clinical lead of NEPTUNE and the programme manager have the necessary experience:

Clinical lead:

- The lead clinician runs the largest clinic for club drug users in the UK and is Chair of the Substance Misuse Faculty of the Royal College of Psychiatrists

Clinical lead and programme manager:

- Proven experience in delivering successful quality improvement projects and understanding of QI theory and methods
- Experience in the development of national guidance and care bundles
- Research and data analysis expertise and experience in evidence-based clinical reviews

Challenges and solutions

The relatively limited timeframe of this SHINE project was the main challenge, as this was a very ambitious project with two substantial components.

The short timeframe affected most particularly testing and the measurement of improvements. This is because of:

- The development of robust, evidence-based clinical guidelines and bundles took a relatively substantial length of time (as identified at the onset in the PID). However, this was much shorter than the 18 months suggested by NICE for the development of guidelines. Bundle development was only possible once guidance was written.

- PDSAs tested a low-volume intervention and the number of patients presenting during the timeframe is low. As a result, at this stage some of our numbers are relatively small and our ability to draw robust generalisations is limited.

In order to address this challenge, NEPTUNE will continue to carry out PDSA cycles to identify learning for improvement beyond the life of the SHINE and are actively looking for additional funding. We are also developing and will be testing additional bundles, for example ED bundles for the management of ‘excited delirium’.

Other challenges included working with ED partners to help them change prescribing practice when indicated. There was resistance, to prescribe the necessary higher doses of benzodiazepine due to existing local protocols. There was also some discussion relating to the use of particular medication, (e.g. Baclofen). This was overcome though discussions, presentations of the evidence-base guidance and by providing them with support from specialist services. Training of ED doctors and nurses was a key part of engaging the workforce.

What we would do differently next time is allocate a more realistic timeframe. This is especially in light of the relatively low volume of presentations relating to club drug-related overdose, dependence and withdrawal syndrome. A lengthier project timeframe would allow us to take adequate numbers through the testing process in order to ensure a more rigorous and robust evaluation.

Part 5. Plans for sustainability and spread

This section is intended to communicate your plans for sustainability and spread (up to 500 words). You should include:

- *How realistic will it be to sustain the benefits of the project beyond March 2014?*
- *How do you plan to spread this innovation beyond the Shine award sites? What additional resources (and from who) will you need to support this activity beyond the Shine funding period?*

Significant resources to complete. Test in wider areas, technology,

- *Please detail any external interest/potential contacts that you have identified that you need to pursue and those that you have already engaged with?*

The spread of NEPTUNE beyond March 2014 and its dissemination nationally have been identified at the onset of the project as main aims. NEPTUNE has captured the attention and interest not only of clinicians who work in this field but of other stakeholders, including government ministers, Home Office, Department of Health and Public Health England. There is also significant interest from the EU's European Monitoring Centre for Drugs and Drug Abuse.

We are confident that will be able to further disseminate the project outputs and products. We have had discussions with the Royal College of Psychiatrists regarding a strategy to disseminate the work of NEPTUNE nationally and expansion of the work. The College is also planning a briefing on club drugs, which will promote the guidance.

We are already in discussion with various national bodies/organisations about dissemination can best be achieved. These include:

- Public Health England
    - Discussion include possible launch event; communication; use of regional teams to support spread

- Department of Health
- Home Office
- Royal College of General Practitioners
- British Psychological Society.
- DrugScope
- British Association of Sexual Health and HIV
- European Union's *European Monitoring Centre for Drugs and Drug Abuse* [4](EMCDDA) have requested that NEPTUNE guidance be made available through their *Best Practice Portal*.

Support for dissemination promised is however in kind rather than financial, as none were able to promise funding.

The funding will be used not only for dissemination, but also to expand the work we are doing already, especially the testing of a larger number of bundles. We are actively looking for additional resources for the following:

- Publication of the guidance document and dissemination (hard copies and electronic)
- Testing the implementation of the bundles in a wider geographic area (including urban/rural locations; high and low prevalence areas) and testing further bundles.
- Publication of bundles in electronic and other innovative formats to improve busy clinicians' ability to access them quickly within their clinical practice
- Development and delivery of a national training programme relating to the guidance and bundle implementation.
- Sustaining a clinical network/ clinical community beyond the life of the project
- Update of the guidance/bundles within the next 3 years, to take into account newly emerging drugs and new research evidence.

[4] http://www.emcdda.europa.eu/

Appendix 3:

Expert group members

	Secretariat
Dr Owen Bowden-Jones	Chair; clinical lead Ccentral and North West London NHS Trust (CNWL)
Dr Dima Abdulrahim	Secretariat; Programme Manager CNWL
	Expert group members
Dr James Bell	Consultant Psychiatrist South London and Maudsley NHS Trust
Dr Nigel Borley	Consultant Urologist Chelsea and Westminster NHS Trust
Dr Steve Brickman	GP Birmingham. Clinical director of Substance Misuse Management in General Practice (RCGP)
Emma Crawshaw Laura Day	Service Delivery Manager, Crew 2000, Edinburgh
Ms Annette Dale-Perera	Director of Addiction and Offender Care CNWL
Mr Mark Dunn	Clinical Nurse Specialist
Ms Stacey Hemmings	Psychologist
Mr Salvo Larosa	Patient
Dr Luke Mitcheson	Consultant Psychologist South London and Maudsley NHS Trust
Mr Monty Moncrieff	Chief Executive London Friend
David McIntosh	Drug Programme Manager City of London
Prof David Nutt	Consultant Neuro – psychopharmacologist Imperial College London Chair of ISCD
Dr John Ramsey	Analytical Toxicologist St George's Hospital London
Dr John Roche	Consultant Psychologist Leeds and York Partnership NHS Foundation Trust
Prof Fabrizio Schifano	Chair in Clinical Pharmacology and Therapeutics; Associate Dean, Postgraduate Medical School Consultant Psychiatrist University of Hertfordshire
Mr David Stuart	Education, Training & Outreach Manager London Friend and Antidote
Dr Ann Sullivan	Consultant sexual health and HIV

Dr Tim Williams	Avon and Wiltshire Mental Health Partnership NHS Trust
Dr Christopher Whiteley	Consultant Clinical Psychologist East London Public Health England
Dr Adam Winstock	Consultant Psychiatrist South London and Maudsley NHS Trust
Dr David Wood	Consultant A&E physician; Medical toxicologist Guy's and StThomas'NHSFoundationTrust and King's HealthPartners,London,
Dr Dan Wood	Consultant Urologist University College Hospital
	Observers
Mr John McCracken	*Department of Health* *Drugs Programme Manager*
Dr Mark Prunty	*Drugs Programme Manager Clinical Director Addictions (DH)*
Mr Paul Chandwani *Ms Melanie Roberts*	*Drugs Programme Manager Home Office*
Mr Pete Burkinshaw	*Public Health England; Skills and Development Manager*

Appendix 4:

The review of the evidence was based on a transparent process used for the development of the British Association for Pharmacotherapy guidelines, which classifies the strength of evidence:

1	Strong research evidence (e.g. Cochrane reviews, meta-analyses, high quality randomised controlled trials)
2	Research evidence (e.g. controlled studies or semi-experimental studies)
3	Emerging research evidence (e.g. descriptive or comparative studies, correlation studies, evaluations or surveys and non-analytic studies for example, case reports, case series)
4	Expert panel evidence/ consensus
5	Expert by experience evidence (service users/ patients)
6	Lack of evidence (No evidence, for or against)
7	Conflicting evidence

In terms of the applicability of the international literature in a UK context, the characteristics listed below have been considered, not for individual studies, but for statements that will be included in the guidance. Methods for the development of NICE public health guidance (second edition) Issue Date: April 2009)

- Population including age, gender, race/ethnicity, disability, sexual orientation/gender identity, religion/beliefs, socioeconomic status, health status
- Setting including country, geographical context (for example, urban/rural), healthcare/delivery system, legislative, policy, cultural, socioeconomic and fiscal context.
- Intervention including feasibility (for example, in terms of health services, costs), practicalities (for example, experience/training required), acceptability (for example, number of visits/adherence required) and accessibility
- Outcomes including appropriate/relevant, follow-up periods, important health effects.