

CSO Clinical Academic Fellowships 2016 - Reviewer comment form

Application reference: CAF/16/06

Reviewer: [REDACTED]

Please score the application in relation to the areas below using the following scale
0 = Inadequate, 1 = Poor, 2 = Satisfactory, 3 = Good, 4 = Very Good, 5 = Excellent

Personal Qualities (including motivation, evidence of the importance of research to career)

Score: [REDACTED]

Comments: [REDACTED] is clearly an excellent candidate for a training fellowship. She has an intercalated degree, honours in her medical degree, and has shown a strong and consistent commitment to research. She has followed an academic training pathway and taken additional time through other opportunities to undergo research training. She's published during her early academic training pathway, and worked hard to gain many practical skills and technical skills associated with research. There's no doubt she's an absolutely excellent candidate for support.

Importance and NHS relevance (Please comment on the originality, relevance to the NHS and implementability of the proposed research to benefit patients)

Score: [REDACTED]

Comments: The proposed work is clearly of importance. Regulation of inflammation by decoy receptors targeting cellular recruitment is relatively under-researched, which is puzzling given the absolutely central role of chemokines in leukocyte trafficking in almost every disease and homeostatic immune pathway. [REDACTED] group have worked extensively on these decoy receptors and produced clear data showing strong regulation of decoy receptor expression in human disease. There's no doubt at all that these receptors are likely to be important regulators of inflammation, immune homeostasis, and tissue positioning of leukocytes. Data from psoriatic skin are fascinating in terms of massive regulation of decoy receptor expression. Evidence for regulated expression in the blood and tissues of people with rheumatoid arthritis confirms the likely importance of these receptors.

There is therefore much to be gained from understanding what regulates the expression of these receptors in disease, exploring their function, and considering their targeting. I like the concept of upregulating decoy receptor function in human disease; activating natural anti-inflammatory pathways as a clinical therapeutic would probably have less adverse effects in terms of immunosuppression, and could usefully complement current expensive mAb-based anti-inflammatory pathways. Targeting chemokine receptors is very feasible. The potential plan to selectively upregulate decoy receptor expression is a bit more speculative, but would be very exciting could it be achieved. Although this project has an appropriate disease focus, it's also highly likely that manipulation of decoy receptor expression would be of wide clinical interest.

Methodology (appropriateness, rigour, and feasibility of the methods)

Score: [REDACTED]

Comments: The experiments proposed are entirely logical and appropriate. Within a confined page limit it's always challenging to get methodological details right. I would have wanted to see more detail/hypothesis on peripheral blood leukocytes to be phenotyped and where changes in decoy receptor expression were likely to occur. I would have wanted to see more detail about the clinical cohorts and I wonder if setting up a study to look at impact of anti-TNF on expression of decoy receptors in the blood would be interesting; it would be feasible to capture treatment-naïve patients and resample after induction of immunomodulatory therapy, to determine to what extent inflammation regulates decoy receptor expression. However, [REDACTED] will be working with very strong supervisors who would be highly likely to automatically provide robust guidance in these areas as the research evolves. The final aim, to induce decoy receptor expression, is a great concept but.

as written here very aspirational and it's not clear whether there's any pilot data or reason to think this will be successful. Nonetheless, it would be a great coup to achieve this, and the other aims examining expression and function in disease are well founded.

Training, Supervision and Environment (is the training relevant/required, do the supervision arrangements match requirements, will progress be adequately monitored)


Score: [REDACTED]

Comments: [REDACTED] is a completely outstanding scientist in his field, and a superb mentor. The associated clinical supervision from [REDACTED] is very strong. I'd advise anyone who has an opportunity to work in the [REDACTED] lab to seize it; a combination of excellent training, superb careful science, and great mentorship would inevitably follow.

Overall (Please summarise the strengths and weaknesses of the application and whether the applicant should be invited for interview - please indicate any questions that you would suggest asking the candidate if they are invited. Note this section is not fed back to applicants)

Score: [REDACTED]

[REDACTED]

CHIEF SCIENTIST OFFICE Chief Medical Office Directorate Project Evaluation Form HSRC - FULL GRANT	Project reference: CZH/4/1084  (External)
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**PLEASE NOTE THAT ANONYMISED COMMENTS MAY BE FED
BACK TO THE APPLICANTS**

To help us, it would be useful if you would make your *anonymised* comments on page 2 in the following categories (please do not write comments on this page):

1. Importance

Please comment on the originality, relevance and implementability of the proposed research.

The proposed study is original in that it aims to test the use of BCT with couples where both have an addiction. It is highly relevant to the Scottish context where parental substance misuse is highly associated with referrals to the child protection and Children's Hearing systems. Implementation appears to be feasible.

2. Methods

Please comment on the appropriateness, rigour, and feasibility of the methods.

The methods appear appropriate – certainly qualitative data is essential for gathering information about feasibility. The data from the standardised measures could only be subjected to minimal quantitative analysis because the numbers are small. There is also no real comparison group other than with 'service as usual' population outcomes.

3. Value for money

Please comment on whether the cost of the research is justified by the potential importance of the findings.

The costs appear modest and appropriate for a study of this kind. It is, therefore, good value for money.


4. Modifications


Please indicate any changes that might improve the research.

The study looks coherent, my only question is whether it is trying to do too much by addressing all three research questions – the issue of BCT as an adjunct to opioid substitution seems to be less overt in the methodological detail, whereas the testing of BCT with dual dependent couples is the sharp focus.

5. Scoring Guideline

- Reject 0 - 1
- Major modification required 2 - 3
- Fund with minor modification 4 - 5
- Fund without modification 6

Please write in score 


Signed _____

Date 28.8.14

Comments on second page

ANONYMISED COMMENTS

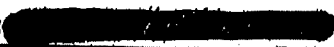



please feel free to comment on any aspect of this proposal

As noted above, the first of the research questions is the sharpest and, in itself, would justify the study and costs. The issue of using BCT as an adjunct to opioid substitution is less clear because there doesn't appear to be a comparison with those who are not receiving substitutes, although the aim of testing feasibility for a full RCT does make sense. The eligibility criteria for the couples is tight – and clearly that is necessary. Ironically, though, the criteria does mean that some of the main risk factors for children are eliminated, especially domestic violence and instability of the relationship. However, it does seem helpful to start somewhere in testing this approach.

Overall I would consider this to bring some helpful insights to the Scottish context and would serve as a good platform for further studies.

Please return by email to






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ANONYMISED COMMENTS MAY BE FED BACK TO APPLICANTS

Make *anonymised* comments on page 2 in the following categories (please do not write comments on this page):

1. Importance (Originality, relevance and implementability of proposed research).
2. Methods (Appropriateness, rigour, and feasibility of the methods).
3. Value (Is the cost of the research is justified by the potential importance).
4. Modifications (Changes that might improve the research).
5. Scoring Guideline
 - Reject 0 - 1
 - Major modification required 2 - 3
 - Fund with minor modification 4 - 5
 - Fund without modification 6

Please write in score 

Signed  Date 7 - 8 - 14


Comments on second page

ANONYMISED COMMENTS

1. Importance (Clinical relevance, and feasibility of proposed research.)

This is an interesting application to adapt a *behavioural couples therapy* intervention (developed in the USA by [redacted]) tailoring it to UK OST patient needs, where both members of the couple are opioid-dependent. It takes that [redacted] intervention – “BCT” – and adjusts that intervention methodology to meet the needs of the “concordant”/both-dependent couple, then implements the adapted intervention with 18 couples, and collects some data on health outcomes and costs. The investigators imply that poor child outcomes may be improved by this intervention, pointing to associations between these parents and child-outcomes (and implying that the poor outcomes are caused by the parental drug use alone). The investigators would then seek funds for a pilot before proceeding to a full RCT.

In principle, it is an important initiative to attempt: to improve the broad health and well-being and social functioning of terribly marginalised OST patients; to keep their family unit intact; and to enhance the well-being of their children. Even if the BCT does little to directly enhance the well-being of the children, it may keep welfare agencies from removing children especially if the opioid-dependent parents are more stable and better able to point to this stability when child-at-risk assessments occur. There is too little attempt to enhance these outcomes, despite the population being identifiable and easily targeted, and despite their children being frequently removed by welfare agencies. In that sense, it is relevant to the needs of this OST/opioid dependent patient group, and relevant to government agency needs, and to professional and general community concerns that these families function better. It is also important to try to add to OST, interventions that will improve psychological and social functioning – this is too little done. Therefore, I think these investigators are addressing an important clinical/family/parental/societal issue, albeit by adapting an existing intervention.

The work is not overly original inasmuch as [redacted] has been publishing on this intervention for over a decade, but the proposed value-add is to transfer it to OST patients and to the UK setting. Of course, the need to foster the development and uptake of non-proprietary interventions needs to be recognised, as these are often not well-researched or implemented. Pharmaceuticals are much better researched, as there is a proprietary aspect that ensures research investment. However, I think the investigators could have better explained what in the existing BCT needs to be adapted, at least by giving some specific examples of how the existing BCT does not meet the needs of opioid-dependent patients.

I believe it is likely that the investigators can implement the plan, given the resources sought, and the involvement of [redacted] and colleagues. [redacted] has [redacted] successfully published RCTs in this area and his involvement enhances the likelihood that the initial processes will lead to applications for a full RCT in due course. However, I think that the answer to the three research questions on page 13 will be “yes” in each case.

2. Methods (Appropriateness, rigour, and feasibility of the methods.)

Overall, the investigators have carefully articulated their methods. I do not see major problems with what they propose, in terms of the initial training of staff, the implementation of the BCT package, the assessment of acceptability and of fidelity, or most of the other methods. Yet, the methods to develop the BCT for OST concordant couples seem rather protracted, although it is an intense and lengthy intervention (see below).

Presumably some of the adaptation has occurred in the 2003 [redacted] work on opioid dependent men (<http://psycnet.apa.org/journals/ccp/71/3/432/>). The investigators need to clarify these issues.

Measures are ok – the parenting and relationship measures seem appropriate, but the sensitivity to change of the child protection notifications and out-of-home-placements may be limited – but that is why one does pilot work.

Focusing on the substance use outcomes, I do not see methadone or buprenorphine dose in OST as a relevant substance use outcome (I am presuming the investigators are suggesting that a lower dose is a better outcome) – arguably being on a higher dose is better as it is associated with better patient stability in OST – see the Cochrane review of methadone dose.

The inclusion of health economic measures is appropriate, although I have never liked the EQ-5D as a measure of utility in OST populations as I think it is too insensitive to between group differences. The investigators will no doubt be able to clarify.

3. Value (Is the cost of the research is justified by the potential importance?)

Again, I point to the need to support the development of non-proprietary remedies. However, I would have thought that for £162K, a pilot of the RCT could be provided. Other than that, I found the budget pages on *Details of full economic costs* confusing – but that may reflect a lack of local knowledge of the way costs need to be broken down in such an application. The *Financial Support* page provided an overview, but not where the costs were being spent to my satisfaction. Thus, I make no further comments on the budget per se.

However, assuming the investigators are implementing [redacted] approach, the *Behavioral Family Counseling and Naltrexone for Male Opioid-Dependent Patients* 2003 paper indicates 56 sessions over 24 weeks of treatment plus individual therapy, group therapy and joint therapy sessions. At 56 sessions, the staff here needs to conduct 1008 sessions for the 18 couples, plus travel, carry out measurements, etc. Given the extent of the involvement, the need for two 0.5WTE staff for one year is reasonable to deliver the intervention. I note there are about 230 working days in a calendar year and if they do 56 sessions per couple they need to do 4.4 sessions per day! The request for a research fellow to evaluate the process is justified.

4. Modifications (Changes that might improve the research.)

I think a modification to the introduction to better describe the background is needed.

This application is not for a research project – it is for development of resources and really training of staff to assess feasibility and likely appeal to OST patients.

I suggest that the utility of the work would be enhanced if this were a true pilot of an RCT.

CHIEF SCIENTIST OFFICE
Chief Medical Office Directorate
Project Evaluation Form

HSRC - FULL GRANT

Project reference: CZH/4/1084

(External)

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Please comment on the originality, relevance and implementability of the proposed research.

2. Methods

Please comment on the appropriateness, rigour, and feasibility of the methods.

3. Value for money

Please comment on whether the cost of the research is justified by the potential importance of the findings.

4. Modifications

Please indicate any changes that might improve the research.

5. Scoring Guideline

- Reject 0 - 1
- Major modification required 2 - 3
- Fund with minor modification 4 - 5
- Fund without modification 6

Please write in score

Signed _____

Date _____

21st August 2014 _____

Comments on second page

ANONYMISED COMMENTS

please feel free to comment on any aspect of this proposal

This is an unusually excellent application which I have no hesitation in recommending should be funded. It addresses a particularly important subject and patient group, namely couples, both with drug problems, with young children. The problems associated with this group are immensely costly in all senses.

The methods have been thought through very carefully and an excellent team of researchers and advisors has been assembled. Both qualitative and quantitative data are to be used. The aims are vitally important but realistic: to adapt an approach which is very well supported by the evidence; to assess its application in the NHS context; and to judge the feasibility of going on to a pilot trial.

I expect a lot to be learned from this study at surprisingly modest cost.

I normally have a lot to say about applications but in this case there is little in the way of modification which I can suggest. Just one issue I might highlight however, and that is the issue of the subsequent sustainability of the behavioural couples therapy (BCT) for this patient group in the NHS in Scotland. In this development and feasibility study the BCT originator and particularly the master trainer from the USA play crucial roles. It is implied that among the things learned will be what skills and resources are required to disseminate the method. Perhaps the applicants could be even more explicit about how the results will bear on the independence and sustainability of the use of the method subsequent to the study.

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Please write in score

Signed

Date 31/08/14

Comments on second page

ANONYMISED COMMENTS

please feel free to comment on any aspect of this proposal

Importance:

There is very little research in the area of couples therapy and substance misuse in the UK; it presents clear challenges to implement and complete but is of huge importance when considering the potential impact on vulnerable children. The need to recognise familial substance misuse on children is well recognised within services and Government initiatives; what is less clear is what would constitute a successful intervention. It is a valuable proposal to train substance misuse staff in specific manualised therapies – this is also likely to benefit other areas of their work.

This is an original and relevant proposal; I have concerns about the implementation. It is an intense, focussed multifaceted intervention in a very difficult to engage group. I think there could be difficult interfaces with social work; couples engaging with this would have much more monitoring than usual care. I would be keen to have greater explanation of how this could work in practice and a discussion of how information gained from the therapy would be shared when decisions about whether to accommodate children were being made. It may be that social work could be an important partner in the research.

Method:

There are quite a lot of changes proposed from the American model – I am not sure of the rationale of using concordant couples, limiting to under fives and moving to the British setting. I wonder if fewer changes would make the study more feasible. The proposal recognises the need for British adaption – I am not sure why it is such a large adaption. In NICE 51 the recommendation is around discordant couples – again I am not sure why this model was not proposed in the British setting initially.

I am concerned that given the proposed study group it will be difficult to recruit and retain study participants. I have looked at the study figures and think it will be a challenge to find couples who fit criteria and are willing to undergo the testing required even given the potential pool of substances misusers in Lothian. Drug misusing parents of under fives are busy; committing to the study as it stands will be difficult for them.

I realise that this is a feasibility study – I wonder if there are also questions around the fidelity of treatment and its assessment given there will need to be adaption of the manual.

Value for Money:


If this work leads to a therapy that reduces substance use in parents, that can be widely implemented within treatment services in Scotland it will be potentially hugely cost effective to a number of agencies such as Health, Social Work and the Police as well as impacting positively on childrens' lives. I am not certain the proposal as written will allow this to be ascertained.

Modifications:

I would suggest fewer changes from the established model; I think discordant couples with older children too would be a more viable study. I wonder if some childcare costs for the service users should be factored into the proposal – this could make it easier for the participants particularly if the proposal plans to continue to recruit both parents of children under five.

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4. Modifications

Please indicate any changes that might improve the research.

5. Scoring Guideline

- Reject _____ 0 - 1
- Major modification required _____ 2 - 3
- Fund with minor modification _____ 4 - 5
- Fund without modification _____ 6

Please write in score 

Signed _____

Date _____ 08/09/14

Comments on second page

ANONYMISED COMMENTS

Importance

There is definite merit on focusing on such a vulnerable group, namely concordant drug dependent parents with preschool aged children. However, I feel in the first instance it may have been best to test the feasibility of implementing BCT in a UK context with the group that the US evidence base exists for i.e. discordant drug or alcohol dependent couples with school aged children. As the applicants allude to there may be many translational issues which impede embedding such an intervention within a UK setting: having the necessary resources, level of staff competence/training and working within a routine, non-research, setting. Although the applicants make a clear case for BCT as an effective intervention they do not note that there have been claims of potential misconduct on some of the federally funded trials involving ██████████, and he is a co-author on two of the key sources (11,13) cited for justification of the proposed study. Also it is not made clear how focusing on substance use and relationship dynamics impacts on parenting behaviour. This should have been explored in more depth to explain or postulate how preschool aged children's outcomes would be improved.

Methods

A development and feasibility study is a sensible approach but as I have mentioned previously the stated aims seem rather ambitious. If seeking to conduct an original investigation, it may be best to look at changing one of the variables i.e. concordant couples, concurrent opioid substitution, preschool aged children, but not all three - while also investigating implementation issues. In addition, 22 months seems slightly excessive for this type of development study as the BCT manual already exists and only requires minor adaptation and 36 participants is also quite large for this type of study. As this is a new treatment approach, it would also be useful to consider what treatment as usual might look like for this group, as this will be required for randomisation, if implementation and the intervention are promising and proceed to pilot study stage. For assessing feasibility, as well as qualitative information, an existing tool such as the Working Alliance Inventory could be used to look at therapeutic relationship. Not clear how quantitative data collected will be analysed and also for the qualitative analysis, narrative and thematic analysis would need to be explained in more detail. The proposed outcome measures all seem sensible, however, there is somewhat of a philosophical clash between the drive towards abstinence in the BCT model combined with substitute prescribing. Given this, the weekly toxicology testing proposed would need consideration.

Value for money

This development work is required to establish whether it is feasible to implement BCT in a UK context. For the proposed study and timescale involved, the costs appear reasonable. However, as stated I believe that this development study could be reduced in scale and still provide enough information to progress to pilot study stage. I would query the need for weekly toxicology tests and also whether on-site fidelity testing is required given advances in secure data transfer. Almost £10,000 to conduct this work seems quite high. Also remuneration to participants for expenses is not specified in the costs, particularly the costs for the five advisory group meetings. Open access journal and international conference costs also seem to have been omitted.


Modifications

As stated I would suggest revising the aims and scale of the proposed study and include more detail on associated costs of patient and public involvement. Also it appears that the intervention will mostly be implemented "off the peg" from an existing manual, there could be a wider consultation phase to adapt some of the features to make them more acceptable to clinicians and service users before training therapists in the approach. Good support from

collaborators would be required as the principal applicant does not appear to have previous experience of leading such a study.

I would also look at the exclusion criteria as co-habiting couples may have lived apart for more than 8 of the last 12 months due to prison sentences which are not unusual in this population.

Assume TLFB stands for timeline follow back Spousal Violence Scale, name should appear in full. Citation for Adept is incorrect in text as listed as 21 and appears as 20 in the reference list.

Please return by email to 

Project Evaluation Form
Health Improvement, Protection & Services Research Committee

Project Reference:	HIPS/16/49
Reviewer:	

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Please comment on whether the cost of the research is justified by the potential importance of the findings.

4. Modifications

Please indicate any changes that might improve the research.

5. Scoring Guideline

- | | |
|--------------------------------|-------|
| • Reject | 0 - 1 |
| • Major modification required | 2 - 3 |
| • Fund with minor modification | 4 - 5 |
| • Fund without modification | 6 |

Please write in score:

ANONYMISED COMMENTS

Please feel free to comment on any aspect of this proposal

1. Importance

The opportunity to gain insight into this natural experiment of how restrictions on behaviour influence people's behaviour is truly unique. This experienced and productive team are well known and have the insight to make a truly important contribution to the drunk driving literature and beyond.

2. Methods

The methods are appropriate for the design.

3. Value for money

The project is appropriately budgeted, and represents value for money.

4. Modifications

I would be very interested in thinking a bit outside the box of the standard subjective reporting. In the end, the sampling limitations and vested interests of licensees means that there is an aspect of the picture missing; what really happens when the pubs and clubs close. Relying on people's reports may be all that is feasible, but it would be great to explore this possibility as well, although there are obviously significant resource implications.

Please return by email to: [REDACTED]

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Please write in score:

ANONYMISED COMMENTS

Please feel free to comment on any aspect of this proposal

1. Importance

I strongly endorse the importance of this research. These are open questions that will not only provide valuable information to progress policy in Scotland to reduce alcohol-related harm, but will be of interest in many other countries. New Zealand has also recently reduced the limit to 0.05 after protracted and highly politicised debate over many years. Evidence about the effectiveness or otherwise of BAC limits on alcohol harm more generally is a critical part of this debate here and elsewhere. Achieving a reduction of 0.05 is not the end of policy development on BAC limits as significant driving impairment remains at this level. However the wider effects of limits on drink-driving patterns and on drinking places and possible unintended harms need to be well understood to develop good policy and to counter resistance to change.

Another interesting aspect of this proposal is the consideration of the role of lower alcohol products following the BAC change and positioning of these.

2. Methods

I believe that one of the reasons that we know so little about these issues from countries where the limit has been lowered previously is that the methods required are high quality robust qualitative methods, not only the quantitative methods that have in the past been so dominant in evaluation of these types of changes.

It appears to me that the methods are entirely appropriate, and the team has the necessary expertise and experience in this field to apply them to their questions with an expectation of useful findings in which we can have confidence.

3. Value for money

As an outsider this difficult for me to comment on, but the budget would be appropriate for a similar study in New Zealand.

4. Modifications

I don't have any specific suggestions for improvement.

Please return by email to: [REDACTED]

Project Evaluation Form
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Please write in score: [REDACTED]

ANONYMISED COMMENTS

Please feel free to comment on any aspect of this proposal

1. Importance

This is an important and timely proposal. The study complements the NIHR funded evaluation. The findings from the two studies will inform both policy and practice.

2. Methods

The study will be conducted by an experienced team with methods used in their previous research. The sampling strategy will recruit people with a range of experiences.

Question 1B may need to be modified slightly: while the study can compare and describe differences between areas and drinking contexts, it will not be able to quantify these differences.

The focus groups and interviews will generate a large amount of data, and I wonder if the team could use slightly more time for the analysis.

3. Value for money

The study offers very good value for money. I would consider requesting another month for the analysis.

4. Modifications

Question 1B could be clarified
Consider extending the time for analysis

Please return by email to: [REDACTED]



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Please write in score:

ANONYMISED COMMENTS

Please feel free to comment on any aspect of this proposal

1. Importance

I believe that this project proposes a timely piece of research on an important topic. Both population alcohol consumption and Road Traffic Accidents represent significant burden's on public health, and a greater understanding of how/if the recent change in legislation impact upon these will be critical for evaluating the legislation and for future interventions/legislation changes.

2. Methods

The qualitative methods proposed (focus groups and thematic analysis) are appropriate for understanding the process behind any change in behaviour and attitudes. A key strength of the proposal is the synergy with a parallel project which employs quantitative methods. The way in which the applicants suggest complementing the qualitative research with the quantitative methods could produce some interesting findings.

3. Value for money

Overall I think that the project represents good value for money. The fact that the quantitative element of the research is funded from elsewhere (NIHR) cuts down the overall cost of the evaluation significantly.

The applicants should explain somewhere in the proposal why they require a tablet for their fieldwork (the purchase of a tablet is not an unreasonable request, but they need to explain more clearly why they need one).

4. Modifications

There are three additional topics that I believe could yield interesting responses in the focus groups (Note that the applicants have not presented an exhaustive list of their focus group questions and so may have considered these issues already):

- Are participants actually aware of the change in legislation? There is a good chance that some people will not be.
- Do participants remember seeing the extensive advertising campaign that accompanied the legislation? If so what were their thoughts on it? Do they believe it contributed to any change in their attitudes/behaviour? This will be an important point in learning lessons for future interventions/legislation changes.
- It would not only be interesting to know if participants believed their *own* attitudes/behaviours changed due to the legislation, but whether they believed that *others'* attitudes and behaviours changed. There is evidence which shows that people are influenced by (their perceptions) of group members' injunctive/descriptive norms.

I would like to have a bit more information about the "public seminar" briefly noted on p16. Where will this be held, who are the likely audience, what is the purpose of this event etc.?

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Project Evaluation Form
Health Improvement, Protection & Services Research Committee

Project Reference: HIPS/16/49

Reviewer: [REDACTED]

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1. Importance

Please comment on the originality, relevance, implementability, and potential impact of the proposed research.

2. Methods

Please comment on the appropriateness, rigour, and feasibility of the methods.

3. Value for money

Please comment on whether the cost of the research is justified by the potential importance of the findings.

4. Modifications

Please indicate any changes that might improve the research.

5. Scoring Guideline

- Reject 0 - 1
- Major modification required 2 - 3
- Fund with minor modification 4 - 5
- Fund without modification 6

Please write in score: [REDACTED]

ANONYMISED COMMENTS

Please feel free to comment on any aspect of this proposal

1. Importance

A qualitative investigation of the impact of changes in drink driving laws is an original contribution to the field. The ability to comment on changes in drinking practices between on-premise and off-premise settings can provide potentially valuable insight into how and why drinking practices may have changed.

2. Methods

The proposal comes from researchers with a credible track record in using the proposed methodologies.

3. Value for money

Good. The researchers have a proven track record using the proposed methodologies. The researchers are also proposing low-cost approaches (such as Gumtree) to complete the more time-consuming approach of focus groups.

4. Modifications

It would be useful for the researchers to include information about any public media and education campaigns that were associated with the law change. This does not not, but it could be, in the form of analysis of key messages, and sub-groups of the population targeted by such messages. Such information would provide context to the data gathered in the proposed grant.

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- | | |
|--------------------------------|-------|
| • Reject | 0 - 1 |
| • Major modification required | 2 - 3 |
| • Fund with minor modification | 4 - 5 |
| • Fund without modification | 6 |

Please write in score: [REDACTED]

ANONYMISED COMMENTS

Please feel free to comment on any aspect of this proposal

1. Importance

This is clearly a timely proposal in that it will extend a larger quantitative study examining the impact of recent changes in the drink-drive limits in Scotland. As the applicants argue, the quantitative study will paint the broader picture but, alone, it will not be sufficient to examine in depth why policy change has an impact (or not) on drink/driving practices – for whom, under what circumstances etc. In addition, the applicants propose to consider possible implications for overall consumption levels – whether such a policy initiative has a more general ‘knock-on’ effect is an interesting question. It will be useful to explore the response of the on-trade business to the limit change and any behavioural changes linked to it as one might expect some adaptation to address possible effects on profits. Understanding the factors that determine whether policies are successful or not, and whether behaviour change following policy change is sustained or not, is extremely important and (if the applicants care to develop a theoretical perspective) has the potential to enhance understanding of the policy process beyond this specific topic area.

The project is well supported by relevant stakeholder groups able to make the most of the findings and to disseminate through their own networks and mechanisms. This has the potential to maximise impact.

The research team are very experienced and have a good track record in conducting this kind of study. They have good networks and relevant contacts and should be able to implement the study successfully.

2. Methods

The use of qualitative methods – individual interviews and focus groups are suitable for the research as a way of exploring attitudes, perceptions and the significance of events/ behaviours etc. I assume that this qualitative research will be concerned with theory building rather than descriptive accounts of factors determining behaviour. While the latter is useful it would make only a limited contribution to understanding the impact of policy change whereas theoretical development could be tested in further studies. The applicants do not discuss broader methodological issues so it is difficult to judge their overall approach. Sampling strategy: The basic parameters (urban/ small town/ rural; workplace/ community; licensees) are acceptable and I appreciate that a mixed approach to recruitment is necessary. However, will there be three main geographical categories with 2 workplace/ 2 community/ 5 individual licensee interviews; or 6 – 9 different geographical areas and how will these be selected? I was not clear about that part of the sampling. Might I suggest that selection could depend on the findings from the quantitative study as there may be different patterns emerging in different areas and that the applicants might consider an iterative approach to gathering the data to allow for exploration of emerging issues (which fits with theory building and testing). It might be difficult to link up licensees responding innovatively to changes with perceptions of members of the public and there do seem to be a lot of variables that the applicants are trying to cover in a very small sample. The kind of research proposed by the applicants is not easy and can run into many problems of recruitment and selection bias etc.

Despite the extensive experience of this very capable team, it would have been reassuring to have some brief discussion of the risks/ problems and some suggestions about how the team might respond. Overall, I felt that the description of the sampling strategy would benefit from greater focus (e.g. geographical areas) and a clearer outline of the sampling frames and selection processes.

The description of how the data will be gathered and the use of findings from the quantitative study in the focus groups is good and the proposed thematic/ framework analyses is appropriate.

3. Value for money

As far as I can judge, the study is value for money and if successful stands a good chance of making an important contribution to policy and practice.

4. Modifications

Some ideas mentioned in the sections above could be considered by the applicants in planning the initial stages of the work – theoretical underpinning and development of theory; locating the sampling strategy within the context of the findings of the quantitative study; clearer description of the sampling process.

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4. Modifications

Please indicate any changes that might improve the research.

5. Scoring Guideline

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- Fund with minor modification 4 - 5
- Fund without modification 6

Please write in score: [REDACTED]

ANONYMISED COMMENTS

Please feel free to comment on any aspect of this proposal

1. Importance

Research in people with major mental illness and co-morbid physical conditions on health outcomes is scant. This research is important as it will address some of the gaps in current knowledge. It is relatively a straightforward research proposal to implement because it uses existing routinely collected datasets. The findings have the potential to impact policies/processes to improve health care for people with major mental health and add to the epidemiological literature that can inform future research, including intervention studies.

2. Methods

Eight linked routinely collected data health data sets will be used for the analysis. Sample size is sufficiently large to answer the research questions and statistical methods appropriate. There are advantages of linking and using the health data sets, such as it being relatively inexpensive to access the data and captures a large portion of the target population. However, as with any study that uses administrative data, there may be potentially biases in case identification, particularly people with major mental illness. Less severe cases may be missed if people are not hospitalised or visit outpatient clinics. However, pilot work is currently being carried out to examine the feasibility of ascertaining cases with major mental illness using several datasets.

Development of a detailed analysis plan to address the research questions and interpretation of the results will require input from the investigators who bring expertise from key content areas (mental health, diabetes, primary care, CVD, multi-morbidity, health inequalities etc.) as well as epidemiology, longitudinal data analysis and routinely collected data. The investigators also have access to the insights and advice from data analysts/statisticians. However, I suggest that a statistician/data analyst also be involved with the decision making process/discussions related to the data management, analysis and interpretation of results from the beginning of the study as they may offer a different perspective.

3. Value for money

The budget is reasonable. Processing and preparing data from secondary sources for statistical analysis takes time and requires attention to detail. Having a dedicated researcher with strong epidemiological/statistical skills to access, prepare and analyse the data is important to ensure the highest quality data for analysis.

4. Modifications

None

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Please write in score:

ANONYMISED COMMENTS

Please feel free to comment on any aspect of this proposal

1. Importance

The topic is of huge importance to public health – the mortality gap from mental disorders is a shocking health disparity which is poorly understood. This study will assist in understanding some of the gaps in clinical care for people with mental disorders, using a series of record linkages. The ability of the study to determine whether differences in process of care variables are responsible for poorer outcomes associated with mental disorders is a particular strength. The translation section is well considered.

2. Methods

These are appropriate. The group has the requisite experience to conduct a linkage of this nature, and the data sources are relevant and informative. The use of a national diabetes registry which includes primary and secondary care and many indicators of diabetic control and clinical activity gives this study a considerable advantage over previous work. The psychiatric record should provide comprehensive indicators of secondary care contact, but will not give a handle on primary care. The emphasis of the study is therefore predominantly on severe mental illness.

3. Value for money

Good.

4. Modifications

Quality of care is likely to vary according to clinician or provider unit and it would be informative from a public health perspective to determine the extent to which poor outcomes in people with SMI is attributable to provider level variation in care quality. Related to this, it is likely that individuals treated within the same unit are not independent of one another, and therefore multi-level models are required.

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Please write in score: [REDACTED]

ANONYMISED COMMENTS

Please feel free to comment on any aspect of this proposal

1. Importance

The proposed research is original and relevant to an area of limited evidence. In particular, research from universal health care settings is warranted to examine differences in both outcome and health care of medical comorbidities among patients with mental illnesses. The comprehensive research project will use nationwide population-based data from eight health datasets in Scotland to examine the impact of key chronic diseases including diabetes, MI and stroke, which is unique from an international perspective. Due to routine individual-level linkable data, relevant and clear research questions, well described research plan and cross-disciplinary experts, the research project is considered implementable. The important identification of interrelations between medical comorbidities and major mental illness are crucial steps toward designing quality improvement interventions and deepen our understanding of the neglected area.

2. Methods

The proposed national datasets are considered appropriate as they previously have been used for research purposes, are shown to be of high quality and have long time-periods of data available. The expected sample sizes are likewise regarded sufficient.

3. Value for money

The cost of the proposed research study is considered justified by the importance of the findings. Moreover, the cost to cover data linkage, data cleaning of eight complex data sets and statistical analysis are justified as this requires a substantial time consuming workload.

4. Modifications

It is unclear whether the proposed research project will stratify their results (health care) according to the severity of the medical comorbidities. E.g. HbA1c to clarify whether this characteristic/severity of medical comorbidity affects a possible difference in diabetes care.

It is unclear whether the aim of the proposed research project is to compare the clinical care/outcomes for physical diseases among patients with and without mental illnesses (mental illness compared to the general population in Scotland). This is not clearly described, although it is assumed.

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Please write in score: [REDACTED]

ANONYMISED COMMENTS

Please feel free to comment on any aspect of this proposal

1. Importance

The life expectancy of people with severe mental illness is reduced by 10-20 years and improvements in life expectancy experienced by the general population have not been seen in those with severe mental illness. This health inequality is a major concern. Most of the deaths in people with severe mental illness are from physical illnesses. This research is therefore highly relevant to current health priorities.

This study is not unique and other groups have examined this issue previously, both in England and overseas. Nevertheless the robustness of the Scottish health datasets will allow an in-depth analysis of the local population.

This research will be able to inform how services are delivered in Scotland and therefore has the potential to impact patient care in the short term.

2. Methods

The project team is well experienced in the physical health of people with severe mental illness having published several high impact papers in this area. They have the necessary experience to interrogate the datasets to address the questions set in this proposal.

The methodology is clearly written and is feasible within the timeframe of the project. The datasets are already established making the work achievable.

3. Value for money

The costs involved in this study are modest and are well justified. As such it provides good value for money

4. Modifications

None

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