Campbell Collaboration Review Protocol

Intervention Protocol

1. Cover Sheet

Title: Systematic Review of Intervention Strategies for the Prevention, Treatment and Management of Violent Behaviour by Adults in Contact with Forensic Mental Health Services or the Criminal Justice System.

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2. Background for the review

Violent behaviour is a significant source of public and political concern, and most perpetrators will eventually come into contact with either the forensic mental health (FMH) services or the criminal justice system (CJS) (or both). This contact provides an opportunity for assessment of the individual's risks and needs and for interventions aimed at managing violence within the institutional setting and preventing future violence within the community. Numerous risk assessment and risk management technologies have been developed over the past thirty years which are available for practitioners to deploy when working with individual perpetrators, and many of these technologies have at least a moderate evidence base. The systematic review proposed here sets out to address the global evidence base underpinning interventions for preventing, treating and managing violence in both FMH and CJS settings. It will be conducted in parallel with another review (submitted to the Campbell Collaboration under separate cover) addressing issues of violence risk assessment.

A very diverse range of interventions have been developed with the aim of preventing and managing violent behaviour by people in contact with these two agencies (Hodgins 2000; Hollin 2003). These interventions range from pharmacological treatment, through a wide range of psychological approaches to, at the social end of the spectrum, environmental manipulations. They may include the use of physical force (Sailas and Fenton 2002). Psychosocial interventions tend to be based on cognitive-behavioural principles but may include psychodynamic, humanistic and/or systems theory elements and may be delivered on an individual one-to-one, group or 'therapeutic community' basis. Intensive interventions may combine many of these components simultaneously. Intervention may take place in forensic in-patient or correctional settings to prevent violence within those settings or in preparation for discharge / release into the community, or they may take place in community settings as part of an outpatient or community offender management programme. Distinctions can be drawn between short-term interventions aimed at preventing imminent violence or managing actual violence by highly aroused and disordered patients on the one hand (NICE 2005), and long-term structured therapeutic interventions delivered in relatively low-arousal settings aimed at preventing future violence in in-patient, prison or community settings on the other. Pharmacological and psychosocial interventions may be 'single dose' or 'multiple dose'. Most interventions will be delivered directly face-to-face with the patient but some relevant interventions (e.g. staff training, environmental changes) are delivered indirectly via a human or physical mediator. It should be noted that the precipitants and mediators of violence by people with a personality disorder can be very different from those related to violence by people with an active mental disorder, particularly psychosis and thus interventions will be tailored appropriately.

After twenty years of sustained activity in this area, the primary research literature is now very large yet the evidence base for making clinical and policy decisions is often bemoaned as inadequate (Department of Health 2000). The evidence base is certainly poor considering the vast number of studies which have been published in the last decade (Cure, Chua et al. 2005), largely because of a combination of methodological difficulties and lack of focus characteristic of the unusually rapid development of interest in the field. A number of systematic reviews have been conducted to summarise and integrate the findings from the literature and these provide evidence on a number of specific areas. However, inevitably these reviews tend to focus on a specific intervention e.g. second generation antipsychotics (Bhana, Foster et al. 2001) and/or a specific outcome (e.g. reoffending) in various special populations (e.g. sex offenders). This review will instead adopt a more comprehensive

approach by aiming to capture research on all interventions relating to a broad range of violence-related outcomes amongst a wide FMH and CJS population. In this way it is anticipated that the fragmented clinical and criminological literatures can be reintegrated to the mutual benefit of practitioners and researchers in both settings (Hollin 2008).

This Interventions review is being conducted in tandem with a review of Risk Assessment approaches with the same population and it is important to emphasise that the two processes should be closely linked. Estimates of predictive validity from a risk assessment tool are of little use on their own if they are not used to design and target effective interventions. The structured clinical judgement approach (Maden 2007) discussed in the introduction to the other review is important in this context as this approach is recognised as encouraging practitioners to focus on risk management and flexibility in choosing appropriate interventions.

The two protocols (Interventions and Risk Assessment) build on the work of a previously completed systematic review in this area. The final report of this review has had significant influence on national policy in England and is currently flagged on the website of the Department of Health / Ministry of Justice (England) National Risk Management Programme (CSIP/NIMHE). It also formed the basis for a set of national best practice guidelines on risk management (Department of Health 2007) and national policy guidance on selection of risk assessment tools (Leitner 2006).

3. Objectives of the review

3.1 To provide a systematic review of primary research evaluating interventions to prevent violent behaviour specifically targeted at people in contact with forensic mental health or criminal justice systems.

3.2 To produce a general statement about the effects of treatment for violent behaviour specifically targeted at people in this group through the synthesis of individual study results.

3.3 To examine reasons for conflicting evidence on effectiveness in this area.

4. Methods

This protocol relates to a systematic review which, in its entirety will cover the publication period from the inception of the research literature to mid-2008. The original review(covering studies published up to the end of 2002) has been completed and resulted in the inclusion of approximately 1200 studies in the Liverpool Violence (LiVio) Research Archive and the construction of an associated SPSS database of extracted information on 200+ variables per study. About half of these studies relate to interventions and half to risk assessment. A technical report on the original review is available (Leitner, Barr et al. 2006). The review update, covering studies between 2002 and 2008 will, in the main, match the original review methods strategy. Any divergence between the methods is noted below.

4.1 Criteria for inclusion and exclusion of studies in the review

For a study to be included in this systematic review it must have the following characteristics:

- I. Participant/Population characteristics
 - 1. The study participants must (a) have an active diagnosis of mental illness, learning disability or personality disorder, OR (b) be an offender (person subject to penal sanction), OR (c) be a person known to have committed one or more acts of aggression constituting an indictable offence (whether or not an indictment has been made). Studies will be excluded if (a) the sample participants are members of the general public, with no identified mental illness and no evidence of having committed an act of violence which would constitute and indictable offence, (b) Substance abuse (including alcohol abuse) in isolation from any other diagnosis of mental illness. Substance abuse (including and separately specified as alcohol abuse) *is* to be identified in relation to *participant characteristics* for the purposes of data extraction, as it is identified in primary studies.
 - 2. The study participants must be aged 17 years and older.

II. Intervention Characteristics

- 1. The intervention must (a) be specifically identified as being evaluated with the intention of preventing violent behaviour OR (b) implemented with the immediate intention of preventing violent behaviour (*e.g. 'naturalistic' evaluation in a clinical setting*). Studies will be excluded if interventions are focussed *solely* on reducing or preventing target behaviours *other* than aggression towards others.
- 2. Interventions must be targeted at the individual level. Studies will be excluded if (a) studies evaluate the impact of broad-based local or national population-level initiatives and which also fail to evaluate outcomes (cf. outcome criteria) at the individual level are to be excluded. Studies which have a focus on a main target behaviour which is not other-directed aggression (the target behaviour may be selfdirected aggression), but which do include an evaluation of the association between exposure to an intervention and rates of other-directed aggression as a subsidiary focus are to be included. (b)Studies evaluate the impact of broad-based local or national population-level initiatives and which also fail to evaluate outcomes (cf. outcome criteria) at the individual level are to be excluded. For example, a study evaluating the impact of a binge drinking campaign on aggression which evaluated outcomes purely by noting changes in population rates of violence across time would be exclude a study evaluating the same intervention but reporting outcomes based on the same set of individuals with behaviour evaluated before and after the initiative would be included. The key point is that the specific individuals being assessed need to be evaluated at outcome.
- 3. Interventions may include, but are not restricted to, pharmacological, physical, psychological, environmental, or training initiatives
- 4. Interventions include both 'single dose' and complex 'multiple dose' or 'multifactorial' interventions
- 5. Studies which have a focus on a main target behaviour which is <u>not</u> other-directed aggression (the target behaviour may be self-directed aggression), but which <u>do</u> include an evaluation of the intervention on other-directed aggression as a subsidiary focus are to be included. Studies will be excluded if they focus <u>solely</u> on self-directed aggression, including self-harm and suicidal behaviours.

III. Setting/location

1. Setting/location of any study is not to be regarded as grounds for excluding that study. Therefore any setting such as (a) any institutional setting/location, (b) any community setting/location, (c) community-based 'institutional' settings such as outpatient clinics, A&E, private practice clinics etc, (d) studies conducted at 'remote' locations, for example studies evaluating interventions conducted by telephone or in writing, are to be included.

IV. Study Design Characteristics

- 1. The study design must be explicitly measuring outcomes following an intervention meeting the above criteria. Studies will be excluded if (a) there is no attempt at any sort of empirical approach likely to elicit at least an association between dependent variables and outcomes, OR (b) there is no clear identification of an intervention taken as either the main *or* as a subsidiary focus of the study.
- 2. For inclusion in empirical analyses studies must be (a) randomized controlled trials with a no treatment or treatment as usual control group will be included, (b) quasi-experimental (non-randomized) comparison group designs with an treatment group and no treatment or treatment as usual control group.
- 3. All other designs will be included and used as supporting evidence.

V. Outcome measure characteristics

- 1. Studies must report (a) directly observed physical *or* verbal aggression by person(s) with an identified mental illness OR (b) directly observed physical aggression (meeting criteria for indictment) by members of the general public or current/previous offenders. Studies will be excluded if (a) There is no evaluation of outcomes, (b) aggressive behaviour (as defined for the population groups considered) is *not* either a main or subsidiary outcome of the evaluation
- 2. Proxy measures of the above (including but not restricted to: self or other report of the above categories of behaviour, including reports established *via* clinical records; official records of offence and conviction; psychometric and other scale based outcomes of mentations or behaviours directly relevant to aggression, for example BPRS measures of 'hostility') Studies will be excluded if directly observed or proxy-evaluated aggressive behaviour (as defined for the population groups considered) is *not* either a main or subsidiary outcome of the evaluation.
- 3. Outcome evaluation must be based on individual-level data. Studies will be excluded if (a) evaluations are based on 'non-attributable' rates and (b) other summary data. 'Collective' acts of aggression, such as terrorism, 'gang' violence, organised violent crime, football violence, drug feuds etc. are excluded from consideration by the review where the focus of the study is on the phenomenon *as* a collective behaviour; studies focussed specifically on individual behaviour *within* these contexts should be included.
- 4. Evaluation of both imminent and non-imminent (future) violence is included within the review

4.2 Search strategy for identification of relevant studies

A search strategy for electronic databases (outlined in generic form below) was developed for in collaboration with information technology staff from the British Library, taking into account lessons drawn from previous work in similar areas, kindly supplied to us by colleagues in the Cochrane and Campbell Collaborations. The search strategy is intentionally broad and designed to serve both the needs of the current review and those of the Risk Assessment Review referred to earlier. The approach adopted for search development was the *Successive Fractions* approach described by Hartley, Keen et al. (1993). Initial trials of the search strategy were carried out on the DIALOG system by British Library information staff and subsequently refined by the Review Team using MEDLINE as a search model. The search strategy is designed to be sufficiently inclusive to provide a comprehensive overview of relevant material in this area. It will be used to identify both completed and ongoing research and will encompass both primary research and review material.

4.2.1 Search term (structure modified to suit individual data sources)

(((Homicid* OR murder* OR manslaughter* OR infanticid* OR parricid* OR assault* OR (bodily AND (harm OR assault)) OR assail* OR bugger* OR sodom* OR molest* OR pedophil* OR paedophil* OR sadis* OR sadomasochis* OR sado-masochis* OR anger* OR cruel* OR rapist* OR (rape* AND offend*) OR physical abus* OR spouse abus* OR partner abus* OR sexual abus*) OR (((dangerous* AND (behavior* OR behaviour* OR histor* OR conduct*)) or violen*) AND (risk* OR predict* OR anteced* OR assess* OR cause* OR reason* OR interven* OR prevention* OR preventing* OR controlling* OR manage* OR treatment* OR treating* OR reduction* OR reducing* OR stop* OR mental* OR forensic* OR psychiatric* OR offend* OR Axis 1 OR Axis 2 OR criminal* OR detain* OR insan* OR NGRI OR retard* OR (learning disab* OR learning-disab*) OR acquit*)) OR ((child abus* OR elder abus* OR hostil* OR killing* OR attack* OR aggress*) AND (mental* OR forensic* OR psychiatric* OR offend* OR acquit* OR detain* OR insan* OR NGRI OR retard* OR killing* OR attack* OR aggress*) AND (mental* OR forensic* OR psychiatric* OR axis 1 OR axis 2 OR criminal* OR insan* OR NGRI OR retard* OR killing* OR attack* OR aggress*) AND (mental* OR insan* OR NGRI OR retard* OR killing* OR acquit* OR detain* OR insan* OR NGRI OR retard* OR killing* OR axis 2 OR criminal* OR insan* OR NGRI OR retard* OR killing* OR axis 2 OR criminal* OR insan* OR NGRI OR retard* OR killing* OR attack* OR aggress*) AND (mental* OR insan* OR NGRI OR retard* OR illow* OR axis 1 OR axis 2 OR criminal* OR insan* OR NGRI OR retard* OR insan* OR NGRI OR insan* OR insan* OR NGRI OR insan* OR insan* OR NGRI OR insan* OR NGRI OR insan* OR NGRI OR insan* OR NGRI OR insan* OR insan* OR NGRI OR insan* OR

4.2.2 Electronic searches

Electronic searches are not restricted by either geographic or site location of the research or the type of publication. In the review update, studies will be restricted to those with an English language abstract and dissertations will be restricted to those available electronically. Electronic searches will be restricted to the publication period 2002-2008. The following sources will be searched

AMED (Allied & Complementary Medicine) Arts & Humanities Citation Index ASLIB (Index to theses) [searched as a full text print-out] British Humanities Index Online British Nursing Index/RCN C2-SPECTR, a trials register of the Campbell Collaboration, covering sociology, psychology, education and criminology [searched on-screen] CINAHL Cochrane Library CRIB (Current Research in Britain) [searched as a full text print-out] DARE [searched as a full text print-out] Econlit **Elsevier Science Direct ERIC/International ERIC** HTA [searched as a full text print-out] IBSS (The International Bibliography of the Social Sciences) Medline NHS EED [searched as a full text print-out] **PsycINFO** Science Citation Index/Web of Science (including proceedings index to conference material) SIGLE (a grey literature database) [searched on-screen] Social Sciences Citation Index Social Services Abstracts Sociological Abstracts/Sociofile PROOUEST

Following a reliability exercise within the team inclusion criteria will be applied to the search results in two stages. Firstly, each reviewer will be allocated a subset of the retrieved citations (title, publication details and abstract) to which they will independently apply the inclusion criteria. Full-text versions of all studies deemed to meet all five sets of inclusion criteria will be obtained for full review. Stage two will involve the application of the inclusion criteria to full-text versions that were identified. Each paper will be looked at by one reviewer. A conservative, inclusive approach will be adopted toward doubtful studies so that reviewers will err in favour of inclusion where any uncertainty exists and decisions regarding inclusion will be made through consultation with a second reviewer.

4.2.3 Handsearching, reference lists and consultation with experts

The original review demonstrated that the benefits of handsearching 34 journals did not justify the effort involved in running it. Therefore, in the review update the five most relevant journals will be identified empirically and handsearched for the period 2002-2008 in order to ensure the comprehensiveness of the review and assess the reliability of the electronic search.

The Review Team will also handsearch the reference lists of all systematic reviews obtained in the course of the review process.

Discussions with, and formal requests to, experts in the field - notably those who have authored reviews and/or are actively engaged in primary research - will also be used to supplement the formal searches. Finally, the Advisory Panel will be asked to review the complete list of selected material for missing studies of relevance to the review.

4.2.4 Data Management

Citations and abstracts downloaded from the electronic searches will be entered into Endnote (a data management package for bibliographic material). Material from separate databases will be combined in a composite database, prior to pre-screening for inclusion, to exclude

duplicates. Citations from each data source will be catalogued separately and tagged to allow the Review Team to keep track of the relative value of each source in contributing to the final review material. As the search strategy has also been developed to inform the Risk Assessment review mentioned earlier, a tagging system will be used in the initial screening stages to track material of relevance to each review, as there will be some overlap. Separate databases will then be established for the two reviews.

4.3 Description of methods used in the component studies

The review report will include descriptions of the principal recurring features of the research design and methodology employed in the specified field. Definitions will be provided of the main methods of investigation used. Using summary data obtained from systematic searches, the proportions of studies falling into each of these categories will be tabulated. Illustrative studies will be presented to clarify these points and to facilitate communication of the findings of the review. Methodological variables have been shown to have important and ineluctable effects on review findings (Wilson 2001) and careful account will be taken of trends arising from methodological artefacts. All analyses that are carried out will incorporate checks for the influence of methodological variables on the findings obtained e.g. moderator analyses.

It should be noted that the review is designed to be as comprehensive as possible and thus to capture non-experimental (including qualitative) designs. Apart from pharmacological interventions, the field is dominated by non-RCT designs due to the complexity of the population and other factors so evidence must be based, with appropriate caveats, on lower-quality designs. An exclusive focus on RCTs would boost internal validity but at the cost of restricting the analysis to a very small number of studies in some areas. Lower quality designs such as single-group pre-post designs can still yield estimates of effect size based on changes from baseline to study endpoint in a single group. The statistical analysis will however follow C2 guidelines and report meta-analysis of RCT, comparative groups and prepost designs separately (see below for further details).

4.4 Criteria for the determination of independent findings

The reviewers will attempt to identify samples reported in more than one study. Where this is detected, the most stringent test (i.e. the study with the longest period between baseline and endpoint will be selected for inclusion in the meta-analysis). Where individual studies report multiple outcomes (k) each of them will be coded separately for analysis. The method of computing outcomes will be coded as a method variable. Discrete analyses will be conducted across effect size measures integrating findings obtained with different measures as separate outcome variables. For all effect size measures so obtained, conversion formulae will be used to present overall findings in several ways, for example as mean effect sizes (Cohen's d), correlation coefficients (r or φ), and odds ratios where appropriate.

Findings utilising identical outcome variables within studies (e.g. from separate sub-samples) will be coded as independent outcome indicators and regarded as equivalent to outcome variables comparably defined from other studies. Where individual studies report a number of

variables, types of outcomes will be coded and in each case mean effect sizes will only be computed for individual variables of comparable types from independent studies. Where studies report multiple outcome measures, the reviewers will identify the main effect size for one primary and one subsidiary outcome measure on the basis of the authors' stated goals. Any additional effect sizes (either for these outcome measures or any subsidiary outcome measures) will be coded in a separate annex to the main coding form.

4.5 Data extraction

Data extraction will be performed by two coders and extracted data will be loaded onto the LiVio SPSS database holding information from the original review. For conceptual clarity the extracted variables will be grouped into the following clusters, which will assist in defining separate analyses and inferential tests to be conducted.

- Data management cluster
- Publication cluster
- Design cluster
- Sample cluster
- Interventions cluster
- Outcomes cluster
- Results cluster

The following variables will be used to check the influence of methodological variables on the findings obtained.

- Aggression is main focus
- Drop out is less than 10%
- Final N is 100+
- Study follow-up is prospective
- Fidelity of implementation evaluated and confirmed
- Baseline aggression evaluated and stated
- Random assignment of participants
- Blinding of at least those evaluating outcomes
- Baseline equivalent for aggression (group comparisons only)
- Other key factors similar for groups at baseline (group comparisons only)
- Equal group sizes at start (group comparisons only)

4.5.1 Data synthesis

A narrative synthesis of the available material will be used to explore and outline the extent, nature and quality of the available evidence in this area. This qualitative assessment of the available data will also be used to explore any observed heterogeneity (in study or sample characteristics, study designs and outcomes) and to inform the structure for quantitative synthesis of the data, including the choice of comparisons to be made and the outcome measures amenable to quantitative treatments. It will also be used to address the issue of generalisability. The extent of heterogeneity will then be established quantitatively (*e.g. Q or*)

12) and, where appropriate, data will be combined in meta-analysis as outlined below, to obtain combined effect sizes for individual interventions and their associated confidence intervals. It is unlikely that individual patient data will be made available to the Review Team given the timescale of the Review. Sensitivity analyses will be used to explore the robustness of the review outcomes to changes in the underlying assumptions regarding the data and regarding the methods applied. Publication bias will be explored using funnel plots.

4.6 Statistical procedures and conventions

Descriptive information and statistics

Descriptive information from the studies located will be extensively tabulated reporting distribution statistics in relation to all criteria coded for independent studies. Explanatory and discursive text will accompany main summary tables with detailed and comprehensive supplementary data sets being included in appendices or in a parallel quantitative data report.

Inferential statistics, outcome effects and supplementary analyses

The most appropriate method of meta-analysis depends on the nature of the data identified. A final decision regarding whether meta-analysis is appropriate at all and, if so, which method(s) should be adopted will therefore be made once the data have been collected. Analysis of studies in the original review identified an unusually high degree of heterogeneity between studies. This was sufficient in fact to rule out meta-analysis as an appropriate approach in all but a minority of sub-groups of the studies included. Judging again from the original review, binary data in meta-analysis can be validly presented either as odds ratios or as relative risk ratios, since the base rates for violence are generally low and both measures give comparable estimates under this condition. Absolute risk differences are less likely to be appropriate, since in the original review variation in baseline event rates was commonly found when comparing across studies, even where these used very similar measures and populations. In comparing odds ratios and relative risk, the eventual choice of effect measure for the meta-analysis of binary data is likely to depend on the eventual audience for the outcomes of a particular analysis. For example, physicians are more familiar with the concept of relative risk and may find results presented using this effect measure more readily interpretable. In contrast statisticians and psychologists are more familiar with odds ratios.

In meta-analyses of continuous data a weighted mean difference effect measure is the most likely choice, with the weight given to the mean difference in each study equal to the inverse of the variance. However, the original review revealed that a number of otherwise comparable studies had measured outcomes using different scales. In such cases, it would be more appropriate to adopt a standardised mean difference approach (dividing the mean difference by an estimate of the within-group standard deviation to produce a unit-free standardised measure of effect). This will produce 'equated effect sizes'. It should also be noted that a number of studies in the original review used survival curve data to summarise outcomes. In combining such studies in a meta-analysis, it would be most appropriate to use hazard ratios as the effect measure.

The statistical analysis will follow C2 guidelines and report meta-analysis of RCT, comparative groups and pre-post designs separately. It is anticipated that the research literature since 2001 has become more coherent given the development of protocols etc and

thus that more recent studies captured in the review update will show a greater degree of homogeneity. Nevertheless it seems likely that a random effects model will be the most appropriate approach to combining data in meta-analysis. The studies identified to date that may be suitable for integration using meta-analysis show considerable heterogeneity, and following the recommendations of experts such as Hunter and Schmidt (2000) a random-effects model is less likely to result in Type I errors, and misleadingly narrow confidence intervals. This will be remain pertinent if it is found that publication bias, poor design and implementation quality remain an issue in more recent studies. We will report tests of heterogeneity for all effect sizes and employ graphical displays such as forest plots.

It was previously identified that moderator variables in this context are confounded. Associations within and between moderators will initially be identified via tests of individual association appropriate to the variables in question (e.g. correlation coefficients for continuous variables, $\chi 2$ statistic for discrete variables). The combined impact of multiple moderator variables identified as confounded will then be modelled using suitable multivariate regression analyses. Additionally where possible, we will examine effects of moderator variables by sub-grouping studies according to hypothesized moderator effects, and conduct parallel analyses within groups.

The original review also identified study design (broadly described here as 'method') as a moderator variable. Given also a priori concerns regarding the quality of distinct designs, the reviewers intend, if sufficient resources are available, to run a set of meta-analyses weighting effect sizes by study design /'quality' rather than simply by sample size in order to evaluate the impact on outcomes. This is referred to as a 'methods adjusted effect size'. Following the outcome of the moderator regression analyses described above, this analysis may be redundant, in which case the plan of analysis will be adjusted accordingly

As stated above, it should be noted that studies identified in the original review were judged to not meet homogeneity requirements and so meta-analysis was not conducted. It is anticipated that the research literature since 2001 has become more coherent given the development of protocols etc. and thus that a proportion of studies in the review update will meet these requirements and be a suitable basis for such analysis. Where methodological criteria and sample sizes permit, inter-relationships of independent, moderator and outcome variables will be explored using logistic regression or structural equation models.

Effect sizes will be computed in a number of patterns as follows:

- Using observed effect sizes from individual studies
- Using method-adjusted effect sizes
- Using equated effect sizes defined in terms of separate variables rendered statistically equivalent for purposes of analysis

For report and communication purposes, meta-analytic findings will be presented in two ways:

- Using original effect size data
- Tabulating conversions of reported effect size data to common-language effect sizes

4.7 Treatment of qualitative research

There are two aspects to this, which will be considered separately in the final reports: Firstly, qualitative aspects of quantitatively-based studies included in systematic reviews will be reviewed and this material will be used to exemplify the nature of the studies described, for example to characterise the nature of key types of intervention, to illustrate the range of interventions, or to typify the kinds of intervention found to be associated with the larger or more consistent outcome effects. Secondly, qualitative research studies per se will be approached using a pre-selected method of research integration for qualitative research (Popay, Rogers et al. 1998; Thomas and Harden 2007).

5. Timeframe

We intend to produce the updated review report by July 2009. The project has been funded and is currently underway, with a project timetable and milestones agreed with the funders as follows:

October 2008: identification of relevant studies completed. December 2008: data extraction and loading completed. March 2009: data analysis completed. July 2009: preliminary report available.

The Review Report to be provided to the funding body will serve as a focus for dissemination. Rather than breaking this large report into separate journal articles, a contract has been obtained with Cambridge University Press for production of a research monograph incorporating both this and the parallel Risk Assessment review. Executive summaries of the report will be made available to relevant stakeholders.

6. Plans for updating the review

All search material will be maintained on Endnote. Updating and subsequent transparency will be supported by clear documentation of the search process. If the Campbell Collaboration accept the review, the expectation would be for biennial updates of the review to be carried out, providing sufficient funding or institutional support could be obtained to secure the necessary staff time.

7. Acknowledgements

We are grateful to the National Forensic Mental Health Research & Development Programme (Department of Health, England) for funding the original review. We also thank the Programme's former Director (Kathryn Harney) for her continued interest in and support of the project and the members of the original project's Advisory Panel (Dr Ron Blackburn; Dr David Cooke; Dr Mairead Dolan; Dr Tom Mason; Mr Cathal Meehan; Dr Malcolm Millar and Prof Jenny Shaw) for volunteering their valuable time to the project. With regard to the review update, we are also grateful to the National Institute for Health Research / Research for Patient Benefit Programme (Department of Health, England) for funding, the members of

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8. Statement Concerning Conflict of interest

None.

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